

FINAL SHOWN

Heydens, William 01-23-2017

Heydens, William 01-24-2017

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Total Time 01:07:46



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192:25 And so it says "Williams, et
193:1 al., 2000." That's the paper we've been
193:2 discussing, right?

193:3 A. That is correct.

193:4 Q. And it says, "An invaluable
193:5 asset," right, sir?

193:6 A. That's what he has written
193:7 there, yes.

193:8 - 193:9 **Heydens, William 01-23-2017 (00:00:02)**

EXHIBIT 312.12.1

WH2_COMBINED_06.5

193:8 Q. And that's a fair

193:9 characterization, you would agree?

193:12 - 194:3 **Heydens, William 01-23-2017 (00:00:44)**

WH2_COMBINED_06.6

193:12 THE WITNESS: So the Williams
193:13 paper, the way I would characterize
193:14 the Williams paper -- I think we
193:15 talked a little bit about it this
193:16 morning -- that was the first time
193:17 that -- all the glyphosate toxicology
193:18 data that existed for regulatory
193:19 purposes in the publications, the
193:20 first time that it was compiled
193:21 together and reviewed by basically
193:22 international experts. So that was a
193:23 very important paper.

193:24 QUESTIONS BY MR. MILLER:

193:25 Q. And what David Saltmiras says

194:1 is that Monsanto responses to agencies? Is
194:2 that one of the things the Williams paper was
194:3 used for?

194:6 - 194:7 **Heydens, William 01-23-2017 (00:00:02)**

EXHIBIT 312.12.2

WH2_COMBINED_06.7

194:6 THE WITNESS: I'm not sure I
194:7 know what he means by that.

194:23 - 195:2 **Heydens, William 01-23-2017 (00:00:13)**

WH2_COMBINED_06.8

194:23 Do you understand what David
194:24 Saltmiras meant when he said in the slide
194:25 panel that you reviewed in 2010 that it was
195:1 going to be used for scientific affairs
195:2 rebuttals?

EXHIBIT 312.12.3

195:5 - 195:11 **Heydens, William 01-23-2017 (00:00:08)**

WH2_COMBINED_06.9

195:5 THE WITNESS: Yeah, I don't

195:6 know. I mean, I'm looking at it now,
195:7 and I don't know exactly what David
195:8 meant by that.

195:9 QUESTIONS BY MR. MILLER:

195:10 Q. Do you know what the word

195:11 "rebuttals" means?

195:14 - 196:15

Heydens, William 01-23-2017 (00:01:04)

WH2_COMBINED_06.10

195:14 THE WITNESS: I know what the

195:15 word "rebuttals" means to me in this

195:16 context.

195:17 QUESTIONS BY MR. MILLER:

195:18 Q. Is what?

195:19 A. Well, to me it's scientific

195:20 affairs assessments or reviews. We do a

195:21 number of those where publications come out.

195:22 I think we probably talked about some of

195:23 them. Publications come out, and we have

195:24 those papers -- we will review those papers,

195:25 either ourselves and/or with other experts,

196:1 to understand what those papers are saying,

196:2 to understand if it's really -- if it's an

196:3 example of good science or if there's perhaps

196:4 some problems with the paper. And maybe

196:5 there's not problems with the paper. And

196:6 then maybe we need to understand more why the

196:7 results were there, and we may need to do

196:8 some work to do that.

196:9 So I look at it as a process of

196:10 assessing other people's scientific

196:11 information. That's what I see when I look

196:12 there.

196:13 Q. Do you understand also that the

196:14 publication Williams was going to be used for

196:15 regulatory reviews?

196:18 - 196:23

Heydens, William 01-23-2017 (00:00:16)

EXHIBIT 913.12.A

WH2_COMBINED_06.11

196:18 THE WITNESS: Yeah, I don't

196:19 know if it was. You'd have to -- we'd

196:20 have to look at that.

196:21 QUESTIONS BY MR. MILLER:

196:22 Q. Go to the page of the deck that

EXHIBIT 913.17.1

Page/Line	Source	ID
196:24 - 197:5	196:23 starts with political science. Heydens, William 01-23-2017 (00:00:21)	WH2_COMBINED_0812
	196:24 Do you have that page, sir?	
	196:25 A. Yes, I do.	
	197:1 Q. Dr. Saltmiras writes in that 197:2 section that "Williams has served us well in 197:3 toxicology over the last decade."	EXHIBIT 312.17.2
	197:4 Do you see that, sir?	
	197:5 A. I do see that.	
197:15 - 197:17	Heydens, William 01-23-2017 (00:00:06)	WH2_COMBINED_0813
	197:15 Q. Would it be fair to say now 197:16 that Williams has served Monsanto well in 197:17 toxicology over the last decade?	
197:20 - 198:16	Heydens, William 01-23-2017 (00:00:52)	WH2_COMBINED_0814
	197:20 THE WITNESS: What I would say 197:21 is really what I said before: This 197:22 was -- it was a very important paper 197:23 because it was the first of its kind, 197:24 it was comprehensive of everything 197:25 that was out there up to that point in 198:1 time, and it was a very, like I said, 198:2 important paper for glyphosate. 198:3 So if people wanted to 198:4 understand what the science of 198:5 glyphosate says, that they had in one 198:6 place a full review. That paper had 198:7 not only the toxicology -- I failed to 198:8 mention previously toxicology of 198:9 glyphosate -- but it also looked at 198:10 surfactant. It looked at everything. 198:11 It looked at some formulations. So it 198:12 was a very important document.	
	198:13 QUESTIONS BY MR. MILLER:	
	198:14 Q. Fair to say you told Donna 198:15 Farmer that you would strangle Dr. Williams 198:16 if he wanted to rewrite the paper?	
198:19 - 198:20	Heydens, William 01-23-2017 (00:00:03)	WH2_COMBINED_0815
	198:19 THE WITNESS: I don't recall 198:20 having said that.	
210:18 - 210:20	Heydens, William 01-23-2017 (00:00:07)	WH2_COMBINED_0816

Page/Line	Source	ID
	210:18 Q. Exhibit 3:28, an e-mail from 210:19 you concerning the glyphosate mammalian 210:20 manuscript.	EXHIBIT 315.1.1
210:21 - 211:4	Heydens, William 01-23-2017 (00:00:18) 210:21 A. Okay. 210:22 Q. Do you remember sending this 210:23 e-mail, sir? 210:24 A. No, I do not. 210:25 Q. Let's take a look at it then. 211:1 This is an e-mail from you the year of the 211:2 Williams paper, 1999, right? 211:3 A. The Williams paper was 2000, 211:4 not '99.	WH2_COMBINED_0817
213:6 - 213:14	Heydens, William 01-23-2017 (00:00:22) 213:6 Q. We're going to mark the 213:7 Williams paper 2000 -- 213:8 A. If that's -- just so we're 213:9 clear, if that's what's -- that's not the 213:10 entire paper. That's part of it. 213:11 Q. Okay. What is exhibit -- then 213:12 you can mark on -- that's 3-29. 213:13 What is that, the short version 213:14 of the paper? How would you describe it?	WH2_COMBINED_0818 clear - EXHIBIT 316.1.1
214:3 - 214:10	Heydens, William 01-23-2017 (00:00:20) 214:3 Q. The question is: How would you 214:4 describe what you're looking at, 214:5 Exhibit 3-29? 214:6 A. I would describe it as three 214:7 pages. I want to look at the backside and 214:8 make sure there's nothing on the back. I 214:9 would describe it as three pages from the 214:10 full publication.	WH2_COMBINED_0819
214:21 - 214:22	Heydens, William 01-23-2017 (00:00:06) 214:21 And the authors are	WH2_COMBINED_0820
215:15 - 215:24	214:22 Dr. Williams, Dr. Kroes and Dr. Munro? Heydens, William 01-23-2017 (00:00:28) 215:15 THE WITNESS: Those are the 215:16 three authors. 215:17 QUESTIONS BY MR. MILLER: 215:18 Q. Let's go back to Exhibit 3-28.	WH2_COMBINED_0821 EXHIBIT 315.1.1

