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

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In the Matter of an Arbitration
Between:

CHEMTURA CORPORATION
(formerly Crompton Corporation),

Claimant/Investor,

and

THE GOVERNMENT OF CANADA,

Respondent/Party.

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HEARING ON THE MERITS

Friday, September 4, 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 9:05 a.m. before:

PROF. GABRIELLE KAUFMANN-KOHLER, Presiding Arbitrator

THE HON. CHARLES N. BROWER, Arbitrator

PROF. JAMES R. CRAWFORD, Arbitrator

Secretary to the Tribunal:

DR. JORGE E. VINUALES

Court Reporter:

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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, now we can start.

PETER CHAN, RESPONDENT'S WITNESS, CALLED

PRESIDENT KAUFMANN-KOHLER: Good morning, Mr. Chan.

For the record, can you please confirm that you're Peter Chan.

THE WITNESS: Yes, I am.

PRESIDENT KAUFMANN-KOHLER: You're Director General of the House Evaluation Directorate of the PMRA.

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: And before that--you've held that since 2006, and before that you've held other positions at Health Canada; is that right?

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: Thank you.

You have given one Witness Statement in this arbitration?

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: And as a witness, you're under a duty to tell us the truth. I would like to ask you to confirm this by reading the Witness Declaration, please.

THE WITNESS: Okay. I am aware that in my examination I must tell the truth.

I'm also aware that any false testimony may produce severe legal consequences for me.

09:06 PRESIDENT KAUFMANN-KOHLER: Thank you.

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

THE WITNESS: Okay.

PRESIDENT KAUFMANN-KOHLER: Mr. Kurelek.

DIRECT EXAMINATION

BY MR. KURELEK:

Q. Good morning, Dr. Chan. I only have only one question for you.

Do you adopt and affirm the contents of your one slim Affidavit?

A. Yes, I do.

Q. Thank you.

PRESIDENT KAUFMANN-KOHLER: That was fast.

Then I turn to Mr. Somers?

MR. SOMERS: Thank you, Madam Chair.

CROSS-EXAMINATION

BY MR. SOMERS:

Q. Good morning, Mr. Chan.

A. Good morning.

Q. I'm Greg Somers, and I'm asking you some questions this morning on behalf of Chemtura Corporation.

A. Great.

Q. I'm going to be referring to your confidential

09:07 Affidavit in my questions, and you have that with you?

A. Yes.

Q. Thank you.

Would it be fair to say that the purpose of your Affidavit is to establish that--and I'm looking at your Paragraph 6 there in your Affidavit, so I'd ask you to turn to that. You say, "Based on the information available to me, I know that Chemtura's allegation is without substance because with only one minor exception, none of the PMRA scientists and managers who worked on the REN were the same as those scientists and managers who worked on the Special Review."

Is it fair to say that that's part of the purpose at least or the purpose, the main purpose of your Affidavit in these proceedings?

A. Well, yes, that's one of them. My understanding is that I'm here for two purpose. One is to explain the composition of the two teams involved in the Special Review and the REN, and the other was the opportunity to clarify the role of my colleagues, John Worgan, with regards to this process.

Q. Okay. Thank you.

In Paragraph 9 of your Affidavit, you state that--and again I'm looking at that paragraph--"Again based on the information available to me on how the Lindane Special Review and REN processes worked, I can confirm that, while he did peer review and sign off on the Health Evaluation Division's Risk

09:08 Assessment in the Special Review, Mr. Worgan was not responsible for approval of the scientific Risk Assessments described in the REN because by that point, he had been appointed to the more managerial position of Director General of the PMRA's Reevaluation Management Directorate."

In his role as Director General of the PMRA's Reevaluation Management Directorate, I'm interested in understanding what authority he had or, in fact, continues to have over the REN over lindane.

A. Okay. So, I'm going to explain then maybe perhaps take you a little bit--give you a bit of background of how the REN process worked as far as the evaluation process is concerned within the Health Evaluation Directorate. So--

Q. I'm sorry, just to interrupt you a little bit. If you could focus very much on Mr. Worgan's role--

A. He basically have limited role. He has--

Q. I'm interested if you could help me in focusing on Mr. Worgan's role in the--that more managerial position you describe in terms of the REN supervision.

A. He basically had very limited role with regards to the conducting of the risk assessment in the REN process, so he was only in the managerial coordination role as the Director General for the re-evaluation management coordination role in that process.

So, his other perhaps linkage is that we--all the

managers--all the Director Generals sit at the Science Management Committee. When we look at all the Risk Assessment that come forward to the Science Management Committee, that's when we look at the Risk Assessment and make decisions on supporting the Risk Assessment coming out from the evaluation, the various evaluation Directorates.

Q. Okay. You have attached to your Affidavit at Tab PC-1 the Terms of Reference of the Science Management Committee. It's Exhibit PC-1 in these proceedings. And I'm looking at the first part of the terms of that Terms of Reference document, and it says "Mandate. The primary role"--before I actually go into that, could you turn to Page 2 of the document. And under membership, it says, and this is membership of the Science Management Committee, "The SMC will comprise the Chief Registrar as Chair, and DGs of contributing directorates; i.e.," and then the third DG there is the DG Reevaluation Management Directorate. That's Mr. Worgan; right? At the current time?

A. Yes.

Q. Okay. So, now I'm going back to the beginning of that document, the mandate of the Committee. "The primary role of the Science Management Committee," it says, "will be to discuss and work to arrive at consensus decisions on significant registration applications, new actives, major new uses, and conversions to full, Special Reviews, emergency registrations,

09:12 and reevaluations of Pest Control Products."

So, the re-evaluation of lindane is part of the Science Management Committee's mandate, isn't it?

A. Yes. It's no difference than any other submissions that go through the process within the Agency.

Q. Right.

A. Where there is for premarket request for authorization to go to market or re-evaluation submission of the existing chemicals, so there is no difference in any of the overall process.

Q. The second bullet as far as their mandate goes says, "discuss and make decisions on science." So, the Committee has a role in discussing and making decisions on science as well. It's not merely administrative or scheduling or anything or those sorts of thing, although those appear to be part of it as well, and process management and related policy issues under that bullet. Is that correct?

A. That's correct.

The decisions, okay, on the science, the first part of the decision that move forward to the SMC actually comes from the evaluating Directorate. For example, in this case, it could be Health Evaluation Directorate and Environmental Assessment Directorate in this case.

Q. Or the Reevaluation Management Directorate?

A. No, because in this case, John is not involved in the

09:13 re-evaluation process of the--during the REN process, so the health evaluation component of the submission came from the Health Evaluation Directorate. So, the science Risk Assessment of the health evaluation component of the lindane REN process, John was not involved. It came from the Health Evaluation Directorate scientists that conduct the Risk Assessment and came forward with that recommendation that a science decision.

Q. But at some point when the REN is in preparation or concluded, it goes to the Science Management Committee, does it not?

A. It's at the end of the evaluation process.

Q. Right.

A. When the health evaluation scientists came to a conclusion or a decision at the time from the health perspective or from the Environmental Assessment perspective. They will then combine and go through the Science Management Committee.

During that process of the evaluation process to the Science Management Committee process, if I understand your question correctly, John was not involved in that process.

Q. No--well, that wasn't my question, but your expansion is helpful.

At the conclusion of the REN process, it would go to the Science Management Committee, I will just come back to that, all right, and the Science Management Committee operates

09:15 on consensus, so any of the individuals who comprise that Committee can prevent the approval of Re-evaluation Decision; isn't that right?

A. Possible, yes.

Q. Okay. The third role of the Science Management Committee is to ensure that all registration decisions integrate value, health, and environmental risks and are based on risk management principles including compliance considerations. The fourth is to set priorities for registration and re-evaluation activities, for example, make decisions on expedited reviews, on deviations to submission management policy. So, the Committee in this regard has the authority to alter or not alter the policy that's applied to submissions made to the PMRA; isn't that so?

A. If you can clarify for me what you meant by changing the policy or altering the policy.

Q. All right. It says deviations here, and I'm wondering if that means changes or alterations.

A. No. We--the SMC is there to make sure that any decision that come out from the Agency follow existing policy, and that is consistent across the Board. And so if there is any deviation from any current policy or practices, that's the Committee's role to identify those and make sure that we are consistent.

And if these lead to any further changes or potential

changes to our existing practices and policy, this may be the Committee that can make that kind of recommendation back to whichever area that needs to address that potential changes.

So, really, the SMC, they don't just change the policy during the meeting or anything of that nature. They just want to ensure when the decision coming up from the evaluation Directorates are consistent with the current practice, and that there is a consistency in the decision making within the Agency.

Q. No doubt that's part of their role, but that's not how I read it here where it says, for example, "make decisions on expedited reviews, on deviations to submission management policy." They make decisions. They don't make recommendations.

A. That's correct. They make decision on the final outcome of that, but they do make recommendation if they say there is something that is not consistent. Let's say health evaluation Directorate as an example. We may be conducting an assessment and then we will submit it to the Science Management Committee. They will look at the process to ensure that the decisions that were made have considered all the criteria and all the--take into consideration all the policies that occur and are in place.

Q. I understand that, but as far as their mandate goes in their terms of reference, they're also empowered to make

09:18 decisions?

A. They are.

Q. Thank you.

A. They are.

Q. On scope of issues to be addressed, that's heading two of the Terms of Reference, it says, "Issues to be addressed would normally include product and active-related issues, including labeling such as Category A submissions, reevaluations."

Again, so the lindane reevaluation would fall under the issues to be addressed by the Committee, wouldn't it?

A. Yes.

Q. Further on in that paragraph, it states--well, I'll read it so that there's continuity, but I'm focusing on that part in the second last line which says, "New approaches to Risk Assessment," so it says, "Issues to be addressed would normally include product and active-related issues, including labeling such as category submissions, re-evaluations, and Special Reviews, minor use issues, submissions with TSMP concerns, submissions with specific issues including compliance considerations and issues, necessary exceptions to the management of submissions policy, and new approaches to Risk Assessments."

So, those include--that's part of the issues that the SMC is empowered to make decisions on and address; is that

09:19 fair?

A. The--usually especially--well, if we are referring to new approaches to Risk Assessment, the process usually is that we will present that to SMC to go through what would they do, if there is any changes, for example, on policy and conducting Risk Assessment usually will go through the SMC for their recommendation and decision to say, yes, this is the policy from here on that we will adopt.

Q. Or they can direct a new approach to Risk Assessment, is how I read that section of their Terms of Reference.

A. Maybe if I can clarify that.

Q. Sure.

A. They don't--normally the SMC prefaces that they don't direct, quote-unquote, direct specifically in that sense. They will say, have you considered this and that, and then the evaluating Directorates will take that suggestions or recommendation to go back to come up with what is perhaps to say the same decision or revised decision, take into consideration of those recommendations, and we will go back to SMC, the Science Management Committee, one more time before they make that final decision.

Q. Thank you.

A. Okay.

Q. And I'm going to the heading of the Terms of Reference under decision making, number four, and at the last line of

09:21 that page, it says, "The DG of the Reevaluation Management Directorate and the Chief Registrar will participate in all science discussions together with other science Directorates."

Now, that DG is again that they are referring to there is currently again Mr. Worgan, isn't it?

A. Yes.

But if we read on--

Q. Yes. It says, "However, REMD, and could you help me who that is, reevaluation"--

A. That's the Evaluation Management Directorate.

Q. "Will refrain from participating in any final registration decisions regarding new actives' major new uses. But the lindane re-evaluation is not a final registration decision, is it? It's a re-evaluation.

A. It's a re-evaluation.

Q. It's not one of those. So, REMD doesn't have to refrain from participating in that. The Chief Registrar does because it says, "and the Chief Registrar will refrain from participating in any final decisions regarding reevaluations or special reviews." So the Chief Registrar has to refrain from participating in final decisions regarding re-evaluations, but the REMD does not?

A. Right.

Q. The REMD will and can or at least can participate. In fact will participate I believe it says.

09:22 A. Right, but the decision, the decision as you mentioned earlier, is based on consensus of the Committee, so the reason for this role, maybe if I can clarify--

Q. Please.

A. --it's because just in case if there is a decision made at SMC that are related to a re-evaluation process, then the Chief Registrar becomes the second level of a process to conduct that peer review from that process. So, try to separate the role from re-evaluation and premarket.

So, then, therefore, if there is a next level of discussion, those people were not, quote-unquote, directly involved in that decision. That's what they refrain from means applied to that, so it's have a cross process so the CRO, the Chief Registrar Office, and the Coordinator, the DG of the Reevaluation Management Directorate, they sort of cross, oversight the decision coming up from the different--real stream.

Q. I appreciate that distinction.

And so, for the Chief Registrar, it's do not participate in reevaluations. For the REMD, it's do not participate in final registration decisions?

A. They do participate in the sense of a contributing--they are a member of the Science Management Committee; right? So, what they say in here, "will refrain from participating in any final registration decisions

regarding new actives or refrain from participating in any final decision regarding re-evaluation,' so I would like to emphasizes word final.

Q. Yes, and I appreciate that distinction.

As far as the lindane reevaluation, though, Mr. Worgan could participate both in the preliminary and the interim and the continuing re-evaluation of lindane as well as the final decision on lindane; isn't that right?

A. No. Maybe if I want to clarify that one more time.

With the Health Evaluation Directorate who conducted the Risk Assessment, Mr. John Worgan was not involved in that process, okay.

Q. Fair enough.

A. So, that's the very first stage of the evaluation process. So, Mr. Worgan, my colleague, was not involved in that. So when Health Evaluation Directorate made that decision, quote-unquote, or recommendation on that decision from Health Evaluation Directorate, it goes to the Science Management Committee.

Q. Right.

A. That is when all the DGs within the Agency will participate at the Science Management Committee to discuss that recommendation whether it's coming out from Health Evaluation Directorate or Environmental Assessment Directorate.

The final decision, okay, John will refrain from

09:25 making that for the--when he assess refrain from participating the final decision regarding re-evaluation, the Chief Registrar will, and John will refrain from participating in any final registration decisions for new actives. That's premarket authorization. So, they refrain from making that decision, but they participate as a member because part of the mandate, part of the consensus building is for all the Director Generals that are members in this Committee to come to that consensus.

Q. I appreciate that distinction.

A. So, in that sense, may I summarize in that sense that John was not involved in the conducting of the REN evaluation process, nor any of those scientific contribution to that process until he is a member of the SMC.

Q. Right. Right.

And in that capacity, he will or did definitely, according to the Terms of Reference, participate in the discussions and in the final decision?

A. Right. He will be bringing his history and his--well, not the history, sorry. He will be bringing his expertise as any other submissions that comes in for REN from whether it is from the premarket authorization request or for re-evaluation decision.

So, all the Director Generals are involved in the same capacity at the SMC. So, that's the way--and we just tried to have that discussion in SMC to make sure that the decision are

consistent throughout from this perspective of whether it's the health, or environment of value or reevaluation with some of the existing chemicals that may link to another chemical. We brought that integrated sort of thinking into making decisions.

Q. And you've said several times and in your statement at Paragraph 10, you also state his role was instead--I'm looking at the last sentence in Paragraph 10--"was limited, instead limited to reviewing the consolidated Report for accuracy and consistency." But, in fact, the Terms of Reference don't limit him to considering the questions of accuracy and consistency. They direct him to participate in all science discussions and entitle him by not having to refrain, to participate in final decisions regarding re-evaluations, and it's not limited to just consistency, is it?

A. No. In this case, it was considered to be at the consolidated Report for accuracy and consistency, and as I mentioned before, the role of the SMC is to ensure this consistency in our decision making for any of the chemical whether it is for premarket assessment, registration, or for re-evaluation. So, in his role, consistency is part of the mandate for the SMC--

Q. I understand.

A. --and that consistency would involve, whether it is dealing with existing policy, existing practice, existing science, all that. So, that's the way of the accuracy and

09:28 consistency of the consolidated Report. That's really a condensed version of the role of the SMC.

Q. Can you point to me where any words like accuracy and consistency arise in the Terms of Reference? I can't find those terms there.

A. Well, I can't pinpoint to you the exact word that reflect that. But what this is is basically is the mandate that when you take--when you digest all the role in here for any decision for any--I think for any government decision, it's important, especially from the scientific perspective, we have to make sure that the information that we put down are accurate, because otherwise we are in trouble; right? So, that's where the accuracy comes in.

And when I call for consistency, as a government point of view, we have to be consistent in order to avoid, quote-unquote, what people may perceive to be different treatment to different companies. So, therefore we have to make sure that the process is consistent. That's why we have all this policy and guidelines that occur within PMRA regarding the conduct of our health evaluation or environmental Assessment. Those are all transparent. Those are all on the Web site. So, that's just to make sure that we have those things out there transparent, talk to people. And then internally during the SMC, we want it make sure that we're actually following all those guidelines and all those policies

09:30 and making sure that the decision is consistent and that the information that come forward are accurate.

Q. Thank you very much. That was thorough.

And I have no more questions for you. You have been very helpful. Thanks very much.

A. Okay. Thank you.

MR. SOMERS: Thank you, Madam Chair.

PRESIDENT KAUFMANN-KOHLER: Thank you.

MR. KURELEK: No questions. Thank you.

PRESIDENT KAUFMANN-KOHLER: No redirect questions. Any questions from the Tribunal? No.

I have no questions either. That was very clear. Thank you very much, Mr. Chan, and that closes your examination.

THE WITNESS: Okay, thank you.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: Then the next witness will be Mr. Worgan precisely.

MR. DOUAIRE de BONDY: That's right.

PRESIDENT KAUFMANN-KOHLER: Can we call him in and just continue.

MR. DOUAIRE de BONDY: While we are waiting for Mr. Worgan, Madam Chair, could I raise a simple point of clarification. At the end of the day yesterday, we had discussed the direct examinations and the length of the

09:31 examinations, and we don't--we propose to follow the Tribunal's directions, of course, in respect to Mr. Worgan's examination. We simply had a question of clarification with regard to Experts, whether the same approach applied to Experts, given that we thought in that case given the technical nature of the evidence, it might be more useful to have a bit more Chief. We are thinking in the range of perhaps 15 to 20 minutes, and also given that the Claimant has not yet presented its Expert Witnesses, its procedural issues that that wouldn't be addressed--wouldn't be a problem.

PRESIDENT KAUFMANN-KOHLER: Can I--Mr. Somers, do you want to express a view on this now, or we can do this later as well. There is no real urgency. Maybe we can discuss it among ourselves during a break, and the Tribunal will think about it. It's true that often for Experts other rules are applied, and it can be helpful, depending on the technical complexity of the issues.

Can I leave this with you that between counsel you would discuss this, and if you come to an agreement, then you let us know, and we will think about it as well. Maybe we could say early afternoon? Early afternoon today you come back?

MR. DOUAIRE de BONDY: Certainly.

MR. SOMERS: That's acceptable with Claimant, too.

PRESIDENT KAUFMANN-KOHLER: Thank you.

09:32 Then I can say good morning to Mr. Worgan. Welcome.

JOHN WORGAN, RESPONDENT WITNESS, CALLED

THE WITNESS: Good morning.

PRESIDENT KAUFMANN-KOHLER: For the record, you are John Worgan.

THE WITNESS: That is correct.

PRESIDENT KAUFMANN-KOHLER: Your current position is Director General of the Reevaluation Management Directorate at the PMRA.

THE WITNESS: Yes, that is correct.

PRESIDENT KAUFMANN-KOHLER: And that is a position you've held since 2006.

THE WITNESS: Correct.

PRESIDENT KAUFMANN-KOHLER: And before that you held other positions at PMRA.

THE WITNESS: Yes.

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

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: And you're heard as a witness, and as a witness you are under a duty to tell us the truth. Could you please confirm this by reading the Witness Declaration.

THE WITNESS: Okay. Thank you.

I am aware that in my examination I must tell the

truth. I'm also aware that any false testimony may produce severe legal consequences for me.

PRESIDENT KAUFMANN-KOHLER: Thank you.

So, then I will turn first to Canada's counsel for a few introductory questions, and then, as you know, we will have questions by Chemtura's counsel.

THE WITNESS: Right, I understand.

PRESIDENT KAUFMANN-KOHLER: Mr. Kurelek, you're asking the questions?

MR. KURELEK: Thank you.

DIRECT EXAMINATION

BY MR. KURELEK:

Q. Mr. Worgan, can you please confirm whether you adopt and affirm the contents of your two affidavits in this matter.

A. Yes, I do.

MR. KURELEK: That's my only question. Thank you.

PRESIDENT KAUFMANN-KOHLER: Mr. Somers, then.

MR. SOMERS: Thank you.

CROSS-EXAMINATION

BY MR. SOMERS:

Q. Hello, Mr. Worgan. I'm Greg Somers and I represent Chemtura in these proceedings. I will be referring to your two affidavits primarily in my questions.

And you have those available to you?

A. Yes, I do.

09:34 Q. Okay. Good. And I will be--I may be referring to the Joint Hearing Bundle on a couple of occasions, but primarily your statement.

Before I begin, in both your statements include a--the Lindane Review Board Report. In the first statement, it's at Tab J--and Exhibit Number JW-30, and you helpfully included it in your second Affidavit as well because of the importance of that document in the lindane story at Tab J.W. 100, so, in fact, it has two exhibit numbers. And we put one in as well, so it's got a third exhibit number, and then it appears in the hearing bundle as well. So, this report used up a lot of trees.

Unfortunately, the version that was filed in your Affidavits and the version therefor that ended up in the hearing bundle missed a page. There is a page missing.

Rather than having to shuffle a lot of documents around, I made copies of that missing page, and I'm in the Tribunal's hands on this, but I'd like to file it either as an exhibit or as just an aid to cross-examination. It's Page 53 of the Lindane Review Board Report that comprises Paragraphs 220, 221, and 222.

PRESIDENT KAUFMANN-KOHLER: It's in the Joint Hearing Bundle; that's correct?

MR. SOMERS: The Joint Hearing Bundle is deficient in missing this page as well. I've made a few copies of it. I'll

09:36 hand them to the Secretary.

If I could ask a copy of this page to be put--given to the witness so that when we do eventually get to the Lindane Review Board Report, you will have it to hand.

Thanks. All right.

BY MR. SOMERS:

Q. Just to start, and appropriately it's sort of in the chronology of lindane issues, we will go back to 1998, and, in fact, 1997. At Paragraph 23 of your first Affidavit, reference is made to the LRTAP Protocol, Transboundary Air Pollution Protocol.

A. Which paragraph?

Q. 23.

A. Oh, 23. Okay. One moment.

Yes, I've got that. All right.

Q. And that Protocol is actually included as part of your Affidavit. It's Tab and Exhibit JW-10.

You state there, "The LRTAP Protocol restricted lindane to six uses, all of which were still registered in Canada in 1998."

And Canada supported the retention of those six uses; isn't that right?

A. Canada agreed to put those into that list of restricted uses because those were currently registered--at that time they were registered in Canada, and we would not have

09:37 been able to agree to a ban until such time that we had done like a full re-assessment of that, and that's exactly what we committed to do at the Aarhus Protocol meeting.

Q. You said until such time as we had done a full re-assessment?

A. Yes. We had agreed that we would do a re-assessment, and then on the basis of that we would determine what, if any, action was required.

Q. Well, suppose you had done a full re-assessment but continued to permit those uses. Then you couldn't agree to a ban, then, either; isn't that right?

A. That is correct.

Q. Okay. So, it's not just that you had to do a re-assessment, but you had to do a re-assessment and determination before you could have them include it or except to include the uses in the Protocol. Is that right?

A. Well, we agreed to include them in the restricted uses because they were registered in Canada.

Q. Exactly.

A. At that time.

Q. I understand.

A. Legally, we would not be able to, you know, have taken action on those, you know, to agree to a ban in the absence of like an assessment or re-assessment of those.

Q. You would not be able to agree to a ban in the absence

of an Assessment and re-assessment of those, and determination because if you--isn't that right? Because if you had agreed to a re-assessment and then reassessed the products and retained those uses, you still could not have agreed to a ban in the international forum.

A. If we had done a re-assessment that indicated that there were risks of concern, we would have--we would proceed with a cancellation of those products.

Q. And only at that point would you be entitled to agree internationally to ban?

A. Well, legally, our--under the Pest Control Products Act, we make risk-based, science-based decisions, and that's exactly, you know--that's our role and responsibility, to protect health and safety.

So, you know, we--when we did our re-assessment, re-evaluation, we looked at the risks associated with those and determined that the risks were unacceptable.

Q. Yeah, I understand that, but that wasn't exactly my question, though.

A. Okay.

Q. But that's fine. That's helpful.

And if you had not, if you had--after your re-assessment found that they were--the uses you were reviewing remained acceptable.

A. It's a hypothetical situation. That wasn't the case.

09:40 Q. Of course, of course.

But, in that hypothetical situation, could you have agreed to a ban, then, in the international forum?

A. I'm not an expert in the LRTAP Protocol.

Q. I see.

A. I couldn't confirm that one way or the other.

Q. As it is then, since they were still registered uses in Canada in 1998, you could not agree at that time?

A. At that time, but we could agree, you know, to a re-assessment as exactly what we did with the commitment to do that within two years of signing of the Protocol.

Q. Thank you.

And you say in Paragraph 25 in the last line of it, literally last line, "and Canada had made specific commitments to review its use of lindane." That arose out of what you call its specific commitment. It was implementing the Protocol which gave rise to that commitment?

A. That was one of the primary drivers, yes, and all of the other, you know, concerns around the health and environmental impact of lindane that had been raised both nationally and internationally, as you know.

Q. Okay. I'm turning now to Paragraph 57 of your statement. In that paragraph, you discuss, and in the prior, you discuss some differences between the EPA and PMRA.

A. Yes.

09:41 Q. In the second sentence, you state, "In particular, the PCPA did not have provisions for using information provided by one Registrant in re-evaluating another Registrant's product." I'm skipping a sentence and then continuing. "By contrast, EPA has its data protection provisions embedded in FIFRA and relevant regulations. This policy allows EPA to use other Registrant data under certain conditions, one of which is monetary compensation for use of protected data."

In the Special Review of lindane, '99 to 2001 Special Review, the PMRA could not, and that--could not, and that's what this difference is between the two agencies, in this regard, could not use occupational exposure data that was proprietary to another company in assessing occupational exposure risk; is that right?

A. That is correct.

Q. Even where the PMRA was aware that there were different and potentially superior data that bore on the issue that it was examining, this restriction on the PMRA, the data protection policy, would prevent it from having recourse to that information?

A. We would not be able to use these data. However, we did have access to a study that was generated by Chemtura--

Q. Right.

A. --and was submitted to us for consideration, which addressed the range of facilities that were in existence in

09:43 Canada at that time.

Q. Right. Okay. And we will get to that in a little bit.

When you were--the range of facilities, as you say, the seed treatment facilities, that's what we are talking about--

A. That's correct.

Q. --that were in Canada at that time, in terms of canola, though, were there particular types of facilities that would be seed treating canola, canola seed itself that where that study might not have been the appropriate one?

A. The study looked at a range of facilities from the small all the way up to the large facilities where canola would be potentially treated.

We also did extrapolate as required from crop to crop or from seed to seed on the basis of things such as the amount of product that was typically used in a day and, you know, the rates of application on specific seeds.

