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ELECTRONICALLY
FILED
Superior Court of California,
County of San Francisco
08/06/2018
Clerk of the Court
BY:VANESSA WU
Deputy Clerk

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

v.

MONSANTO COMPANY

Defendants.

Case No. CGC-16-550128

DECLARATION OF PEDRAM ESFANDIARY IN SUPPORT OF PLAINTIFF'S OPPOSOTION TO MONSANTO COMPANY'S MOTION FOR DIRECTED VERDICT

Hon. Suzanne R. Bolanos

Department: 504
Hearing Date: August 6, 2018
Hearing Time: 10:00 a.m.
Trial Date: June 18, 2018

DECLARATION OF PEDRAM ESFANDIARY

I, Pedram Esfandiary, declare and state:

I am an attorney at law admitted to practice before all of the courts in the state of California. I am an attorney at Baum, Hedlund, Aristei & Goldman, P.C. attorneys of record for Plaintiff Dewayne Johnson. I am over eighteen years of age and am fully competent to make this Declaration in support of Plaintiff's Opposition to Monsanto Company's Motion for Directed Verdict. Except as otherwise expressly stated below, I have personal knowledge of the facts stated in this declaration, and if called to testify, I could and would competently testify to the matters stated herein.

1. Attached hereto as **Exhibit 1** is a true and correct copy of excerpts of the trial transcript from July 9, 2018.

2. Attached hereto as **Exhibit 2** is a true and correct copy of excerpts of the trial transcript from July 12, 2018.

3. Attached hereto as **Exhibit 3** is a true and correct copy of excerpts of the trial transcript from July 13, 2018.

4. Attached hereto as **Exhibit 4** is a true and correct copy of excerpts of the trial transcript from July 17, 2018.

5. Attached hereto as **Exhibit 5** is a true and correct copy of excerpts of the trial transcript from July 18, 2018.

6. Attached hereto as **Exhibit 6** is a true and correct copy of excerpts of the trial transcript from July 20, 2018.

7. Attached hereto as **Exhibit 7** is a true and correct copy of excerpts of the trial transcript from July 23, 2018.

8. Attached hereto as **Exhibit 8** is a true and correct copy of excerpts of the trial transcript from July 26, 2018.

9. Attached hereto as **Exhibit 9** is a true and correct copy of excerpts of the trial transcript from July 27, 2018

10. Attached hereto as **Exhibit 10** is a true and correct copy of excerpts of the trial transcript from July 30, 2018

11. Attached hereto as **Exhibit 11** is a true and correct copy of excerpts of the trial transcript from July 31, 2018

12. Attached hereto as **Exhibit 12** is a true and correct copy of excerpts from the deposition designations of Daniel Goldstein.

13. Attached hereto as **Exhibit 13** is a true and correct copy of excerpts from the deposition designations of Mark Martens, played in tria11 on July 10, 2018.

14. Attached hereto as **Exhibit 14** is a true and correct copy of excerpts from the deposition designations of Kirk Azevedo, played in trial on July 27, 2018.

15. Attached hereto as **Exhibit 15** is a true and correct copy of excerpts from the deposition designations of Donna Farmer.

16. Attached hereto as **Exhibit 16** is a true and correct copy of excerpts from the deposition designations of William Heydens.

17. Attached hereto as **Exhibit 17** is a true and correct copy of excerpts from the deposition designations of Daniel Jenkins.

18. Attached hereto as **Appendix A** is a true and correct copy of the Plaintiff's supplemental brief in support of punitive damages.

19. Attached hereto as **Appendix B** are true and correct copy of the Exhibits cited in Plaintiffs Brief.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed August 6, 2018, In San Francisco, California.

By: _____
Pedram Esfandiary,
Declarant

EXHIBIT 1

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Monday, July 9, 2018, Volume 5, before the Honorable Suzanne R. Bolanos, at 9:09 a.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2958698

Pages 1276 - 1533

to contradict in any way those visions that Robert Shapiro set forth?