Page/Line	Source	ID
	215:19 It's an e-mail that you sent in July of 1999.	
	215:20 Do you see that, Doctor?	
	215:21 A. I do.	
	215:22 Q. And it's sent to imunro@cantox.	
	215:23 That's the same I. Munro who was an author of	
	215:24 the Williams paper, right, sir?	
216:7 - 216:9	Heydens, William 01-23-2017 (00:00:05)	WH2_COMBINED_0622
	216:7 A. I. Munro would be Ian Munro at	
	216:8 Cantox.	
	216:9 Q. Same person?	
216:23 - 217:4	Heydens, William 01-23-2017 (00:00:14)	WH2_COMBINED_0623
	216:23 THE WITNESS: Okay. Now I have	
	216:24 3-28 and 3-29 in front of me, and Ian	
	216:25 Munro would be the same person.	
	217:1 QUESTIONS BY MR. MILLER:	
	217:2 Q. All right. So you're writing	
	217:3 to Ian about this paper; is that fair,	
	217:4 Doctor?	
217:13 - 217:21	Heydens, William 01-23-2017 (00:00:31)	WH2_COMBINED_0624
	217:13 A. My -- this e-mail in 3-28	
	217:14 refers to the Cantox publication.	
	217:15 Q. And you say in this e-mail that	EXHIBIT 315.1.2
	217:16 you send to him, "Finally, attached are the	
	217:17 text, tables and references. I've sprouted	
	217:18 several new gray hairs during the writing of	
	217:19 this thing, but as best I can tell, at least	
	217:20 they have stayed attached to my head."	
	217:21 Did I read that correctly?	
217:25 - 218:5	Heydens, William 01-23-2017 (00:00:07)	WH2_COMBINED_0625
	217:25 THE WITNESS: Yes, that is	
	218:1 there in the document -- in the	
	218:2 e-mail.	
	218:3 QUESTIONS BY MR. MILLER:	
	218:4 Q. So you got gray hair writing	
	218:5 this paper, okay?	
218:10 - 218:15	Heydens, William 01-23-2017 (00:00:15)	WH2_COMBINED_0626
	218:10 Q. You can answer.	
	218:11 A. Yes. So as I look at this now,	
	218:12 you know, probably what I was really	
	218:13 referring to was that it was a lengthy	

Page/Line	Source	ID
218:18 - 218:22	<p>218:14 process, as a seminal review paper would 218:15 probably be. Heydens, William 01-23-2017 (00:00:09)</p>	WH2_COMBINED_0627
219:2 - 219:11	<p>218:18 A. Seminal and comprehensive. 218:19 Q. Yes, sir. 218:20 And you write that, "Everyone 218:21 at Monsanto has agreed with adding you as an 218:22 author. Please do so."</p> <p>Heydens, William 01-23-2017 (00:00:29)</p> <p>219:2 Q. Did I read that correctly? 219:3 A. You read that correctly. I 219:4 don't know why that is there, because Ian was 219:5 always going to be an author as far as -- to 219:6 my recollection. I'm not sure why that's 219:7 there. 219:8 I mean, he participated in the 219:9 review to the same degree that the other two 219:10 scientists did, so I don't know why that's 219:11 there.</p>	EXHIBIT 315.1.3 WH2_COMBINED_0628
219:12 - 219:15	<p>Heydens, William 01-23-2017 (00:00:11)</p> <p>219:12 Q. Well, two months before that 219:13 you wrote an e-mail where you said you would 219:14 manage your experts as authors. 219:15 Do you remember that, sir?</p>	WH2_COMBINED_0629 c1c3c
219:18 - 219:23	<p>Heydens, William 01-23-2017 (00:00:02)</p> <p>219:18 THE WITNESS: I don't remember 219:19 that. 219:20 (Heydens Exhibit 3-30 marked 219:21 for identification.) 219:22 QUESTIONS BY MR. MILLER: 219:23 Q. Let's take a look at it.</p>	WH2_COMBINED_0630
219:24 - 220:2	<p>Heydens, William 01-23-2017 (00:00:15)</p> <p>219:24 Exhibit 3-30, an e-mail you sent in May 219:25 of '79. I have a copy for you and counsel. 220:1 A. '79 or '99?</p>	WH2_COMBINED_0631 EXHIBIT 317.1.1
220:3 - 220:22	<p>Heydens, William 01-23-2017 (00:00:51)</p> <p>220:2 Q. Excuse me, '99. My fault. 220:3 A. Okay. 220:4 Q. Yes, sir. 220:5 This is an e-mail that you</p>	WH2_COMBINED_0632

220:6 wrote in May of '99, right, sir?

220:7 A. That appears to be correct,

220:8 yes.

220:9 Q. And you wrote it to a William

220:10 Graham, also a Monsanto employee?

220:11 A. Yes, that is correct.

220:12 Q. And I just want to go over a

220:13 few points in it. Your point number 2:

220:14 "Outside scientific experts who are

220:15 influential at driving science, regulators,

220:16 public opinion, et cetera, we would have

220:17 they" -- I think you meant "the," but I'll

220:18 ask you -- "we would have the people directly

220:19 or indirectly behind the scenes work on our

220:20 behalf."

220:21 Was that part of your strategy

220:22 in May of 1999?

221:1 - 221:13

Heydens, William 01-23-2017 (00:00:33)

221:1 THE WITNESS: Those words are

221:2 written there. I don't remember this

221:3 e-mail.

221:4 QUESTIONS BY MR. MILLER:

221:5 Q. Was one of your jobs to --

221:6 quote, "Monsanto people who are responsible

221:7 for dissemination and coordination of

221:8 scientific information within and outside of

221:9 Monsanto. They will play a role in

221:10 establishing and, quote, managing

221:11 relationships with outside experts."

221:12 My question to you, sir, is:

221:13 Why did you put "managing" in quotes there?

221:17 - 222:10

Heydens, William 01-23-2017 (00:00:59)

221:17 THE WITNESS: So as I said just

221:18 a moment ago, I don't remember this

221:19 e-mail. As I look at it now, I would

221:20 interpret that as just meaning who has

221:21 the contact relationship.

221:22 Usually with -- quite often,

221:23 anyway, with -- different scientists

221:24 would have perhaps different key

EXHIBIT 017.1.2

WH2_COMBINED_0633

EXHIBIT 017.1.3

WH2_COMBINED_0634

221:25 contact points. So, for instance, if
 222:1 an external scientist was a genetic
 222:2 toxicologist, then we might have one
 222:3 of our own genetic toxicologists be
 222:4 the contact person for that. So
 222:5 that's what I think I meant by that.

222:6 QUESTIONS BY MR. MILLER:

222:7 Q. And number 4 you write, "As far
 222:8 as how we get, quote, people to get up and
 222:9 shout glyphosate is nontoxic," end quote.
 222:10 Was that one of your jobs?

EXHIBIT 217.1.4

222:14 - 222:15 **Heydens, William 01-23-2017 (00:00:01)**

WH2_COMBINED_0635

222:14 QUESTIONS BY MR. MILLER:

222:15 Q. Was that one of your jobs, sir?

222:17 - 222:23 **Heydens, William 01-23-2017 (00:00:18)**

WH2_COMBINED_0636

222:17 THE WITNESS: No. As I stated
 222:18 this morning, it really -- my job is
 222:19 to make sure that the best science
 222:20 gets conducted on glyphosate and the
 222:21 best science using sound principles is
 222:22 communicated. That's always been my
 222:23 role in glyphosate.

263:18 - 263:20 **Heydens, William 01-23-2017 (00:00:09)**

WH2_COMBINED_0637

263:18 Q. Okay. Has there been a
 263:19 decision to preclude the use of POEA as a
 263:20 surfactant with glyphosate in Europe?

263:25 - 264:12 **Heydens, William 01-23-2017 (00:00:54)**

WH2_COMBINED_0638

263:25 A. So I'm aware of some places in
 264:1 Europe where that proposal -- and, in fact,
 264:2 has taken place. What I will say is that is
 264:3 due to political reasons and is not supported
 264:4 by the scientific data.
 264:5 In fact, the risk assessments
 264:6 that have been done by the German BfR -- it
 264:7 was approximately back in 2010, 2012. That
 264:8 is the same organization -- or the same
 264:9 regulatory agency who was the rapporteur for
 264:10 glyphosate in the reevaluation. That very
 264:11 agency evaluated tallow amine and came to the
 264:12 conclusion that there's no unreasonable risk.

Page/Line	Source	ID
264:16 - 264:16	Heydens, William 01-23-2017 (00:00:02)	WH2_COMBINED_06.96
	264:16 Q. Let's look at Exhibit 3-36, sir.	HEYDENS 3.1.1
264:24 - 267:24	Heydens, William 01-23-2017 (00:03:50)	WH2_COMBINED_06.40
	264:24 Q. Is that your handwriting where 264:25 we see on Exhibit 3-36 "reasons for defending 265:1 tallow amines"?	HEYDENS 3.1.2
	265:2 A. It looks like my handwriting.	
	265:3 Q. And this is an e-mail from you 265:4 in the bottom of the first page of that 265:5 document, from Bill Heydens, January 2010, to 265:6 Richard Garnett.	HEYDENS 3.1.3
	265:7 I believe he's a Monsanto 265:8 employee in Europe?	
	265:9 A. That is correct.	
	265:10 Q. Yes, sir.	
	265:11 A. couple of comments. This is 265:12 you, quote, "First, there is still a strong 265:13 sentiment in STL" --	HEYDENS 3.1.4
	265:14 Is that St. Louis?	
	265:15 A. That is correct.	
	265:16 Q. Which is where the Monsanto 265:17 headquarters is?	
	265:18 A. That is correct.	
	265:19 Q. Okay. "There is still a strong 265:20 sentiment in St. Louis that we need to 265:21 continue to defend tallow amines, even though 265:22 we prepare to switch over because of their 265:23 impending demise."	
	265:24 Did I read that correctly?	
	265:25 A. You did.	
	266:1 Q. And what did you understand in 266:2 2010?	
	266:3 Why was there an impending 266:4 demise of tallow amine?	
	266:5 A. Well, the conversation that we 266:6 were already hearing in our conversations 266:7 that, as you have already said, that there -- 266:8 some of the regulatory agencies and some of 266:9 the -- some of the politicians were starting 266:10 to talk about enacting bans on tallow amines.	