Q. Now, turning to your Paragraph 66, where you discuss the beginning of the REN re-evaluation note process for lindane--

A. Yes.

Q. --you state there, "To demonstrate the extent of its willingness to scientifically review lindane, all of these other areas of the Special Review, the various categories of

09:45 concern--

A. That's right.

Q. --that are enumerated in prior paragraphs, were taken up again by PMRA to generate its lindane Re-evaluation Note (REN) in 2008. As I will explain below, this extensive investigation simply provided at significant public expense further additional reasons to cancel the use of lindane beyond the very good reason based on occupational health that the PMRA had already discovered in 2001."

Could I ask you to turn to Tab and Exhibit JW-61. It's in the second volume of the first Affidavit. The document is called Science Management Committee Briefing, and it's dated August 31, 2006.

A. Um-hmm.

Q. This is a--this document appears to be, and I will ask you for your confirmation or correction, a deliberation on whether to follow the recommendations of the Lindane Review Board in scientifically reviewing lindane, if I could use your Affidavit.

A. No, actually what it was is that as you can see in the third paragraph, EPA had released their Addendum to the RED in August of 2006. They had identified that the risks outweighed the benefits and proposed that they--you know, said that they were no longer eligible for re-registration.

So, the reason we had this discussion is we wanted to

09:47 know whether or not we should look at option number two, whereby we would inquire with the Registrants--that would include Chemtura--about their intention of doing something similar in Canada because we realized that they had voluntarily agreed to cancellation of their products in the U.S., in light of the significant concerns that had been raised in the Addendum to the RED.

Q. Oh, okay. Okay.

And, indeed, at the beginning of that document you say, "In response to the recommendations of the Lindane Review Board, the PMRA has initiated a follow-up review of lindane."

A. Yes. So, it's to see whether or not the Registrants were still, you know, interested in continuing in Canada when we became aware of this decision in the U.S.

Q. Right.

Could I ask you, don't turn the page, but I'm now having to go to another document, and it's in the Joint Hearing Bundle at Tab 280. It's actually--

A. Do I have that here?

Q. I'm sorry, Volume 10 of the Joint Hearing Bundle, Tab 280.

A. Okay.

Q. This is entitled "Memorandum to the Associate Deputy Minister Lindane Board of Review. Issue Health Canada's Response to the Report of the Lindane Board of Review."

09:48 A. Right.
Q. Were you involved in the preparation of this document?
A. I believe I had some involvement in that I probably did a review of the version, the final version, but I believe it was drafted by the Executive Director or somebody in her office at the time, but I know that I did see this document before it was sent off.
Q. Okay. I guess what I'm trying to explore is the decision by PMRA to initiate the re-evaluation following issuance of the Lindane Board of Review Report because obviously--I shouldn't say obviously--because the Lindane Board of Review recommended. It didn't mandate or obligate PMRA to conduct a reevaluation.
I'm suggesting to you or asking you to confirm that the reason that the PMRA decided to conduct a re-evaluation was because of these proceedings?
A. Which proceedings?
Q. The proceedings that I'm asking you these questions in right now. It says here on this document, "The timing and substance of the response," in the middle paragraph. Do you see that?
A. Right.
Q. "Of the response to the Review Board Report could have impact on a NAFTA Claim." That's us here today.
A. I think, you know, that was a consideration that would

09:50 be addressed at this particular very senior level of Health Canada, but the--you know, we had asked the Board of Review for recommendations. We received some recommendations that we took very seriously, and we decided that it would be--that we would actually, you know, undertake a follow-up review in light of that.

So, you know, we had those recommendations. We looked at them. We'd asked for the advice. We took them seriously and implemented them. So, that was really the motivator here.

You know, this is, you know, just background information basically with respect to considerations.

Q. Right. Okay. Thank you for that.

I'm going back to Exhibit JW-61.

A. JW-61? Okay.

Q. That's the Science Management Committee.

A. Right.

Q. On the second page of that. It states in the third paragraph on that page, "The PMRA has consulted with the Trade Law Bureau and legal counsel to assess the impact that the next steps of re-evaluation could have on the Registrant claims to the Federal Court and the NAFTA Tribunal. The recommendation of both the Trade Law Bureau and Justice Canada is to complete the Assessment of Lindane."

Now, it seems to me if they had to recommend to you complete something, that there was some question as to whether

09:51 you would complete something.

A. No. Actually, you know, as we state here, the intent was to inquire with Chemtura and the other Registrants to see whether or not they were interested in pursuing reinstatement of products in Canada. If they were not, in light of, you know, the decision in the U.S., then, you know, there would be no need to proceed. It was just that, you know, given that this had happened in the U.S., we wanted to inquire with respect to, you know, what the intentions were of Chemtura.

Q. I appreciate that, and there was a reference to that on the prior page, but here it says the recommendation is to complete the Assessment, period.

A. Yes. But we were not at that time, you know, intending on, you know, stopping the re-assessment that eventually was finalized in the REN. It was just in light of this decision in the U.S., we said, well, you know, maybe we should phone Chemtura and find out what their intentions are. That was the only reason why we had this discussion at the Science Management Committee.

Q. Oh, because this gives a different reason in the next sentence where it says, "This would clarify/substantiate the position taken by the PMRA in 2001." That presumably is the Special Review. "And support the government's position in Court."

That seems to be the reason that you're giving here to

09:53 complete the Assessment.

A. No. The Assessments are, you know, done, you know, to determine the acceptability in terms of risk, both health and environmental risk of products, and that's really the basis for continuation of the review. It wasn't, you know, to, you know, support our government position in Court. We had committed--we had committed to, you know, undertake a follow-up review, and that's something that we were pursuing. In light of this decision in the U.S., we were just going to inquire with respect to what the intentions were of the Registrant. And we decided on the basis of a very brief discussion that, no, we will obviously, you know, continue and finalize the review.

Q. I'm going back to your first Affidavit at Paragraph 70.

A. Right.

Q. And there you describe a policy decision you've made where you state, "The policy decision I have described to rely as much as possible on EPA's already extensive Data Call-Ins would have made a standard Data Call-In exercise by PMRA redundant."

A. That's correct.

Q. Now, I suppose it would have been redundant if you'd received identical or comparable information from a call-in as you would from the EPA's database. But in the cases we talked about a minute ago about the occupational exposure study from

09:55 1 1992 that you relied on--
2 A. Right.
3 Q. --and given that you were aware of the more up-to-date
4 Helix occupational exposure study, it would not have been in
5 that case redundant, would it, to have issued a call-in for a
6 better study? I know you can't use the Helix study because of
7 our restrictions, but--
8 A. Right.
9 Q. --I ask you to confirm that that wouldn't have been
10 redundant.
11 A. In the case of the Special Review, the exposure
12 assessors did take a look at the Helix Assessment at that time
13 and did a quick calculation to see whether or not under those
14 very strict conditions of use that only existed in a very
15 limited number of plants in Canada, would we achieve acceptable
16 risk from an occupational point of view, and the response was,
17 no, that it did not. However, we would not be able to, you
18 know, use that to support registration.
19 But an examination of that data was looked at, so, you
20 know, to--even if we had access to that data, it would have
21 resulted in unacceptable risk for the Assessment.
22 Q. And that's because of the risk factors that the PMRA
23 determined in the Special Review?
24 A. That would be one of the considerations, yes.
25 Q. If the risk factor had changed and the Helix study or

09:56 a study that was--reflected the same practices as the Helix study had been used--

A. Possibly.

Q. Possibly.

A. Theoretically.

Q. The outcome might have been different?

A. Yes, you know.

Q. Turning to Paragraph 82 of--

A. Okay, 82?

Q. Of your first Affidavit.

There you say, "The Special Review case is exactly the opposite of a registration of a new product. While a special review is delayed by further Registrant submissions, the product remains in use and continues to be a potential threat."

A. Right.

Q. "Indeed, the sort of endless regress of data submissions by the Registrant is exactly what we've experienced in the most recent--I'm sorry--"in the recent reevalatuion process concerning lindane."

A. That's correct.

Q. Obviously--I've got to stop saying that. Nothing is obvious here.

You're not saying that the Special Review was delayed by further Registrants' submissions, are you, or by significant Registrant submissions of any kind?

09:58 A. No, no, because we had, as you'd mentioned, Mr. King. We were relying on the Data Call-In from the U.S. EPA, and the data that was available to us in the public literature as well as the data that would be available in-house to us.

Q. So, there was no endless regress in that case?

A. Not in this specific case, no. That's because we were relying on Data Call-Ins that had been generated for other regulatory agencies.

Q. And further to that, in the re-evaluation process, there was no risk that you identify in that sentence where the product remains in use and continues to be a potential threat. You had terminated them years before.

A. That is correct.

Q. So, there was no danger of the sort that's identified here?

A. Right, that's correct.

Q. Okay, thank you.

Going to Paragraph 103 of your first Affidavit, there you state, "In all of these Assessments the PMRA must determine the appropriate margin of safety to be applied when evaluating evidence."

A. Right.

Q. Section 20 of the PCPA 2002 specifies that in determining appropriate actions during a reevaluation or Special Review, the precautionary principle must be taken into

account."

Now, can you point me to where in the Special Review decision you took the precautionary principle into account?

A. That was prior to the coming into force of the Pest Control Products Act. That was not until 2006, that, you know, it came in force.

Q. So, the precautionary principle was not applied in the case of the special--

A. No, all of our Assessments, you know, are very precautionary in nature.

Q. Do you mean conservative?

A. We--no, are health-protective and protective of the environment. It is our mandate, you know, to protect the health of Canadians and Canada's environment.

Q. Right. I appreciate that.

But the precautionary principle, though, is a specific principle. It means more than just cautious, let's say.

A. Right.

Q. In the Special Review was the precautionary principle as that term is understood by you used?

A. In the Special Review, we did not use that terminology because the new act was not yet in force. However, we took, you know, obviously a precautionary approach, as we do in all of our Risk Assessments, as do all our regulatory agencies.

Q. Did the precautionary principle come to bear on the

10:01 decision in the Re-evaluation Note, the REN?

A. Again, you know, we obviously, you know, do apply precaution in all of the Assessments that we do, and, you know, where there are threats of serious or irreversible damage, you know, we will not, you know, allow, you know, lack of certainty, you know, to prevent the implementation of mitigation measures. But in this case lindane was not registered, so, you know, there was no need to implement regulatory action to address those uncertainties. Our approach is obviously precautionary in all cases. It's the role and responsibility.

Q. The precautionary principle is not cited in the REN? It's not mentioned. It doesn't enter into the deliberations and the decision per se anyway.

A. I don't believe so.

Q. Okay. Is there anything in your governing legislation that directs you to follow the precautionary principle?

A. Could you repeat the question again, please.

Q. Are you compelled by your legislation, the Pest Control Products Act, the Regulations to apply the precautionary principle?

A. In the new Pest Control Products Act, you know, we will take that in or we will take, you know, precaution into account, but, you know, in fact, we go beyond the precautionary principle because only products that meet acceptable standards

10:02 are allowed for registration in Canada.

Q. Okay. You go beyond?

A. We do, yes. We have a precautionary approach.

But in this particular case in the re-evaluation, as I mentioned, you know, there was no registrations in Canada, so there was no threat of serious or irreversible damage at that time, so we did not need to undertake, you know, mitigation in concordance with the precautionary principle.

Q. And that's consistent with the definition of the precautionary principle at Paragraph 103.

A. Yes.

Q. It's not in your statute, but is this a policy decision to apply the precautionary principle?

A. It's in the Pest Control Products Act, as mentioned here in Section 20.

Q. And just for the record, I will define it and say the precautionary principle states that where there are threats of serious or irreversible damage, lack of full scientific certainty shall be not be used use a reason for postponing cost-effective measures to prevent adverse health impact or environmental degradation.

A. But there was no need to invoke this precautionary principle because there were no registrations in Canada.

Q. Right.

And at the time that those registrations were

terminated, the precautionary principle wasn't in force against PMRA?

A. The Pest Control Products Act was not yet in force.

Q. But had predecessor legislation?

A. Yes.

Q. That did not--

A. Specifically, no, it did not mention the precautionary principle.

Q. Okay. I'm going ahead to Section 3 which begins at Paragraph 110 of your first Affidavit.

A. Right.

Q. And in there you talk about the initiation, I guess, of the Special Review.

A. Right.

Q. In Paragraph 111 in the second sentence, you say, "We, being the PMRA's, exposure to re-evaluation section, were simply focusing on the scientific question of whether lindane was safe for continued use."

Who directed you or the re-evaluation section to launch the Special Review?

A. That was an Agency decision.

Q. Can you be more specific. Where in the Agency are those decisions made?

A. I am not familiar with all of the details on that, but we initiated this because of the issues around lindane. There

had been a number of health and environmental concerns that had been raised over the years from the 1970s all the way through to the 1999s (sic).

And as I mentioned earlier, we also had a commitment under the Aarhus Protocol to initiate a special review, but the actual discussions I don't remember, but it was the commitment at the Aarhus Protocol that would require us to initiate a special review, a re-assessment of that, and complete it within two years.

Q. I'm sorry. You don't recall who directed you to initiate the Special Review; is that correct?

A. As I mentioned in the previous paragraph, I became involved in the Special Review of lindane in 2000. Before that, I was working on the New Products side.

Q. Admittedly rare, the PMRA had carried out Special Reviews before the lindane, and had it carried out any since?

A. Since lindane, no, not to my knowledge--no, we have not. But we have undertaken a very extensive re-evaluation program that we initiated in around 2000 that has addressed a fairly significant number of the Active ingredients. We are currently around 90 percent of the Active ingredients that were subject to re-evaluation that had been addressed so would have likely picked up any issues of concern.

But Special Review is triggered by specific concerns that had been raised, and we had some concerns with respect to

10:07 some other active ingredients in the past, and we addressed those through a Special Review, such as carbofuran, the tributyltins, and lindane. It's--there are a number.

Q. These are the only three I know about. Are there others?

A. That's it.

Q. Whenever the discussion of the Special Review comes up, perhaps a future witness of Canada will be able to assist, but I'm a bit surprised that you don't know who directed the initiation of the Special Review. I appreciate that you were only brought in in 2000, in other words, the year after it began, but it was a significant endeavor.

A. Well, it would have been likely the Re-Evaluation Management Committee at the time because in the past, there was a Committee called Re-evaluation Management, as the program was being set up that likely would have made that decision, but, you know, we also have a planning process within to allocate resources where required, and it's standard business practice.

Q. We discussed at the beginning of our conversation here that the 1998 Aarhus Protocol required Canada to reassess.

A. Um-hmm.

Q. The--I'm looking at Tab 31 of the Volume 1 of the Joint Hearing Bundle.

A. Okay.

Q. Actually, it's Exhibit JW-10. You have it already in

front of you as Tab 10 of your statement, so that's helpful. I'm going to Annex 2 of that document.

Do you have it?

A. Yes, I do have it in front of me, sorry.

Q. You're faster than I am.

And that is where I find the lindane and those six uses are carved out, restricted, so it says in Annex 2, substance is scheduled for restrictions on use, implementation requirements at the top cell?

A. Right.

Q. And then the middle column, restricted two uses, and in the third one down products in which at least 99 percent of the HCH isomers in the gamma form, lindane.

A. Right.

Q. And then under conditions, for lindane are all restricted uses of lindane shall be reassessed under the Protocol no later than two years after the date of entry into force.

Do you know when the Protocol came into force?

A. I believe it was--I believe that our commitment was that it would be reassessed by 2002, so it's probably--I'm just sort of going from calculations 2000, that would have actually come into force. But I would need to verify that to be a hundred percent sure.

Q. Right.

10:11 And you're kind of calculating backwards because you recall a commitment to be reassessed by 2002. You're just saying, well, within two years. So it must have come before. But my question wants to go the other way because--and we were talking about who ordered the beginning of that re-assessment which came to be called the Special Review, and part of that is when should we conduct, when we should conduct as PMRA, that re-assessment. But you're not aware of when that Protocol--

A. I do not have an exact date.

Q. All right. Turning to Paragraph 129 of your Affidavit now?

A. My first Affidavit?

Q. Yes.

A. 129. All right.

Q. This is a midst of a discussion about the conduct of the Special Review?

A. Um-hmm.

Q. And the last sentence of that paragraph starts, fourth line up, "As occupational exposure was being raised at such a high-level meeting signaled by the presence of the PMRA's Executive Director, the Claimant can't reasonably assert that this issue was off the table or, indeed, even of only minor concern.

The meeting you're referring to is that October 4, 2000 meeting at the beginning of that paragraph; right?

10:12 A. Yes.

Q. I'm going to continue at Paragraph 130: "Mr. Rob Dupree of Chemtura Canada confirmed in a letter of October 6, 2000, that the PMRA had identified concerns with overexposure."

Now, you go on here, "In particular the PMRA noted that the use pattern of lindane for seed treatments in Canada often differed from that of other countries. We thought"--we being the PMRA, presumably--"thought that extrapolating from databases such as the Pesticide Handler Exposure Database," that's PHED, "might not be appropriate in these circumstances." In essence the PMRA was indicating that the available exposure data had limitations.

A. That is correct.

Q. But--

A. If to use PHED does not contain seed treatment studies, and that's why it was felt that that particular database would not be an acceptable database for estimating exposure for estimating exposure for those scenarios.

Q. And so, that's the concern that was being identified, that the data wasn't appropriate.

A. No. The concern was that there had been issues raised in other regulatory jurisdictions such as the U.S., the U.K. Pesticides Safety Directorate. There were also some concerns that had been raised in the E.U. with respect to occupational exposure, so it's clear from, you know, this discussion that we

had raised that as an issue in light of the risks that had been identified by other regulatory agencies who then proceeded to cancel lindane seed treatment uses.

Q. But I guess--

A. That, in and of itself, would, you know, serve as a trigger for a special review where another regulatory Agency has taken action against a chemical on the basis of risks that have been identified. We need to at least take a look at it.

Q. That's not what it says in Paragraph 130. In Paragraph 130, it says the Pesticide Handler Exposure Database might not be appropriate. It doesn't say the U.K. had a concern for worker exposure and terminated or restricted or anything like that.

A. Um-hmm.

Q. And I'm asking you to confirm that in the October 4th, 2000 meeting, that's what was discussed, what you wrote here in your testimony.

A. That's one of the issues that was discussed, yes, between Claire Franklin and representatives from Chemtura, but the whole issue of the risks that had been identified, you know, by the U.K. PSD were also, you know, discussed. So, if they had risks of concern, it's obvious that, you know, we would also need to examine that for its relevance to the Canadian scenario. It would have been a trigger for review.

Q. Can I ask you to turn to the tab in your first

10:16 statement, JW-30. That's the exhibit and the tab number.

A. Right, okay.

Q. And that's the Lindane Board of Review Report. And I'm going to refer to Paragraph 108 of that Report.

A. Um-hmm. One moment.

Q. At 108, the Board stated, "With the foregoing in mind, the Board notes that it was not PMRA but rather CIEL that brought the issue of occupational risk to the parties' attention. Moreover, the Board does not believe that occupational risk was discussed to any significant extent, and further was not presented as a fundamental aspect of PMRA's Special Review until the Risk Assessment was completed in October 2001."

So, based on maybe not your statement, but based on the testimony that you just gave me, you don't agree with the Board of Review, do you?

A. Not with respect to the details on this specific point. We took a look at the recommendations and thought those were reasonable, but, you know, with respect to every aspect in the Report, I mean, there are obviously going to be some differences of opinion. We were of the mind that this was a significant discussion raised at a high level between representatives of CIEL and ourselves.

Q. Again, in paragraph--well, actually, in Paragraph 143 of your statement, of your first Affidavit, you cite that same

10:17 meeting in the last line.

A. That's Paragraph 143?

Q. That's right.

A. Right, thank you.

Q. The last sentence, "Notwithstanding the Claimant failed to propose any closed system or other protective measures or study during this the Special Review, including when the PMRA specifically raised concerns about worker exposure at its October 4, 2000 meeting.

A. Right.

Q. And you cite that meeting again in Paragraph 152.

A. Right.

Q. Second sentence, "I've described above in my Affidavit how the PMRA expressly raised the occupational data issue"--I think that's probably a fair way to put it.

A. Right.

Q. "With Chemtura in a high level meeting with Dr. Claire Franklin, the Executive Director of PMRA, on October 4, 2000."

A. Right.

Q. In that paragraph, you go on at the last sentence, "As the Claimant itself admits at that meeting, Dr. Franklin indicated some concerns because the use pattern for seed treatments in Canada often differed from that of other countries."

A. Yes.

10:19 Q. So, it was about the adequacy of data. It wasn't about concern that worker exposure risks were going to become or were an important part of the Special Review.

A. There were obvious discussions about worker risk concerns. If it you look at the notes, I believe there are notes by Chemtura from that meeting. It does indicate that we have concerns with respect to worker risk or worker exposure risk.

Q. I guess our issues joined.

A. Right.

Q. Thank you.

I'm going to Paragraph 154 now of your statement. In that paragraph, you say, "Given these facts, it is ironic that the Claimant is arguing, as it did before the Board of Review, that the PMRA knew that the application practices used in the 1992 Dupree study were no longer applicable."

A. Right.

Q. Now, setting aside the irony, isn't that true? The PMRA knew that that--the application practices were not applicable, at least to canola seed treatment, since it had the Helix Study?

A. We were--well, the Helix Study was representative of a small number of plants with very high engineering controls, including very closed systems. The--not all plants in Canada at the time when the Special Review was done had that level of

10:20 technology. The Dupree study represented that range of exposure potential. And furthermore also represented what was currently on the labels at that time, so we had an obligation to address the existing use pattern. We took into account the Dupree study that had different levels of control from small plants up to large plants, some of which had some controlled conditions as well.

And as I'd mentioned earlier, we also did a quick check against the Helix Study to see whether or not that would have been, you know, something that would provide that level of--that level of mitigation would have provided acceptable risk, but it did not.

Q. And for the reasons we discussed before about that certainty factor in having that effect on it; is that right?

A. That was one of the issues, yes.

Q. Here--this will no doubt reflect my ignorance in the process of a Registrant and an Agency meeting or failing to meet on either an approval or a re-evaluation or a Special Review of this type.

So, I'm going to--naively, I will say this: An alternative scenario, the PMRA received the Dupree study, received it in the same manner that it did?

A. Right. And, in fact, we already had it in our database, and it was something that was looked at by our exposure assessors when they screened the database at the

10:22 initiation of the review.

Q. So, in fact, the fact that Rob Dupree submitted it to the Agency? October of 2000 made no difference whatsoever?

A. It was not new information to the assessors.

Q. And it made no difference to the assessors or to the--I'm sorry, to the Assessment. It would have been used anyway?

A. It would have been used anyway, yet.

Q. Fair, fair, thank you.

A. And it was also used by the U.S. EPA essentially in their Assessment.

Q. So, I'm going back to my naive world. It was in the database. PMRA was aware of it. It was aware that it was 1992, and that it reflected a use pattern, a variable use pattern?

A. It represented the use pattern that was in existence at the time, yes, and was also on the labels.

Q. Well, not the use pattern that was reflected in the Helix Study.

A. No. That was a limited number of plants that, you know, had those high level of engineering controls, but there was no restriction that was proposed by the Registrant to limit it just to those plants.

Q. No, that's right.

A. So, we had to assess the existing use pattern.

10:23 Q. So, when you assessed it according to the Dupree study, you could have assessed it in light of what you knew to be the new technology and then come back to them and rather than terminate them on the basis of unacceptable exposure, say, you're allowed to use it, but it's got to be in these state of the art plants.

A. It's the responsibility of Registrants, you know, to support their active ingredients. They did not come forward with any recommendations for placing--allowing seed treatments to take place in those only very limited number of plants. And as I'd mentioned earlier, we had done a quick calculation using the Helix Study, and it did not provide for adequate protection, and, therefore, it would have been unethical, I think, you know, for us, you know, to go back to the Registrant and ask for new data, for, you know, new data, for example, u know to support that particular use pattern.

Q. Unethical? Can you explain what you mean.

A. Well, just that, you know, for them to go and to generate the data at considerable cost when, you know, it would have--it still are resulted in unacceptable risk estimates. That's all.

Q. I understand.

A. But, you know, they did not approach us about either generating data or limiting the use to individual type plants.

Q. So, I apologize that this sounds naive, but what I

10:25 would have thought would be that whether you received the study from Chemtura in 2000, you already had it in your database, you used it.

A. Right.

Q. You could have, rather than say that it's the responsibility of the Registrant to propose mitigation measures, and in light of the consequences of termination, you could have--couldn't you have told them? You always could have told them about the occupational exposure risk and then allow them to make the decision as to whether they wanted to spend that money.

A. Well, we did actually. We had a conference call with the Registrants on October the 30th, and also on November the 5th to outline what the risk concerns were, so we did identify to them very clearly that we had risks with respect to occupational exposure, that the margins were exceedingly low. So, we raised the issue with them.

Q. October 30th of...

A. Of 2001, sorry, after we had released our--

Q. Right?

A. To them, for comment.

Q. But that was after the Assessment was concluded; isn't that so?

A. That's after the Assessment had been provided to them for comment. Then we did take a look at the comments that we

10:26 did receive, and a final decision was made as a result of that process.

Q. Right, right.

And I guess my hypothetical, if I could call it that, was that you might have told them, as you were finding this out rather than as a virtually fait accompli, but for a comment period for a few weeks?

A. The comment period ended up being approximately a month.

Q. Right, four weeks.

A. Right.

But, you know, the Claimant as well was well aware of, you know, the concerns that had been raised internationally with respect to occupational exposure, and I'm kind of surprised that, you know, they didn't knock on our door to propose specific mitigation measures, you know, if they had those in mind, given the concerns that they were well aware of that had been raised internationally on this chemical.

Q. The Lindane Review Board has some comments about that. Perhaps we can turn to them shortly.

I'm turning to Paragraph 163 now.

A. 163.

Q. Okay. It states, "The conclusions of the internal exposure assessment study submitted by the Claimant on December 3rd, 2001, handler exposure Assessment for lindane use as a

10:27 commercial seed treatment were of no use.

Is that internal exposure Assessment study the Jones Korpalski study?

A. No, that was not. I was done by I believe Mr. Korpalski, but it was basically a recalculation of the Assessment from some of the Registrants' point of view. It wasn't based on any new data, which would have been the Korpalski study. The Korpalski--the Jones Korpalski study was not done until substantially later. It was not presented until the Board of Review. So it was basically just an alternative Risk Assessment based on data that we had already looked at. And as you can see in there as well, there was a calculation error that was made underestimating the exposure by the Claimant.

Q. In fact, to the Claimant's prejudice, no?

A. No. It was the other way around, actually. Underestimating--the margins were actually much lower than they had calculated. It's just the opposite. They had underestimated exposure by an order of magnitude as a result of this calculation, so there is no new information here.

Q. In Paragraph 169 of your statement that's on the next page--

A. Right.

Q. --the Claimant has complained that the overall period given for comment was too short.

10:29 A. Right.

Q. And there you say but the period granted was consistent with that used for other re-evaluations done at the same time.

A. Right.

Q. Going back to the Lindane Board of Review Report, that's again JW-30 at Tab--not tab, I'm sorry, at Paragraph 120.

A. Right.

Paragraph 120?

Q. Yes, please.

A. One moment.

Q. "The Board finds," I'm reading from that paragraph, "that the comment period afforded to Crompton once PMRA completed its Risk Assessment was inadequate," so the Board disagrees with you.