A. Yeah, there are a couple experiences that I had that really, kind of, changed my mind on these things for safety. One of which was -- well, the first one was doing local market manager training in St. Louis, Missouri. And at some point during that time, we had a meet-and-greet with the vice presidents of the company and different managers and so forth. And in sharing, you know, some of this information with one of the vice presidents, I remember, you know, talking about the vision of Robert Shapiro. Like, talking about reducing of processed waste and the factories of the future not being these pollution factories but, you know, being these plants. They're going to be green. And we could, you know, help save the world in this regard. And speaking of this vision, kind of quoting from the prospectus, where Robert Shapiro is speaking on, you know, the vice president pulled me aside and says, 'Hey, we don't know what Robert Shapiro is really talking about here. He's just kind of this visionary guy. And this sort of thing isn't what we're really about. We're about making money. So get it straight.'"

(End of video.)

MR. WISNER: I asked a lot of questions about

Applicators and other handlers must wear long-sleeved shirt, long pants, shoes and socks, and if they get wet, you should discard that clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them. And it says if you do get wet, you should wash your hands before eating, drinking, chewing gum, et cetera, and you should remove the clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

16:18:38 And so it's not that there's no warning on the label. It's that there's an appropriate warning on the label. It's the label that the science justifies.

So let's turn now to Mr. Johnson and let's turn now to that part of the case because Mr. Johnson, the 16:18:57 evidence is going to be, actually went well beyond what the label requires. He wore that Tyvek suit. That's the kind of suit that people who deal with hazardous materials wear. He had chemically resistant gloves, rubber gloves. He had chemically resistant boots. He 16:19:17 wore a sweatshirt with a hoodie that he pulled tight. So Mr. Johnson did a great job of minimizing his exposure to Ranger Pro. Mr. Johnson -- this is one of the ways that Mr. Johnson sprayed, was with a backpack sprayer. I'm not sure if this is literally the one he used or one that 16:19:41 he said is a closely resembling one. I think it's the

EXHIBIT 2

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Thursday, July 12, 2018, Volume 8, Afternoon Session, before the Honorable Suzanne R. Bolanos, at 1:20 p.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2958711B

Pages 1776 - 1945

with such an analysis?

A. Oh, there are plenty. First of all, if -- if -- exposure matters. If the bigger exposure gives you higher risk, then if you could break it down into those different exposure groups, you might be able to see that.

15:47:32

So that's -- that's an advantage of the other measures. The disadvantage of the other measures, which becomes an advantage of the ever-never, is people usually get it ever never. They -- people do remember whether they were exposed to this or not exposed to this. But sometimes getting a quantitative measure for that is a little more difficult, and that can be a problem in some of the studies.

15:47:53

What else do you want to know about it?

Q. No, that's exactly what I wanted to get at.

15:48:06

Now, did Dr. McDuffie in 2001 do a sort of an intensity or duration analysis?

A. I have to look at my notes for a second. Yes, he did.

Q. Okay. If you turn to Exhibit 818. It's in the second binder. Is that a fair and accurate copy of the study?

15:48:20

A. Yeah, that is the McDuffie study.

MR. WISNER: Permission to publish, your Honor. I believe we've agreed we've published these literature

15:48:47

but not enter them into evidence.

THE COURT: Any objection?

MR. GRIFFIS: No, we haven't.

THE COURT: All right. So you may publish Plaintiff's 818.

Q. BY MR. WISNER: All right. So this is the McDuffie paper, and we can see up here in the title non-Hodgkin's lymphoma and specific pesticide exposure in men across Canada, study of pesticides and health.

Do you see that?

A. Yes.

Q. And we have here it's done by Dr. Helen McDuffie. Do you see that?

A. Correct.

Q. Now, in the table, this is where you got -- oh, sorry.

If we look at table 2, this is where you have the 1.2 number; is that right?

A. I'm looking for it. Give me a minute. Yes, I see it.

Q. Do you see Roundup, glyphosate, and then you have this 1.26 and this 1.2. Do you see that?

A. Yes, I see it.

Q. And you used the most adjusted one which got you that number on the chart, which is 1.2; right?

A. That is correct.

Q. So if you also look at the next table, and this is table 3, and it talks about -- oh, this is insecticides. Let's go to pesticides.

15:50:21 A. Table 4.

Q. Table 4. Oh, thank you. All right, table 4 is fungicides, frequency of exposure to fungicides classified in the major chemical classes as individual compounds.

15:50:33 Oh, wait, Doctor, this is fungicides.

A. Yeah, but they did a separate analysis with glyphosate is a different table, I think.

Q. Yeah, let's find the table. Here we go. Herbicides. All right. Table 8.

15:50:50 Frequency of exposure to selected herbicides. Do you see that, Doctor?