266:11 Q. And you were responding to an
266:12 e-mail that had come from you -- come to you
266:13 from a Richard Garnett, the Monsanto employee
266:14 in Europe, right, sir?

266:15 A. Yes.

266:16 Q. And he asked in his e-mail, the
266:17 top of page 2, "Anyway, there are
266:18 nonhazardous formulations, so why sell a
266:19 hazardous one?"

266:20 Do you remember him asking you
266:21 that question?

266:22 A. I think that's more a
266:23 rhetorical question, if you will.

266:24 Q. Back to the first page. What
266:25 you write, sir, is that you were very
267:1 worried -- excuse me. Let me get it right.
267:2 "Reason to do so: Domino
267:3 effect on ether amines, defend other world
267:4 areas to the best of our ability. Second, I
267:5 was in Brazil all last week - they are very
267:6 worried about this coming across the Atlantic
267:7 to their part of the American hemisphere."
267:8 Those were the reasons you were
267:9 defending tallow amines?

267:10 A. The reason why defending tallow
267:11 amines is because I believe -- we believe
267:12 that the science is behind tallow amines. If
267:13 the science is behind the product, then I
267:14 think it's -- certainly you should be making
267:15 sure that decisions are being made about your
267:16 material based on sound science.

267:17 Q. Well, you were going to defend
267:18 tallow amines or POEAs as long as the price
267:19 of them didn't get too high, right?

267:20 A. I'm not sure I said that.

267:21 Can you --

267:22 (Heydens Exhibit 3-37 marked
267:23 for identification.)

267:24 QUESTIONS BY MR. MILLER:

Page/Line	Source	ID
	267:25 Q. Let's take a look at it.	
	268:1 Exhibit 3-37.	
268:22 - 269:13	Heydens, William 01-23-2017 (00:00:48)	WH2_COMBINED_05.42
	268:22 Q. Do you remember this series of	
	268:23 e-mails, sir?	
	268:24 A. Ever so vaguely.	
	268:25 Q. All right. Let's look at the	
	269:1 first page. This is an e-mail sent by you,	_1_HEYDENS 3.1.1
	269:2 September 2010, regarding new formulations	
	269:3 LAS-POAE -- I'm sorry, POEA as surfactants,	
	269:4 right, sir?	
	269:5 A. Yes.	
	269:6 Q. And what you say in the second	_1_HEYDENS 3.1.2
	269:7 paragraph is, "So for now, I think we	
	269:8 continue to defend POEA as long as the price	
	269:9 doesn't get too high, and we continue to	
	269:10 develop backups for when and if other areas	
	269:11 become in jeopardy."	
	269:12 That was your plan as of	
	269:13 September of 2010, right?	
269:18 - 269:20	Heydens, William 01-23-2017 (00:00:08)	WH2_COMBINED_05.43
	269:18 THE WITNESS: And that's not my	
	269:19 plan. There I am offering my personal	
	269:20 opinion.	
289:19 - 296:16	Heydens, William 01-24-2017 (00:06:09)	WH2_COMBINED_05.44
	289:19 Q. Can you tell the jury what your	clear
	289:20 profession is, Dr. Heydens?	
	289:21 A. Yes. I'm a toxicologist by	
	289:22 profession.	
	289:23 Q. And what is your current title	
	289:24 at Monsanto?	
	289:25 A. Currently I'm product safety	
	290:1 assessment strategy lead.	
	290:2 Q. And can you tell the jury what	
	290:3 you do in that role?	
	290:4 A. In that role, my job is to work	
	290:5 with other scientists as we get new products	
	290:6 that come in that would need to be tested for	
	290:7 safety to work on, devise the overall testing	
	290:8 strategy and sets of studies that we would do	

290:9 to support the safety of that product.
290:10 Q. Are there standard studies or a
290:11 guide to what kind of studies need to be done
290:12 for a new product?
290:13 A. There are for some -- for the
290:14 traditional pesticides, there are a set of
290:15 guideline studies. A couple different sets
290:16 of guideline studies that we can use and we
290:17 can -- if necessary, we can adapt those for a
290:18 different product concept.
290:19 Q. Are there any required studies
290:20 that would have to be done for a new
290:21 herbicide or pesticide?
290:22 A. For new pesticides, for which
290:23 herbicide is one, yes, there's a whole set of
290:24 studies, a very comprehensive set of studies
290:25 that need to be done, all way from acutes,
291:1 subchronics, gene tox studies, reproductive
291:2 toxicity, developmental toxicity, cancer,
291:3 metabolism, just -- neurotoxicity,
291:4 everything.
291:5 Q. Who specifies what studies need
291:6 to be done?
291:7 A. Here in the United -- that's by
291:8 regulatory agency. So here in the United
291:9 States, that would be the Environmental
291:10 Protection Agency.
291:11 Q. I want to briefly review your
291:12 background.
291:13 Can you tell the jury where you
291:14 went to college?
291:15 A. For undergraduate, I went to
291:16 Grand Valley State.
291:17 Q. And what state is that in?
291:18 A. That's in the state of
291:19 Michigan.
291:20 Q. And what degree did you receive
291:21 from Grand Valley State?
291:22 A. My degree was a bachelor's
291:23 degree in biomedical sciences.

291:24 Q. Was that a bachelor of arts or
291:25 a bachelor of science?
292:1 A. A bachelor of science.
292:2 Q. Okay. And what year did you
292:3 get that degree?
292:4 A. That was 1977.
292:5 Q. And did you have any further
292:6 academic training after you graduated from
292:7 Grand Valley State?
292:8 A. Yes.
292:9 Q. What else did you do?
292:10 A. I went to the University of
292:11 Michigan, the toxicology program there, and
292:12 culminated in receiving my Ph.D. in
292:13 toxicology.
292:14 Q. And what year did you get your
292:15 Ph.D.?
292:16 A. That was 1984.
292:17 Q. Did you complete any class work
292:18 on toxicology either as part of your BS
292:19 degree or your Ph.D. degree?
292:20 A. Completed -- the Ph.D. program
292:21 the first two years was all class work, a
292:22 variety of different toxicology classes and
292:23 also other medical sciences such as
292:24 pharmacology and things of that nature.
292:25 Q. Did you write a thesis as part
293:1 of your Ph.D. program?
293:2 A. Yes, I wrote a thesis.
293:3 Q. What was your thesis on?
293:4 A. It was the effects of
293:5 thiocyanate on postnatal -- on prenatal and
293:6 postnatal development in rats.
293:7 Q. And did you actually conduct
293:8 experiments on animals as part of that Ph.D.
293:9 thesis?
293:10 A. Yes, approximately did that for
293:11 almost three years.
293:12 Q. Are there different kinds of
293:13 toxicologists?

293:14 A. Yes, there's a variety of
293:15 toxicologists. Generally there's people who
293:16 are generalists and then there are other
293:17 toxicologists who can specialize in a
293:18 particular area.

293:19 Q. Is there an area called
293:20 regulatory toxicology?

293:21 A. There is an area of regulatory
293:22 toxicology.

293:23 Q. Have you been involved in
293:24 regulatory toxicology during your employment
293:25 at Monsanto?

294:1 A. Most of my employment has been
294:2 in regulatory toxicology.

294:3 Q. What does a regulatory
294:4 toxicologist do?

294:5 A. A regulatory toxicologist is
294:6 responsible for actually making sure that
294:7 they either conduct the studies or make sure
294:8 that the studies are conducted that are
294:9 required by regulatory agencies for that
294:10 product and for the safety and safety
294:11 evaluations that need to be conducted.

294:12 Q. What did you do after you got
294:13 your Ph.D.?

294:14 A. After receiving my Ph.D., I
294:15 came to work for Monsanto.

294:16 Q. And why were you interested in
294:17 a job at Monsanto?

294:18 A. I had actually -- when I was in
294:19 graduate school between my first and second
294:20 year, there was like an internship program
294:21 where you could go to -- come to Monsanto and
294:22 work in the toxicology lab that Monsanto had
294:23 actually conducting the studies. That
294:24 sounded interesting to me so I, in fact, did
294:25 that and I went back to school to get my --

295:1 to finish out my Ph.D. and about the time
295:2 that I was finishing my Ph.D., the lab, it
295:3 was called the Environmental Health

295:4 Laboratory, had an opening, the person that
295:5 had the opening who remembered me, called me
295:6 up and said -- asked me if I wanted to come
295:7 and apply for the role of that they had open.
295:8 So I did apply and obviously I took it.

295:9 Q. And so what was your first
295:10 position when you joined Monsanto?