A. They felt that it should be longer than 30 days.

Q. Right.

In other words, the Claimant complaining that it was too short was backed up by the Board.

And then in your Paragraph 169 of your first Affidavit, like I just read, you said the period granted was consistent with that use for other re-evaluations, but the Board says in the last sentence, "In his evidence John Worgan of PMRA himself admitted that it was unusual for PMRA to come

10:30 to a decision so quickly and without adjusting its findings at all after comments from Registrants."

A. Unusual in that over time we did, you know, adjust the comment period, so now that it is in the range of 45 to 60 days instead of 30 days.

Q. Well, you have extended it?

A. Yes.

Q. So, it used to be--it used to be shorter?

A. It was shorter at this time, in that, you know, our re-evaluation activities began probably in earnest around 2000.

Q. Sure.

A. We did a limited number of reevaluations initially, but some of them did include things such as chlorpyrifos and diazinon, and we were also working on the tributyltins at that time. For these, for the residential uses of chlorpyrifos, as we were proceeding with our re-evaluation, we determined that there were risks of concern for children and some homeowner risks due to the use of chlorpyrifos, so we took quick regulatory action and, you know, had a relatively short comment period with Registrants who voluntarily discontinued their products as good product stewards.

Q. Thank you, but I'm going back to Paragraph 120. At Board of Review, you said that was an usually short period; isn't that right? Am I reading that correctly?

A. Yes, you are. Yes.

10:32 Q. Okay. I think--I think I made the point, I hope.
Jumping ahead to Paragraph 171, and there I think--well, confirm for me or correct me, you're giving reasons as to why that comment period after the Special Review was so short, you say, it must also be remembered that this was a comment period relating to a special review, where the PMRA had reason to believe that continued use of the product could lead to damage to human health and the environment.
A. Right.
Q. So, that's sort of an urgency appeal that you were making there; is that right?
A. That was part of the consideration because a special review is triggered by specific concerns. In the case of lindane, based on that Risk Assessment, we had significant serious concerns with respect to worker risk.
Q. Hence, this four-week comment period.
But--and we know that the Special Review led in fairly short order within a few months to the termination of Chemtura's registrations, but that if Chemtura had signed on the dotted line, as other Registrants did, it would have been allowed to continue to sell for two more years?
A. That was their choice.
Q. Right, I understand that.
A. They chose to be terminated because that was the only other option that was available to us.

10:33 Q. Right.

But I guess what I'm going to is the urgency didn't seem so pressing in the case of other Registrants as to the abbreviated and, as you said at the Board, an unusually short comment period when, in fact, the product continued to be in the market, be used for two more years.

A. No. Ideally, you know, in the best of all possible worlds where we do identify risks of concern, we would be able to remove that product from the marketplace almost immediately. However, there are some very practical type considerations. We allowed for a--two different phase-out time frames, depending on the crops, so it was really to address the practical type considerations. Ideally, it would be almost immediate.

Q. And this is just now, I'm not talking--I'm not talking about lindane, but going on to suppose the PMRA became aware of a pesticide that was a very serious and unacceptable risk. Would it not have the power to terminate it without giving this phase-out period?

A. Yes, we could.

Q. But is there a special finding it would have to make before it took those drastic consequences?

A. It would be an exceptionally serious, you know, end point of concern, yes, but typically, we, you know, do allow for a phase-out, and the duration of that phase-out is going to be dependent on a variety of factors, including the risks of

10:35 concern.

Q. Right, okay.

A. It's basically just practical type considerations.

Q. I guess I'm looking at the Board of Review Report again, and this time in Paragraph 103. As far as urgency and process, the Board stated at 103, "While it is appropriate for PMRA officials to manage the Special Review process in a way that allows it to come to an informed and expeditious conclusion, and in accordance with the requirements of the Regulations, in the opinion of the Board, Registrants should be permitted the opportunity to make representations to those officials before a decision is issued that adversely affects their products, particularly where the decision is, as it was in this case, as dramatic as a cancellation of registrations."

A. And they were offered an opportunity to come in and make representation after the conference call, and they did. As you'd mentioned, they provided us with the alternative Assessment, and they also made, you know, some recommendation--they actually made some recommendations, I think, for some mitigation in there as well, but we looked at that, and that was not sufficient.

Q. I guess--I'm suggesting to you, though, that the Lindane Board of Review disagreed with the PMRA as to the adequacy of the comment period. In Paragraph 103 and again in 106; is that fair?

10:37 A. Yes, that is correct.
Q. Okay. Thanks.
In Paragraph 174 of the statement--of your first Affidavit.
A. Okay. 174.
Q. There you state if Chemtura--do you have it?
A. No, I don't have it. 174. Yes.
Q. "If Chemtura had presented data on potential limitations on formulations or protective measures including during the comment period following the release of the PMRA's draft Assessment," you say there, "in October 2001, PMRA would have been in a position to take such steps into consideration."
A. That is correct.
Q. In fact, though, the Board of Review put the responsibility on PMRA, didn't it, to inform Chemtura of its occupational risk concerns.
A. Which we did.
Q. And given an opportunity to address them--I'm sorry?
A. Which we did. Yes. We informed them of the risk concerns, and they were given an opportunity to address those concerns through the consultation period.
Q. Okay. I'm now going to Paragraph 106 of the Board of Review Report?
A. Okay. Which tab was the Board of Review?
Q. I'm sorry, Exhibit JW-30. Same tab.

10:39 A. I'm a little slow here today.
Which paragraph?
Q. 106. 105--
A. Right.
Q. There the Board states, "Although the PMRA maintains that Crompton was given an adequate opportunity to provide input regarding the conclusions reached in the Special Review regarding the registration of Lindane Products, the Board is of the view that to give life to Section 19 of the Regulations in a manner consistent with the principles articulated in Baker--that's a Canadian fairness case, legal case--a meaningful opportunity for input should have been given to Crompton particularly when PMRA officials began forming the view that the registration should be canceled and after the Risk Assessment was completed but before the Minister's decisions were finalized."
I guess the Board obviously disagreed with the Agency on that.
A. They felt that the comment period should have been longer, yes.
Q. I guess I read a little more than that, but--into that, where an adequate opportunity to provide input regarding the conclusions.
A. But this is--there had been a number of concerns related to lindane over the years, and occupational risk was

10:40 one that had been identified by a number of regulatory agencies, so, you know, I think Chemtura would have been well aware that, you know, there are need for mitigation measures in seed treatment plants in Canada and elsewhere to address risk concerns that had been identified by a number of regulatory agencies.

Q. And I think that's exactly the Board's--I will propose to you that that's exactly the Board's concern. It's not that everyone or anyone, whether the Board or the Claimant is saying, what's the problem with lindane, everybody knows there is a problem with lindane. What the Board, I put it to you, was suggesting or even recommending was that, given the seriousness of these issues, it would have been better to entertain a dialogue with the people who would be in a position to either assist or be consulted anyway on mitigation of those risks. But, in fact--

A. But they were given an opportunity. I recognize that the Board felt that it was too short, but it was still a month, and the issues around lindane had been raised for a number of years. The Chemtura would have been well aware that there would have been possible mitigation measures that they could have come in to address with us, but essentially what they did is they just rejected the Assessment. They didn't come in and inquire with respect to what were some of the possible mitigation measures.

10:42 And as you know, the Board of Review was also very critical of Chemtura for failure to engage during this whole process.

Q. I guess I'm reading 106, Paragraph 106 as saying more than relating to the comment period because, as I was reading, in the third line from the bottom or let's say starting after the word Baker, "A meaningful opportunity for input should have been given to Crompton particularly when PMRA officials began forming the view that the registration should be canceled, not after they had concluded their view and offered a comment period, but, in fact, in the process." So, while the Board did have concerns about the length of the comment period, isn't it right that they were saying more than that in 106 in that Chemtura should have had opportunity for input before that view for cancellation of registrations had been formed?

A. Yes, that's my understanding of that as well, but our process is that these Assessments are done, and they are brought forward to SMC, our Science Management Committee, for direction as to what the next steps are. So, it's something that would not have been substantially more in advance of the time that we actually contacted Chemtura.

At that stage, around October, we'd identified significant risks of concern, and we finalized our Assessment, then had that discussion with Chemtura and others to solicit input from them. So, it was around that time that the risk

10:43 issues had been identified, sometime in October. Our concerns had been identified. It was at that stage that we were able to say these are significant enough concerns. There are endocrine effects, there are sensitivity effects that, you know, we need to address, and so we did that in our Risk Assessment and had our discussion with Registrants forthwith.

Q. When you said October, did you mean October 2000 or 2001?

A. 2001.

Q. Oh, all right. But--

A. With respect to our Risk Assessment.

Q. Right. That was the conclusion of the Special Review?

A. Um-hmm, right.

Q. And I--

A. We could not predict exactly what our Risk Assessment would have shown until that time, until we had completed our own Assessment. But risks of concern had been identified by other regulatory agencies, and that was brought to the attention a full year in advance to Chemtura.

Q. We discussed that.

A. We discussed that.

Q. Can I direct your attention now to Paragraph 179 of your first Affidavit.

A. 179.

Q. Page 46.

10:45 A. Yes, I see that.

Q. There you state, "Even before the release of the Board of Review's Report on August 17, 2005, the PMRA decided to carry out a de novo scientific review of lindane in order to examine and consider any new scientific information generated on lindane since the 1999-2001 PMRA Assessment." And your footnote 42 takes us to Exhibit JW-29. Could I ask you to keep a finger, if you would, in the Page on 179, Paragraph 179, but turn up--

A. JW-29?

Q. Right.

A. Right.

Q. That's, as you describe it in your footnote, an E-mail from a person Karen Lloyd.

She is at the PMRA, or was?

A. At the time, she was at the PMRA, yes, as Director General of the Environmental Assessment Directorate.

Q. Could you turn the page and go to the second page of that E-mail, and looking at the only complete sentence on that page, and it says--I'm sorry, the first complete, "As soon as the recommendations of the Lindane Board of Review become public, I will share them with you."

ARBITRATOR CRAWFORD: Where is it?

PRESIDENT KAUFMANN-KOHLER: Where is it?

MR. SOMERS: Second page of Exhibit JW-29, at the top

10:47 of the page there, "as soon as the recommendations," that sentence.

BY MR. SOMERS:

Q. I guess I just want to ask you, the way I read that sentence, that means that Karen Lloyd had a copy of the Lindane Board of Review Report or recommendations but couldn't share them with you until they became public. Can you confirm whether that's so?

A. I know that for this E-mail there was some confusion with respect to the date, as I think we had misread how they put the date here. This would have been August the 6th, I believe. Is that correct? Which date is that? No, that would have been September 6. This must have been a copy of the Report once it had been given to the PMRA.

Q. And before it became public?

A. Yeah, just before, I suppose.

ARBITRATOR CRAWFORD: The Report itself is dated 17th of August.

THE WITNESS: 17th of August.

ARBITRATOR CRAWFORD: That's when the Report is dated.

THE WITNESS: Okay. Yeah, because I know again that there was confusion with respect to the dates on this.

Yeah. I'm sorry, I can't help you there.

BY MR. SOMERS:

Q. So, you weren't aware whether Karen Lloyd had a copy,

never mind sort of the dates for now.

A. She would have had a copy when that document was given to the PMRA.

Q. But you didn't?

A. At the time--I had a copy when it was given to the PMRA.

Q. Okay.

A. I just don't remember all of the details as to how soon in advance we got it before it was put up publicly. That's all. It was just standard normal process. We received a copy I'm sure as did Chemtura at the same time, and then it was posted shortly thereafter, but again it was just, I think, in this case here, it was just really a confusion with respect to the how the dates were presented. I don't believe she would not have had an advance copy other than the one that had been submitted by the Board of Review to us.

Q. Right.

But--okay. And the only reason I'm belaboring this point is because in Paragraph 179, you say, "Even before the release of the Board of Review's Report on August"--

A. There it is, yes. Yes.

Q. --"2005, the PMRA decided to carry out a de novo scientific review of lindane.

The implication is that the PMRA would have carried out a scientific review of lindane, irrespective of the Board

10:50 Report, isn't it?

A. Again, this was an error on my part, you know, looking at the dates of this E-mail.

Q. Oh, oh.

A. I thought Karen Lloyd had, you know, decided that she would initiate some level of review, but it was just an error.

Q. Okay.

A. It was an error. It was an honest mistake.

Q. So, we should just revise Paragraph 179?

A. That's correct.

Q. Okay, I'm sorry.

A. And I think during the document discovery exercise we did indicate that it was just a clerical error on my part.

Q. Thanks for that. That's helpful.

Looking at Paragraph 184 of your first Affidavit now, where you say, of course the Board of Review would have taken a different approach on various points and had different evidence before it. My colleague, Cheryl Chaffey, reviews the PMRA's thoughts on various recommendations of the Board, and I therefore refer to the Tribunal to her evidence. What I do note is that the Board of Review process was a discussion between scientists about a scientific process discussing the range of options open from a scientific point of view.

A. That's correct.

Q. The Board of Review never called in question the

integrity of the PMRA process.

Now, I'm going to ask you to turn again to Tab JW-30 in the Board of Review's Report and just by way of example point to Paragraphs 103 to 106, and ask you to either confirm or correct me. Those paragraphs--

A. 103?

Q. 103, 104, 105, and 106.

They're a discussion of fairness, aren't they, they're a discussion of process, of adequate time to respond, of consultation. They cite a Supreme Court in Paragraph 104 of the Supreme Court of Canada decision.

And so, in fact, the Board of Review did call the integrity of the process into question, didn't it?

A. The Board of Review--what we are referring to here is the scientific process that we have followed, and the Board of Review did conclude that the--while they may have taken a different approach on some parameters in the Assessment that overall the scientific process and Risk Assessment was well within the range of acceptable. So, they did not criticize the process. They would have maybe come to a different--the process, scientific process, the Risk Assessment was well within what would be expected.

Q. I guess I'm going to a different point from that, where you say it was a discussion between scientists about a scientific process.

10:53 A. That's true.
Q. But it was--
A. It's the Risk Assessment process.
Q. It was also--it was--the Board of Review was more than that. It was a discussion about the overall deficiencies in fairness about the process, and that's why in Paragraphs 103 to 106 they talk about fairness. They don't talk about science and at risks and percentages or anything like that?
A. Not at that point, but this particular text is related to, you know, the scientific Risk Assessment that's in--described in Cheryl Chaffey's Affidavit.
PRESIDENT KAUFMANN-KOHLER: Mr. Somers, I assume your cross-examination will last somewhat longer, or is it close? Because you're still at the first Witness Statement, so when you come to a point where it's easy to stop for a break, you can decide yourself what is a good time.
MR. SOMERS: Thank you. I'm actually, although it's true that I'm only in the first statement, that that is where the bulk of my examination sits, so I'm going to try to estimate how much longer I have.
I will be prepared to break now and come back.
PRESIDENT KAUFMANN-KOHLER: That's a good thought.
So let's take a 20-minute break, then.
(Brief recess.)
PRESIDENT KAUFMANN-KOHLER: So, Mr. Worgan, you're

11:23 ready to start again.

THE WITNESS: Yes, I am.

PRESIDENT KAUFMANN-KOHLER: Good, Mr. Somers.

MR. SOMERS: Thank you.

BY MR. SOMERS:

Q. Hi, Mr. Worgan.

A. Hello.

Q. I'm still in your first Affidavit.

A. Okay.

Q. And now I'm at Paragraph 238.

A. Yes.

Q. Now, in this section, you're discussing the development of the Re-evaluation Note, the process leading up to that--

A. Um-hmm.

Q. --decision.

So, I will pick up at Paragraph 238.

By April 1st, 2008, HED had completed the human health Risk Assessment for lindane--

A. Right.

Q. --integrating the revised approach to the application of uncertainty factors and the new PCPA factor.

A. Right.

Q. PCPA factors of 3-fold and 10-fold were applied to the acute and chronic dietary Risk Assessments respectively.

11:24 A. Yes.

Q. These additional factors were applied to account for the sensitivities of vulnerable subpopulations, pregnant females and instants--

A. Um-hmm.

Q. --as well as any residual concerns and certainties pertinent to these subpopulations.

Weren't those subpopulations the same justification as the PMRA used in the Special Review to have chronic uncertainty--or, I'm sorry--an Occupational Risk Assessment of 10-fold on top of that interest species variation, and the term escapes me now, and the other 10-fold increase yielding a total risk factor of a thousand? Isn't that the same reason as was given in the Special Review, the vulnerable subpopulations?

A. Yes, that was one of the considerations. However, I am, you know, not fully familiar with all of the details of how this PCPA factor was applied in terms of this Risk Assessment because I do not--you know, I'm not responsible for the Health Risk Assessments. That would be Dr. Chan.

But yes, there was issue both in the Special Review as well as here with respect to the sensitivities, sensitivity issue, after we looked at the additional--the new information that had been provided.

MR. SOMERS: In the last sentence of that paragraph, indeed you say: In the Occupational Risk Assessment, an

11:26 additional factor of 10-fold was used to address the same considerations that supported the use of the PCPA factor in the chronic dietary Risk Assessment, given that the workforce could include pregnant or lactating women.

A. That is correct.

Q. So, that's the same as the Special Review.

A. Yes, yes.

Q. Now, could I ask you again to turn to my favorite exhibit, the Exhibit JW-30, the Lindane Review Board Report.

A. Okay.

Q. And as I explained to the Tribunal at the outset, you will have to go to that page that I gave you because that was inadvertently omitted from both of your affidavits, and it's Page 53 of the Lindane Review Board Report, and I'm looking at Paragraph 222.

A. Right.

Q. There it says that the Board is of the view that the additional 10X uncertainty factor is not justified.

A. Um-hmm.

Q. So, I guess I had a couple of questions coming off of that, and one is: Isn't it so that there is no better justification now in the re-evaluation than there was in the Special Review, because your reasons are the same and the Board found them unjustified, so the Board would equally have been constituted to review the Re-evaluation Note and come to the

11:28 same conclusion: It's not justified. It's the Board.

A. Again, I'm not familiar with all of the details with respect to the Health Risk Assessment not being responsible for that.

Here what they are doing is they are recommending and the recommendation was that we consider another uncertainty factor, safety factor for this particular issue. It is something that was looked at by our scientists that were involved in the re-evaluation follow-up review, in light of the new policy that we have with respect to uncertainty and safety factors; and also having looked at, I believe there was some data in the published literature and this whole issue of sensitivity was, you know, re-examined, and then on the basis of that new data, that new information, that it confirmed the need for a 10X safety factor to cover up sensitive subpopulations. So, you know, at that time they were recommending a different factor, but, you know, it has been looked at by our scientists in light of our new policy, in light of new information, and they've arrived at the conclusion that the 10X is justified.

Q. The Board made that recommendation to change--to change, not to just look at again. The Board, in Paragraph 222, went on to say: "It therefore recommends that PMRA consider an adjustment factor other than the 10X justification default." That is the recommendation. But the

11:29 recommendation, I suggest to you, is based on their scientific rejection of the justification for the additional 10X. They did recommend a different one, quite so, but the reason they did that was, as you testified earlier in the conversation of scientists between scientists, that it wasn't justified, and the justification is a scientific evaluation of assessments of evidence leading to a logical conclusion.

A. Right.

I think, you know, you also need to look at, you know, the Board's conclusions regarding the toxicological Assessment and they are saying that the evidence is suggestive as opposed to conclusive, and they recommend that that be taken into account when considering the need for an additional certainty factor. This is Paragraph 217 of the JW-30. That is exactly what was done by our scientists in light of the safety factor policy document that we developed in consultation with a variety of stakeholders, including industry.

But again, you know, the details with respect to the actual application in this case and how they arrived at those questions would need to be directed to, you know, the scientists and Health Evaluation Division.

But we did reconsider it. We, I believe, had new information, you know, that was gleaned from the published literature, and, you know, on the basis of that, deemed that it was fully supported, that there were, you know, clear

11:31 indications of sensitivity, but, you know, that they would need to be, you know, discussed further with the health evaluation scientists. I manage the process. I'm not directly involved in the Risk Assessments per se.

Q. I guess what I would ask you to distinguish from, on the one hand, is policy.

A. Mm-hmm.

Q. And you testified, I think, that the PMRA changed its policy in regard to uncertainty factors?

A. The PMRA had a consultation process, a public consultation process, on the uncertain--application of uncertainty factors, safety factors in Risk Assessment. There are a few meetings, I believe, plus a document that went out the door for comments. We looked at those comments or it was looked at by the scientists in Health Evaluation Division, and the policy was finalized in light of those comments that we did receive. So, we underwent that policy review, you know, as one of the commitments that we had made as a result of the Board of Review Report that we received.

Q. But notwithstanding the establishment of this new policy, as I read your testimony and the Board of Review and the Special Review, the justification for the 10X factor on the testimony is the same, and yet the Board found that it wasn't justified. And so my assertion to you, and I would ask you to confirm, is that the Board would recommend again if it was

11:32 assessing the REN for the same reasons--
A. Right.
Q. --that it be looked at again.
A. Right.
Q. You go back and use a different uncertainty factor.
A. Well, you know, again in terms of the details, I really can't speak to that, but they were saying that the evidence was suggestive at that time. I believe that--and you would need to verify with Health Evaluation Division, that they looked at the evidence again and found that it was certain as opposed to suggestive, but I really--I can't go any further than that with respect to the details of application of safety factors for specific chemicals having not been directly involved in the Risk Assessments for this chemical or any chemical for that matter. They applied their policy that they developed, you know, in consultation with a variety of stakeholders, including Chemtura's own industry association.
Q. And ended up with the same result, ten--1,000X; right?
A. In this case, yes, based on the evidence that they looked at.
Q. I'm turning now to Paragraph 242 of your Affidavit, first Affidavit.
A. Okay. Just one moment.
Q. On Page 5 of the REN you state there that PMRA points to its conclusions regarding the feasibility of possible

11:34 mitigation procedures. Risk reduction measures to address some of the potential risks from use of lindane are identified in this Assessment but are not proposed for implementation.

A. Mm-hmm.

Q. It is not feasible to reduce risks sufficiently to address the levels of concern which had been identified for human health, even with maximum personal protective equipment--

A. Right.

Q. --and engineering controls risks to workers handling lindane and lindane-treated seed were unacceptable.

A. That is correct.

Q. That is, again, we can see between the lines the operation of that thousand fold uncertainty factor; isn't that right? Wouldn't that work directly into that calculation of the impossibility of mitigation?

A. I wouldn't say the impossibility. You know, in this case, you know, even with all of those--extensive mitigation, we still had risks of concern.

I mean, we routinely, you know, apply, you know, our safety factor as per our policy, and there are a number of chemicals, you know, such as 2,4-D, for example, or Helix for that matter, where an application of an additional 10X still results in acceptable risk.

Q. Yeah, I guess my interest is in your testimony and in lindane.

11:35 A. Right.
Q. As I understand that there are mitigation procedures for others--
A. Mm-hmm.
Q. --that are quite happily implemented and the Registered product continued to be used--
A. Right.
Q. --with those additional precautions.
A. Right. Because, you know, the risk is going to be dependent, is chemical specific, is dependent on the hazards of associated with a particular chemical.
Q. Right.
And in this case, you didn't want--you didn't accept the use of my word "impossible," so your word is un--not feasible--not feasible to reduce risks sufficiently--I'm at the top of page 64--to address the levels of concern which have been identified for human health.
A. Mm-hmm.
Q. And I was just asserting to you, asking you to confirm or not, that that's a direct result of the selection of that additional 10X factor leading to a thousand-fold uncertainty risk factor that makes it not feasible to reduce risk sufficiently.
A. Well, it's the result of the, you know, the risk associated with lindane. It's a result of the, you know, the

11:36 hazards that are associated with this chemical as well as the exposure potential as well as the safety factor. So it would be a combination of things, not just attributable to one single factor.

Q. Continuing down that paragraph, the last line of the quote from Page 5 of the REN, it states: "There are no known reported measures that would effectively mitigate the release of the waste chemicals produced in the manufacture of lindane."

First of all, I need--are you with me?

A. Yes, I am.

Q. All right. My first question is: What does it mean to effectively mitigate the release? Isn't mitigating release not releasing? In other words, if we put a lid on those waste products and sequester them securely, wouldn't that be mitigating the release?

A. That would be one possible way of mitigating it, yes.

Q. Well, there are reports in the literature of safely stored waste isomers. In fact, in the record, there are photographs of sites which contain safely stored waste isomers. So, wouldn't that mitigate the release?

A. Well, it would depend on how they are stored. I mean, there have been problems with, you know, these isomers that are generated, you know, as waste byproducts, you know, from the use of lindane, and, you know, they are being released into the environment, as is evidenced by concentrations that are

observed well away from areas where lindane would actually be used.

So, you know, just storage degenerate, you know, for every tonne of lindane, you know, several tonnes of waste isomers, and to store it somewhere, I mean, I don't think that, you know, that would be a reasonable mitigation measure. Just storage itself, no.

But that--

Q. There's evidence elsewhere in the record of--and I'm considering whether to put it in front of you--but there is evidence elsewhere in the record that safely secured stored waste chemicals that were produced in the manufacture of lindane, are you not aware of those?

A. We are aware of the information that was provided by the Registrant with respect to how some of the waste isomers, you know, can be cracked into other chemicals for other use. We did make a revision to the REN as it was to be published, and we do indicate there that they have provided us with information to suggest that that is a possible mitigation measure.

However, this is really--the risk associated with lindane as described in the follow-up review is related to the gamma isomer. We did include some discussion with respect to the alpha and beta isomer, but lindane itself was assessed in the Risk Assessment, and we found that there were unacceptable

11:40 dietary risk, there were unacceptable occupational risk, and also unacceptable environmental risk.

So, that really was the basis of the Risk Assessment. The other is a secondary issue, while important is nonetheless a secondary issue.

So, even if you were, you know, to store those, as you say, somewhere where there would be zero environmental release, the risks associated with lindane are attributable to--for us, are attributable--we base our Assessment on the gamma isomer or the lindane itself, not on the isomers.

Q. Well, the REN itself, and your testimony spent some time discussing the isomers. When we say waste chemicals produced in the manufacture--

A. Right.

Q. --not we, when the REN does--in the manufacture of lindane, that is referring to the alpha and beta isomers; is that right?

A. It was included in the REN for completeness because of the potential for long-range transport and the designation of both the alpha and beta isomers as POPs under the Stockholm Protocol, for example.

So, you know, but it wasn't a driver in the Risk Assessment. It was a consideration.

Q. I understand.

A. But it didn't drive the Assessment.

11:41 Q. No, it was an additional reason for the conclusions of the REN.

A. It was a secondary issue. The main issue was related to lindane itself, and those had--even without that issue, the Risk Assessment for lindane was unacceptable, both from a health and environmental point of view--multifaceted.

Q. I'm going to read--nevertheless, the REN comments in this way: It is not feasible to reduce risk sufficiently to address the levels of concern which have been identified for human health, environment. And it goes on to say: There are no known reported measures that would effectively mitigate the release of the waste chemicals produced in the manufacture of lindane.

So, while it may not have been a driver, it may not have been the main reason--

A. Mm-hmm.

Q. --it was another reason for the conclusions, an additional enough--significant enough to be repeated in the REN, significant enough reason to not change your assessment that the levels of concern identified for lindane were too high to permit it to be re-registered in Canada.