A. Yes.

Q. Okay, great. And if we look in here, do you see this reference to glyphosate?

15:50:56 A. Yes, I do.

Q. Okay, great. All right. So walk us through what these different numbers reflect.

A. So the first is the group of unexposed people. I can't see the top of the table.

Q. Sorry.

A. That's okay. You can keep it there. I'll go look at...

Q. You can see it now.

A. The N is the number of cases that were unexposed. The second line, the next point is percentage of -- total percentage of cases that were exposed -- unexposed. Next line is the controls, the number of exposed, the percentage. And then the final line is the ratio we were talking about. Here it's one because it's comparing itself to itself. It's classically always listed as one.

The next line is compared against that unexposed line, and these are for people who typically use glyphosate more than zero times a year but less than or equal to two times per year. So one or two times a year they will use glyphosate. That's the answer to the survey question with those groups.

And you can see the numbers, 28, 5.4 percent, 97, 6.4 percent. The ratio there is about one. There's just no change based upon that exposure pattern.

The next group is greater than twice per year, and when that's compared to the unexposed, you get a ratio of 2.12 with a confidence bound from 1.2 to 3.73.

Q. So what we have here, then, is a more than doubling of the risk for people who have been exposed for

more than two days a year, and that result is statistically significant?

A. Correct.

MR. GRIFFIS: Objection. Leading.

15:52:43 THE COURT: Sustained.

MR. WISNER: Your Honor, this is an expert.

THE COURT: I sustained the objection. You may rephrase.

Q. BY MR. WISNER: Okay. What do we see here, Doctor?

A. You see that after -- or people who have non-Hodgkin's lymphoma and are exposed for more than two days per year, they are two -- more than two times as likely as the unexposed -- as the controls to be exposed

15:53:11 to glyphosate.

Q. Now you've heard of something called a dose response relationship. Have you heard that before?

A. Correct.

Q. And in the epidemiological context, the fact

15:53:24 that the more that people are being dosed here to glyphosate, is this similar to a sort of dose response?

A. Yes. In epidemiology, they call it exposure response.

Q. And although the never-ever results don't show a

15:53:39 statistically significant risk, the more than two days a

region of Canada found an increased risk of NHL associated with glyphosate use that increased by the number of days used per year."

That's what we were just talking about with the McDuffie study; correct?

15:58:18

A. That is correct. Referenced the McDuffie study.

Q. "These few subjective findings provide some impetus for further investigation into the potential health effects of glyphosate even though one review concluded that the active ingredient is non-carcinogenic and non-genotoxic."

15:58:35

Do you see that, Doctor?

A. I see that's what it says, yes.

Q. All right. So in this point in the science, we have a couple of positive and suggestive findings linking NHL to glyphosate or Roundup exposure.

15:58:47

Is that fair?

A. Yes, that's fair.

Q. And Dr. De Roos is saying these provide further impetus for investigation even though one review concluded it was non-carcinogenic and non-genotoxic.

15:58:59

Do you see that?

A. Correct, yes.

Q. And that's -- what's the citation? Is that citation 50?

15:59:16

A. Correct.

Q. All right. I'll pop it up on the screen.

If we look here, the citation for number 50 is a study called Williams Kroes Munro.

15:59:28 Do you see that?

A. Yes, I do.

Q. Published 2000. Is this a study that you reviewed?

A. I've read the study. I've reviewed it, yes.

15:59:38 Q. And would you recognize a copy of it if you saw it today?

A. Yes, I would.

Q. Permission to publish -- please turn to Exhibit 884 and let me know if that's a fair and accurate

15:59:51 copy of that exhibit of that study.

A. Yes, it is.

MR. WISNER: Okay. Permission to publish, your Honor.

THE COURT: Any objection?

16:00:05 MR. GRIFFIS: No objection to the Williams review article.

THE COURT: All right. Very well. You may proceed.

Q. BY MR. WISNER: We're looking at the Williams

16:00:13 review article. You see up here the title "Safety

Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, For Humans."

Do you see that, Doctor?

A. Yes, I do.

16:00:23 Q. And you see it has three authors: Gary Williams, Robert Kroes, and Ian Munro?

A. Yes.

Q. All right. Now if we look at the end of this document, there's actually an acknowledgement section.

16:00:37 Do you see it on the last page right here?

A. Yes, I see it.

Q. All right. It says: "The authors acknowledge the assistance of individuals who participated in the preparation of this document. First, we are grateful to

16:00:47 those who gathered and made available the large amount of information used to write the manuscript for this document."