295:11 A. My first position, I was an
295:12 inhalation toxicologist.

295:13 Q. And where did you work in that
295:14 first position at Monsanto?

295:15 A. That was -- that was at our
295:16 toxicology lab, which was called the
295:17 Environmental Health Laboratory.

295:18 Q. And sometimes that's referred
295:19 to in documents as the EHL, correct?

295:20 A. That's correct.

295:21 Q. Okay. And where was the EHL
295:22 located?

295:23 A. EHL is located just on the
295:24 skirt -- it's in St. Louis, on the edge of
295:25 St. Louis.

296:1 Q. And what did you do as an
296:2 inhalation toxicologist at Monsanto's EHL?

296:3 A. I was responsible for -- I was
296:4 for conducting the studies in the role of
296:5 study director. And so, like I say, I was
296:6 responsible for all aspects of the study
296:7 conduct for those studies that were conducted
296:8 by the inhalation route of exposure. And
296:9 those could have been acute studies,
296:10 subchronic studies, fertility and
296:11 reproduction studies.

296:12 Q. Were you doing any studies on
296:13 glyphosate in that role?

296:14 A. I may have just conducted one
296:15 or two acute studies that would have been in
296:16 that time frame.

297:5 - 299:11

Heydens, William 01-24-2017 (00:02:18)

297:5 Q. How long did you work at the

WH2_COMBINED_0645

297:6 EHL?

297:7 A. A little less than four years.

297:8 Q. So that would take us till

297:9 about 1987?

297:10 A. That is correct.

297:11 Q. What did you do after EHL?

297:12 A. After EHL I went to the --

297:13 what's called the product toxicology group.

297:14 That was a small group of toxicologists who

297:15 were responsible for the overall -- all the

297:16 products that were in or were coming into

297:17 Monsanto's agricultural pipeline.

297:18 Q. And how many products would you

297:19 have been assigned as a toxicologist at one

297:20 time in the products toxicology group?

297:21 A. It would vary. It could be as

297:22 few as two and possibly as many as four or

297:23 five.

297:24 Q. And was glyphosate one of the

297:25 products that you had responsibility for in

298:1 that role?

298:2 A. For a period of time, yes.

298:3 Q. And when was that time?

298:4 A. So I had responsibility for

298:5 that starting essentially in 1988 and into

298:6 1992.

298:7 Q. And at the time in 1998 when

298:8 you were first involved with glyphosate, had

298:9 glyphosate been approved in the United

298:10 States?

298:11 A. Yes, it had been.

298:12 Q. What were your main

298:13 responsibilities on glyphosate while you were

298:14 in the product toxicology group?

298:15 A. My main responsibilities would

298:16 have been to make sure that any studies that

298:17 were necessary were performed, the studies

298:18 both on glyphosate itself as well as studies

298:19 on glyphosate-containing formulations. Also

298:20 had some responsibilities for investigating

298:21 the toxicity of some surfactants and some
298:22 other related materials that were part of the
298:23 overall portfolio for Roundup.
298:24 Q. And were any studies -- so the
298:25 studies on glyphosate that you were involved
299:1 in, where were those studies done during that
299:2 time period?
299:3 A. Most of the studies were done
299:4 right there at our Environmental Health
299:5 Laboratory. Some of them might have been
299:6 done out at a contract resource agency, but
299:7 for the most part at that lab.
299:8 Q. And I think you said you were
299:9 there until '92; is that correct?
299:10 A. Well, I was there longer. That
299:11 was the period that I worked on glyphosate.

300:5 - 301:4

Heydens, William 01-24-2017 (00:00:58)

WH2_COMBINED_06.48

300:5 Q. And what did you do in 1998?
300:6 A. In 1998, then I just had a
300:7 variety of special projects that I was
300:8 assigned to.
300:9 Q. And then during -- and then did
300:10 you become the director of the toxicology
300:11 group at some point?
300:12 A. Yes. That happened in 1999.
300:13 Q. And then what were your
300:14 responsibilities as director of the
300:15 toxicology group?
300:16 A. As director of the toxicology
300:17 group, as a combination you both have -- you
300:18 have responsibilities that go just with
300:19 management of all the people that are in the
300:20 group, and then also you have scientific
300:21 oversight responsibilities for the work that
300:22 those toxicologists are doing.
300:23 Q. And in 1999 when you became
300:24 director of the toxicology group, was there a
300:25 person handling the glyphosate products?
301:1 A. Yes, there was.
301:2 Q. Who was that?

302:9 - 303:5

301:3 A. At the time that I took that
301:4 over, that would have been Donna Farmer.

Heydens, William 01-24-2017 (00:01:15)

302:9 Q. Okay. And did you take on any
302:10 additional responsibilities at any point
302:11 while you were in that role?

302:12 A. Yes. From the -- really from
302:13 the period of 2000, excuse me, through 2005,
302:14 2006, a number of other groups were rolled up
302:15 under the function that I headed up; groups
302:16 like ecotoxicology group, environmental
302:17 sciences group. And then later in the period
302:18 of 2006 to late in 2008, I was asked in
302:19 addition to my responsibilities with the
302:20 science groups, I was also asked to be an
302:21 interim director for our chemical
302:22 regulatory -- US chemical regulatory affairs
302:23 group.

302:24 Q. And what did you do after 2008?

302:25 A. In 2008 because the --
303:1 Monsanto's chemistry portfolio was expanding,
303:2 again, quite rapidly and the needs were thus
303:3 expanding and so I was asked to go full time
303:4 as the lead for the chemical regulatory
303:5 affairs group.

303:12 - 309:7

Heydens, William 01-24-2017 (00:06:03)

303:12 Q. And what does the chemistry
303:13 regulatory affairs group do at Monsanto?

303:14 A. Chemical regulatory affairs
303:15 group is responsible basically for -- they're
303:16 kind of the go-betweens between the
303:17 scientists, all of the work that gets done in
303:18 the science, and the regulatory -- the
303:19 regulatory officials like EPA.
303:20 So they would be responsible
303:21 for making sure that whatever documents and
303:22 evaluations the agency needs or has asked
303:23 for, making sure that they get it, that it's
303:24 formatted properly and then submitted to the
303:25 appropriate individuals.

WH2_COMBINED_0647

WH2_COMBINED_0648

304:1 Q. Going back to 1998 when you
304:2 first joined -- well, soon after you joined
304:3 the company, did you ever become responsible
304:4 for regulatory submissions to the EPA on
304:5 glyphosate, any submissions at all, or
304:6 studies?

304:7 A. Myself directly?

304:8 Q. Yeah.

304:9 A. I did not make submissions, per
304:10 se.

304:11 Q. All right. Were you
304:12 responsible for any studies that would have
304:13 been submitted to the EPA in support of a
304:14 registration decision?

304:15 A. Yes. There were two studies.
304:16 There was a rat reproduction study, and then
304:17 there was a two-year rat study.

304:18 Q. And that two-year rat study, is
304:19 that sometimes referred to as a rat
304:20 carcinogenicity study?

304:21 A. Yes.

304:22 Q. Okay. And do you know when
304:23 that study was completed?

304:24 A. That study was completed
304:25 approximately 1990.

305:1 Q. Okay. And have you ever heard
305:2 of the phrase "bioassay"?

305:3 A. Yes.

305:4 Q. What does that word refer to?

305:5 A. That's synonymous. It's the
305:6 same as a carcinogenicity study, the way we
305:7 use it.

305:8 Q. And what role did you have in
305:9 that 1990 rat carcinogenicity study?

305:10 A. I joined the group shortly
305:11 after that study began, so I -- at that point
305:12 in time I became what was called the study
305:13 monitor for that study.

305:14 Q. And can you explain what a
305:15 study monitor does?

305:16 A. Yes.

305:17 So a study monitor is

305:18 responsible -- and this is starting at the

305:19 beginning. The study monitor is responsible

305:20 for placing the study, where it's going to

305:21 go; working with the laboratory personnel to

305:22 make sure that an appropriate protocol is put

305:23 in place; and then once the study actually

305:24 starts, just monitor as the name implies,

305:25 data that comes in over the course of the

306:1 study; and then at the end of the study,

306:2 there would be reviewing of the report that

306:3 comes out of that, making sure that it's --

306:4 you know, for clarity and things of that

306:5 nature; and then using those reports in any

306:6 safety assessments that may need to be done.

306:7 Q. Can you explain to the jury

306:8 what the purposes of a rat carcinogenicity

306:9 study are?

306:10 A. The primary purpose is to see

306:11 if the chemical has the ability to produce

306:12 tumors in the laboratory animals.

306:13 A. secondary purpose is just to

306:14 explore any potential toxicity that you might

306:15 observe after the animals have been exposed

306:16 throughout their lifetime.

306:17 Q. And what does the word

306:18 "carcinogenicity" mean in layman's terms?

306:19 A. It means the ability or the

306:20 possibility of causing cancer.

306:21 Q. And you just said that one of

306:22 the goals is to look for tumors.

306:23 How does that relate to

306:24 carcinogenicity?