A. The decision on the Risk Assessment was based on the gamma isomer. The risks were clearly unacceptable.

The other issue we felt was worth noting, but it was a secondary issue.

11:43 And, furthermore, the information that had been provided by the Registrant about the practices in that one plant were for a plant in Romania that is no longer functioning as a result of their accession to the E.U.

Q. I'm not addressing that. My question is addressing your statement, the PMRA statement--

A. Mm-hmm.

Q. --who you represent, in the REN, not Romania and not anything along those lines.

I'm reading from a statement the confidential Affidavit of your colleague Cheryl Chaffey.

A. Right.

Q. At Paragraph 40 of that Affidavit.

A. Right.

Q. It's in Volume 1 of 2, Confidential Affidavit of Cheryl Chaffey.

Do you have that?

A. I don't have it yet.

Q. The Affidavit, Paragraph 40.

A. 40 A?

Q. Four-zero.

A. Yes, this is Cheryl's.

MR. DOUAIRE de BONDY: It's Paragraph 40, I believe.

THE WITNESS: Or, paragraph. I don't know if I've got--this is just the attach--the exhibits.

11:45 BY MR. SOMERS:

Q. It's right at the front--

A. Yeah, oh I see.

Q. Under Volume 2. This is volume 1 of 2.

A. Okay. Paragraph 40.

Q. All right. In that paragraph--do you have it?

A. Yes, Paragraph 40, I have it.

Q. Okay. And I'm about halfway down that paragraph, and in that paragraph, Ms. Chaffey states: Annex A of this report contains photos of mounds of toxic HCH waste sitting in warehouses in the Netherlands and in Spain, waiting to be buried in highly controlled disposal sites.

A. Mm-hmm.

Q. In the latter case, at an announced cost of 30 million euros.

A. Mm-hmm.

Q. When not disposed of in such secure sites, waste alpha and beta HCH generated in lindane production travel through the atmosphere in the North--when not disposed--

A. Mm-hmm.

Q. When they are, by necessary implication, they do not travel. Would that not be a reported measure that would effectively mitigate the release of waste chemicals produced in the manufacture of lindane, contrary to the statement in the REN?

11:46 A. That's possible, but, you know, we are talking about, you know, you know, waiting for disposal, and, you know, personally, I don't have, you know, specific knowledge with respect to how these would actually be disposed of and whether or not there would be any release. But again, it's entirely a secondary issue, it's--

Q. Are you prepared to say that the PMRA can resile from its environmental waste isomer concerns in terms of the REN?

A. No. What I'm saying is that it's a secondary issue, that the risks associated with the gamma isomer are significant enough to result in, you know, a determination of unacceptable health and environmental risk.

Q. And we discussed lindane already.

A. Mm-hmm.

Q. The REN talks about this as well.

A. Right.

Q. And it's either worth commenting on, it's either material--

A. Mm-hmm.

Q. --or it's insignificant.

And I put it to you that the PMRA considers it material or they wouldn't have included it in the REN. It's this elusive thing where it's not the driver--

A. Yeah.

Q. --therefore it's not really important, but it is

11:47 important enough to condemn lindane. It is problematic for me and--

A. It's entirely like a secondary issue. And in the REN, as a result of the comments that we did receive, and, you know, this version that you're citing from, I don't know if this is the final version of the REN, but, you know, we did indicate in there that the Registrant had provided some information to show that use in cracking process in that plant in Romania could be a possible way of addressing, you know, the release of that. But, you know, there would be no way for us really, you know, to verify that, that statement over time at least, to ensure that that process was actually being applied, and the plant's closed so...

Q. Does--

A. But if you were to remove that risk, it still doesn't remove the critical risk that we've determined for lindane itself.

Q. One of the issues in this hearing is the scientific integrity of the PMRA's process--the Claimant has put that in issue--and in order for us to be able to explore that issue, it is necessary for us to look at conclusions of the REN and to understand why the PMRA reached the conclusions it did.

A. Mm-hmm.

Q. And so the issue about the release of waste chemicals, if it's noted as one of the unfeasible risk reduction issues is

11:49 important to important as to understanding the reason the PMRA got to the decision it does, and that's why I'm belaboring the point.

A. It's really just for completeness, recognizing that, you know, lindane has been stored in various sites around the world. It has been released into the environment.

But again, it's not the issue that--you know, not the significant issue that we had with respect to lindane. It was more of a secondary issue that, you know, unless you could, you know, address the issues for the gamma isomer, well, the other is purely academic, I think.

Q. I'm going to suggest to you that we referred--I'm sorry, let me position you first, to be fair. I'm looking again at Exhibit JW-61.

A. One moment, please.

Q. It's in the second volume of the Confidential Affidavit of John Worgan.

A. JW-?

Q. JW-61.

A. Six-one, okay.

Q. The second page.

A. 61, second page. Okay.

Right. Second page. Okay.

Q. Right.

We've looked at this already at the beginning of your

11:50 examination?

A. Mm-hmm.

Q. And when you say that the waste isomer, the waste chemical issue is--

A. Oh, sorry, I have the wrong--oh, no, sorry. Okay.

So, this is the Briefing Note dated August 31, 2006? Am I looking at the right document?

Q. That's exactly the date.

A. Right. Okay.

Q. The second page.

And I'm going to that sentence I took you to before, the last sentence in the third paragraph: This would clarify/substantiate the position taken by the PMRA in 2001 and support the government's position in Court.

When you say that the environmental issues regarding the release of waste chemicals was put into the REN for completeness--

A. Mm-hmm.

Q. --I suggest to you that you're substantiating the position taken by the PMRA in 2001. You're defending that position by including additional statements to the effect that there are no known reported measures which would effectively mitigate the release of waste chemicals, when your colleague has given evidence about secure sites which do not result in the release of waste chemicals.

11:52 A. May not.
Q. May not?
A. But, you know, this--the purpose of including that information was that--and again, it was not the driver at all in the Risk Assessment. Again, it was for completeness. Those issues have been raised in the past. Not to address it somehow, you know, it would raise questions as to what the risks were associated with that.
So, but again, you know, I think we are belaboring this because, you know, I wasn't the driver in the Risk Assessment, and its purpose was not to clarify/substantiate the position. It was to be as complete as possible. The Assessments are science-based.
Q. Thank you.
A. It's not to substantiate something that was taken before necessarily.
Q. I see.
I'm going ahead now to Paragraph 245 of your first Affidavit.
A. Okay.
Q. Two paragraphs down from where we--I think, where we just were.
A. Paragraph...
Q. 245.
There, you quote from the 2002 EPA Lindane--

11:53 A. Right.
Q. Which concluded that, you say--well, I will--I will start at the beginning of the quote that you put in about the RED.
A. Mm-hmm.
Q. And, in fact, this is a quote from the Addendum--
A. Right.
Q. --to the 2002 RED. It is the August 2, 2006, document. And there the quote that you've extracted says: This RED Addendum reflects the Agency's conclusions on the remaining lindane seed treatment uses in light of the information gathered since the 2002 RED.
A. Right.
Q. The seed treatment use is a source of human exposure to lindane, and it will add to the reservoir of lindane already present in the environment.
A. Okay.
Q. I'm skipping to the next sentence and going to, after the lacuna there: Lindane's persistent and bioaccumulative nature is also of concern to the Agency.
A. Right.
Q. In addition, the Agency's updated analysis of the seed treatment use indicates very minor benefits to growers.
A. Right.
Q. The EPA, Mr. Worgan, conducts a cost-benefit or

11:54 risk-benefit analysis, doesn't it?

A. Yes.

Q. Does the PMRA?

A. We do an assessment of value, risk from health and environmental point of view, and for registration of an active ingredient--all of those have to be acceptable, so we don't do that balancing of risk versus benefit.

Q. Right.

A. We cannot use benefit to override risk.

Q. Whereas?

A. In the U.S., they can consider, according to their legislation, more of the benefits but--

Q. And that's what this quote is about, isn't it, where it says analysis of the seed treatment use indicates very minor benefits to growers because the uses have been withdrawn, and so what benefits remain? Isn't that right? There is no benefits to virtually any risk, so almost any risk at all would cause that tilt, so they do, as you said, the comparative analysis of the risk cost benefit.

A. Right.

Q. Isn't that how you understand that?

A. My understanding of that is there are alternatives that are registered, and therefore you know, this has limited benefit to them, to their growers, to the U.S.

Q. Isn't alternatives that are registered, isn't that

something that the PMRA does? That's what something you would examine as to whether in the value of a pesticide, there are alternatives available.

A. Right. We--

Q. That's not the same.

A. As parts of our re-evaluation, if we identify risks of concern, we will do some assessment with respect to the availability of alternatives for the purposes of determining, for example, an appropriate phase-out schedule. That would be one of the variables that we would include in there. But, you know, we don't use value or benefit, you know, to override, for example, a risk assessment. They all have to be acceptable.

Q. But--and the word "override," you're referring to what the EPA does, in fact, do; is that right?

A. No, they just take that into account in their decision-making.

Q. Don't they do a risk-benefit analysis?

A. They do some risk-benefit analysis, yes.

Q. Okay.

A. But you know, if there, you know, are significant risks of concern related to, you know, say, dietary risk, they're not going to, you know, factor in the benefits in an assessment like that. Risks would be clearly unacceptable to them.

Q. Okay. I'm turning to your second Confidential

11:57 Affidavit right now.

A. I think I have it here.

Q. No, it's the bundle.

A. Oh, this one here? Okay, of course, yeah.

Q. Thank you.

And looking at Paragraph 34, indeed it echos a conversation we had earlier this morning, where you state in the second sentence of Paragraph 34: Canada, indeed, could not agree in the Aarhus negotiations to include lindane.

Do you have it?

A. I'm sorry, I've got it now.

Q. Okay.

Canada, indeed, could not agree in the Aarhus negotiations to include lindane on the list--

A. Mm-hmm.

Q. --of banned products--

A. Right.

Q. --because it could not legally commit at the international level--

A. Yes.

Q. --to banning a then-registered product.

A. Yes.

Q. And we had talked about that.

A. Right.

Q. And that after the Special Review--and I'm putting

11:58 this to you now--after the Special Review and determination of Chemtura's lindane registrations and all others--all other agricultural, anyway.

A. Right.

Q. --Canada could commit legally at the international level to banning of then registered--not registered product; isn't that right?

A. Because we would have done a safety assessment that indicated that the risks are were unacceptable to us.

Q. That's why you terminated them.

A. Um-hmm.

Q. But as far as your legal ability to commit at the international level, that was because there were no registered Lindane Products in Canada?

A. Can you repeat that question again, please.

Q. In May of this year, Canada, along with other countries--

A. Right, at Stockholm.

Q. At Stockholm.

A. Yes.

Q. --agreed to put lindane on Annex A of the Convention which will eventually, when implemented, result in the banning of the use, the distribution, the manufacture of lindane; isn't that right?

A. That is correct.

11:59 Q. And the only way that Canada could do that legally--and I'm looking at your statement--was because it had no registered Lindane Products in Canada. If Canada had registered Lindane Products in Canada, this--your statement would apply and it could not legally commit to Stockholm in May; isn't that right?

A. Again, I'm not totally familiar with all the details with respect to Stockholm. I did not attend--

PRESIDENT KAUFMANN-KOHLER: I think we should say, just to be fair to Mr. Worgan, it's actually a legal question what a State can commit on the international level, whatever its internal legislation is.

So, you have said legally in your statement, so that's why the question does arise, but you should tell us your understanding. You're not a lawyer. You're a biologist, I understand.

THE WITNESS: Right.

PRESIDENT KAUFMANN-KOHLER: So, you should give us your understanding in your function at the PMRA, how did you see the legal obligations or the legal possibilities.

But then beyond that, I think it would be unfair to extract anything.

MR. SOMERS: Thank you.

PRESIDENT KAUFMANN-KOHLER: You don't remember the question?

12:01 MR. KURELEK: Maybe the question could be repeated because it's not clear to me either.

THE WITNESS: Yeah.

PRESIDENT KAUFMANN-KOHLER: Mr. Somers, can you restate it, please?

MR. SOMERS: Thank you.

BY MR. SOMERS:

Q. To your knowledge, if registrations for lindane pesticide products remained in effect in Canada, could Canada legally commit at the international level to ban them?

A. I think on the--perhaps on the basis of the Risk Assessments that we had done, it's possible; I believe so.

Q. Canada could have agreed to ban them internationally, even though they had domestic--we had domestic registrations in Canada?

A. Oh, I was thinking in terms of this particular on lindane where we didn't have registrations.

Again, I'm not sure I really would be able to comment with respect to the Stockholm Protocol.

Q. I'm turning to--I will leave the legal stuff for argument.

A. Okay.

Q. Thank you very much. I realize I was belaboring with a point that wasn't directly in your core area.

A. Mm-hmm.

12:02 Q. In Paragraph 80--I'm looking at Paragraph 87 of your second Affidavit.

A. Right. Mm-hmm.

Q. In heading Roman seven, just before Paragraph 87, you say, "I was not directly involved in the REN scientific risk assessments," which I can't resist: The use of the word "directly" suggests that you were indirectly involved.

A. I was not involved in the actual Risk Assessments, except at the very end of the process where the science groups such as health and environment brought forward their Assessments to our Science Management Committee. I'm on that committee. I hear that. We accepted the Risk Assessments that had been done.

So, like I have a--my role is basically management of the overall process. You know, that would mean, you know, interaction, you know, with Registrants and managing the data that, you know, comes in and sending off to the evaluation groups.

The responsibility for the Risk Assessments groups lies within those other groups and those individuals do not report to me, so I'm not involved--the first time I see those Risk Assessments is essentially when they get brought forward to Science Management Committee for consideration.

Q. We heard about that Committee from--

A. Oh, okay.

12:04 Q. --Mr. Chan this morning.
A. Yeah.
Q. And so--but I appreciate that.
Well, I guess I will take you, if I could, briefly to that. It's included at JW-117 of your second Affidavit.
A. Right.
Q. This is your Terms of Reference, again.
Did I understand you correctly when you said the persons who do the scientific risk agents don't report to you?
A. They don't report to me; that's correct. The individuals doing the Health Evaluation Assessments in the environmental evaluation sections are in different directorates than mine. My group manages the overall process, interacts with Registrants and so on, and also, you know, does coordination of, you know, documentation at the end of the process.
Q. Would they report to a colleague of yours who sits on the Science Management Committee?
A. The--well, depending on what level they are, you know, if there is like an evaluator, they report to a Section Head, and the Section Head to a Director, and then the Directors to, you know, the Director Generals, yes.
Q. And so, ultimately, one way or the other, those science Risk Assessments would find its way to the Science Management Committee.

12:05 A. That is correct.

Q. And the Science Management Committee arrives--and I'm looking at JW-117--discuss the primary role of your Committee is to discuss in order to arrive at consensus decisions on, among other thing, re-evaluations of Pest Control Products.

A. That's correct. It's for new products and re-evaluations, among other things.

Q. And you, as a member of that Committee, which operates by consensus, ensure that all registration decisions integrate value, health--I'm looking at third bullet--

A. Mm-hmm.

Q. --and environmental risks based on risk management principles and so forth.

A. Right.

Q. So, through the Committee, I assert--and I ask you to confirm it--you exercise significant authority on the science and on the process of re-evaluations.

A. The focus of the Committee is on risk management. The Risk Assessments lie or the primary responsibility for those lie within the individual Directorates. They have the ultimate responsibility for the Assessments that are done. They get brought forward for discussion, and then if required, risk management is done.

In the case of lindane, however, it was a risk assessment that was brought forward. We heard the scientific

12:06 evaluators. It was--again, it was an independent scientific team that did the review of this. We heard them, and, you know, we asked questions, and, you know, those Assessments were accepted, those Risk Assessments.

Q. And if for some reason you had differed from the decisions of those Risk Assessments, they needn't have been adopted. They could have been changed.

A. Not by me, no. It's a consensus decision on the part of the SMC, and we would not overturn a decision based on a risk assessment that had been done by a scientific group.

Q. I'm not asking you if you would have. I'm asking if you could have.

A. No, no--

Q. You could--

A. I would not--I would not be able to overturn a decision that had been made by our scientists. I have no authority in that area.

Q. I'm suggesting the Committee could, not you.

A. The Committee, you know, could ask questions, could, you know, send it back for consideration of something, but, you know, in the end, the DG of Health and DG of Environment are responsible for those--the Risk Assessment. That's their focus. Our focus is more on the risk management and integrating all of these bits and pieces into an integrated decision. But in this case, it was the individual Risk

12:08 Assessments that had been done in Health and Environment that were brought to us at the SMC.

Q. Your first term of reference and your primary role, according to your Terms of Reference, is to discuss and work, to arrive at consensus decisions on significant registration application, et cetera, et cetera, Special Reviews, and re-evaluations--

A. Right.

Q. --of pest--you arrive at decisions. You're not merely informed. You actually have to by consensus, as a member of that Committee--

A. Right.

Q. --arrive at consensus decisions on re-evaluations; isn't that right?

A. But the lindane was a Risk Assessment that is brought forward. We did not, you know, like discuss risk management because these products are not registered in Canada at this. So, you know, that's our focus. Our focus is on risk management, after we've heard from the team who are the independent, you know, the scientists that had worked on the Assessments, brought those forward. You know, we can ask questions, but in the end, it is the Health Directorate and the Environment Directorate. They are ultimately responsible for those. We will discuss them, and we will integrate them, but our focus is more on the risk management than the Risk

12:09 Assessment.

Let me just see where that--and we will talk about, you know, things, you know, such as appropriate phase-out schedules in light of the risk that has been identified and/or value, for example, for products that, you know, are registered, but it's--we deal with the risk management component.

Though they came forward, they presented the Risk Assessments, independent group of scientists that had looked at all of this new information that had been provided by the Registrant, had completed their reviews, brought these--had gone through peer-review process within their own Directorates to ensure that the--you know, that the documentation had been peer-reviewed, and then they get brought forward for presentation to SMC, and that's when I see it, and in this case, because it was a risk assessment document, it was not a risk management type document or decision.

Q. It was a re-evaluation, wasn't it?

A. Yeah. It was a re-evaluation, but, you know, it is a re-evaluation note, but in this case, because there were no registrations, then, you know, we weren't looking at, for example, phase-out plans that would be required.

Q. Right.

Thank you very much. You have been extremely helpful.

A. Thank you.

12:11 Q. Thank you for your candor. I appreciate it very much.

MR. SOMERS: Thank you, Madam Chair.

PRESIDENT KAUFMANN-KOHLER: Thank you.

MR. KURELEK: No questions.

PRESIDENT KAUFMANN-KOHLER: No redirect questions?

MR. KURELEK: No.

PRESIDENT KAUFMANN-KOHLER: Any questions from the Tribunal? Yes?

Please.

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR BROWER: You had been taken previously to the document appearing at Tab 61 as an exhibit to your Affidavit. It's in Volume 2 of 2, JW-61.

THE WITNESS: Right. Okay.

ARBITRATOR BROWER: Were you the author of this document?

THE WITNESS: I'm sorry, I did not hear.

ARBITRATOR BROWER: Were you the author of this document?

THE WITNESS: Of this document?

ARBITRATOR BROWER: There's a name of sponsor John Worgan--

THE WITNESS: Oh, yeah but that's--

ARBITRATOR BROWER: And at the bottom there is Merissa Romano.

12:12 THE WITNESS: Romano, who worked for me as a re-evaluation coordination person.

These issues are generally brought forward by a sponsor, but in almost all cases it would be the Director General of, you know, the re-evaluation group, or on the new product side, it would be Chief Registrar, one of the directors who would bring it forward, you know, just to get it on the committee as a member, but, you know, did not personally author, you know, this document. I must have reviewed it, but, you know. For example, it says Merissa Romano, who was the author of that particular document. But, you know, just for process, we put the name of the Director General down, you know, to indicate that, you know--

ARBITRATOR BROWER: Right.

And on the second page, tab at the very beginning, EAD, what does EAD mean?

THE WITNESS: EAD is one of the Directorates within the PMRA. It's an Environmental Assessment Directorate. They look after the environmental fate and toxicology studies.

ARBITRATOR BROWER: I see. Okay.

And then I had a question with respect to your first Affidavit, Paragraph 245 you were taken to.

THE WITNESS: Yes.

ARBITRATOR BROWER: You were asked about the difference between PMRA and the EPA as regards issues of cost

benefit.

THE WITNESS: Right.

ARBITRATOR BROWER: My understanding is that the PMRA, even if there were little known benefit to whatever you're reviewing, still must review it.

THE WITNESS: If there is limited benefit, yeah, but we would review it. You know, say it was a new product, we would review the--it would come into the Agency through our submission process. We would review the health and the environmental stuff, and then we would also review the efficacy.

And, in the end, you know, we could make a determination that it was of limited value when the value was not acceptable for registration. If it's limited benefit. It doesn't work, for example, limited benefit, and we wouldn't register it, but we would review it. It comes in, and we do a scientific assessment because our decisions are based on science.

ARBITRATOR BROWER: Okay, thank you.

THE WITNESS: If it meets that criteria, then it's acceptable for registration.

ARBITRATOR BROWER: That's what I thought. Thank you.

THE WITNESS: Right. You're welcome.

ARBITRATOR CRAWFORD: Mr. Worgan, what would be the result of your initial review had been if you had chosen a risk

12:15 factor of hundred rather than a thousand?

THE WITNESS: I--you know not being involved directly in that Assessment, I can't say what it would be, but I would need to verify with the actual documentation.

ARBITRATOR CRAWFORD: If you're the wrong person to ask that question, I will ask it to the right person.

THE WITNESS: Right. Okay.

I'm--I just off the top of my head I cannot answer that question with certainty, and you would need to go to somebody in the Health Environment--Health Evaluation Directorate, or we could find out and get back to you.

But there were, you know, in the case of lindane, there were other risks as well associated with this, and all of the risks would need to be acceptable.

ARBITRATOR CRAWFORD: The Claimant's case in respect of your reviews--and obviously there were two reviews, the 50(1), and the REN after the Board of Review--

THE WITNESS: Right.

ARBITRATOR CRAWFORD: --is that there were basically foregone conclusions in that you went through the motions of a review but you basically already decided, you being the PMRA, really basically decided that lindane was unacceptable. What's your response to that?

THE WITNESS: I totally disagree with that. We took this very seriously, and, you know, we have a scientific

process that has a lot of integrity. We--in this particular case, we assigned a different group of evaluators than those that had worked on the lindane Assessment. We provided them with absolutely no direction with respect to what the outcome should be, what we were expecting. We had no vested interests, for example, in a particular outcome. The science will lead you where the science goes. It was not a foregone conclusion. We had some additional information on the worker exposure side. We had some additional toxicology that our scientists looked at. We also had--we undertook a review of some of the other areas that we had not completed previously. We took all of those into account in the decision. That is definitely not a foregone conclusion.

ARBITRATOR CRAWFORD: I take you to Paragraph 122 of the Board of Review Report.

THE WITNESS: That's Tab 30?

ARBITRATOR CRAWFORD: It's JW-30 in your Witness Statement.

THE WITNESS: Right.

ARBITRATOR CRAWFORD: I'm going to read the whole paragraph and then I'm going to ask you to comment on it.

THE WITNESS: Which paragraph is that?

ARBITRATOR CRAWFORD: Paragraph 122.

THE WITNESS: Okay. One moment.

ARBITRATOR CRAWFORD: "The Board appreciates that at

12:18 1 least some of the concerns raised by PMRA in its review, most
2 notably issues related to the sensitivity of the young, might
3 give rise to concerns of an imminent nature."
4 THE WITNESS: Okay.
5 ARBITRATOR CRAWFORD: "Notwithstanding that, the Board
6 is of the view that given the timing of the announcement of the
7 outcome of the Special Review by PMRA, and the limited use
8 season for lindane, other options for effective control could
9 have been invoked in the short term."
10 THE WITNESS: Mm-hmm.
11 ARBITRATOR CRAWFORD: "This, in the Board's opinion,
12 was a major flaw in the process, leading to an unsatisfactory
13 result. Addressing mitigation, in the Board's opinion, is
14 fundamental to conducting a robust scientific inquiry leading
15 to regulatory decision. It is clear to the Board that this did
16 not occur in the case of lindane."
17 Would you comment on that.
18 THE WITNESS: Well, you know, in terms of the
19 negation, I spoke about that previously. We did in the
20 Occupational Exposure Assessment done in 2001, you know,
21 consider the mitigation that had been used in the Dupree study,
22 these different levels of plants--small, medium and large--some
23 of them closed systems. We took that into account.
24 We also took into account, you know, as I say, we did
25 that quick calculation to see what the margins of exposure, the

12:19 safety levels would be. We used the Helix Study, which was done in a more closed system and small number of plants in Canada, still we had unacceptable risk.

And one of the other areas as well was the Registrants had proposed a respirator and some other mitigation measures, but, you know, after they had received the Assessment for comment, and we took that into account, but it didn't really change the results of the Assessment.

Whether or not the--you know, the timing of the announcements and the limited use season, you know, we at that time, you know, it was fairly common practice, you know, for the Active ingredients where we had risk concern to give relatively short periods of time for consultation. In this case, you know, it's an active ingredient for which there had been a number of concerns identified internationally on occupational exposure. You know, they should have known that, you know, there were risks of concern here and come in, if they felt it was appropriate, with additional mitigation, above and beyond what we had already proposed. It's the responsibility of the Registrant. The onus is on them to defend their products, and we assessed it based on the use pattern that was existing at the time.

ARBITRATOR CRAWFORD: You don't agree that there was a major flaw in the process.

THE WITNESS: I don't think so, no. I think that, you

12:21 know, again like for the Board of Review, they said, well, you know, why--you know, what do you do now? And I said, well, now we have a slightly longer comment period; it's 45-60 days, depending on the Active ingredient and, you know...

Were we perfect? No, we weren't perfect. Was it reasonable at the time in light of the risks that had been identified? Yes, we felt it was.

ARBITRATOR CRAWFORD: As I read that paragraph, it's concerned with the problem of imminence--

THE WITNESS: Mm-hmm.

ARBITRATOR CRAWFORD: --and what might be described as the transition. It refers to options for effective control which could have been invoked in the short term.

THE WITNESS: Mm-hmm.

ARBITRATOR CRAWFORD: Do you have any comment on that aspect of that paragraph? I mean, it seems to me, reading the Board of Review Report--

THE WITNESS: Right.

ARBITRATOR CRAWFORD: --that it's probably the most serious criticism made. I'm interested in the sentence which refers to effective control being invoked in the short term.

THE WITNESS: Well, the effective controls would need to be in the form of, you know, something like personal protective equipment and, you know, clothing, and, you know, we did, you know, consider those kinds of protective measures,

12:22 but, you know, still found that, you know, the risks were unacceptable, and, you know, given, you know, this what we felt was like, you know, a concern, a significant concern around the, you know, endocrine disruption potential of the lindane, we felt that, you know, we needed to propose a phase-out.

And, you know, that was borne out by the follow-up review, which was done by another group of independent scientists within the PMRA.

ARBITRATOR CRAWFORD: Thank you, Mr. Worgan.

THE WITNESS: You're welcome.

PRESIDENT KAUFMANN-KOHLER: I'd like to follow up on one of the questions of Professor Crawford.

I have trouble reconciling different elements that I gather from your testimony and from the record generally. On the one hand, you say--and there is a number of elements on record that show that there was a scientific Risk Assessment, and what dictated the outcome was science.