"Second, we thank toxicologists and other scientists at Monsanto who made significant contributions

16:01:00 to the development of exposure assessments and through many other discussions. The authors were given complete access to toxicological information contained in the great number of laboratory studies and archival material at Monsanto in St. Louis, Missouri, and elsewhere. Key

16:01:17 personnel at Monsanto who performed scientific support

were William Heydens, Dr. Farmer, Marian Bleeke, Stephan Bratton, and Katherine Carr.

Do you see that?

A. Yes, I do.

16:01:33 Q. Now, I assume you read this acknowledgement when of course you reviewed this study.

Is that fair?

A. I can't be certain. I don't always read the acknowledgement.

16:01:41 Q. If -- does anywhere in this document it suggest or indicate that a Monsanto employee actually wrote the article?

A. No.

Q. Are you familiar with something called

16:01:57 ghostwriting?

A. I've heard the term.

Q. What is your understanding of it?

A. Somebody writes the article and somebody else puts their name on it.

16:02:05 Q. If in fact this article had been ghostwritten, does this acknowledgement tell you that?

A. No.

Q. All right. Let's move on to the next study.

Well, I want to stop for a second.

16:02:17 You mentioned that De Roos adjusted for, what,

69 pesticides; is that right?

A. Something in that range.

Q. Is that a common thing to do in an epidemiological analysis?

16:02:31 A. That's a bit extreme.

Q. And notwithstanding that fact, the results showed the logistical regression -- a doubling of the risk; is that right?

A. That's correct.

16:02:41 Q. And that risk, notwithstanding adjustment for 69 pesticides, was significantly significant; is that right?

A. That's correct.

Q. Does this study tell you anything about the risk of confounding in these studies?

16:02:55 A. It tells me a little bit. Confounding from pesticides, I assume, is what you're asking, because there's other potential confounders they looked at in here.

It would be better if I saw the unadjusted 16:03:08 analysis, because then I can make the comparison. But here, since they've adjusted by almost 70 pesticides, I'd say that there's probably not a big effect of the pesticides on confounding in this particular study, but I've have to see an unadjusted evaluation first.

16:03:29 Q. And, in fact, in the De Roos article, they did

not see any significant confounding by other pesticides, did they?

A. They didn't discuss it.

Q. Okay. It says here the Bayesian modeling.

16:03:41 Do you see that?

A. Correct.

Q. And Bayesian statistics, it's a type of statistics that makes assumptions a priori before you conduct the experiment; is that right?

16:03:53 A. Correct.

Q. And based on those assumptions, it influences how you assess data that you see?

A. To some degree, yes.

Q. And in this study, they made an assumption about

16:04:05 the carcinogenic potential of glyphosate before conducting this Bayesian model; is that right?

A. That is correct.

Q. And they made an assumption about the likelihood of carcinogenicity based in part upon whether or not

16:04:16 there was an IARC finding; correct?

A. That is correct.

Q. And at this point in 2003, IARC had not, in fact, made an assessment of glyphosate, had it?

A. That is correct.

16:04:27 Q. And because of that, it resulted in a Bayesian

assumption of, like, 30 percent probability of carcinogenicity; is that right?

A. They did that for all pesticides without an IARC review unless they had other reasons to put it lower or higher, but yes.

16:04:43

Q. Okay. So if we were to redo the Bayesian approach today, that starting number would be significantly higher than .3?

A. It would be .6 by their rules.

16:04:54

Q. And if you increase the starting assumption, that would ultimately increase the ultimate risk?

A. It's likely, but it's not guaranteed.

Q. Okay. Less turn to Eriksson study 2008. Are you familiar with this study, sir?

16:05:07

A. Yes, I am.

Q. All right. And what is this study -- where was this study conducted?

A. I think it's in Scandinavia somewhere, but I have to look. I don't know which tab it is, but -- I

16:05:28

can't tell you without looking at the actual document.

Q. Okay. Would you like to look, sir?

A. Yes, please.

Q. All right. It should be Exhibit 758.

Did I skip one? I did. Okay. We'll come back

16:05:49

to that.

A. Again, it's Sweden. It's a case-controlled study in Sweden of -- in this case, they're still looking at "yes" or "no" exposure to glyphosate.

Q. And when they looked at glyphosate and didn't do any adjustments but just looked at the raw impact on the data, what did it show?