306:25 A. Well, if that -- that is the

307:1 major end point of that study is to look to

307:2 see -- in a variety of tissues and organs to

307:3 see if any tumors were produced by the

307:4 chemical or not.

307:5 Q. Why are rodents used in these

307:6 studies?

307:7 A. Rodents are used because
307:8 they're a good, practical species in that
307:9 they're relatively small and they have
307:10 relatively manageable lifespans. So for
307:11 rats, their lifespan is approximately two
307:12 years. For mice, their lifespan is
307:13 approximately 18 months.
307:14 So -- and because of their
307:15 size, so what it enables you to do in those
307:16 assays is you can have a relatively large
307:17 number of animals that you study over a
307:18 manageable period of time.

307:19 Q. Have the results from rodent
307:20 studies been found to be useful in evaluating
307:21 health effects for humans?

307:22 A. Yes, they are the standard
307:23 model, and it's the standard studies that all
307:24 regulatory agencies globally ask for to
307:25 register lots of chemicals, but specifically
308:1 here pesticides and herbicides as well.

308:2 Q. In evaluating whether there's
308:3 tumors present, is there any evaluation of
308:4 the tissues of the animal?

308:5 A. Yes.

308:6 Q. And is there a specialty in
308:7 science that is related to tissue evaluation?

308:8 A. That would be pathology. So
308:9 those determinations are made by board
308:10 certified pathologists.

308:11 Q. And what is a pathologist
308:12 looking at?

308:13 A. A pathologist is looking at
308:14 actually -- that is the individual who looks
308:15 at all the organs and tissues that come from
308:16 all of those studies. And they will look at
308:17 them both grossly, so that would be visually
308:18 looking at the organs, and then also in a
308:19 histopathological examination, which is where
308:20 tissues are taken, they're sliced up, put

308:21 onto microscopic slides and then the
308:22 pathologist then will examine them through
308:23 the microscope.

308:24 Q. How many organs or tissues does
308:25 a pathologist examine as part of an EPA
309:1 regulatory rat study?

309:2 A. In those bioassays, typically
309:3 40 to 45 different tissues and organs are
309:4 examined.

309:5 (Heydens Exhibit 3-39 marked
309:6 for identification.)

309:7 QUESTIONS BY MR. JOHNSTON:

309:8 - 317:24

Heydens, William 01-24-2017 (00:09:49)

WH2_COMBINED_0649

309:8 Q. I would like to mark as
309:9 Exhibit 39 a document titled "Chronic Study
309:10 of Glyphosate Administered in Feed to Albino
309:11 Rats" on the letterhead of the Monsanto
309:12 Agricultural Company.

EXHIBIT 716.1.1

309:13 Have you seen this document
309:14 before?

309:15 A. Yes, I have.

309:16 Q. Can you tell the jury what the
309:17 document that we've marked as 3-39 is,
309:18 please?

309:19 A. This is the final report that
309:20 was issued for the study, the rat study, that
309:21 we just talked about.

309:22 Q. The study that you were the
309:23 study monitor for that was completed in 1990?

309:24 A. That's correct.

309:25 Q. And where was this study
310:1 conducted, can you tell from this document?

310:2 A. It was conducted at the
310:3 Environmental Health Laboratory of Monsanto.

EXHIBIT 716.1.1

310:4 Q. Now, let's look at page 4 of
310:5 this document, and it goes on to page 5.

310:6 Can you describe for the jury
310:7 the kind of information that appears in the
310:8 appendices to this kind of study report?

EXHIBIT 716.1.2

310:9 A. Yes. So starting over, sort of

310:10 over halfway down on page 4 is where the
310:11 appendices are, and there's -- this is the
310:12 summaries of all the different kinds of data
310:13 that are obtained during the course of the
310:14 study. So you'll see, first of all there,
310:15 there's the survival data.

EXHIBIT 716.4.3

310:16 Q. What does that mean?

310:17 A. How well the animals survived,
310:18 did the chemical cause some of the animals to
310:19 die early or not.

310:20 Q. Okay. What else do you see
310:21 there?

EXHIBIT 716.4.4

310:22 A. There's body weight data. So
310:23 the body weights of the animals are taken
310:24 every week to see how they're growing and
310:25 what their body weights may be. And that's
311:1 actually very informative information because
311:2 sometimes it can be a very sensitive
311:3 indicator of toxicity. It doesn't tell you
311:4 what's going on, but it tells you that
311:5 there's something that is going on that you
311:6 need to know more about.

EXHIBIT 716.4.5

311:7 There's also food consumption
311:8 data you'll see there. And then the next --
311:9 then there's clinical science. What that's
311:10 about is every week you take the animals out
311:11 of the cage and you observe them. It's kind
311:12 of similar to what -- if you go to the doctor
311:13 to get a physical exam, what the doctor would
311:14 do, well, we do that to the animals as well.

EXHIBIT 716.4.6

311:15 Then you'll see a summary of
311:16 hematology, which is blood, white blood
311:17 cells, red blood cells, things of that
311:18 nature. And serum chemistry, so a series of
311:19 enzymes and a lot of different things.

EXHIBIT 716.4.7

311:20 Basically the same things if you and I went
311:21 to the doctor and the doctor was going to do
311:22 a physical on you and drew your blood to run
311:23 a series of analyses on, that's what's done
311:24 with the animals there and that's what's

EXHIBIT 716.4.8

311:25 summarized in those tables.

312:1 Q. If we look on page 5, there
312:2 other summary tables that contain data and
312:3 findings from the study?

312:4 A. Yes.

312:5 Q. Okay. And then if we look on
312:6 page 6 of the table of contents, there's
312:7 another set of tables and appendices; is that
312:8 correct?

312:9 A. That is correct.

312:10 Q. Can you tell the jury what
312:11 sorts of materials appear in Appendix 2, 3,
312:12 4, 5, et cetera?

312:13 A. So these are the appendices
312:14 what I was describing just previously, that
312:15 was the summary data. So that's -- you would
312:16 take all the information, like get means and
312:17 averages and then show all of that summary
312:18 information.

312:19 Here, these tables are showing
312:20 all the individual data. So in these
312:21 reports, the study requirements are that
312:22 every piece of data that is generated
312:23 throughout the course of the study is
312:24 recorded in this report. So when you look
312:25 here, you'll see -- and that's a lot of data
313:1 obviously, and so that's why if you look all
313:2 the way down to the end there, you'll see in
313:3 this particular study that there's 2,175
313:4 pages of overall evaluation and data.

313:5 Q. And is that data set given to
313:6 the EPA as part of the submission of this
313:7 study?

313:8 A. Yes.

313:9 Q. So the EPA has access to all of
313:10 that data, correct?

313:11 A. Every single data point.

313:12 Q. Now, if you look on page 3 of
313:13 the actual report, you see in the section on
313:14 conclusions there?

EXHIBIT 716.1

EXHIBIT 716.1

EXHIBIT 716.2

313:15 A. Yes.

313:16 Q. Can you read for the jury what
313:17 the last sentence of that conclusion
313:18 paragraph states?

313:19 A. "An oncogenic effect was not
313:20 observed in this study."

313:21 Q. And what does that mean?

313:22 A. That means that glyphosate did
313:23 not produce tumors in the animals studied.

313:24 Q. And that means it didn't cause
313:25 cancer in those animals?

314:1 A. That is correct.

314:2 Q. Do you agree with that
314:3 conclusion?

314:4 A. I agree with that conclusion.

314:5 Q. Now, if you look on page 26 of
314:6 the study, you see there's a statement of
314:7 compliance that is signed?

314:8 A. Yes.

314:9 Q. And who is the signatory on
314:10 that statement of compliance?

314:11 A. There's two signatures there:

314:12 There is the Larry Stout, who is the study
314:13 director for the study; and also Roger Folk
314:14 who is the laboratory for the EHL.

314:15 Q. And can you read what that
314:16 statement of compliance says for the jury?

314:17 A. It says, "To the best of our
314:18 knowledge, the study EHL 82122, parentheses,
314:19 ML-87-148, was conducted in general
314:20 conformance with the good laboratory
314:21 practice, parenthetically, GLP, standards of
314:22 the EPA, parentheses, USA, FIFRA, 40 CFR part
314:23 160, and MAFF, parentheses, Japan, 1984, and
314:24 the GLP principles of the OECD, parentheses,
314:25 1981."

315:1 Q. What is good laboratory
315:2 practices?

315:3 A. Good laboratory practices are a
315:4 comprehensive set of not guidelines, of

EXHIBIT 7163.1

EXHIBIT 716_26.1

EXHIBIT 716_26.2

EXHIBIT 716_26.3

CIVIL

315:5 requirements to ensure the quality and the
315:6 integrity of the data of the studies that
315:7 gets done. And it's a very comprehensive
315:8 standard, set of standards, that go into
315:9 play.

315:10 And basically what they do is
315:11 they require virtually everything that gets
315:12 done in a laboratory and in the studies in
315:13 the laboratory that it has to be done in a
315:14 specific way.