THE WITNESS: Right.

PRESIDENT KAUFMANN-KOHLER: On the other hand, there are elements that seem to indicate that there was a--"bias" may be too strong a word, but inclination by the PMRA that was opposed to lindane. And for instance, if I go back--there are different documents that could be interpreted that way. I'm not saying they should be, but I'm just asking you. The document, for instance, that's JW-61, that is this memorandum

12:24 of August 31, 2006, for which you sign as sponsor. You're not the author, but you're the sponsor, so you are responsible for it.

When it says, "We have to complete the Assessment of Lindane, and this would clarify/substantiate the position taken by the PMRA in 2001 and support the Government's position in Court."

So, you do not envisage that the outcome this time of the Risk Assessment may be different, for instance, because you don't use 1,000 as a risk factor but some other factor.

THE WITNESS: Right.

PRESIDENT KAUFMANN-KOHLER: You consider that the completion of the Assessment will substantiate your previous position. That's one example.

THE WITNESS: Right. Right.

PRESIDENT KAUFMANN-KOHLER: I could show you others, but that's not my point now going through the documents. I'd like to have your explanation on how do I reconcile these apparently contradictory elements that I see at this stage.

THE WITNESS: Yeah--and I--you know, and I think that sentence, "clarify/substantiate," maybe that was a poor choice of words, but again, I was not responsible for the Risk Assessments and had absolutely no bias--

PRESIDENT KAUFMANN-KOHLER: You were responsible for these words, and words are rarely innocent.

12:25 THE WITNESS: Yeah. But our scientists, they work--the integrity of the regulatory process is very important to them, as it should be, and our decisions are based on science--the best available science that we can possibly have. They don't go into this with a preconceived notion because that would impact on the integrity of the process. The PMRA, as a regulatory agency, I think, is held in high esteem internationally, and that's one of the reasons why EPA and, you know, other regulatory agencies in Europe want to work with us, because, you know, they see the quality of the work we do.

Our scientists--they have no bias going into this. It is what it is at the end of the day in terms of Risk Assessment. If it comes out acceptable, it's acceptable. If it doesn't, you know, that's the only way that you can have a system that, you know, has integrity. And our scientists, I believe, take their role very seriously. They want to have the best science possible supporting registration decisions and re-evaluations with an eye to protection of human health and the safety. And that's the way you get that, is through the best science available.

PRESIDENT KAUFMANN-KOHLER: Now your scientists, of course, don't work in isolation. I mean, there was a general movement in the world that went against lindane. How does this play in the scientific assessment?

THE WITNESS: They look at--they look at the

12:27 information that they've got. In the case of, you know, lindane, they looked at a number of things. They looked at--they focused on the science and not on the politics and not on all of the stuff on the side. They look at the available data. They look at the reviews that had maybe been done by other international regulatory agency, but from a scientific point of view, and we make our own independent scientific decisions on the basis of a scientific assessment and applying our own standards and principles to that, like it's not, you know--

Just because one agency has made a decision, it doesn't mean that necessarily we will arrive at the same decision. You know, in the case of the U.S. EPA, in many cases--in most cases, I'd say that decisions are essentially harmonized, but they're not entirely harmonized maybe in terms of the mitigation measures. So, most of the time we can work around some of the policy differences, but there are times when we apply different standards, you know? These are normal--

PRESIDENT KAUFMANN-KOHLER: In science there is a part of judgment.

THE WITNESS: Of course there is judgment. There has to be. It's not just a mathematics or numbers. You have to look at the weight of the evidence, basically, and that's where the judgment comes in, you know, and our toxicologists and exposure assessors and...

12:28 PRESIDENT KAUFMANN-KOHLER: Thank you.

Any further questions? Yes, Mr. Douaire de Bondy?

MR. DOUAIRE de BONDY: Thank you, Madam Chair. Could I just ask a quick redirect arising out of the question Professor Crawford put to the witness?

PRESIDENT KAUFMANN-KOHLER: Yes, I think you can.

And if you have something to follow up, you will get a chance as well.

MR. DOUAIRE de BONDY: Thank you.

REDIRECT EXAMINATION

BY MR. DOUAIRE de BONDY:

Q. John--Mr. Worgan, could you please go back to Tab JW-30 of your first Affidavit. It's Volume 1 of 2.

A. Right.

Q. And please go back to the paragraph that Professor Crawford brought to you--brought you to. It's Paragraph 122.

A. Um-hmm. Thank you. Um-hmm.

Q. Just take your time. So, you're at the paragraph.

A. Right. I have it here.

Q. Okay. Now, Professor Crawford directed your attention, in particular, to the second sentence of that paragraph, which says: "Notwithstanding that, the Board is of the view that, given the timing of the announcement of the outcome of the Special Review by PMRA and the limited use season for lindane, other options for effective control could

12:29 have been invoked in the short term."

I'm just wondering, in the first place, could you remind us the date of release of the outcome of the Special Review, at least when you released it in draft to the stakeholders.

A. In--on October 30, I believe, 2001, it was released to the Registrants.

Q. Right.

A. And we had a conference call with them at that time.

Q. Right.

And are you aware of the fact that, under the terms of an agreement of voluntary withdrawal, there had been a phase-out date for the use of canola in Canada?

A. Yes.

Q. Do you recall what that date was?

A. July 2001, I think.

Q. That's correct, July 1st, 2001.

A. Yeah. Okay.

Q. So, at the time your Risk Assessment was issued in October of 2001, would the main use of lindane in Canada have actually been--this use on canola had been on the market, or had it been phased out?

A. No, it would have been phased out--date of last use, that's true.

Q. So, when the Board is talking here about other options

12:31 for effective control could have been invoked in the short term, what sorts of--I mean, are we talking about a big market--are we talking about...

A. No. It's--the bulk of the market was canola. To my understanding, it's a very small percentage that was, you know, for the other seeds.

Q. So, at this point the bulk of the market had already been eliminated for lindane?

A. That is correct.

Q. Through the Voluntary Withdrawal Agreement?

A. Through the Voluntary Withdrawal Agreement.

Q. Thank you.

A. You're welcome.

MR. DOUAIRE de BONDY: Those are my questions.

PRESIDENT KAUFMANN-KOHLER: Nothing further? No?

MR. SOMERS: No thank you, Madam Chair.

PRESIDENT KAUFMANN-KOHLER: Fine.

Then that closes your examination. Thank you very much--

THE WITNESS: Okay, thank you.

PRESIDENT KAUFMANN-KOHLER: --for your explanation, Mr. Worgan.

THE WITNESS: Thank you.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: So, now we will take a

12:31 one-hour lunch break. Remember that you are to discuss the question of the direct examination of expert witnesses and get back to us this afternoon, if possible.

MR. DOUAIRE de BONDY: Madam Chair, we actually had a quick opportunity to discuss this, and having discussed this with the Claimant, Canada has agreed that we'll proceed with the process which the Tribunal laid out yesterday evening so that the examinations would be essentially the few warm-up questions.

PRESIDENT KAUFMANN-KOHLER: So, same rule for experts as for fact witnesses.

MR. SOMERS: Yes.

PRESIDENT KAUFMANN-KOHLER: Agreed?

MR. SOMERS: Yes. Thank you.

PRESIDENT KAUFMANN-KOHLER: Fine. Then have a good lunch.

(Whereupon, at 12:32 p.m., the hearing was adjourned until 1:35 p.m., the same day.)

AFTERNOON SESSION

PRESIDENT KAUFMANN-KOHLER: Mr. Zatylny, good afternoon.

THE WITNESS: Good afternoon.

TONY ZATYLNY, RESPONDENT'S WITNESS, CALLED

PRESIDENT KAUFMANN-KOHLER: For the record, can you please confirm that you're Tony Zatylny. And I apologize if I don't pronounce your name correctly.

THE WITNESS: I am, and you did a very good job.

PRESIDENT KAUFMANN-KOHLER: Thank you.

You are Product Manager; that's your current position at the LifeScience of North America?

THE WITNESS: Correct.

PRESIDENT KAUFMANN-KOHLER: And earlier during the time that we are interested in, and especially from '96 to March '99, which was your role for us, you were Vice-President of Crop Production and Regulatory Affairs at the Canola Council of Canada.

THE WITNESS: Correct.

PRESIDENT KAUFMANN-KOHLER: You have given two Witness Statements in this case.

THE WITNESS: Yes, I have.

PRESIDENT KAUFMANN-KOHLER: And you heard as a witness, as you know, you are under a duty to tell us the truth. Can I ask you to confirm this by reading the Witness

13:34 Declaration that is in front of you on the table.

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

PRESIDENT KAUFMANN-KOHLER: Thank you.

Now, you will first be asked a few questions as introduction by Canada's counsel, and then you will be asked questions by Mr. Bedard, is your name?

MR. BEDARD: Bedard, yes.

Madam President, rather than interrupt Ms. Shaker, I think I would like to comment that we've just received the 16 Tab binder for direct examination, and I would just like to reiterate our position, and I believe the Tribunal's position that Section 54 of the first procedural order does not contemplate extensive direct examination. I think we are all aware of that, but I just rather than interrupt, I thought I'd raise that now.

PRESIDENT KAUFMANN-KOHLER: Thank you.

MS. SHAKER: Thank you, Madam Chair. I'm aware of that. I apologize. Those binders were put together before that discussion took place. I will not be going through all 16 tabs. The reason I gave it to you is just in case I refer to it in redirect, if that's all right.

PRESIDENT KAUFMANN-KOHLER: If that's the case, then that's fine. And you can proceed.

13:36 MS. SHAKER: I'm Yasmin Shaker, and, Mr. Zatylny, I will be asking you some questions.

DIRECT EXAMINATION

BY MS. SHAKER:

Q. Three introductory questions this afternoon before I pass you over to Mr. Bedard.

Before I begin, is there anything you wish to correct in your Witness Statements?

A. Yes, there is.

Q. And what would that be?

A. In Paragraph 45 of my second Affidavit, I referred to a letter that I mistakenly assumed I received from Bill Hallatt. This, in fact, was an internal Chemtura document. I never did receive this letter.

Q. Can you turn to that in your second Affidavit to confirm that. I think that's your first. No, your second Affidavit. It's at TZ-43.

And in the witness bundle it's actually Tab 1.

A. Okay. Could I look at the witness bundle.

Yes, this is it.

Q. Thank you. Is there anything else you would like to correct about your Witness Statements?

A. No, there is not.

Q. Okay.

PRESIDENT KAUFMANN-KOHLER: Can I just ask a

13:37 clarification. So, you did not receive the letter from Bill Hallatt of November 26, '98?

THE WITNESS: No, I believe I did not.

PRESIDENT KAUFMANN-KOHLER: And you did not call him on the basis of the letter because the paragraph was on the letter prompted a phone call.

THE WITNESS: I did call him, but it was on a different matter. It was not in reference to this letter. On November 26, I always received from Bill Hallatt a draft of the Press Release, so I had his comments to our Press Release, so I did talk to him at that time period, but not specifically about this.

PRESIDENT KAUFMANN-KOHLER: So, it was not prompted by this letter?

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: Thank you.

BY MS. SHAKER:

Q. I think it would be quite useful to the Tribunal if you could expand a little bit more from your Witness Statements on the nature of the CCC as an organization. So, in that respect I'm just going to ask you two introductory questions.

A. Okay.

Q. The first is: Can you explain to us how the CCC is structured.

A. Okay. I will start with the grower component.

13:38 The Canadian canola growers are structured provincially, so they are under provincial mandate as an association that has a refundable checkoff. Checkoff is usually about a dollar a tonne that's collected when the farmer sells his canola and goes into the association.

So, each provincial association is under provincial mandate, so they have--each member is a voting member, and they elect a Board of Directors. Each provincial association then falls under the umbrella organization the Canadian Canola Growers Association, which represents all of the canola growers collectively in Canada.

The Canadian Canola Growers Association then appoints board members to the Canola Council of Canada. So it's really a pyramid structure from the ground root organization to the Canola Council.

Other members of the Canola Council are the exporters. They export canola to other countries, and the crushers. So, those three groups have equal voting right on the Board of Directors of the Canola Council. The chairmanship of the Canola Council is rotated between the growers, the exporters, and the crushers, and then there are staff members like myself who was working for the Canola Council at the time.

Q. Thank you.

The second and last question is how did the canola industry come to the decision to pursue a Voluntary Withdrawal

13:40 Agree initiative?

A. The Canola Council is a body that as its mandate has the common interests as the canola industry as its primary reason for existing. When we received the letter like we did from one of our key customers, Procter & Gamble in early 1998, that prompted a series of activities. The information would be diffused back down to each of the growers association, the crushers and the exporters. They would look at within their Committee structure and debate, discuss, and bring back to the Canola Council is this important or not.

So, from a ground roots perspective, they would look at individually and come together in an organization like the Canadian canola growers to decide on what course of action should be taken.

So, from that perspective, each of the provincial organizations essentially has a veto vote. If one Province does not agree with the recommendation of the others, then it's generally a no-go, so it's every--every organization has equal rights within the Canadian Canola Growers Association and the council to support or reject any action.

So, in this case, a big issue like the lindane Voluntary Withdrawal Agreement would require a huge amount of agreement and consensus building among each of the groups to result in a decision.

Q. Thank you very much. That's all my questions for now.

13:41 Mr. Bedard.

ARBITRATOR CRAWFORD: Follow-up.

The Canola Council of Canada doesn't include, for example, producers of canola seed.

THE WITNESS: It includes growers. It includes crushers and exporters.

Now--and it's an interesting debate that we had at the time. Canola, one of the quirks is canola seed refers to both the seed for planting and the seed for consumption, so it was always a very difficult point of clarification, and we need to be very specific what we are talking about, seed for consumption or seed for planting.

And in the case of seed for planting, those are also canola growers. They have their separate organization, the Canadian Seed Trade Association, but as growers, they would also fall under the Canadian Canola Growers Association as well.

I hope that answers your question.

ARBITRATOR CRAWFORD: Probably tells me more about the structure of seed producing than I need to know.

The suppliers, for example, the Claimant was not a member of the CCC?

THE WITNESS: They would not be a direct member of the CCC, but they can get involved through the Committee structure. It's a voluntary Committee, so we have had many initiatives

13:43 where it's an open invitation to any stakeholder who is interested.

So, at the Committee Level the Claimant could certainly get involved in the decision-making process like that. And they often did in this matter and others as well.

PRESIDENT KAUFMANN-KOHLER: So, now I can turn to Mr. Bedard.

MR. BEDARD: Thank you, Madam President.

CROSS-EXAMINATION

BY MR. BEDARD:

Q. Mr. Zatylny, my name's Ben Bedard. I'm here on behalf of Chemtura, and this is actually where I wanted to start, so maybe we could continue because you have given us a lot of information, but I would like to pursue it a bit more.

Some letters were sent out from CCGA, some letters were sent out from CCC. If I look at the two letters and I went to 167 Lombard Avenue, Suite 400, I think I'd enter the office of both organizations; is that right?

A. At the time you would have. At some point the Canadian Canola Growers Association formed their own office in Manitoba, so they moved over to the office.

By the time--especially in my role, I was VP of the Canola Council and Secretary-Treasurer of the Canadian Canola Growers Association. As a service we provided as Canola Council.

13:44 So, at that time both parties were interested in the issue.

Q. Okay. And just to go back to your opening comments, who you say exporters, who are these entities and what are they doing as a constituent of the CCC?

A. Exporters. Okay. Sorry. The exporters are grain companies that purchase canola for consumption from growers and export it to Japan, the United States as full seed.

Q. Okay. They're not processing?

A. They're not processing.

Q. They're pure exporters?

A. They're pure exporters, yes.

Q. And so the three subgroups under CCC, exporters, crushers, and the CCGA each had an equal number of Directors? Is that what you said?

A. That's correct. Yes.

And essentially each had a veto vote, so if they didn't support an initiative, they could veto it. And if the other two members decided to proceed, it would be outside the Canola Council essentially, so everybody was treated equally within the membership.

Q. Okay. And then the CCGA, which was one-third of the CCC, was itself composed of the four or five provincial Canola Associations?

A. That is correct.

13:45 Q. And those associations were--were they set up by provincial statute, for example?

A. They are under provincial statute.

Q. Okay. And each of the five, if it's five, have an equal vote to the CCGA?

A. That is correct. And again, they have a veto vote, that although all the associations are run under Robert's Rules of Parliamentary Procedure, there is always a vote before the vote, and they would ask if everybody is going to agree. And generally, if there is disagreement, a matter would be tabled and put back to Committee quite often.

So, if you look at the votes recorded during my tenure there, essentially they're all unanimous votes.

Q. Okay. And for the provincial organizations, how would the Board of Directors, let's take Saskatchewan, how would the Saskatchewan canola growers Board of Directors be elected?

A. They would--each Province is split into regions, so there would be a Director from each region, and generally the Board of Directors would elect the Chairman for that year and appoint directors to chair committees.

Q. Sorry, did you say generally?

A. Yeah.

Q. So, we've got a Province that has regions?

A. Right.

Q. Each region has a Director?

13:47 A. Right.
Q. And how is each Director elected?
A. Each Director is elected in his region by nomination and vote at the annual general meeting, and then each of the Directors in their first Board meeting would choose a chairman.
Q. Okay. And that election in the region is where canola growers vote?
A. Yes, exactly.
Q. Okay. And the refundable checkoff, how was that levied and collected?
A. The levy is collected at the point of sales, so if a farmer delivers his canola to an elevator company, they would collect the levy. If he delivers to a crusher, they would collect the levy. And so, every six months there would be a tally of the canola delivered, and the grain companies or the crushers would reimburse or pay the provincial association.
Q. So, those funds would go to provincial associations?
A. Correct.
Q. Who moved some portion of that up to CCGA?
A. They would move it up to the CCGA, and would also fund activities of the Canola Council of Canada.
Q. And would the council also get funding from the other two subgroups?
A. Yes, exactly. The exporters and crushers would also have a voluntary checkoff that they would make those funds

13:48 available to the Canola Council.

Q. Okay. And that's based on sales, essentially?

A. Based on sales, yes.

Q. Okay. And I believe you were starting to talk about decision making and major decisions, so we will get sort of into the Withdrawal Agreement, but a decision like that, a decision for the organization and the industry to move forward with an agreement like that, who is voting on that? How is that decision being made?

A. The decision would be made by the elected officers, so essentially the Board of Directors of each canola region would either have a public meeting or make the decision within their Board. So both are very common. They sometimes have a plebiscite, which is they will send out a newsletter, a request for a vote, so they actually have quite a number of mechanisms for making a decision. In this case I think it was the board of each provincial organization that ultimately worked through some individual system to come to a conclusion.

Q. Okay. Was there a vote by the CCC Board of Directors to go ahead with the Withdrawal Agreement?

A. There was.

Q. And was there a vote by the Board of Directors of the CCGA?

A. There was.

Q. And you're saying there would have been a vote by the

13:50 provincial organizations as well?

A. Yes.

Q. And sometimes in the documentation it describes the Withdrawal Agreement as a CCC-driven initiative?

A. Right.

Q. If I take your evidence correctly, CCC and CCGA were for all intents and purposes acting as one?

A. In this particular issue, they're aligned. And if you look at the policy statements of the Canola Council of Canada, they refer to a policy that they will not support any pesticide registered in Canada for which there is no registration in the U.S. or no tolerance in the U.S.

And the canola growers had a similar type of policy.

So, in this case, the growers--at the Board of Directors of the Canola Council of Canada, they looked at who should take a lead position on this issue, and the crushers and exporters and the growers agreed that the growers had the highest stake in this issue, so they would take the lead on this particular issue.

In other issues, it's the exporters or the crushers that will take the lead. This one, the Board felt that the canola growers had the most to gain or lose.

Q. Did I understand correctly you said both the CCC and the CCGA had a policy--

A. Yes.

13:51 Q. --to encourage members not to use pesticides not registered in the U.S.?

A. Well, and the Canola Council of Canada is even more specific. It says they will not support registration of a pesticide in Canada that is not registered in the U.S. or has no tolerances in the U.S., so it's quite specific.

Q. And if the Council--I realize now you haven't been with the Council for a while, but if the Council is aware of an application in Canada for a product that's not being pursued simultaneously in the U.S., will they actively get involved either to oppose that application or to strongly pressure that Applicant to go to the U.S. and get registered?

A. Well, I think that's the key that the Canola Council has no regulatory authority, so all it can do is influence the Registrants to pursue a registration.

And since these documents are public, we hope that each of the Registrants would know that this is a standing policy of the Canola Council of Canada.

Q. Mr. Zatylny and Madam President and members, I'm going to be mostly, if not almost entirely, looking at the affidavits of Mr. Zatylny, first and, second. Mr. Zatylny, if we could just flip quickly to your first Affidavit--sorry, second Affidavit.

A. Okay.

Q. Paragraphs 16 and 17, I'm just looking here--again,

this is kind of--it appears from the documents that one day it's CCC and the next day it's CCGA, so at the bottom of Paragraph 16, for instance, by mid-October, the CCGA formally indicated to the PMRA that it had been in discussion with the Registrants.

Next sentence, "In the meanwhile at the CCC's request, the PMRA advised the EPA of our planned action."

A. Sorry?

Q. That was Paragraph 16 of your second Affidavit.

A. 16. Okay. What page number?

Q. It's page number six.

A. Okay. So we are not quite aligned here, by the looks of it.

Q. Of your second Affidavit.

Paragraph 16. Does it start in September 1998?

A. No, it doesn't.

Q. I have the second Affidavit of Mr. Zatylny.

A. Okay. Very good.

Q. Now, I'm very curious as to what your Paragraph 16 says.

Towards the end of the Paragraph 16, it says, "By mid-October the CCGA formally indicated to the PMRA that it had been in discussion with the Registrants." The next sentence is: "In the meanwhile at the CCC's request, the PMRA advised the EPA of our planned action."

13:54 A. Correct, right.

Q. Was there a formal distinction between what CCC was doing and what CCGA was doing?

A. No, there is no difference. At this point we are acting as one. Both the CCC and the CCGA had come to the conclusion this was an issue that was of significant importance that it really didn't matter whose letterhead we were going on.

We tried to make sure that anything that, for example, Jean Dextrose was signing was on CCGA letterhead, and notes that I was more responsible for doing was on CCC letterhead.

But both--the information was shared equally between CCGA and CCC.

Q. And I think you only had a Canadian Canola Council E-mail address because you used that address on CCGA letterhead?

A. Yes.

Q. You touched on this point. The CCC--neither the CCC nor the CCGA had any control or authority over its members.

A. Correct.

Q. Growers were and are free to use whatever products they choose.

A. That is correct.

Q. And, therefore, neither the CCC nor the CCGA could have forced Registrants to stop using something or to start using something for that matter?

13:56 A. Correct, yes.

Q. And growers presumably grow canola to make money and generally would be inclined to use the products that are most effective and most cost-effective for them.

A. I'm not sure I entirely agree with that statement.

In the seed treatment area for canola seed in particular, a big part of the decision making is--resides at the seed company level. After I left the Canola Council, I worked for Dow AgroSciences as Product Manager for their canola seed business. In 2000, for example, I made the decision to treat all of my seed with Helix, so any farmer who chose to purchase my seed had no choice on the seed treatment that they were getting.

And at the time I would say 90 percent of the seed the farmers are purchasing came from a seed company, and some companies would offer a choice of one or two seed treatments. Other companies, like the one I was working with, we only offered one seed treatment.

So, to say the farmers could choose whatever they wanted, not necessarily a simple question.

And generally, I don't agree with the statement the farmers always buy the cheapest product. There is no evidence to support that. There's lots of factors go into decision making, including warranty that comes with the product.

Q. The efficacy?

13:57 A. The services, the efficacy, the recommendation of a dealer, another farmer, an influencer, quality, the reputation of a company, the health risks associated with using a product.

So, I don't think it's a simple question to say farmers will always choose the cheapest product available.

Q. Sorry, I didn't mean to say that would be their only decision.

Getting back to your earlier point in that answer, certainly the CCG--neither the CCC nor the CCGA had any authority or control over seed treaters?

A. Correct.

Q. Seed treaters can use whatever product they choose?

A. Right. Anything generally speaking, anything that's registered, has a label, can be used by growers or seed treaters.

Q. Prior to joining the CCC, you worked in the pesticide industry?

A. That's correct.

Q. And that was for another Dow, a Dow predecessor?

A. Yes.

Q. And when you joined CCC, you were working in matters related to pesticides relating to canola?

A. Correct.

Q. And at this time, by which I mean '97-'98, what percentage of the Canadian canola industry, Canadian canola

13:59 growers were using lindane seed treatments on their canola?
A. The majority of farmers would have a lindane-based seed treatment on their seed.
Q. The vast majority?
A. As much as was available from seed companies. And again, I think that was probably closer to 90 percent of the seeds, so the other 10 percent, whether nay used a seed treatment or not, I can't say.
Q. And of those using a seed treatment for their crops, do you know what percentage would have been coming from Uniroyal at the time than Crompton?
A. I don't have information on that.
Q. They would have been the largest?
A. I would assume so.
Q. If we go now to your first Affidavit.
A. Okay.
Q. Your Paragraph 7 says, I hope, halfway through the paragraph, "Even before lindane on canola became a specific problem, the CCC and CCGA were aware of the possibility of Canadian canola losing access to the United States because of the pesticides used in Canada and not registered in the U.S."?
A. Correct.
Q. That issue related to a range of pesticides, not just lindane.
A. Exactly.

14:00 In 1997, one of the Board members of the Canola Council of Canada asked me and asked us specifically to look at what the impacts of the Food Quality Protection Act would be on the canola industry. So, as early as mid-1997, we began to look at what was the impact--sorry, by early 1997, by the start of the year, we were already examining the impact that the Food Quality Protection Act in the U.S. could have on the canola industry.

Q. And prior to that activity, did you have any special knowledge of U.S. food or agriculture legislation?

A. At that point, we were not concerned about the U.S.--I shouldn't say that. There are certain elements of food quality we were aware of, but not from a production perspective.

Q. By which you mean...

A. So I mean, for example, oil quality and all of those--we were very interested in what the U.S. rules were, but as far as pesticides go, really until prompted by our Board, we weren't involved in any issues related to harmonization or pesticides in general.

Q. In Paragraph 11, we don't need to read it, but resulting from this new rule you took on, you say, "I make contact with Wendy Sexsmith at the PMRA."

A. Correct.

Q. Was that your first interaction with Ms. Sexsmith?

A. Yes, actually it was.

14:02 Q. And was that 1997?
A. That would be 1997.
Q. Okay. And if we go to Paragraph 13 of that statement, this is what you alluded to, I believe, in April 1997. You say--
A. Yes.
Q. --canola stakeholders came together for a meeting to develop a framework?
A. Yes.
Q. Do you recall who attended that meeting?
A. It was--well, not as many people as were expected to attend because it was the storm of the century in Winnipeg. Anybody who flew in on the night before was able to get to the meeting. All the locals who had to drive in could not attend. So, I was the only one who actually from Manitoba or Winnipeg was able to attend that meeting.
Q. So, do you recall some of the stakeholders?
A. Absolutely. There was most of the--most of the ag and seed treatment companies were represented. Uniroyal was represented for sure. There was a number of the growers from Alberta, Saskatchewan, and Ontario. The Manitoba growers could attend. PMRA was there. Both Wendy Sexsmith and Dr. Claire Franklin were in attendance. We had--the world Wildlife Fund was there.
So, a broad range of stakeholders, growers, industry,

pesticides companies, government, ag Canada, provincial Ministries were there. So, it was a large audience.