16:06:02

A. Significant increase in the relative risk ratio of 2.02 with the confidence bound that did not include 1, so it's significant.

16:06:18

Q. And then they conducted something called a multi-varied analysis; is that right?

A. Correct.

Q. And that took into account other pesticides?

A. If I remember correctly, I think they did two different types of analyses, but, yes, they adjusted for other pesticides.

16:06:30

Q. And what happens to the risk ratio when they did that?

A. It dropped. It drops to 1.5, and it's no longer statistically significant. Although again, it still shows an increase above 1.

16:06:43

Q. I'm going to read a statement to you. I want you to tell me if this is true. "And when Eriksson did that adjustment, do you know what the result was? No effect. No effect of glyphosate." Is that a true

16:06:57

statement?

A. No, of course not. It's a nonstatistically significant positive increase.

Q. And when you read these two numbers together, does it show you or indicate anything to you?

16:07:12

A. It, again, indicates that other pesticides were somehow confounded with the glyphosate result, and it shows it -- they take away some of the significance of that glyphosate finding.

Q. And, Doctor, did Eriksson in this study try to do something different than a never/ever analysis, try to do a, sort of, exposure analysis?

16:07:32

A. Again, I'm going to look at my notes here, but I think yes.

Yes, he did.

16:07:50

Q. And when they did a never, how did they break it down? I know that McDuffie was greater than two days a year. What did they do in Eriksson?

A. They tried two different breakdowns. One was less than ten days' exposure, I believe, per year, and the other one was greater than or equal to ten days of exposure per year.

16:08:03

Q. Great. We'll talk about that one. I don't really care about the other one.

A. Okay.

Q. Let's talk about the greater than ten days of exposure per year. When they looked at people who had more than ten days of exposure to Roundup per year, what did the data show?

16:08:26 A. It was a significant increase. The -- the risk ratio -- the relative number is 2.36, and it's statistically significant in terms of having its confidence bounds above 1.

Q. And the lower one, the less than ten days a

16:08:44 year, what was the results for that?

A. 1.69 risk ratio, and it -- the confidence bound did go below 1, but it is still increased, just nonstatistically significant.

Q. So when we, kind of, compile the two exposure

16:09:01 assessments, we have McDuffie, when they adjusted for greater than two days per year, it's statistically significant, doubling of the risk; is that right?

A. Correct.

Q. And for Eriksson, the other one that did

16:09:13 exposure analysis, greater than ten days per year, again it's statistically significant?

A. Correct.

Q. Is that something you -- from a scientific perspective, is that something you want to see in the

16:09:24 data to help you understand causality?

A. Again, yes. When you look at Bradford Hill, which we'll do later, that's one of the criteria you want to look for.

Q. All right. We skipped over one here, De Roos 2005.

16:09:42

Do you see that, sir?

A. Yes, I do.

Q. We also have Andreotti down here, 2018?

A. Correct. We have Orsi as well.

16:09:49

Q. Sure. Why don't we just talk about Orsi, and then we can talk about those two, because those two are related.

In Orsi, this one, of all of these, is clearly 1.

16:09:57

Do you see that?

A. Correct.

Q. It's exactly -- exact ratio of 1; right?

A. Correct.

Q. And it has a ratio of .5 and 2.2, so it's not statistically significant?

16:10:09

A. Correct.

Q. What about -- what is worthy or interesting about this stuff?

A. It's a case-controlled study. It was done in France. It wasn't the smallest study. They were

16:10:15

EXHIBIT 3

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Friday, July 13, 2018, Volume 9, Morning Session, before the Honorable Suzanne R. Bolanos, at 9:30 a.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2958714A

Pages 1946 - 2058

A. No.

Q. Why is that?

A. The study has some very serious flaws associated with it. They had roughly 40 percent of the people who were in their cohort of almost 55,000 people not respond to the questionnaire, so they couldn't tell whether those people had changed their exposure patterns or not since the last time they asked them, which was in 1993 to 1998.

09:34:39

So they -- they did a thing called an imputation algorithm where they use the people who did respond and their characteristics, and they build a mathematical formula, and then use that formula and the characteristics for the people who didn't respond to estimate what their exposure should have been.

09:35:03

09:35:22

That's an iffy enterprise in most cases, although it is used in epidemiology. But with this big of a proportion not responding, it -- it's questionable. Then they -- they had serious errors. They -- they took a bunch of people who did respond and put them off to the side, and then they built their formula, and then they used that formula to try to predict what the people who did respond, what their exposure really was.