315:15 For every -- for every piece of
315:16 equipment -- so there's kind of two
315:17 components of that. There's requirements
315:18 around all the equipment that's used in the
315:19 laboratory, how it gets used, how it gets
315:20 calibrated, how often it gets calibrated, so
315:21 on and so forth. And then there's a set of
315:22 requirements around -- for everything that
315:23 you would do in a study, you have to have a
315:24 standard operating procedure established for
315:25 everything you do.

316:1 And then there's a set of
316:2 requirements for what needs to go into the
316:3 studies and what needs to go into the
316:4 protocols.

316:5 Q. Does good laboratory practice
316:6 regulations require any quality assurance
316:7 processes?

316:8 A. Yes.

316:9 So a laboratory in order to be
316:10 a GLP compliant laboratory, they have to have
316:11 a separate QA group that reports not to the
316:12 scientists, but actually reports directly
316:13 into the laboratory director and it is their
316:14 job to monitor all phases of work that gets
316:15 done in the laboratory.

316:16 Q. And are they ever asked to
316:17 inspect or conduct audits of the laboratory's
316:18 findings?

316:19 A. Yes. That is a routine

316:20 function that they perform, so they'll be
316:21 involved in all phases of the study.
316:22 Starting off even before the study is
316:23 generated, they will be involved in making
316:24 sure that the protocols are GLP compliant and
316:25 have everything in there that they need to
317:1 do.
317:2 Then during the conduct of the
317:3 study, they will actually go in at different
317:4 times and they will audit something -- an
317:5 activity and activities that are being done
317:6 in the study.
317:7 And by audit, what that means
317:8 is they actually walk in the room and they
317:9 actually observe to see that what was
317:10 supposed to be done was actually being done.
317:11 Then -- and so there will be a
317:12 series of those inspections throughout the
317:13 study.
317:14 Q. Is there a certifying agency
317:15 for GLP compliant laboratories?
317:16 A. Well, those are administered
317:17 through -- here in the United States through
317:18 the Environmental Protection Agency.
317:19 Q. Does the EPA have any ability
317:20 to verify that the lab is compliant with GLP?
317:21 A. Yes. EPA periodically actually
317:22 comes in and does site visits at the
317:23 laboratories that are conducting those kinds
317:24 of studies.

318:3 - 319:25

Heydens, William 01-24-2017 (00:01:51)

318:3 Q. I'm going to hand you what's
318:4 been marked as Exhibit 3-40 is a document on
318:5 the letterhead of the United States
318:6 Environmental Protection Agency; is that
318:7 correct?
318:8 A. That is correct.
318:9 Q. And it's dated July 22, 1996?
318:10 A. Correct.
318:11 Q. Can you tell -- have you seen

WH2_COMBINED_06.50

EXHIBIT 711.5.1

EXHIBIT 711.5.2

318:12 this document before?

318:13 A. Yes, I have.

318:14 Q. Can you tell the jury what this
318:15 document is?

318:16 A. This is a document that was
318:17 sent back to the laboratory, the
318:18 Environmental Health Laboratory, after EPA
318:19 had come in and actually done an inspection
318:20 of the laboratory.

318:21 Q. And the cover letter states,
318:22 "This letter is formal notification of the
318:23 results of the September 14th and 17th, 1993
318:24 inspection conducted by representatives of
318:25 the Environmental Protection Agency pursuant
319:1 to Sections 8 and 9 of the Federal
319:2 Insecticide, Fungicide and Rodenticide Act,
319:3 FIFRA."

319:4 Did I read that correctly?

319:5 A. Correct.

319:6 Q. And if you turn to the next
319:7 page, this is a two-sided copy, but you see
319:8 that the third page of this exhibit is a
319:9 cover page?

319:10 A. Yes.

319:11 Q. It says, "FIFRA GLP inspection
319:12 report"?

319:13 A. Yes.

319:14 Q. Have you seen documents like
319:15 this before?

319:16 A. Yes.

319:17 Q. What does this document
319:18 contain?

319:19 A. This is the actual report from
319:20 EPA that documents the fact that they did an
319:21 inspection and what their conclusions are
319:22 from the inspection.

319:23 Q. If you turn to the summary,
319:24 which appears I think on the fifth page of
319:25 this double-sided copy document, so it's on

320:1 the left-hand side, you see -- can you read
320:2 for the jury what this paragraph says? "A
320:3 FIFRA."

320:4 A. "A FIFRA GLP inspection was
320:5 conducted at the Environmental Health
320:6 Laboratory of the Monsanto Agricultural
320:7 Company in St. Louis, Missouri, on
320:8 September 14 through 17, 1993. A GLP
320:9 standards compliance review was requested by
320:10 LDIAD and was done. Three studies that were
320:11 conducted by this laboratory and submitted to
320:12 EPA were audited. The GLP inspection found
320:13 that the procedures followed by the Monsanto
320:14 EHL at the time of the inspection were in
320:15 accord with the FIFRA GLP regulations. The
320:16 data audits that were done found no
320:17 discrepancies between the raw data and the
320:18 reports submitted to EPA."

320:19 Q. Do you know whether one of the
320:20 three studies that was audited was the 1990
320:21 rat study that you were the study monitor on?

320:22 A. Yes, that was one of the
320:23 studies that EPA reviewed.

320:24 Q. And found compliant with GLP?

320:25 A. That is correct.

321:3 - 321:15

Heydens, William 01-24-2017 (00:00:24)

WH2_COMBINED_0652

321:3 QUESTIONS BY MR. JOHNSTON:

321:4 Q. Do you know whether or not the
321:5 1990 rat study that you were the study
321:6 monitor on was found to be compliant with GLP
321:7 when it was audited by the EPA?

321:8 A. Yes.

321:9 Q. So what did they find?
321:10 What did EPA find when they
321:11 audited the 1990 rat study?

321:12 A. No significant findings. They
321:13 found that the results were what they were.

321:14 Q. And were they consistent with
321:15 GLP?

321:18 - 321:23

Heydens, William 01-24-2017 (00:00:08)

WH2_COMBINED_0653

321:18 THE WITNESS: It states in

321:19 there that it's compliant with GLP.

321:20 QUESTIONS BY MR. JOHNSTON:

321:21 Q. Were they or were they not

321:22 compliant with GLP?

321:23 A. They were compliant with GLP.

321:24 - 322:9

Heydens, William 01-24-2017 (00:00:18)

WH2_COMBINED_0654

321:24 Q. You mentioned previously that

321:25 glyphosate was re-registered in 1993,

322:1 correct?

322:2 A. Correct.

322:3 Q. I would like to discuss the

322:4 toxicological data that EPA considered at

322:5 that time, so let me show you what we will

322:6 mark as 3-41.

322:7 (Heydens Exhibit 3-41 marked

322:8 for identification.)

322:9 QUESTIONS BY MR. JOHNSTON:

322:10 - 323:7

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WH2_COMBINED_0655

322:10 Q. And you might want to write

322:11 3-41 on that because it's possible that I may

322:12 come back to that in later questions, so I

322:13 want you to be able to find it.

322:14 A. 3-41?

322:15 Q. 3-41, yes.

322:16 A. Oh, sorry.

322:17 Q. Have you seen this document

322:18 before?

322:19 A. Yes, I have.

322:20 Q. Can you tell the jury what this

322:21 document is?

322:22 A. This is EPA's re-registration

322:23 eligibility decision document, otherwise

322:24 known as the RED. It is the document that

322:25 EPA documents the conclusions of the agency

323:1 after they have gone through the

323:2 re-registration process.

323:3 Q. And as part of the

323:4 re-registration eligibility decision for

323:5 glyphosate, did EPA conduct a human health

EXHIBIT 712.5.1

323:6 risk assessment?
323:7 A. Yes, they did.