Q. Okay. And you said the action plan in that meeting arising from that meeting was to, in part, encourage manufacturers to obtain U.S. tolerances for all canola pesticides registered in Canada.

A. Correct.

Q. And so if lindane was the largest, the most important product being used at the time, presumably your group of stakeholders were interested in lindane getting a U.S. tolerance?

A. Exactly.

Q. Your--the growers were interested in continuing to use lindane?

A. Exactly. Yes.

Q. When you first started speaking with Ms. Sexsmith during this 1997 period, was it that broader issue of pesticides used in Canada not registered in the U.S.?

A. It was.

And if you look at point three of the action plan is to develop an integrated pest management strategy, and Wendy Sexsmith had a direct involvement in alternative pest control measures, so primarily that was one--the key points that I got involved with her is in developing an integrated pest management strategy, but also talking more specifically about

what would it take for harmonization, what can the Canada PMRA do to support harmonization efforts, so generally it was early on a pretty steep learning curve for me to make sure I was keenly aware of what the pesticides registration requirements were in Canada as well as the U.S.

Q. From there, if we go to the next section of your first Affidavit, Paragraph 18, now there has been developments in the U.S., and you say at the end of that paragraph, Paragraph 18--let's go back to the start of Paragraph 18: "The EPA confirmed that since the unregistered pesticides--this is following the Gustafson letter--was applied to the seed for a pesticidal purpose, it was not exempt under FIFRA and importation of the seed into the U.S. would be illegal."

You then said, "EPA then alerted the USDA and the FDA, the agencies responsible for monitoring imported food that might contain pesticides. As a result of this action, discussions ensued around the possibility of a border closure."

Did you--there's lots of--several documents on the record from EPA. Did you ever get a document from FDA or the USDA that said the border will be closed to these products?

A. I don't recall getting any specific documents from the FDA, but we understood their mandate was to monitor imports of food that may contain pesticides, so we had no direct contact with the FDA, but we know that they routinely sampled a wide variety of commodities, food, feed for pesticide residues, and

14:07 so we knew that they were always looking.

Q. On this issue of correspondence from the EPA, your attachment TZ-12 is a letter from the EPA to you, November 23rd, 1998. It's unclear to me from the letter, what's the genesis of this letter? It seems to--

A. Yeah, the--if you go back, October 19th, we sent an official letter from the CCGA to the PMRA, saying that we intend to proceed with the voluntary withdrawal of canola from lindane seed treatments. There was several questions around, well, isn't it true that people are working on establishing a tolerance or getting lindane registered in the U.S.

So, the real--the question asked to the EPA was: Was there any petitions in front of them for a tolerance or an exemption from tolerance or a registration for the use of lindane on canola, and that's really what the last--second page, first paragraph, last sentence, "No petition supporting additional lindane uses or tolerances including the use as a seed treatment on canola has been received by the Agency."

So, really that said to us, in the short term, there was really going to be no release from relief of possibility of closure from the border.

Q. You said the EPA was asked this question.

A. Yes.

Q. Who asked the question?

A. I asked the question.

14:09 Q. To Lynn Goldman?
A. Yes.
Q. At a meeting with Lynn Goldman?
A. No. This was in a formal letter to--during this time period, after we declared on October 19th that we intended to pursue a voluntary registration. We believed we had support from all of the Registrants, but there was continued dialogue, and the Claim had been made that we do not need to proceed with the voluntary withdrawal because we are going to have registration or tolerance in the U.S. That's what prompted the letter, and the response then said that really there was no short-term solution to this bigger problem of lindane seed treatments and lindane use.
Q. I don't believe, and correct me if I'm wrong, that your letter to the EPA's in your evidence, is it?
A. It is not.
Q. You don't have a copy anymore?
A. It's 10 years ago, and it's--but that is my recollection of why we had this letter sent to us.
Q. Okay. Thank you.
ARBITRATOR CRAWFORD: The letter from Dr. Franklin doesn't reference a letter from you. It simply says I'm writing to you at this time to provide an update.
THE WITNESS: Right. And this is from Lynn Goldman.
ARBITRATOR CRAWFORD: Yes.

14:11 THE WITNESS: On the November 23rd. And it says, "Dear Mr. Zatylny, I'm writing to you at this time," so it was a response to me prompted by a letter from me, to the best of my recollection.

ARBITRATOR CRAWFORD: Fine.

BY MR. BEDARD:

Q. If we flip ahead again to your second Affidavit, there is an exhibit there, Exhibit TZ-21. It's an E-mail from Jeff Adams to Marvin Hildebrand.

Who are these individuals?

A. Marvin Hildebrand worked in the Embassy in Washington. He was one of my contacts when I would be in Washington. I would call him to find out what the scoop was and what was happening. Jeff Adams worked at Foreign Affairs.

Q. And how did you get this E-mail?

A. Through this time period, we were starting to implement really our three point policy of harmonization, of making sure that products are registered on both sides of the border, IPM.

So, we met with various stakeholders. This is after the lindane issue. I met with all the provincial Ag Ministers. I met with Lyle van cleave, the Federal Ag Minister. In this case, I met with Foreign Affairs because we were concerned of if the border closes, what do we do? Not only canola growers, but as a nation? This issue from our perspective as at the

14:13 Canola Council and the Canola Growers had much wider implications than just a small crop. It was a big deal, and that's--Foreign Affairs was--Agriculture Canada was involved in this meeting, so we had a pretty wide stakeholder group that was concerned about this issue.

Q. It appears to be an internal E-mail between the Department of Foreign Affairs and the U.S. Embassy.

A. Yes. The Canadian Embassy in Washington.

Q. Was it Marvin Hildebrand that gave you a copy of this E-mail?

A. I see no fax numbers on there, but I don't know the origin or the source of this, but it somehow ended up in the filing cabinet, and I was very aware of who these people are and what their roles were.

Q. You would have received this around that time sometime in 1998?

A. Yes. It was--the date on it looks like March the 7th, 1998.

Q. Did--your comment from a few moments ago was that you were concerned that the FDA would enforce at the border and find oil--find residues in canola oil?

A. That's correct.

Q. Did you ever see any data or documents that said there would be residues of lindane in canola oil?

A. Well, one of the--to answer your question in a

14:14 roundabout way, the Food for Quality Protection Act said that if there was no detectable residue, it did not mean that there was no residue present. So if there was no tolerance or exemption from tolerance, they would have to go to half the limit of detection and put that number as a number of pesticide residue.

So, whether it was found or not wasn't necessarily the point. The point was there was no tolerance or exemption from tolerance, so the EPA could apply a number based on the sensitivity of the testing equipment.

So, that in itself was a problem. Not having an exemption or a tolerance was the problem.

Q. But even when they don't have a number and they take half the limit of detection, that's still a number?

A. That's still a number.

Q. And they have to find something?

A. They don't have to find anything. They just assume that there is always going to be pesticides there. And this is right out of the FQPA. It's--if there is no detectable residue, it doesn't mean there is no residue. We just can't find it, so we will apply half the limit of detection. And there is a number that has to be included now in the risk cup assessment in the U.S.

Q. If a pesticide is used on strawberries--

A. Yes.

14:15 Q. --the number means something. In other words, the fact that--they have to be able to detect something, some lindane in that canola oil for there to be an issue.

A. No. In this case, they didn't have to. If--their assumption was if there is no detectable residue, it means that the equipment is not sensitive enough to detect it.

So, their assumption in the FQPA is, unless you have a tolerance or an exemption from tolerance, they will assume that half of the limit of the detection equipment is the number they will use in their calculation.

ARBITRATOR CRAWFORD: You're damned if you do, damned if you don't.

THE WITNESS: Exactly. And that is ultimately one of the issues with the FQPA for all countries in the world. If you're exporting food or food products or feed into the United States, you need to have a tolerance or an exemption from tolerance or an assumption will be made that even if there is no residue detected, that they will plug in a number of half of the--the number that's equal to half the detection level that the equipment is going.

So, if they're testing to parts per million, they would go and make an assumption on parts per billion is there.

So, zero is zero in their case. Zero is not zero. It's something.

BY MR. BEDARD:

14:17 Q. We will follow this up with the regulatory Experts.
A. Absolutely. This is--the information I got on the FQPA came from people like Dan Barolo, who wrote the Food Quality Protection Act. He advised us on the strategy to deal with it. So, although I'm not an expert on the FQPA, I was surrounded with people who were. And so, this no tolerance or exemption from tolerance was a big deal.
Q. If we flip--if we stay in Exhibit TZ-21 and flip to the second page, so this is Department of Foreign Affairs to the Canadian Embassy in Washington, 5-A of this internal E-mail says the U.S. Canola Association noted to WSH D.C. I don't know who that is. Do you know what that stands for?
A. I'm not familiar with that acronym.
Q. On March 5, 1998 the FDA has done residue testing on these products in the past and is unconcerned about lindane residues on canola.
A. And I have seen that reference in other places as well. If we look at a letter from the EPA to Roger Johnson, it says we are not concerned for this season, so again, this is a long-term--a long-term concern because if they are not concerned this year, they could be concerned next year. And as long as there is no tolerance or exemption from tolerance, there is always a risk that some administration or some administrator or some congressman would ask them to look with more sensitive equipment.

14:19 Q. The reference we just looked at isn't time limited anyway. They just said they are not concerned?

A. Yes.

Q. To your knowledge, did the FDA ever take enforcement action against lindane on canola?

A. The FDA routinely monitored. It never took action.

Q. Or maybe they never found anything--they never took any action.

A. They never took any action.

Q. If we go back to your first Affidavit, Paragraph 26, here you're saying partway through this paragraph, the EPA confirmed that it would, indeed, be closing the border. Here you're talking about treated seeds; is that right?

A. In this case, yes.

Q. And was this discussion limited to lindane?

A. Lindane was a lightning rod that attracted all the attention prompted by the letter from Gustafson. And so, where prior to the Gustafson letter we were all working on harmonization. It's a slow process, a slow pace, but lindane became the focal point after the Gustafson letter to the EPA, and it became an issue for the growers in North Dakota. It became an issue for the politicians and the regulatory bodies. So, it became an issue for us as well. It polarized--it really--it crystallized the importance of what we were doing around harmonization.

14:21 Q. If we go to your Exhibit TZ-8, this is the Environmental Protection Agency writing to Roger Johnson of North Dakota. This is talking about the Gustafson letter. They're talking about Premiere Plus. Are you aware of what the Active ingredients in Premiere Plus were?

A. Sorry, I couldn't--I couldn't tell you offhand.

Q. The letter itself only ever talks about Premiere Plus specifically and a non-U.S. registered pesticide.

A. Right.

Q. If we went through most of the EPA correspondence, that's generally what they talk about when they write these letters. It's unregistered U.S. pesticides. Would you agree with that?

A. Well, if we go back to the 1992 letter, which would be in--it was the letter--I'm not sure I have it here, but it's EPA to Surrick (ph.) in 1992. Do we have that from my witness bundle? It's the one that the Gustafson people reference.

And let's go to the Gustafson letter, if we can't find that document because--sorry, let's go to the Press Release of February 26th that was issued by Gustafson. And if we can find it here.

MR. DOUAIRE de BONDY: It's TZ-5.

MR. BEDARD: TZ-5. I will let you make your statement, obviously, Mr. Zatylny, but I'm trying to focus on the EPA reaction as opposed to Gustafson interpretation.

14:23 THE WITNESS: Well, okay. If we go to the 1992 letter that the EPA sent, which I don't have here--

MS. SHAKER: Mr. Zatylny, if you would really like to look it, it's Wendy Sexsmith 82.

THE WITNESS: Okay. Where do I find that?

MS. SHAKER: We will get it for you.

THE WITNESS: Okay, excellent.

ARBITRATOR CRAWFORD: What's the date of it?

MS. SHAKER: It's December 2, 1992.

THE WITNESS: Okay. So, this letter clearly states in here that not only are they concerned about the importation of treated seed for planting, but they're also--FDA has or EPA has the authority to establish tolerances or exemption from tolerances for pesticides which may be used on food or feed. Tolerances are required for imported seed if that seed has the potential to be a food or feed crop. "We generally do not consider seed to have this potential if"--it goes on. "However, we do require tolerances for crops grown from treated seed regardless of the source of that treated seed."

So, that implies that seed grown in Canada is going to be a food in the U.S., requires a tolerance or exemption from tolerances. If we go to the Gustafson letter or the Gustafson Press Release of February 26, it references this specifically as a reason why they wanted to prevent lindane-treated seed for planting from going from Canada to the U.S.

14:25 So, where EPA says one thing in one letter, this actually sets the tone for much of the action as a result of the Gustafson letter.

Q. Following the 1992 letter, as I understand it, nothing actually happened. EPA didn't enforce any restrictions either on treated seed or on product grown from seed.

A. Well, as we got into 1998, there was a call from growers in North Dakota in particular calling on the EPA and the FDA to enforce their own rules.

Q. Let's go to the EPA's response to Gustafson, which is TZ-19. And if you have looked at this recently, I hope you will agree with me that the response to Gustafson talks about using pesticides not registered for use in the United States. There is actually not a single mention of lindane in this letter.

A. That is correct.

Q. Okay. Paragraph 44 of your first statement, you say, "The importance of this plan," which was the preliminary Withdrawal Agreement, "was reinforced when on October 23rd, 1998, a shipment of treated canola seed was turned back at the border."

Next sentence. "At the same time as I already mentioned, media reports were suggesting that lindane was toxic, linking harmful chemicals to canola products caused a great deal of concern."

14:27 The shipment that was turned back, was it treated with lindane?

A. It was treated with another pesticide for which there was no tolerance or registration in the U.S.

Q. Not lindane?

A. Not lindane.

Q. Okay. So, if we go back to 1998--sorry, your statements kind of deal with things in both statements, even though they're in chronological order, so that's why I'm flipping back and forth. The sequence crosses the two statements, but Paragraph 12 of your second statement, "From January '98 until the summer of 1998, I pursued the harmonization of lindane Regulations between the U.S. and Canada."

Here you're still talking about a tolerance solution, not a cancellation solution?

A. That's correct. And there was never--it was not in our power to talk about cancellation anyway, so it was really a tolerance, which was we were asking Gustafson to establish tolerance in the U.S.

Q. Sorry, you said it was not in your power to talk about cancellation?

A. We have no regulatory authority.

Q. Okay. And then if we flip ahead still in the second statement to Paragraph 14, "By the end of the summer, I began

14:28 to seriously consider the idea of a voluntarily withdrawal of lindane by Canadian canola growers. I approached the PMRA to convey our concerns and solicit their support in facilitating a possible voluntary withdrawal."

A. Right.

Q. Was the voluntary withdrawal really your idea, being the point person at CCC and CCGA on this?

A. No, that's a question I can't answer honestly. I--where the idea actually came from, whether it was from one of the committees in the grower groups or it was collective think exercise, and the best option that was finally agreed to and supported by everyone was a Voluntary Withdrawal Agreement. And at that point I was giving my marching orders to really make it happen.

Q. And would there--these votes that we talked about at the beginning by the provincial associations and the CCGA and the CCC, would they have happened that summer?

A. Yes.

Q. To authorize you to speak to the PMRA?

A. Yes.

Q. So, you took that idea to PMRA sometime, I guess, after the summer, the end of summer, 1998?

A. Right.

Q. And was it well received by the PMRA?

A. Well, I think at the end of August, early September,

14:30 we had finally, as the grower groups had decided this is what they are going to pursue, I phoned Wendy Sexsmith and said, it is our intention to ask for a voluntary withdrawal of canola from lindane seed treatment labels, that we would--and we laid out kind of the essential plan. October 18th or 19th we followed up with a formal letter, and the time gap there is farmers were busy harvesting September, early October.

So, by early September we had made our intention clear. We had by that time talked to all the Registrants and felt we had support in principle for proceeding. And then we started working on putting together the Voluntary Withdrawal Agreement.

Q. When you said you would ask for the modification--withdrawal from the label of canola use, you mean you would ask the Registrants to ask?

A. Exactly.

Q. Okay. We have alluded to it a bit, but in 1998, there were several pesticides used in Canada on canola not registered in the U.S., is that right?

A. That's correct.

Q. And this Withdrawal Agreement that you had was focused solely on lindane?

A. It was focused on lindane.

Q. The EPA, in its communications to you and others that summer merely restated U.S. law, that a U.S.--pesticide not

registered in the U.S. could not be treated to seed with the seed imported into the U.S.?

A. That's correct.

Q. Was there concern by the association that other products would raise the ire of the U.S. EPA?

A. We were concerned about making sure we had a tolerance or exemption from tolerance for all pesticides used in Canada on canola.

Q. Why not seek voluntary withdrawal of all those other products?

A. If we go back to--one of the drivers for this was the reaction of the growers in North Dakota to the Gustafson letter to the EPA and their response, that the response was--and this started out with--strictly an economic question is, I purchased seed in Canada. Will I get my seed? And you see a letter from Senators Dorgan, Conrad, and Pomeroy saying this is unacceptable, to stop this practice.

So, the EPA said we will not enforce the seed issue until after the planting season so the farmers can get their seed.

So, essentially the U.S. farmers lost lindane in one season. They had no access to it at that point.

So then the discussion went, well, from an economic discussion of will I get my seed to this is unfair, and finally to if Canada--if U.S. growers don't have access to lindane,

14:33 neither should the Canadian growers, and there began to be a pressure from keeping the border open to pressure to got lindane off the market in Canada so there could be a level playing field.

So, as we were working through all the product--and we had success on a number of other molecules where there was tolerances put in place where PMRA, EPA, and the Registrants worked together and found a way to establish tolerances for other pesticides. Lindane was in my discussion with the EPA. They had no interest in getting a tolerance established for it. They mentioned that to others as well.

By this time, the World Wildlife Fund had indicated to us that they were going to publish a report highlighting the use of lindane on canola. Canola was being sold as a healthy oil, and that kind of publicity from World Wildlife Fund would definitely damage the reputation of our product.

So, it was driven by anger in the U.S. that the border shut down the seed. It led to political pressure to do something to create a level playing field, and Gustafson as well were fueling the fire because if you look at their--let's turn to that February 26 Press Release that they issued, and I believe it is--do we have that?

MR. DOUAIRE de BONDY: TZ-5.

THE WITNESS: TZ-5.

Okay. So, this is February 26th, and there is a

14:35 couple of interesting things. This is from Gustafson. They highlight lindane as the issue here. And then they go down at the bottom. They say that they have--it soon became apparent that extensive data requirements outlined to the EPA to complete this registration would make the project both difficult and cost prohibitive, particularly given the size of the U.S. market. Instead they're going to pursue Gaucho.

So, they helped to highlight the issue, and they also said to farmers that they weren't going to pursue a registration, so at this point we had no confidence that there would be a tolerance or exemption from tolerance, and it became clear that it would be very difficult to save lindane in Canada as a product, given the global pressure, the potential for bad press, the fact that even it appeared that Gustafson was giving up on lindane as a seed treatment product.

BY MR. BEDARD:

Q. Mr. Zatylny, I appreciate that some tolerances were achieved for other products, but you would agree that there were several products used at that time, continued to be used after that for which no U.S. tolerances were obtained?

A. For some time, but the plan was to pursue the tolerances, and we got commitments from other companies as they would work on tolerances. So, today essentially there is a harmonized pesticide industry that products in Canada and the U.S. are harmonized and available to farmers in both.

14:36 Lindane seemed to become a lightening rod for attracting the attention because it was clear to us that or became clear that the EPA had no interest in harmonizing that product.

Q. Are you familiar with the product the active ingredient carbaryl? It's in the Bayer Product 7.

A. No, I'm not familiar with that product, not familiar with it.

Q. You're not involved in canola anymore?

A. I am not.

Q. And you said you didn't know the Active ingredients that were in Premiere Plus?

A. No, I don't.

Q. The Withdrawal Agreement that was conceived in the summer of 1998 had a variety of components, the December 31, 1999, and the production date, the July 1 succession date. You, I think, are fairly familiar with that November 26, 1998, letter that sets out those terms as they were laid out by the CCC or CCGA in its letter.

Were those the elements that you and your group came up with that summer?

A. And if you go back to the initial plan for harmonization, those are key elements there, so we really were looking at harmonization, having new products that are registered on both sides of the border, and the element of the

voluntary withdrawal of canola from lindane seed treatments was really the different element than what we had initially envisioned throughout the harmonization process.

Q. One of the components--two of the components of that Withdrawal Agreement were, one, that the PMRA would expedite the registration of lindane-free formulations, existing formulations where you pull the lindane out.

A. Yes.

Q. Second aspect of that was that they would facilitate the registration of lindane replacement products.

A. Correct.

Q. Crompton's products at the time, Vitavax and the Vitavax family of products, do you know what the Active ingredients were in those products?

A. Well, lindane was certainly one of them.

Q. Right.

A. Thiram and--I can't recall the other one, but--

Q. Would it surprise you if it was carbothion?

A. It wouldn't surprise me.

Q. Okay. Were you aware that the Lindane Products on the market, the fungicide component of the Lindane Products, many of them did not have a U.S. registration or tolerance?

A. I was aware of that, yes.

Q. So, as part of this agreement to diffuse the trade situation, PMRA agreed to fast-track the registration of

14:40 products which would themselves, according to the EPA, not be allowed untreated seed and could cause an FDA problem.

A. Right.

Q. And yet the industry--PMRA itself fast-tracked those products as part of the solution to the trade irritant?

A. Well, if--this was a long-term process. The lindane was the one that caught the attention of the U.S., caught the attention of the EPA. There was at no time as we believe that lindane was the only issue, and so it did not start with lindane. It did not end with lindane, that lindane was just one of the products that was a potential trade irritant.

And by the actions of the growers on both sides of the border and the associations and working with Registrants, harmonization has finally been achieved.

Lindane became the lightning rod for many, many stakeholders in this process.

Q. Your evidence is that all products are harmonized?

A. To my belief, I had met with a canola grower in North Dakota a short while ago, and he said thank you for your efforts in 1998 that--this came out of the blue, but we believe--he believed that it's a level playing field between Canada and the U.S. today, and they're satisfied.

But every country in the world has to deal with tolerances and exemption from tolerances with the U.S. It's the number one concern for exporting countries.

14:41 Q. But you're not involved in canola anymore?
A. I am not.
Q. You're not aware of what's registered in Canada for canola?
A. I'm not following it that closely, no.
Q. And going back to these fungicides which were part of the solution to the trade irritant, you said before that the FDA was checking shipments all the time.
A. Right.
Q. January 1st, 2000, July 31, 2001. If they had inspected a shipment of canola oil from Canada, according to you where the limit of detection, half of the limit of detection is a number, but it doesn't mean anything, that shipment would have been banned if it had carbothion, thiabendazole?
A. That is correct.
Q. It would have been banned.
A. Yes.
Q. And yet the industry did--it pursued tolerances for some of these products, but that took some period of time after the voluntary withdrawal?
A. That is correct.
Q. In your first Affidavit at Paragraph 39, and we were here--you have it there?
A. Yes.

14:43 Q. You described it--the CCC's plan required the support of PMRA, but I think as you've described it today, you needed more than the support. PMRA was the only regulatory authority involved in this plan.

A. They're the only ones who could receive a petition from Registrants to have canola taken off lindane labels. They're the only Agency that could grant a grace period for the exhaustion of treated seed, and they're the only ones who could regulate replacement products, yes.

Q. And any "agreement" between CCC and the Registrants would have no regulatory authority?

A. That's correct.

And just add to that, that's why it was a Voluntary Withdrawal Agreement. We as growers used our influence to Registrants to say we no longer want to use these products, and please take canola off your labels to ensure that that trade irritant doesn't result in a border closure.

Q. And without the PMRA, there is no agreement?

A. As a facilitator, the PMRA would accept the host petitions for removal of canola from the labels. They would--without a grace period, they're the only ones who could grant a grace period, certainly.

Q. A product--a pesticide product in Canada, in order to be used for a certain purpose, has to have that use approved on the label?

14:45 A. That is correct.

Q. So, that grace period that you're talking about from January 1st, 2000, until at least July 1st, 2001, the PMRA was sanctioning--was turning a blind eye to the fact that all of this sale and use and planting was illegal.

A. In...

Q. Well, the canola came off the label December 31, 1999.

A. Right.

Q. So, that at least year-and-a-half period.

A. Right.

Q. I don't remember if it's you or Ms. Buth, someone described it as technically illegal.

A. You have to ask the PMRA about that, but as long as--as long as there is a label, that probably can be used, and I assume that they allowed those labels to remain in use until July of 2001.

Q. Okay. You're not aware of whether that was illegal or not?

A. No.

Q. Okay, fair enough.

You made a reference at the very beginning of your comments, and it's in Paragraph 5 of your second statement, that it was Procter & Gamble, our most important customer of canola products in the U.S., that made the CCC aware.

A. Yes.

14:46 Q. Whose most important customer is Procter & Gamble?
A. They buy the majority of canola oil for the U.S. market, so they are the most important U.S. customer for the canola industry.
Q. The Canadian canola industry?
A. Yes.
Q. In 1999 you left CCC to join Dow AgroSciences?
A. That's correct.
Q. And in your first Affidavit, Paragraph 59, and I do apologize for all the flipping back and forth, you make that statement, and then say, "I had no further involvement in the implementation of the VWA. However, I was contacted from time to time by JoAnne Buth with questions about the lindane file, and also got an occasional update from Wendy Sexsmith."
So, now we are in 1999. You're at Dow AgroSciences?
A. Correct.
Q. Wendy Sexsmith is calling you to give you updates on the Withdrawal Agreement.
A. I wouldn't characterize it as calling me to give updates, but because I was still part of the industry, we did run into each other from time to time, and she would give me an idea of how things were going.
Q. And you were with Dow AgroSciences until what year?
A. Until 2002.
Q. Until 2002.

14:48 So, the lindane situation, if I could call it that, went through the Special Review and then cancellation of the other products?

A. That's correct.

Q. Would you get updates from Ms. Sexsmith as you ran into her during that period?

A. Well, in 1999, when I joined Dow, I was Product Manager for their seed business, so I had an interest in seed treatments and the issues related to that. So, it would be not unusual for me to find out what's going on in the seed treatment front, especially since we were interested in not using lindane on our seed, and we were curious as to when the new replacement products were coming. So, well within my scope of my job at Dow to have an update on the status of replacement products, certainly.

Q. Great.

And you said you were involved in the Dow Nexera canola program?

A. Yes.

Q. Is that a fungicide product?

A. No, it's a line of canola seed.

Q. Oh, it's a line of canola seed itself.

A. Yes.

Q. To which you would apply pesticides?

A. Yes.

14:49 Q. So, you were still involved in the canola industry?
A. At that point.
Q. Until 2002?
A. Yes.
Q. Okay. And then you joined Arysta. And are you involved in product pesticide registration matters with PMRA today?
A. Yes. In a roundabout way. It's not my primary job, but I do get involved in product registration globally, so I'm still involved in this to some degree, yes.
Q. Arysta has a product for canola?
A. We have a product, yes, clothodim. It's a grass herbicide for canola.
Q. You're not involved with that product?
A. I am involved, and I'm directly responsible for that product.
Q. Oh, okay. When we had spoken earlier about you continuing to be involved in the canola industry?
A. Well, it's--as a herbicide, it's used on a lot of crops, including canola.
Q. Fair enough. Okay.
In 1998, obviously part of the proposed voluntary withdrawal was for replacement products.
A. Yes.
Q. The registration, the facilitation of registration for

14:50 replacement products. Were you aware at that time of the possible replacement products out there?