09:35:47

And when they did that, then 7 percent of those people who said they were exposed were estimated by the algorithm to not be exposed, and it could be worse than

09:36:06

that, because they didn't give me the full characteristics.

So the bottom line is that they have serious exposure misclassification. That brings the relevant risk down towards 1, and then they have a bias in the exposure classification, and that can bring it below 1. And so in my opinion, what we're seeing in the Andreotti study is what you would expect to see because of these misclassification problems.

09:36:37 And so it doesn't tell me anything about what it could be, because even if the truth were 1.4 or 1.6, because of these flaws, we'd expect to see it near 1, even possibly below 1.

Q. That's what we saw; is that right?

09:36:53 A. That's what we saw.

Q. Now, this imputation issue, Doctor, isn't it true that epidemiologists use imputation to study pesticides in other cases?

A. Yes, they have.

09:37:08 Q. And so why is glyphosate different?

A. Because of this misclassification that they're getting of putting people who are really exposed in the control group. Typically, with imputation, if it's done right, you're going to get errors on the order of

09:37:27 1 percent, one-half percent, maybe as high as 2 percent.

A 7-percent difference here is a major difference, and in fact, if you look at the data across all the pesticides, because they had to do this -- the AHS study is not just glyphosate. It's lots of pesticides, and when they wrote their studies, they're doing studies on a lot of different endpoints.

09:37:45

And so they -- when you look at their prediction algorithm against the other pesticides, then what you see is as the number of people who are exposed to that pesticide gets bigger, the error gets bigger. So it's a systematic error.

09:38:06

So, for example, for malathion, there were about 50 percent of the people exposed and their exposure error was, I think, about 4 percent. But glyphosate had almost 80 -- they had more than 80 percent of the people exposed at one point or another, and they were off by 7 percent, and so it's a line that's, sort of, dropping.

09:38:24

Q. Now, glyphosate use, we discussed whether or not it changed between 1993 and 2015. Do you recall?

09:38:42

A. Yes.

Q. And I believe you stated that you couldn't really remember. You had to look at your report.

A. Yes.

Q. Did you have a chance to look at your report?

09:38:50

A. Yes. I have the numbers here.

Q. Okay. What was the change in glyphosate use between 1993 and 2015?

A. I didn't have 1993 in my report.

Q. Okay.

09:38:59 A. And I went back to the original reference in my report to make sure I knew what I was looking at. In 1995, by agricultural sector alone, okay, so that's -- that pertains to the people in the agricultural health, it's a health survey, 12.5 million kilograms were applied

09:39:22 in the United States at that time.

Q. Say that again?

A. 12.5 million kilograms.

Q. Okay.

A. In 2014, it's 113.4 million kilograms, so that's

09:39:36 roughly a tenfold increase.

Q. And if you could look at Demonstrative 1030 or Exhibit 1030 in your binder, in the second volume. Yes.

A. I don't have a 1030.

Q. Okay. Well --

09:40:12 THE COURT: Any objection on 1030?

MR. GRIFFIS: No.

THE COURT: Exhibit 1030 may be published.

MR. WISNER: All right.

Q. All right. So, Doctor, we're looking at

09:40:28 Exhibit 1030. This is taken from the EPA's report. And

can you tell the jury what we're seeing here?

A. This is showing the estimated use on agricultural land in pounds per square mile of glyphosate in 1993. The darker colors are where they spray more, and the lighter colors are where they spray less.

09:40:52

Q. And the states -- well, where were the states of the agricultural health study?

A. North Carolina and Iowa.

Q. And you'd agree with me that both of those states are yellow to lightly -- slightly orange?

09:41:06

A. Yes.

Q. Okay. All right. Now, let's look at the same data from 2015. What does this show, Doctor?

A. It's the same basic structure, estimated use on agricultural land in pounds per square mile. The same scale, I think. I don't think that's changed. And again, now you see much more dark brown, much less light yellow in the agricultural parts of the United States.

09:41:22

Q. And so the dark brown says, "Over 88.06 pounds per square mile"; is that right?

09:41:45

A. That's correct.

Q. And so if we go back to 1993, that's less than four pounds; right?

A. For the light yellow, yes.

Q. Yeah. So if it goes from light yellow to dark

09:41:58

or brownish, that could go upwards of a twentyfold increase?