323:8 - 325:22 **Heydens, William 01-24-2017 (00:02:25)** WH2_COMBINED_06.58

323:8 Q. Let's turn to the table of
323:9 contents in this document. It's on page 2-1
323:10 of the actual report in this document. EXHIBIT 712.14.1
323:11 There's a heading called "Science
323:12 Assessment," correct? EXHIBIT 712.14.2
323:13 A. That is correct.
323:14 Q. Can you -- and then there's a
323:15 subheading B.
323:16 Can you read what that
323:17 subheading is for the record, please?
323:18 A. B is human health assessment.
323:19 Q. Was a human health risk
323:20 assessment conducted for glyphosate as part
323:21 of the RED decision-making process?
323:22 A. Yes, it was.
323:23 Q. What sorts of items are
323:24 evaluated as part of RED human health
323:25 assessment that are listed here on this table
324:1 of contents?
324:2 A. It's a very detailed assessment
324:3 that includes all of the toxicology studies
324:4 that were done, the acute, subchronics,
324:5 chronics, carcinogenicity, developmental,
324:6 reproductive, metabolism, mutagenicity --
324:7 Q. And this goes on to page 3, EXHIBIT 712.15.1
324:8 right?
324:9 A. It goes on to page 3.
324:10 Mutagenicity, metabolism, neurotoxicity,
324:11 other toxicological end points, and then they
324:12 determine a reference dose. That's the
324:13 hazard assessment.
324:14 Then there is an exposure EXHIBIT 712.15.2
324:15 assessment that is done as well in Section 2
324:16 there for both dietary and occupational and
324:17 residential exposures. And then the data
324:18 from Section 1 and Section 2 then flows into
324:19 a comprehensive risk assessment that is done EXHIBIT 712.15.4

324:20 in Section 3. And then in this -- everything
 324:21 that we've talked about here has been for the
 324:22 mammalian and human risk assessment.
 324:23 There's also an environmental
 324:24 assessment that gets done in Section C where
 324:25 there's exposure assessment that gets done,
 325:1 and then also a possible ecological effects
 325:2 on organisms in the environment.
 325:3 Q. And did Monsanto conduct any
 325:4 studies that were relied on by the EPA in
 325:5 this evaluation in the 1993 RED?
 325:6 A. Certainly some of the studies
 325:7 Monsanto conducted, yes, were included in
 325:8 here. One of them we just talked about.
 325:9 Q. Did that include the rat
 325:10 carcinogenicity studies that Monsanto had
 325:11 previously conducted?
 325:12 A. It included that study, yes.
 325:13 Q. Did it include other rat
 325:14 carcinogenicity -- other rodent
 325:15 carcinogenicity studies?
 325:16 A. It included other
 325:17 carcinogenicity studies not conducted at
 325:18 Monsanto but conducted by Monsanto.
 325:19 Q. Let's look at the EPA's
 325:20 evaluation of the rodent carcinogenicity data
 325:21 on page 14 of the actual report. Page 15,
 325:22 sorry.

325:23 - 327:25

Heydens, William 01-24-2017 (00:02:26)

325:23 Can you read for the jury the
 325:24 paragraph that appears right above
 325:25 "developmental toxicity"?
 326:1 A. Yes.
 326:2 "On June 26, 1991, the agency
 326:3 classified glyphosate in Group E,
 326:4 parentheses, evidence of non-carcinogenicity
 326:5 for humans, based on a lack of convincing
 326:6 evidence of carcinogenicity in adequate
 326:7 studies with two animal species, rat and
 326:8 mouse."

EXHIBIT 712.15.5

CWM

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EXHIBIT 713.36.1

326:9 Q. So were there mouse studies
326:10 submitted by Monsanto?
326:11 A. Yes, there were.
326:12 Q. How many?
326:13 A. There was one mouse study.
326:14 Q. And how many rat studies did --
326:15 we've talked about one.
326:16 Were there any others besides
326:17 the one that you were involved in?
326:18 A. There was another study, so a
326:19 total of two.
326:20 Q. Do you agree with EPA's
326:21 classification of glyphosate?
326:22 A. Yes, I do.
326:23 Q. Now, let's turn to page 57.
326:24 You see a heading called "Eligibility
326:25 Determination Decision" -- sorry, let me say
327:1 it again.
327:2 Do you see a heading stating
327:3 "Eligibility Decision"?
327:4 A. Yes.
327:5 Q. Can you read for the jury the
327:6 two -- the first two paragraphs under the
327:7 Eligibility Decision heading?
327:8 A. "Based on the reviews of the
327:9 generic data for the active ingredient
327:10 glyphosate, the agency has sufficient
327:11 information on the health effects of
327:12 glyphosate and on its potential for causing
327:13 adverse effects in fish and wildlife and the
327:14 environment. The agency concludes that
327:15 products containing glyphosate for all uses
327:16 are eligible for re-registration. The agency
327:17 has determined that glyphosate products,
327:18 labeled and used as specified in this
327:19 re-registration eligibility document, will
327:20 not pose unreasonable risks or adverse
327:21 effects to humans or the environment."
327:22 Q. Do you agree with that
327:23 conclusion in the RED document from 2003?

EXHIBIT 710.76.1

EXHIBIT 710.76.2

EXHIBIT 710.86.1

328:4 - 329:22

327:24 A. Yes, I do.

327:25 Q. I'm sorry, from 1993?

Heydens, William 01-24-2017 (00:01:42)

328:4 THE WITNESS: Yes, I do.

328:5 QUESTIONS BY MR. JOHNSTON:

328:6 Q. Now, since the re-registration
328:7 decision was issued by EPA in 1993, has
328:8 glyphosate continued to be a patented product
328:9 for Monsanto?

328:10 A. Yes, it was a patented product
328:11 for a number of years.

328:12 Q. Is it still a patented product?

328:13 A. No, it is not.

328:14 Q. When did the patent expire?

328:15 A. There is a series of patents
328:16 that started expiring in the 2000 to 2002
328:17 time frame.

328:18 Q. As a result of the patents
328:19 expiring, is there any consequence to who can
328:20 sell glyphosate?

328:21 A. Once the patents expire, then
328:22 other companies are free to develop and
328:23 market their own glyphosate formulations.

328:24 Q. Did other companies manufacture
328:25 glyphosate formulations?

329:1 A. Yes, they did. There were
329:2 several.

329:3 Q. And did these companies have to
329:4 get regulatory approval for their products?

329:5 A. Yes. All of them would need to
329:6 get their own approval with EPA.

329:7 Q. Would they have to submit their
329:8 own data to EPA?

329:9 A. They would have to do one of
329:10 two things: They would have to either
329:11 purchase the data from an existing registrant
329:12 such as Monsanto, or they would have to
329:13 develop the data themselves and submit it to
329:14 the agency.

329:15 Q. Has the EPA evaluated the

WH2_COMBINED_0658

CWF

329:16 carcinogenic potential of glyphosate since
329:17 the 1993 registration eligibility decision?

329:18 A. Yes, they have.

329:19 Q. Do you know when the first time
329:20 they did that since then was?

329:21 A. Well, they've actually done it
329:22 a number of times.

365:12 - 368:18

Heydens, William 01-24-2017 (00:03:36)

WH2_COMBINED_08 54

365:12 Q. Hand you what's been marked as
365:13 Exhibit 3-45.

365:14 Can you tell the jury what this
365:15 document is?

EXHIBIT 147.1.1

365:16 A. Yes. This is the results of
365:17 work that we conducted on formulated product
365:18 and this was published in the peer-reviewed
365:19 literature.

EXHIBIT 147.1.2

365:20 Q. It was published in the Journal
365:21 of Agricultural and Food Chemistry, correct?

365:22 A. That is correct.

365:23 Q. And it was published in 2008,
365:24 correct?

365:25 A. Yes, it was.

366:1 Q. And can you tell the jury the
366:2 title of this paper?

366:3 A. The title is, "Genotoxic
366:4 Potential of Glyphosate Formulations:
366:5 Mode-of-Action Investigations."

366:6 Q. And you were the first author
366:7 on this paper, correct?

366:8 A. Yes, that is correct.

366:9 Q. Why did Monsanto undertake to
366:10 write this paper?

366:11 A. We undertook this investigation
366:12 because there were some reports in the open
366:13 literature which suggested that glyphosate
366:14 formulations were genotoxic. And it was our
366:15 hypothesis that those studies had problems
366:16 with them, which led to improper conclusions,
366:17 and so we wanted to test to see if that was
366:18 true or not.

END

366:19 Q. Can you generally describe the
366:20 methods that you employed in doing this
366:21 study?

366:22 A. Yes. Basically what we did was
366:23 we selected two of the main studies that were
366:24 done in the open literature and then we
366:25 basically did the same study design as they
367:1 did. So we replicated the study design and
367:2 then went on to investigate in more detail
367:3 what the relevance of the findings were.

367:4 Q. And what were the results of
367:5 your experiments?

367:6 A. So the results of our
367:7 experiments were basically that we -- for the
367:8 most part, we could replicate what they had
367:9 done. There was one important difference.
367:10 There was one major finding that they
367:11 reported that we could not reproduce, but
367:12 basically we saw the same things that they
367:13 saw.

367:14 But what we did see moreover,
367:15 or more importantly, that the facts that they
367:16 were reporting were only seen under
367:17 conditions of extreme exposure and extreme
367:18 toxicity to the cells to the point where in
367:19 some cases they were actually killing cells.
367:20 And when you got to that level, then you saw
367:21 some of the responses that they were
367:22 referring to as genotoxicity, but really are
367:23 not direct genotoxicity but really are the
367:24 result of the fact that you're just killing
367:25 the cells.

368:1 The other thing that we found
368:2 was we added a component to the study -- in
368:3 the studies that they did, these were studies
368:4 where the test material was injected directly
368:5 into the abdomen of the animals, and in
368:6 some -- in one case, the study added a bunch
368:7 of additional material to those test material
368:8 that they injected. We added another

368:9 component where we exposed the animals to
 368:10 that same test material with the additional
 368:11 materials via the oral route of exposure,
 368:12 which would be relevant for humans. And when
 368:13 you do that, you don't see any of the effects
 368:14 that they reported.