A. We were. We were talking to all Registrants, so those people had Lindane Products as well as--and part of my job at the Canola Council is also as I managed their field research program, so we had all the replacement products tested in our research program, so I was aware of what was in the pipeline, what was being registered, all the products at that time.

Q. And Mrs. Buth in her statement had some comments about Gaucho. You are familiar with Gaucho?

A. I am.

Q. And you're familiar with Helix?

A. Yes.

Q. And I think Premiere Z was the third possible candidate?

A. Yes.

Q. You're familiar with all of those?

A. I'm familiar with all of those, yes.

Q. And at the time, did CCC have a view on those three products, their likely efficacy, how the CCC perceived them as replacements for the industry?

A. We looked at all those products on our--in our research program, and the conclusion was that they were all effective in controlling flea beetles, so--and looking at research that was done in the U.S., the same conclusion was

14:52 also reached; that it appeared through '98, '99, 2000 that the replacement products from the work we did and others had done were all capable of controlling flea beetles.

Q. You say in your second Affidavit at Paragraph 19 that there were discussions between EPA and PMRA at this time, 1998.

A. Yes.

Q. What was the content of those discussions? In other words, two things. Number one, someone came up with July 1st, 2001; and, two, there was a whole lot of faith out there that the EPA was going to turn a blind eye until that date.

A. Right.

Q. Where did those two pieces of information or faith come from?

A. Well, the first part of your question was there was a lot of discussion between PMRA and EPA, and that is true because it was the beginning of the NAFTA harmonization of pesticides working group, which I and others were involved in in the whole harmonization issue.

So, I was involved in some of those meetings where representatives from the U.S., Canada, and Mexico would get together to discuss harmonization of pesticides. So, it was lots of discussion already.

The date on the final use was actually a compromised date because when we put out the invitation on November 3rd--November 4th to come to a meeting in Ottawa, we actually

said January 31st. So, as we worked through the details, a more reasonable date appeared to be July of 2001, and that would give time for seed that was treated to be exhausted from the system.

Q. Sorry. So, who were the people or groups that came up with that date?

A. That was the grower associations. That was the date they had chosen. The date that we chose as growers was January 31, and you will see that in the invitation. That will outline what we are going to talk about.

At the meeting on November 24th, the compromised date was July 31st, so it would be the stakeholders that were involved in that meeting, including the Registrants.

Q. Okay. And then part two, everyone assuming everything was okay until July 1st, 2001 that the EPA was not going to--

A. Well, that's where I think in terms of what were the guarantees, what were the assurances? At the same time, there was the bilateral trade agreement that was coming together that met on December the 4th of that year, and I think it's in here somewhere at--what's it called?

Q. Are you referring to the Record of Understanding?

A. The Record of Understanding. Thank you.

The Record of Understanding, it was very important that the canola growers were recognized in there. That, in our mind was the commitment made by the EPA that they would accept

14:56 the Voluntary Withdrawal Agreement. We worked towards harmonization, and that if this thing down the road came off the rails, we could point to that notice in that agreement, that we hoped that it would help prevent any future trade action on canola because we have already shown through our willingness to proceed with the Voluntary Withdrawal Agreement our good intentions to support harmonization.

So, that's the assurances we felt we had, and we got that the EPA would live up to their commitments and essentially work with us through the harmonization period.

Q. Just a question to the side a bit. I asked you about the Product 7, which you weren't familiar with. Are you familiar with the product Excel Superherbicide which is also used on canola?

A. I'm not familiar with that.

Q. That's fine.

You make the comments as Canada--the other Canadian witnesses do in several places--this is in Paragraph 27 of your second Affidavit--that dozens of existing lindane uses of the product were already withdrawn. I think this is 1998 or so you're speaking?

A. That's correct.

Q. As someone in the crop protection business, you would agree with me that there are lots of reasons to withdraw registration.

14:58 A. Correct.
Q. It's expensive to maintain a registration, isn't it? And, therefore, to give you a further qualification, if a company is going to go to the effort of maintaining the registration, there has to be a market that justifies that cost?
A. Correct.
Q. And over time, the uses of a product change, so whereas maybe 20 years ago it would be entirely foliar or mostly foliar or at least above ground, seed treatment as a niche use has appeared increasingly because it much more environmentally friendly?
A. Right.
Q. And I was looking for the reference, but I think you will agree with me, in the ROU, the United States EPA doesn't make any commitment not to enforce. I think if I read your evidence, there was an understanding from the ROU?
A. Right, exactly.
Q. There would be no enforcement?
A. Until harmonization was complete or until there was no pressure on the border, it was always going to be a risk. There was--and until there was harmonization, there would always be a risk, and there was continued--after lindane, after the Voluntary Withdrawal Agreement, we continued to work on harmonization issues for the next two or three years. One of

14:59 the requirements was to draw up a short list that both Canada and the U.S. growers got together and said these are the products that we may--that we really need to have.

So, it didn't start with lindane, didn't end with lindane. It was--lindane was just part of the products that we were trying to find a solution for.

Q. In your materials, and I don't think we need to flip to specific citations, but you make certain references about the health image of canola and concerns based on media coverage and that sort of thing. And you're making these statements as of 1998.

A. Right.

Q. You would agree with me that the growers themselves, actual growers and seed treaters, used lindane as long as they could in Canada. They used it right until the end of the '01 deadline, and then your organization got a commitment so that it could be used, the seed could be planted for 2002; is that right?

A. No, not really because in 2002, all Nexera canola sold by Dow AgroSciences had no lindane on it.

Q. There was a lot of effort on the part of CCC in 2001 to get permission from the PMRA to allow the lindane-treated seed to be used in 2002?

A. You will have to talk to JoAnne about that, but I would assume it was because there was leftover seed in the

15:01 system that needed to be exhausted.

The choice you have, when you have a treated seed is to incinerate it or plant it. Actually the most environmentally friendly way to dispose of seed is to plant it, so you can ask her about that, I don't believe there was driven by any strong desire to continue using lindane, but more of necessity to finally exhaust the system of treated seed.

Q. We can ignore 2002.

Your mention of these concerns started in 1998. Growers were using a significant amount of lindane as they always had in 1999. Is that your impression?

A. Yes.

Q. And in 2000?

A. In 2000 there started to be a transition away from lindane as Helix was registered.

Q. Sorry, Helix was registered in November 2000, so I don't believe any growers or treaters would have used Helix in the 2000 season.

A. In November of 2000.

Q. So lindane would have been used to the same extent in 2000?

A. Right, yes.

Q. And by 2001, I get the impression you were fairly far removed from these issues?

A. No. In 2001, I was managing seed business. And as

15:02 soon as we could put Helix on our seed, we did. So us and a number of other companies started to transition away from lindane, even when the choice was available.

Q. So, Dow used Helix in 2001?

A. Yes, as well as intermountain canola and proven seed, so there were a number of companies that started to use the product. And it was three times more expensive or four times more expensive than lindane.

Q. Do you know who you--you referred a couple of times to the Gustafson letters, and I believe you said that they could have pursued a registration of an intolerance in the U.S. Did Gustafson U.S. hold the registration, the lindane product registrations? Do you know?

A. Yeah, I believe so, yes.

Q. Not Crompton?

A. I think it was Gustafson, but I'm not a hundred percent familiar with that.

Q. Okay. That's fine. Thank you very much, Mr. Zatylny.

MR. BEDARD: Thank you.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Any redirect questions?

MS. SHAKER: I do just have a few short questions.

PRESIDENT KAUFMANN-KOHLER: Yes, please.

REDIRECT EXAMINATION

BY MS. SHAKER:

15:04 Q. At one point you agreed with Mr. Bedard that the CCC and CCGA could not force growers to stop using lindane.

In your view, was the position taken by CCC and CCGA supported by the farmers, all your membership, essentially?

A. Yes.

Q. Another point Mr. Bedard stated that in 1997, 1998, the majority of farmers are still using lindane seed treatments. I'm just wondering if you can tell me if at that point there were any other options on the market that farmers could have chosen at that time?

A. Lindane was at the time was the most widely used seed treatment for canola.

Q. Were there any replacement products on the market?

A. There was some in Ferrero insecticides like Turbofos, which was still available in Canada, but it wasn't available in the U.S. It wasn't a very good option for farmers.

And then shortly thereafter Gaucho was registered in the U.S., so the U.S. farmers had access to Gaucho.

Q. If you could turn to Paragraph 18 of your first Affidavit, Mr. Bedard was pointing out that, although there were concerns on part of the EPA, you were suggesting that there was no letter from the USDA or FDA on this issue.

Could you turn to witness bundle document number three for one moment.

PRESIDENT KAUFMANN-KOHLER: You said witness bundle.

That's your direct examination bundle, yes, thank you.

MS. SHAKER: It's also TZ-19, if that's better.

THE WITNESS: Got it, thank you.

BY MS. SHAKER:

Q. So, could you look at the last paragraph on this page as well as the final paragraph on the document and tell me if it mentions anything about the USDA and the FDA here.

A. Yes. In here it does mention that in the last paragraph, it says that the Agency, referring to the EPA, will discuss with appropriate authorities USDA, FIFRA. And further we will bring the issue to the attention of the Food and Drug Administration, the Agency responsible for monitoring imported food products that may contain pesticides.

Q. Thank you.

And following up on your discussion that farmers wouldn't always choose the cheapest product, I just to want clarify that point. So you're saying a farmer wouldn't automatically choose a lindane product over, say, Helix?

A. No, they would not--not automatically choose. And that goes for any product. They don't always choose the lowest priced product.

Q. And you mention as one of the factors that's taken into account is the question of effectiveness. Can you comment on the effectiveness of Helix versus, say, lindane-based products, in your opinion.

15:08 A. One of the claims that Helix made was seasonal long flea beetle control, whereas with lindane it was short-lived. So it was really controlled, flea beetles that are present at the time. There was some evidence that the long-term control would be better with Helix, yes.

Q. So, can you clarify you're saying that Helix is an effective product?

A. Helix is an effective product.

Q. And vis-à-vis you compared to lindane, would you say--

A. It has different qualities but it's as effective and potentially has some features that would make it more effective in the long term.

Q. Thank you.

Just can you clarify whether or not the Canadian canola growers would have been interested in using lindane-treated seed if you were not able to export your product to the American market?

A. No, they would not be interested in using the product.

Q. Just one final point. It's come to my attention Mr. Bedard was asking about Premiere Plus and whether or not it was a lindane product; is that correct?

MR. BEDARD: I was asking about the Active ingredients in it. I think we all agree it's a lindane product.

MS. SHAKER: Okay, I just wanted to clarify that. Thanks.

15:09 That's all my questions.

PRESIDENT KAUFMANN-KOHLER: Are there any questions from the Tribunal? Judge Brower.

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR BROWER: I'm fascinated by the fact that the Canadian--I'm sorry--Canola Council of Canada is a statutory organization?

THE WITNESS: Yes.

ARBITRATOR BROWER: By Federal statute?

THE WITNESS: Well, I better be careful in answering. The provincial grower association, Alberta Canola Producers Commission, the Manitoba Canola Growers Association, those types of organizations are under provincial mandate, they have a provincial Charter for their existence. I believe that Canola Council of Canada is a stand-alone industry association. I don't believe it's a chartered organization.

ARBITRATOR BROWER: What do you mean by chartered?

THE WITNESS: I don't believe they operate under any Federal authority. It operates under the financial support to have--of the members, and although it says Canola Council of Canada, it's not a Federal Agency.

MR. DOUAIRE de BONDY: But the collections that you indicated were made on the delivery of canola in one form or another, is that mandated by law in some way?

THE WITNESS: Yes, it is. In each of the Provinces,

15:10 it's fully refundable checkoff, so that by law the purchasers of canola are automatically deducting a checkoff. That is passed on to the grower associations. An individual farmer can request to have his money reimbursed to him.

ARBITRATOR BROWER: All right. But neither your organization, CCC or the CCGA is in any sense a part of the Federal or any provincial government?

THE WITNESS: They are not.

ARBITRATOR BROWER: And may I inquire why you're here today.

THE WITNESS: This consumed quite a bit of my 1998. It was a pretty big year for me, and I felt that it would be important to put closure to this issue, and Bruce Dalgarno, who was one of the growers involved very heavily in 1998, phoned me and said, please get involved on behalf of the growers and see this through.

So, actually, that prompted my involvement in support of--continued support of the growers and my own organization to see it through was a big factor in me being here.

ARBITRATOR BROWER: So, you were or were not first contacted by the Canadian Government in some form?

THE WITNESS: No. I was contacted by Bruce Dalgarno, who--his name appears on several of these documents as well, so through his encouragement, the next call came from the Federal Government.

15:12 ARBITRATOR BROWER: Thank you.

PRESIDENT KAUFMANN-KOHLER: Professor Crawford.

ARBITRATOR CRAWFORD: Did the proposal for the Voluntary Withdrawal Agreement come from the PMRA?

THE WITNESS: Had it?

ARBITRATOR CRAWFORD: Did it come from the PMRA?

THE WITNESS: It did not.

ARBITRATOR CRAWFORD: Would you say that Crompton was effectively compelled to enter into the VWA by the PMRA?

THE WITNESS: I would not say that's the case. This was the initiative of the growers. They were consistent in their response all through this process, that they no longer wanted to use a product. They did not want the health issues raised by nongovernment groups and consumer groups. They did not want issues at the border. It was their solution, and the PMRA was involved to facilitate the Agreement. It was--it was really the growers' solution. We analyzed the problem. Let's face it, all the lindane used in Canada would amount to $20 million at the most. The industry was worth $1.8 billion, 600 million of which was exports to the U.S. When we balance from the growers, when the industry balanced the use of lindane against the health of the industry, there is really no choice, and the solution was--was hammered out and agreed to by the industry, by the participants, and presented to the PMRA looking for their support.

15:14 ARBITRATOR CRAWFORD: When did you first become aware that Crompton was reluctant to go along with the VWA?

THE WITNESS: Well, I think on December 17th or shortly thereafter I got a call from Wendy Sexsmith saying that Crompton had said they support the Voluntary Withdrawal Agreement, but there was some additional--some additional demands were being asked for. So, all through this, there was a sense that all the Registrants were supporting the Voluntary Withdrawal Agreement.

As a result of this arbitration, I find notes, internal notes, from Crompton where they say things like this is our public--this is what we are saying public, but internally we are negotiating separately with the PMRA. That was kind of disappointing because all through this process, even though there is issues to be resolved, the comments we were receiving from Crompton was that they were going to support the Voluntary Withdrawal Agreement.

And so, disappointing and somewhat shocked actually that they weren't dealing with the growers in good faith all the time.

Could I just make one more comment on that, is that we weren't necessarily concerned about the details because it was a Voluntary Withdrawal Agreement. All the Registrants had to support it. Anybody could have said we don't support the Voluntary Withdrawal Agreement and it was dead. There was no

other solution.

So, as long as they were saying we support it in principle, that was good enough. The only thing that would stop the thing was anybody saying we did not support it. And the deal never would have happened. There was--it was strictly a Voluntary Withdrawal Agreement, so I think that's an important point in this, that they had the power to kill the deal at any time.

ARBITRATOR CRAWFORD: Let's assume the Voluntary Withdrawal Agreement had fallen through, for whatever reason, what do you think would have happened then in terms of the market for treated seed in Canada?

THE WITNESS: Well, it's pure speculation, but if you look at the Goldman letter of November 23rd, she says she's really disappointed that it looks like the deal was falling apart and that they were going to have to do what they were going to have to do. So, ultimately, I believe that had the Voluntary Withdrawal Agreement fallen through, there would have been enormous pressure from the U.S. growers to shut down the border until lindane was gone or it registered in the U.S.

And so I believe--I know still to this day that we were close to losing access to the U.S. market, and lindane was the driver for that. So, I believed it then, and believe it now, it was the right decision for the growers to make, and ultimately not only saved our industry but grew the North

15:17 American business to be one of the top contributors to our country's farmers' income.

ARBITRATOR CRAWFORD: Thank you very much.

ARBITRATOR BROWER: Going on with this hypothetical situation, had the voluntary withdrawal fallen through, the Canadian canola growers still would have been all right if they did not use lindane-treated seeds.

THE WITNESS: They would have been all right had they not used lindane-treated seeds, correct.

ARBITRATOR BROWER: So, was there a problem at that time that there was nothing else available to produce the crops the way that they should in order to be able to compete?

THE WITNESS: That is correct. The replacement--the effective replacement products were one or two years away in Canada, so that would have been the choice: To take a risk on not being a very successful canola grower or not grow canola.

So, the industry would shrank considerably. It would have.

ARBITRATOR BROWER: And as it turned out, they were able to use lindane or less long enough until they could deal with Helix; is that right?

THE WITNESS: That's correct. And other products came along, Gaucho was registered, and eventually Premiere Z from Zeneca, so eventually there was--Helix was--I think Gaucho was the first one that came to market. Helix was second.

15:19 ARBITRATOR BROWER: But the Gaucho you referred to was not an all-in-one?

THE WITNESS: It was.

ARBITRATOR BROWER: It was?

THE WITNESS: For whatever reason, Gustafson chose to register it in the U.S. and not in Canada, and--so, it was available to the U.S. farmers, but not to Canadian farmers at that time. It was at least a year before it was available.

ARBITRATOR BROWER: Thank you.

ARBITRATOR CRAWFORD: Gaucho CS FL was registered in the U.S. before it was registered in Canada?

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: At the November 24th, '98, meeting, did you have the impression that there was an agreement reached?

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: On what?

THE WITNESS: Well, on the basis of we were committed to not leave the room until we had an agreement or sign off on an agreement being reached. I think it was around 3:00. We had a big board of issues that we were working through and dates, and finally there was no more questions, so I asked the Registrants to confirm yes or no: Are they going to support the Voluntary Withdrawal Agreement? Every Registrant said yes, they're going to support the Voluntary Withdrawal Agreement.

15:20 So, we kind of leaned back and said, "We have a deal."

The memory is burned in my mind because that was the critical point. We went through all the issues. We put an action plan together. We finally asked for the support, and we got the support. And starting the day after, the 26th, we started to get feedback on the Press Release. We started working with Registrants. I phoned Julie Langer from the World Wildlife Fund and said, "Lindane is going to be out of the canola business, and so leave us alone." So, lots of things happened after that.

So, yes, in my mind, and I believe everyone's mind that sat in the room that day, there was an agreement reached for voluntary withdrawal of lindane seed treatments.

PRESIDENT KAUFMANN-KOHLER: And the agreement included the different conditions?

THE WITNESS: That included the three main points. Those are the ones you're referring to that every company would submit in writing to the PMRA that there would--they wanted canola taken off their labels, that we would work together on registration of new pesticides for canola and that there would be a phase-out period going to July 31 of 2001.

And that was the three elements of--

PRESIDENT KAUFMANN-KOHLER: July 1st.

THE WITNESS: July 1st, sorry. Thank you.

PRESIDENT KAUFMANN-KOHLER: And so, what was this July

15:22 1st, 2001, time limit for? What could be done until then, and what could not be done thereafter?

THE WITNESS: I think the belief of the growers was that seed treated with Lindane Products could be planted until July 1 of 2001, after which point there was no more lindane seed treatments available for canola.

PRESIDENT KAUFMANN-KOHLER: So, if they had seeds left over from the previous seasons, they could not plant them?

THE WITNESS: Our expectation was that that was the case, that everybody knew the time lines and that by the end of the first part of July, all seeds that had lindane treatment on it would be planted. Ultimately, there was conditions that required an extension of that, but in 1998 that was our intention.

PRESIDENT KAUFMANN-KOHLER: Was this entire withdrawal issue a question of trade or a question of health and environmental risk?

THE WITNESS: Both played a part in it.

Canola has always been sold as a healthy product, the healthiest oil; it's still sold as that. It won the Health Food of the Year in the U.S. Procter & Gamble got that award for canola oil.

Having connections to lindane found in breast milk and the healthiest oil was just not compatible. It was just not the imagery we wanted to see for our oil. It was--so, that had

15:24 a big role to play in it. And I think Jean Dextrose in many comments through this said it's not just trade. It's the public perception about the healthiness of our products. So the image of canola is important.

And you could see why growers are so passionate about it. They started the industry. This is not some government program. In the 1960s, they started looking for an alternative crop. They formed the Western Rapeseed Association, which later became the Canola Council of Canada. When the industry was threatened in the late Sixties and early Seventies because of erusic and glucosinolates in it, they went from rapeseed to canola through their initiative.

When you mention canola to a Canadian farmer, they have a lot of passion. In 1998, they saw that industry threatened again. So, it's not surprising they rallied to the support of their industry, and it actually came up with an eloquent solution to transition away from it, that kept the border open, dealt with the trade issues, dealt with the health issues, and went on to a stronger, healthier industry.

PRESIDENT KAUFMANN-KOHLER: So, how did it go about replacement products? Because among the conditions, as you state them of the November 24th agreement, if there was one, there was the cooperation of replacement products.

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: What was the discussion

about this? Was there an expectation that there would necessarily be replacement products registered available in time when the phase-out was expiring?

THE WITNESS: We knew from--we knew that Gaucho was in the queue, so we knew that it would be--

PRESIDENT KAUFMANN-KOHLER: When you say "Gaucho," do you mean Gaucho CS FL, or the two what I call the two small Gauchos?

THE WITNESS: No, the one that included the new insecticide--the imidacloprid, I believe--so it was in the queue.

PRESIDENT KAUFMANN-KOHLER: So, that's the all-in-one with the fungicide?

THE WITNESS: All-in-one with the fungicide, and the insecticide had been submitted. So, regular time lines would be 18 months to two years, so that would definitely put us within the window of replacement.

We knew that Syngenta or Novartis at the time had Helix ready to go. It wasn't submitted, but they did a Joint Review, so they gave the package to both EPA, PMRA; they split the package in half; each country viewed their section and shortened the time line, so we were fairly confident.

There was no guarantees, but we knew at least two of the products were either submitted or about to be submitted, so we did our calculation in thinking that we could get there in

time with replacement products.

Again, that could have derailed this whole thing? If we had no replacement products, it would have been--it was one problem that we could deal with at a time.

In our calculation, we felt even in the worst-case scenario, the replacement products would be there on time.

PRESIDENT KAUFMANN-KOHLER: Thank you. That answers all the questions I had. Thank you very much for your explanation, Mr. Zatylny.

There is a follow-up question?

MR. BEDARD: Yes, and one clarification that will be important for the record.

PRESIDENT KAUFMANN-KOHLER: Okay.

RECROSS-EXAMINATION

BY MR. BEDARD:

Q. Mr. Zatylny, hello again.

You made a comment in your discussions with Professor Crawford about Premiere Z. Was that product ever registered and used in Canada?

A. I know we tested it at the canola production center, so I know it had at least gone into the testing environment. But at the same time there was an acquisition of Zeneca by Novartis, so whether they divested it or put it on the shelf because Novartis already had the Helix, so they could well have shelved the product.

15:28 Q. And you made the comment, if I heard it correctly, that the product being used in the United States, the Gaucho product, was an all-in-one fungicide-insecticide?

A. Yes.

Q. Just for clarification of the evidence, I appreciate that your impression or understanding at the time was that, but the record is quite clear, if you return to it, that the Gaucho product in the U.S. registered at the time was just a stand-alone insecticide. I simply refer you back to the record and if your understanding was different.

PRESIDENT KAUFMANN-KOHLER: I don't think there was a misunderstanding on this.

MR. BEDARD: Pardon me? Sorry?

PRESIDENT KAUFMANN-KOHLER: I don't think there was a misunderstanding.

MR. BEDARD: Oh, okay. I thought Mr. Zatylny was under the impression that it was a combination products registered in the United States at that time, which it was not. It was simply an insecticide.

THE WITNESS: Simply an insecticide, yes, yes.

BY MR. BEDARD:

Q. And I do want to ask a question arising with respect to Professor Crawford's first question.

Apart from three-and-a-half years with Canola Council, you have always been involved in the industry with businesses

15:30 1 that deal with the PMRA?
2 A. I have, yes.
3 Q. And so, on the question was Crompton effectively
4 compelled to enter into the VWA as a company whose livelihood
5 depends on registrations in dealing with the regulator, you
6 would agree with me that, as a practical matter, Crompton had
7 limited options in terms of how that sequence of events played
8 out? Would it have told PMRA, "Forget it"?
9 A. They certainly could have told PMRA that they weren't
10 interested. I'm not sure they could have told the growers they
11 were not interested because the PMRA role was to regulate the
12 pesticides. They had to accept or whatever Crompton decided.
13 It was the growers that they would have to answer to.
14 Q. As someone who has been in this business for 26 years,
15 give or take, would you in Crompton's position have ever told
16 the PMRA, "Forget it; we are not playing ball"?
17 A. Last year, Dow AgroScience sued PMRA, so it's not
18 unheard of that Registrants and regulatory agencies come to
19 heads from time to time. So, I can't answer that question, but
20 I don't know what Crompton did or what I would do, but it's
21 certainly not unusual for Registrants to take on the PMRA in a
22 very direct way.
23 Q. Okay. Thank you, Mr. Zatylny.
24 MR. BEDARD: Thank you, Madam President.
25 PRESIDENT KAUFMANN-KOHLER: Thanks.

15:31 So, this now really closes your examination. Thank you.

THE WITNESS: Thank you.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: We will take a 20-minute break, and then we continue with Mrs. Buth; this is right.

(Brief recess.)

JOANNE BUTH, RESPONDENT'S WITNESS, CALLED

PRESIDENT KAUFMANN-KOHLER: So, we are all ready now. Good afternoon?

THE WITNESS: Good afternoon.

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

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: You're the President of the Canola Council of Canada?

THE WITNESS: Yes, I am.

PRESIDENT KAUFMANN-KOHLER: You had this function since 2007?

THE WITNESS: Yes, I have.

PRESIDENT KAUFMANN-KOHLER: And before that you were Vice-President Crop Production of the CCC, and that was since 1999?

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: Just March when

15:53 Mr. Zatylny left? Is that right?

THE WITNESS: Yes, I started in March 22nd, 1999.

PRESIDENT KAUFMANN-KOHLER: Fine. Thank you.

You have given two Witness Statements.

THE WITNESS: Yes.

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

THE WITNESS: I understand.

PRESIDENT KAUFMANN-KOHLER: I would like to ask you to confirm this by reading the Witness Declaration that is in front of you, please.

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

PRESIDENT KAUFMANN-KOHLER: Thank you.

Now, you will first be asked questions by Canada's counsel, and then we will turn to Chemtura's counsel.

Mr. Douaire de Bondy.

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

DIRECT EXAMINATION

BY MR. DOUAIRE de BONDY:

Q. Ms. Buth, could you first please confirm that you have your two Witness Statements in front of you?

A. Yes, I do.

Q. All right. And my only question is, do you adopt and

confirm the contents of your two affidavits?

A. Yes, I do.

MR. DOUAIRE de BONDY: Thank you.