368:15 Q. And what conclusions can you
 368:16 draw based on those results, those findings?

368:17 A. Our conclusion is that those
 368:18 formulations do not produce genotoxicity.

397:4 - 398:13

Heydens, William 01-24-2017 (00:01:27)

397:4 Q. I hand you what's been marked
 397:5 as Exhibit 3-50.

397:6 Have you seen this document
 397:7 before?

397:8 A. Yes, I have.

397:9 Q. This is an article drafted by
 397:10 Gary William, Robert Kroes and Ian Munro?

397:11 A. Correct. That's correct.

397:12 Q. And this is titled "Safety
 397:13 Evaluation and Risk Assessment of the
 397:14 Herbicide Roundup and Its Active Ingredient,
 397:15 Glyphosate, for Humans," correct?

397:16 A. That is correct.

397:17 Q. What is this document to your
 397:18 knowledge?

397:19 A. So this document summarizes the
 397:20 evaluations that were done by these three
 397:21 authors on various aspects of the toxicology
 397:22 of glyphosate and Roundup.

397:23 Q. Yesterday plaintiffs marked
 397:24 Exhibit 3-29 as the Gary Williams, Robert
 397:25 Kroes and Ian Munro paper, correct?

398:1 A. Yes.

398:2 Q. That document was only three
 398:3 pages long, correct?

398:4 A. Correct.

398:5 Q. 3-50, how long is the document
 398:6 that we marked as number 3-50?

398:7 A. This document -- well, it takes

EXHIBIT 147.5.3

WH2_COMBINED_06.00

CWF

EXHIBIT 416.5.1

EXHIBIT 416.5.2

CWF

398:8 up pages 117 through 165, so approximately 50
398:9 pages.

398:10 Q. And will you agree with me that
398:11 all of those pages are contained in the
398:12 document that I've marked as Exhibit 3-50?
398:13 A. Let me look. Yes.

398:14 - 402:7

Heydens, William 01-24-2017 (00:03:45)

WH2_COMBINED_06.01

398:14 Q. Why did this paper get written?
398:15 What caused this paper to be
398:16 written?
398:17 A. I think we talked a little bit
398:18 about this yesterday, but so this -- prior to
398:19 this project, there was really no -- not a
398:20 lot of toxicology information in the open
398:21 literature. Basically it's pretty
398:22 uninteresting reading because the molecule is
398:23 not toxic and journals aren't real enthused
398:24 by getting data that doesn't really say --
398:25 doesn't show any problems.
399:1 But around -- in the late '90s,
399:2 this is a point in time when some of the
399:3 studies that we discussed yesterday, and
399:4 actually discussed today, some of the studies
399:5 with some problems, as it turns out, started
399:6 to show up in the literature, primarily in
399:7 the area of genotoxicity.
399:8 So it was just thought at this
399:9 point in time that it would be a good time to
399:10 do a thorough review of all the information
399:11 that was available on glyphosate at that
399:12 point in time and just get that summarized in
399:13 the open peer-reviewed literature, and that's
399:14 what this project was about.
399:15 Q. I want to ask you about the
399:16 authors.
399:17 Who is Gary Williams?
399:18 A. Gary Williams is an
399:19 internationally known expert on genotoxicity
399:20 and carcinogenicity.
399:21 Q. And where is he employed; do

399:22 you know?

399:23 A. He's employed at the New York

399:24 Medical College. To my understanding, he is

399:25 still there.

400:1 Q. How long has he been there; do

400:2 you know?

400:3 A. I don't know how long he's been

400:4 there exactly, but I believe it's in the

400:5 range of 20 to 30 years.

400:6 Q. Can you tell me who Robert

400:7 Kroes is?

400:8 A. Robert Kroes was a well-known

400:9 general toxicologist from the Netherlands,

400:10 again, with an international reputation.

400:11 Q. And do you know where Dr. Kroes

400:12 is employed?

400:13 A. Unfortunately, Dr. Kroes passed

400:14 away a number of years ago.

400:15 Q. Do you know where he was at the

400:16 time he participated in this paper?

400:17 A. He was at the University of

400:18 Utrecht.

400:19 Q. Okay. And who is Ian Munro?

400:20 A. Ian Munro is another scientist

400:21 with an international reputation who had also

400:22 been a regulatory toxicologist working for

400:23 the Canadian government for a number of

400:24 years. And at the time that this paper was

400:25 produced, he -- actually at that point in

401:1 time he had left and started Cantox, and he

401:2 was working at Cantox at the time of this

401:3 paper.

401:4 Q. What did he -- you said he

401:5 left.

401:6 What had he left?

401:7 A. The Canadian government.

401:8 Q. Okay. Thank you.

401:9 And is he still employed by

401:10 Cantox?

401:11 A. No. Unfortunately, Dr. Munro

401:12 passed away a few years ago as well.

401:13 Q. Do you know what data these

401:14 three experts -- expert authors reviewed in

401:15 preparing this paper?

401:16 A. They had access to all the

401:17 information that was available. All the

401:18 studies that Monsanto had. At the time those

401:19 were the only studies that existed as well as

401:20 studies that were out there in the

401:21 peer-reviewed literature of which at that

401:22 time there was not as much as there is now.

401:23 Q. I want to call your attention

401:24 to the last sentence of the abstract and ask

401:25 you to read that for the jury.

402:1 A. "It was concluded that, under

402:2 present and expected conditions of use,

402:3 Roundup herbicide does not pose a health risk

402:4 to humans."

402:5 Q. Now, I want to look back at the

402:6 acknowledgements for this paper on page 160

402:7 of the journal.

402:8 - 404:15

Heydens, William 01-24-2017 (00:02:41)

402:8 I want you to start with the

402:9 authors in the acknowledgement, and can you

402:10 read that for the jury, please?

402:11 A. "The authors were given

402:12 complete access to toxicological information

402:13 contained in the great number of laboratory

402:14 studies and archival material at Monsanto in

402:15 St. Louis, Missouri, and elsewhere. Key

402:16 personnel at Monsanto who provided scientific

402:17 support were William F. Heydens, Donna R.

402:18 Farmer, Marian S. Bleeke, Steven J. Wratten,

402:19 and Catherine H. Carr."

402:20 Q. Okay. You can stop there.

402:21 Your name is in that list of

402:22 folks, correct?

402:23 A. That is correct.

402:24 Q. And so this paper disclosed in

402:25 the acknowledgements that you were involved

EXHIBIT 416.1.3

EXHIBIT 416.44.1

WH2_COMBINED_06.02

EXHIBIT 416.44.2

403:1 in the preparation of the paper, didn't it?
403:2 A. That is correct.
403:3 Q. What was your role with respect
403:4 to this paper?
403:5 A. My role was I played a role
403:6 primarily -- in the middle of the process.
403:7 The way the process worked was that, you
403:8 know, the expert panel, obviously they
403:9 started with evaluation of all the data as
403:10 they say here in the paper. Then they made
403:11 their conclusions from there -- based on
403:12 their evaluations. Then all of that was
403:13 written up in a draft manuscript. That draft
403:14 manuscript was written by the next person
403:15 that's acknowledged there, Douglas W. Bryant.
403:16 Then at that point --
403:17 Q. Who did he work for?
403:18 A. I'm sorry, he worked for
403:19 Cantox.
403:20 Q. Okay. What -- continue with
403:21 your discussion of your role on the paper.
403:22 A. Yes.
403:23 So Douglas wrote the draft of
403:24 the evaluation, like I say, took what the
403:25 experts gave him, and he put that together in
404:1 a draft. And then I received that draft, and
404:2 that's the point in time where I made my
404:3 contributions. So I provided some editing
404:4 and rewriting. It was things like editing
404:5 relatively minor things, editing for
404:6 formatting, just for clarity, really just for
404:7 overall readability to make it easier for
404:8 people to read in a more organized fashion.
404:9 I then provided that back to
404:10 Douglas, and then it was up to Douglas and
404:11 Ian and the other authors to complete that
404:12 manuscript.
404:13 Q. Did your edits change any of
404:14 the authors' conclusions that they had
404:15 reached prior to you receiving that draft?

Page/Line

Source

ID

404:18 - 404:22

Heydens, William 01-24-2017 (00:00:05)

WH2_COMBINED_0603

404:18 THE WITNESS: No, they did not.

404:19 QUESTIONS BY MR. JOHNSTON:

404:20 Q. Did your edits change any of

404:21 the authors' evaluations that are set forth

404:22 in this paper?



404:25 - 405:1

Heydens, William 01-24-2017 (00:00:02)

WH2_COMBINED_0604

404:25 THE WITNESS: No, they do

405:1 not -- did not.



Total Time = 01:07:46**Documents Shown**

_1_HEYDENS 3

EXHIBIT 147

EXHIBIT 312

EXHIBIT 315

EXHIBIT 316

EXHIBIT 317

EXHIBIT 416

EXHIBIT 710

EXHIBIT 710_

EXHIBIT 711

EXHIBIT 712

HEYDENS 3