Those are our questions-in-chief.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Mr. Bedard?

MR. BEDARD: Thanks you, Madam President.

CROSS-EXAMINATION

BY MR. BEDARD:

Q. Ms. Buth, my name is Ben Bedard. I'm here on behalf of Chemtura. I will be relying almost exclusively on your first and second Affidavits for questions.

Obviously, most of your--a significant part of your evidence has to do with the Withdrawal Agreement that was entered into in the late 1990s.

You would agree that the Canadian Canola Council had no authority to enter into an agreement with anyone that had a regulatory effect.

A. Correct.

Q. And we have--needless to say, we had some discussion with Mr. Zatylny about the CCC and its structure and how it operates, so we have some background on that.

You would agree that the CCC--neither the CCC nor the CCGA has any control over its members or over seed treaters in terms of the decisions they make for the seed they plant, what

15:55 they treat it with.

A. Correct.

Q. If I can take you to your first statement. If we start at Paragraph 28, the end of that paragraph: Over the course of summer--this is 1998--and fall, it became clear that Chemtura Corporation had been communicating with the PMRA in an attempt to unilaterally change the terms of the withdrawal agreement to their benefit, as you describe it. This development was communicated to us by the PMRA.

Who at PMRA would have communicated that to you?

A. Wendy Sexsmith would have.

Q. And in this time period 1999-- well actually, you joined the CCC in March of 1999, so when would this development have been communicated to you?

A. It would have been--you know, I don't actually recall communication because when I came in, I was aware that the--I'd been made aware of the voluntary withdrawal, and I was not aware that there were any issues with any of the Registrants when I came in.

It would have been towards the end of the summer, beginning of the fall, but I don't recall exact dates.

Q. Would it be fair to say that during 1999 you had a fair amount of interaction with Wendy Sexsmith at the PMRA?

A. Yes. Yes.

Q. If we go to Paragraph 31, in the middle of that

paragraph--this is talking about replacement products--we knew one of them, Premiere Z would not likely be effective.

Do you see that statement?

A. Yes.

Q. How would you have known that?

A. I have a background in pesticides. I have worked in pesticides for about 30 years, and so I'm aware of the mode of action of different insecticides.

And what you're looking for in a seed treatment is something that's systemic, so as the seed grows, the pesticide would then enter the seed and be in the cotyledons, the first leaves of the plant.

Premiere Z is a synthetic pyrethroid insecticide, and they have no known systemic effect, and so they would--the company would be relying on the fact that the chemical would vaporize off the seed, come through the soil and protect the seedling, and I really had my doubts that that would be possible.

Q. Many others must have thought it was possible. Obviously, Zeneca was investing a lot of money in this product, PMRA was describing it as one of the three possible replacements. This was your opinion based on what you knew of its mode of action--

A. That's correct. I mean we would be--oh, sorry. Okay.

Q. This was your opinion based on what you knew.

15:58 Obviously you wouldn't have had its entire formulation or that sort of thing or the data surrounding the product, but this was your general impression of the product.

A. That's correct. We would be waiting for the evaluation of the product and the determination by PMRA in terms of its efficacy.

Q. The lindane seed treatments that were available in 1999, were these combination insecticide fungicides?

A. Yes, they were.

Q. There were no stand-alone Lindane Products for canola.

A. No, I don't believe so.

Q. Okay. And then in Paragraph 32 of your statement, you say there, it was your understanding that PMRA had made a commitment to expedite the review process for certain--I'm not reading directly--to expedite the review process for certain lindane replacements. That was part of the withdrawal agreement.

A. That's correct. We didn't want to leave growers in the situation where they had no seed treatment products--clearly.

Q. Because an insecticide for canola was very important for Canadian farmers.

A. That's correct.

Q. And you were having discussions with PMRA about replacement products and about the specific options available

16:00 in the queue?

A. Well, PMRA was limited in terms of what they could tell us. I mean, they didn't discuss the packages with us. We knew what had been applied for, but at that point in time there was not as much transparency within PMRA that there is now in terms of the products and where they are at in the queue.

So, we didn't really know a lot of details about it, but we knew they were moving through the system.

Q. And you knew which products were in the queue at this time.

A. Yes, that's correct. It was communicated to everybody, including--well, all of the industry at the various meetings that we had.

Q. And obviously you knew enough about enough about Premiere Z to have an opinion on its likely efficacy.

A. Correct.

Q. When you were before CCC, you were with the Manitoba Department of Agriculture.

A. Yes.

Q. And in that capacity, did you have interaction with PMRA back then?

A. Yes, I did, because I was responsible for the Pesticides and Fertilizers Control Act in Manitoba Agriculture, and also the Noxious Weeds Act. So, I was part of a--there was an organization that was a--like a provincial territorial group

16:01 that met with Federal regulators on pesticide issues because responsibility for pesticides is split between the Federal Government in terms of registration, but sale is regulated by the Provinces.

Q. Did you know Wendy Sexsmith when you were with Manitoba?

A. I recall meeting Wendy Sexsmith at one of the meetings. I believe at that point she might have been a regulator in one of the other Provinces.

Q. In this discussion about replacement products, what would the situation have been if lindane were gone from the market and there were no replacement products? No insecticides?

A. It would have been very difficult to grow canola. Farmers need an insecticide, preferably a seed treatment. Some of the growers would have--there still would have been canola produced, but it would have been much more difficult. Growers would have to rely on a foliar insecticide that they would apply after the flea beetles had entered the field, and it's much more difficult to predict.

There is a real range of flea beetle density across the prairies. Some are typically--some areas are typically higher density flea beetles, where seed treatment is quite important. Other areas, the growers could have gotten away without a seed treatment, but they would have used a foliar.

16:02 In some cases, in some areas, in some years they don't need anything.

Q. And a foliar application would result in more accumulation--exposure into the environment. It's more exposure for workers and that sort of thing as compared to a seed treatment--more of the pesticide being released.

A. You know, I'm not sure.

Q. Okay.

A. Yeah.

Q. Paragraph 33--and it's the top of Page 10--now we're in 2001, and you say the PMRA again clarified that its commitment had been to review the three applications submitted within a certain time frame.

What was that time frame that PMRA had committed to review these replacement products?

A. Well, that was actually--that reference there applies to the fact that they were submitted within a certain time frame, not that they committed to review them within a certain time frame.

The commitment--I don't know if it was a commitment. Our understanding was that they would review them as quickly as possible with the view to having a replacement product available in 2000.

Q. And when were they to have been submitted?

A. I believe that--well, the industry was starting to

look for replacement products prior to the issue with lindane, so those products would have been submitted prior to the November meeting, where the discussion occurred on the voluntary withdrawal, because it was pretty sure at that point the three--the three submissions had already been made for Gaucho, for Premiere Z, and for Helix at that time.

When I came in in March of 19 or--1999, that was my understanding, was that those were the three products under review.

Q. Maybe we'll just go to the exhibit that you--

A. Yes.

Q. --cite in that paragraph, and it's JB-14 to your first statement.

And here you have said this is a letter from Wendy Sexsmith to you, February 6, 2001. You have written to Ms. Sexsmith supporting the registration of an Aventis seed treatment product. She is responding that the PMRA made a commitment to work with EPA growers and Registrants to facilitate access to replacement products, but nowhere did we commit to three replacement products. If you recall when this issue was being discussed, there were three applicants that had products to submit in the short open window. And then she goes on to say: Only products of two of the Applicants turned out to have reviewable submissions. These products have been subsequently registered.

16:05 So, I believe back in your Paragraph 33, you were paraphrasing this open window in which products' applications could be submitted. Does that--

A. Correct.

Q. --as you read that?

ARBITRATOR BROWER: When you are referring, these documents refer to "Gaucho," what Gaucho are we talking about?

MR. BEDARD: When Ms. Sexsmith says these products have been subsequently registered, that would have been in 2001 Gaucho 75 and Gaucho 480.

BY MR. BEDARD:

Q. Ms. Buth, you have paraphrased that letter to say the three applications had to be submitted within a certain time frame, and I was just asking you whether--Ms. Sexsmith uses the phrase "a short open window," and you've paraphrased that as "within a certain time frame," and I was just asking whether you knew anymore about what that time frame was.

A. No.

Q. No, okay.

In Paragraph 36, you say you were frequently in contact with Ms. Sexsmith, periodically in touch with Anne Lindsey of the EPA. My communication with Anne Lindsey was to ensure that she was aware of our commitment to the Withdrawal Agreement and to ask for the EPA's consideration of this commitment in any cross-border movement of seed. You were--

16:07 MR. DOUAIRE de BONDY: Sorry, Mr. Bedard. It actually says seed, oil, and meal.

MR. BEDARD: I'm sorry. I didn't mean to--that wasn't to--seed, oil and meal, as Mr. Douaire de Bondy clarified.

BY MR. BEDARD:

Q. How often were you in contact with Anne Lindsey or anyone else at the EPA in this time frame, '99, 2000, 2001?

A. I can recall a couple of meetings that I was at where I spoke to Anne Lindsey. They were not specific to the lindane issue, but she was there, and I took the opportunity to talk to her off to the side, and I--I believe I called her perhaps twice just to let her know and update her what was happening on the voluntary withdrawal.

Q. And did the EPA give you a commitment that, based on your Withdrawal Agreement, the EPA of the United States would turn a blind eye until 2001 for the continued use of lindane?

A. No. I wouldn't have expected a regulator to have provided that kind of assurance.

Q. But the understanding of the industry or the hope, maybe is a better way to put it, of the industry was that this agreement the U.S. would turn a blind eye, as I say it, to the fact that lindane was continuing to be used for those subsequent two years.

A. Yes. That was our hope.

Q. At the time of the voluntary withdrawal, you're aware

16:09 that there were several products registered for use on canola in Canada that were not registered in the U.S. and that had no U.S. tolerance.

A. Yes. There were about 20 pesticides that were registered in the U.S. that didn't have a tolerance or a registration in the U.S.

Q. Registered in Canada?

A. Registered in Canada, sorry.

Q. Okay.

And if you--I know you weren't with CCC in 1998, but you will, I'm sure, have seen a lot of the correspondence from EPA in 1998, and they consistently refer to the general prohibition that a product treated with a pesticide registered in Canada that's not registered in the U.S. cannot be imported into the U.S. Yet, obviously, the Withdrawal Agreement focused entirely on lindane, notwithstanding that there were many other products being used and registered in Canada for which there was no U.S. registration.

Why was that? Why was there only a Withdrawal Agreement for lindane and none of the others?

A. If I can put it in--just in the context of the entire harmonization effort, we had a very close relationship with the U.S. Canola Association and the U.S. growers because of this issue, and we had a North American crop protection strategy so that we would work together on harmonizing pesticides on both

16:10 sides of the border once we became aware that this was an issue.

And so we specifically knew which products that we had issues with that weren't registered on both sides of the border, and we put a program in place to tackle those on a priority basis. It happened that lindane became a priority because of the issue that was raised by Gustafson, that Gustafson raised the issue of the treated seed going across the border. That then spilled over to the issue of, well, if it's been treated with lindane in Canada, then any residues in the canola seed oil or meal coming into U.S. would be illegal, so that really tripped the issue for us and led us to deal with that issue first.

Q. The Gustafson letter was talking about the product Premiere Plus? Are you aware of that, that the Gustafson letter that started--that was sent in 1997 was talking about the product Premiere Plus? Are you aware of that?

A. No. I thought the Gustafson letter was talking about the product lindane--oh, Premiere Plus--sorry. Premiere Z, Premiere Plus, yes. Premiere Plus was the lindane product. It wasn't the replacement product.

Q. Right.

And are you aware of the fact that Premiere Plus was a combination insecticide-fungicide comprised of lindane, thiram, and thiabendazole?

16:12 A. Yes.

Q. Okay.

At that time, was there at that time was there a registration or tolerance for thiabendazole?

A. Not that I recall.

Q. No.

And that would have been consistent with a lot of products, as you said, at least 20.

A. Yes.

Q. And so this fear of border action by the U.S. was in part addressed by the Lindane Withdrawal Agreement, but if there was a concern about the FDA checking for residues of products, the Withdrawal Agreement was only perhaps a small part of that issue, and they could have found residues of these 20 other products used on canola.

A. Yes, that's correct.

My recall--or what I believe is that, you know, we had this list of 20 products, and there was no way we were going to deal with them all at once. We had to set some priorities. Lindane was under review internationally. We've had communication from the World Wildlife Fund, from an aboriginal group, from the National Roundtable on the Environment and the Economy. It was clearly being targeted internationally and also in Canada, and so that was the focus for us was the lindane issue.

16:13 Q. You've been with the CCC ever since. Have you ever reached a time where the products--all of the products used in Canada on canola had a U.S. registration in tolerance? Is that--is there harmonization today?

A. You know, I had meant to go back and take a look specifically, but there is only one product that I can recall right now where we don't have a tolerance in the U.S. or a registration in the U.S. that we do in Canada.

I would say we were largely successful at either having the Registrants withdraw those products from the market in Canada so there was no trade issue, or getting a tolerance or a registration for the product in the U.S.

Q. Are you familiar with carbaryl in the Product 7?

A. Yes.

Q. Which is registered and has a label use for canola?

A. Yes. I'm not sure it's commercially available. So there were some products that we knew that were not commercially available or not used on a large number of acres, and they were lower priority products that we would tackle.

Q. You're not certain whether or not 7 is used on canola in Canada.

A. No, I'm not certain. Foliar insecticides are not used that often.

Q. But they are used.

A. Yes, they are.

16:15 Q. The product fenoxaprop-p-ethyl?
A. Has been--is no longer commercially available.
Q. Excel Super herbicide?
Let's go a different way.
A. Sure. Okay.
Q. What's the product you know of that's used in Canada that does not have a U.S. registration or tolerance?
A. Epridion (ph.).
Q. And so today, if someone is using that product and the canola is either treated and is sent across the border as treated seed or is sent as canola meal or canola oil, there is a risk that FDA will find residues in the product.
A. That's correct.
Q. So, the Withdrawal Agreement certainly hasn't taken this issue away. There is a live issue that has been ongoing for the past 10 years.
A. It's a constant issue, and we remind Registrants on a regular basis that the Canola Council of Canada policy is that we do not support a registration in Canada unless there is a simultaneous registration on canola in the U.S., because we don't want to get into the situation with other products, and we continue to try and harmonize the products that are out there.
Q. We talked about those EPA documents from 1998, which were sort of ominous in suggesting, by the way, we've mentioned

16:16 FDA that these products are being used in Canada and there may be residues.

Was there ever a document from FDA saying we've found residues of lindane in canola oil or that stop the shipment of canola where they found lindane residues in canola oil?

A. FDA did a special study on canola because the issues had been raised, where they checked for residues. I can't remember the exact publication date. It was either 2000 or 2001, I believe, and it was a monitoring study to see whether or not there were the potential for residues. They found two products, one of them being lindane.

Q. They found residues in processed oil, refined oil?

A. They found residues in seed and meal.

Q. Seed and meal, which doesn't--obviously doesn't answer the question of whether they would be found in processed oil because--

A. No, but the fact that they have been found in meal would create an issue for us if meal was rejected at the border, because if the tolerance is zero, the U.S. is our largest market for canola meal.

Q. Meal would be going into the U.S. as feed?

A. Yes.

Q. So, that, in turn, requires an animal tolerance for whether once you feed it to the animal it shows up in the animal product; is that right?

16:18 A. Yes.

Q. In Paragraph 54 of your first statement--again this is about interactions with Chemtura, and there is a teleconference involving the PMRA and the four Registrants on October 22nd, 1999. You then say, in the middle there: We and the PMRA confirm that there was a process for reinstating canola on the lindane label with the PMRA.

Why would CCC be confirming PMRA reinstatement policy?

A. We were facilitating the discussion, and we were--we were very aware that this was also a competitiveness issue in that all four Registrants had to have the same information. So in discussions with Wendy prior to that, I had been informed that there was a reinstatement process. So clearly I couldn't have informed them of what the possess was, but we had been assured that there was a reinstatement process, and PMRA provided the details on that call.

Q. If we move ahead to Paragraph 71 of your first statement, it says: "When we set the date of July 1, 2001."

Is that--the CCC set that date? Is that what you're saying?

A. We set it in cooperation with the Registrants, yes.

Q. Okay.

A. Who was part of the conditions of the voluntary withdrawal.

Q. Did PMRA have input on that date? They were involved

16:19 in the decision that led to that date?

A. I don't know if they were involved in the decision as much as it was a discussion about after you ceased to have a registration, how long would be a reasonable time for that product to be used up. It's fairly standard to have a period of time for the product to be used up, if it's a change in registration, and so we would have looked at, you know, how much product would be out there, how much treated seed might be out there, and how long a time period would you need for growers to move that through the system.

Q. When you were speaking with the PMRA about replacement products, you've given your view on Premiere Z and the fact it was not likely to be effective, and you were ultimately right; the product was never registered. You've made some other comments in your evidence about your views on Gaucho. By process of elimination, I guess it would be fair to say that you were supportive of Helix based on the fact that, in your view, that there had to be a replacement product if there was no lindane, and you didn't have a strong positive feeling about the other two.

A. I was supportive of all of them. I didn't think that Premiere Z was going to work. I didn't think it would make it through, meaning we were supportive of Gaucho, clearly, because it had been used in the U.S., but as you stated, I was aware there were some issues regarding efficacy of Gaucho, and we

16:21 were also supportive of the Helix product.

Q. Just going back, before we forget about it, in your second statement, at Exhibit JB-23, we are now into the time when you are having some fairly significant--making significant and serious efforts with PMRA to allow use of the stock, the carryover seed in 2002. At that time, PMRA was not making a decision, I guess it would be fair to say, about whether that seed that had been treated with lindane could be used in the 2002 season; is that right?

A. Correct.

Q. So, this is a November 20, 2001, letter from you to Wendy Sexsmith at the PMRA? You've got it?

A. Yes, I do.

Q. Okay. And, so, in your first numbered point at the bottom of that page, "In 1998, we did not know the likelihood of detecting residues in canola seed oil and meal."

So, you're saying--this is your letter to say please allow to us plant the seed for 2002.

A. Yes. It was--this was a one-off situation. We knew we had to deal with this seed issue, and it was the--the reason for mentioning this information was that it was a way essentially to assure the industry that--that the risks were lower than we originally thought--

Q. Okay. And on that--

A. --in terms of detection.

16:23 Q. Right. And on that point, in your third bullet under number one, you say: "Residue testing by the lindane manufacturers has shown .0058 parts-per-million lindane and canola seed but no detectable residues in refined canola oil or meal."

A. That's correct. That was the information at the time.

Q. And you're saying there is a subsequent study that--by FDA dealing with residues in meal?

A. Yes.

Q. Is that study on the record?

A. In the record here?

Q. Yes.

A. I'm not sure.

Q. Okay. This was your position in 2001?

A. Yes.

Q. Okay.

There was some discussion in your evidence about the fines and the potential for a $250,000 fine if growers used treated--if growers used seed in 2002--treated seed in 2002. And your evidence, if I understand it correctly, is that the PMRA, when asked, would say, if you use this treated seed--if you plant this treated seed after 2000--July 1st, 2001, the maximum penalty under the Act is $250,000, so they described the penalty provisions of the Act. Am I summarizing that correctly?

16:25 A. Yes.

Q. Okay. And I understand from your evidence, you were in the room at some of these meetings with Mr. Reid, and you came away with the impression that yes, they were describing the penalties under the Act, but it would only be in rare circumstances that the penalties would be applied. That was your impression with your regular communication with PMRA?

A. That was my impression, yes.

Q. So, for the 70,000 growers or so, if they're hearing this information like from a Canadian seed treaters association, Fast Facts, and just hearing the penalties and the fact that planting after July 1, 2001 could result in fines of $250,000. To people that are a little farther removed from the regulatory Agency than you are, obviously, they might have some fear?

A. They might, but I think that growers were fairly aware of pesticide use and what they should and shouldn't be doing, and they were also aware of the fact that it was very rare for PMRA to be in the field looking for things, unless there was some really obvious misuse that had been going on. And, so, my belief was that, although this was, although the, this was--may have been communicated to growers that there wasn't a lot of fear out there, and I didn't receive a lot of calls from growers about, you know, what would happen to them.

Q. By contrast, when the EPA says, "If we detect

16:27 residues, that import will be stopped. If you are using an untreated--if you're using a seed treated with a product not registered in the U.S., that product will be stopped."

Wasn't the EPA in all that correspondence simply describing the law and the possible enforcement action?

A. Correct.

Q. In much the same way that the PMRA was.

A. We couldn't risk detections.

We also had experience with the FDA making--doing monitoring or testing cargoes and other crops prior to that time. And frankly the border between Canada and the U.S. has continued to get even thicker in terms of allowing products in and testing and monitoring.

So, when, you know, you have a 500 million-dollar, 600 million-dollar industry, it was not something that we were prepared to risk by saying, well, they'll--you know, we hope they will look the other way. We were already doing that for a three-year period, and frankly crushers and exporters were sitting on pins and needles waiting for the whole process to be completed so that we wouldn't have the threat of this hanging over us.

Q. But a fair summary of what you're saying is that everyone thought PMRA would look the other way, and no one thought EPA would.

A. I don't--I don't think everyone thought PMRA would

look the other way.

Q. So, some people--people a little bit farther removed from the industry association and the PMRA process, if they see a fax from a seed treatment association, fines are $250,000 if you have seeds left over, they might be worried. That's a reasonable conclusion.

A. I have to go back to the fact that I think there is a wide variety of growers out there with different levels of knowledge and sophistication, and that many of the growers, because they use pesticides every year are aware of what they're legally supposed to do and not supposed to do and how they can push the limits.

So, I would think that, you know, there would be a range out there of growers that would say, well, you know, I don't think this will happen--I don't think I'll get caught, whereas, as an industry with that much at risk, we couldn't say, "Well, we don't think we will get caught when it came to the EPA."

Q. Why did the CSTA issue that fax warning about the fines?

A. To pass the liability on, essentially, so that they weren't liable.

Q. And they hired outside counsel to give them the, CSTA, an opinion on potential liability? Are you aware of that?

A. I don't recall, no.

16:30 Q. No?

And to your earlier point--and I don't remember the name of the active ingredient, but there are still farmers today using product registered in Canada for which there is no U.S. registration or tolerance on canola.

A. Yes.

Q. That situation still exists today?

A. It would be very, very small.

Q. But the risk--the risk of canola being stopped at the border exists because of that--because that seed could end up in a crushing plant with other seed?

A. That's correct, although we have--we do residue testing as well. The Canadian Grain Commission does residue testing on a regular basis, and there are very few pesticide residues found in canola.

Q. Of any pesticide?

A. Um...

Q. There are no residues--is what you're saying--of pesticides in the oil being tested--very few.

A. There are few--very few, yes.

Q. Okay. Thank you very much, Ms. Buth.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Any redirect questions?

REDIRECT EXAMINATION

BY MR. DOUAIRE de BONDY:

16:31 Q. Ms. Buth, perhaps just one question on redirect. Mr. Bedard was talking about Helix and Gaucho and your views about Helix and Gaucho as potential replacement products. I just wondered if you could--first of all, is it fair to say that Helix was successful in the Canadian canola marketplace as a replacement product?

A. Yes, they took a large percentage of the acres in the years following the lindane withdrawal.

Q. And to what you would account the success of the Helix in the marketplace after its introduction? What--were there particular efforts on the part of Syngenta, for example?

A. Syngenta was a very aggressive marketer--still is--and they made--some of the things they do is--that they're in close communication with the organizations that need to know about the product, people that are called "key influencers," that when growers may have questions or the industry has questions, they would be able to answer those types of questions. And so, Syngenta would have meetings, tours. You would see the product in the field. There would be demonstrations. They would ramp up marketing efforts by doing large-scale plots out there, showing yield data, and quite an extensive marketing program in addition to the outreach that they would do with universities, agronomists, et cetera.

Q. I think in your statement--one of your statements you've also mentioned the bundling issue--the bundling of newly

developed seeds with Helix. Could you talk to us about that for a moment.

A. Yes, the canola industry changed quite a bit in terms of the types of varieties that are available, and so as we were going into specialty varieties and also into hybrids that had much higher yields.

Q. Sorry, just when you say "varieties," what do you mean by "varieties"?

A. Canola--their--

Q. Seed?

A. Their specific--yes, seed, sorry, seed.

Q. Okay.

A. And so, there are very specific types of seed varieties that will give you a specific oil profile or will be high yielding, and companies at that point were starting to produce hybrids and also some specialty varieties, and Syngenta had their product applied to those varieties, so that their product would be on the high value products or the products where growers were looking for increased returns because of the yields, and so they bundled their products with specific seed developers in order to get the product out there.

Q. So, would those--how--would those bundling efforts have contributed to their success?

A. Clearly.

Q. And how--could you compare the marketing efforts of

16:34 Syngenta to those of Chemtura in marketing Gaucho, for example?
A. We didn't have as--we didn't have nearly as much communication from Chemtura. There wasn't as much communication directly with us or our agronomists. I don't recall ever being asked to be on a field tour. And I don't recall--I believe they did some bundling, but it was not with some of the higher yielding varieties, so there wasn't as much of a marketing program that Chemtura did.

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

PRESIDENT KAUFMANN-KOHLER: Do my co-Arbitrators have questions? Judge Brower? Professor Crawford? No?

Now I don't know whether I have questions. I need to check.

(Pause.)

QUESTIONS FROM THE TRIBUNAL

PRESIDENT KAUFMANN-KOHLER: In 2008, you expected to produce a record crop at over 10 million tonnes.

THE WITNESS: Yes. We produced a record crop at 12.6 million tonnes.

PRESIDENT KAUFMANN-KOHLER: And what do you expect for this year?

THE WITNESS: Well, the crop is just coming off right now. We had a tough spring, a lot of moisture in some areas and drought in others, and a cold rainy summer across the west,

except in the drought areas. And so we're expecting--right now those numbers changing, but right now the industry estimate is somewhere between 10 to 11 million tonnes. So, we probably won't make the record we did last year, but we will still be high.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Now the other questions I have all been asked and answered. So, I thank you very much, and that closes your examination.

THE WITNESS: Good, thank you.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: Good. Do you want to start the next witness? Or not? Do we keep the next witness for tomorrow? What is your plan?

MR. DOUAIRE de BONDY: Just a point of clarification, I think we were expecting this examination to go a bit longer, and Ms. Sexsmith is not actually here, so--

PRESIDENT KAUFMANN-KOHLER: That's why I was asking that question. I always want to go as fast as possible, but that resolves the question. If we are fast these coming days, maybe you make sure that they are available or can be called on short notice, because we are progressing rather well. I thank you.

MR. DOUAIRE de BONDY: Yes.

PRESIDENT KAUFMANN-KOHLER: You've been very

16:37 disciplined in asking questions.

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

Just a point of clarification on that point specifically. The only restriction we have is Dr. Costa is flying in from Italy over the weekend and so wouldn't be available until Monday.

PRESIDENT KAUFMANN-KOHLER: We have--he's scheduled for Monday in the morning; yes, that's fine.

MR. DOUAIRE de BONDY: Yes.

PRESIDENT KAUFMANN-KOHLER: Excellent. So, we will start tomorrow morning with Mrs. Sexsmith and then go on with Mrs. Chalifour and then Dr. Franklin; is that right? Good. So, have a nice evening.

(Whereupon, at 4:38 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