A. In some areas, potentially, yes.

Q. And specifically in Iowa?

09:42:11 A. It certainly has gotten dark brown.

Q. Okay. And is that, Doctor, one of the reasons why there's an issue with regard to exposure misclassification in the AHS?

A. Yes. That is another reason there is an issue. 09:42:28 Since they took five years to ask people about their exposure experience, people at the beginning of the five years may not have been using glyphosate, but the increase was so rapid that by the end of the five years, they might have been using it, but they'd already 09:42:47 answered the question five years earlier, and they didn't get asked again, so their estimate of exposure could be wrong.

Q. All right, Doctor. I want to show you something that was shown to the jury previously.

MR. WISNER: Can you please turn on the Elmo?

Now, your Honor, I already covered this with the defendants. This is a slide from Mr. Lombardi's opening statement.

THE COURT: Very well.

09:43:09 Q. BY MR. WISNER: All right. Doctor, so this is a

A. So in -- with the epi, it's all Roundup. It's not -- you can't make a firm statement about glyphosate from the epidemiology data alone. In my looking at this data, I conclude that there's a demonstrated association here. In the meta-analysis, it's statistically significant. When you look at this nice flat summary here, you can see that virtually in all the studies on the right-hand side, that's consistency of the association. So I conclude that there really is an association here.

09:47:59

09:48:17

The next question is, is that association causal or is it just like the pelicans and -- like the storks and the births? I can't conclude it's causal. I can conclude that it -- causality is reasonable here, that it could be causal. There's nothing that says it can't, and there are times when you can know that it's multi-causal, like the pelicans -- like the storks and the births.

09:48:33

Because we have case control studies here where you're asking people about their exposure and they're talking -- they're thinking about what they did in the past, but they already know whether they have the disease or don't have the disease, sometimes that can create a bias. So I can't rule out that bias. Each of the studies looked at it and tried their best to address how bad it could be. But I still can't rule it out.

09:48:53

09:49:07

The effects are small. They're not huge, tenfold relative risks, and so I can't really rule out chance. And whereas most of them did a pretty good job with cofounders, some maybe didn't, but I don't think 09:49:27 confounders are a big problem in this set of data. But even still, I can't rule out that there aren't confounders.

So I come to the exact same conclusion as IARC. There's an association. It's reasonable that it could be 09:49:39 causal, but I can't rule out bias, chance or confounding.

Q. Now, Doctor, would it be scientifically appropriate to just look at the epidemiology and ignore the animals studies and the mechanistic data?

A. If the -- no. Under no condition would it be. 09:49:58 Even if I saw a strong epidemiology across the board, tenfold increased relate risk, I'd still want to look at the animal data to see if -- if there isn't something in the animal data that tells me this -- there's a confounder missing or there's something here that I'm 09:50:16 missing, because this is not realistic based upon what we know about mechanistics and animals, so it would -- it would tailor my judgement a little bit, but, no, it's never good to look at just one set of data.

Q. Is it fair to say that before you can make an 09:50:32 assessment about causality, you have to look at all the

Number of negative is the number of negative studies.

The "2" is the total number of negative studies, and the "1" in parentheses is the number of studies that were submitted to the regulatory authorities from that group that are in that category. So these are studies that are submitted by industry for EPA or others to look at.

09:59:59

So that's how I distinguish between industry studies versus the other studies.

10:00:17

Q. So the number of negative is a total of two, of which one of them was just an industry study?

A. Correct.

Q. All right. And then you have the cell type or tissue. What is that referring to, high level?

10:00:29

A. Well, in the human *in vitro*, you're looking -- oh, I'm sorry. You have them both there. *In vivo* in the humans, they took blood from humans after they were exposed and looked for DNA damage. So that's peripheral blood. That's the tissue they used.

10:00:47

In vitro, there are different types of studies. The ones in lymphocytes, they actually took people's blood, separated out the lymphocytes, put the lymphocytes into a petri dish, and then expose it to the chemical and look for changes in those lymphocytes.

10:01:04

that there is a lot more positive studies than negative?

A. Well, most of the humans -- yes, there is some significance to that, of course. But you have to look carefully. Let's say this is corroborated -- the lymphocyte studies are fairly strong corroborating studies to what you saw in the peripheral blood studies.

But the other cell lines, they have two, et cetera. Those are additional information but not as strong information to add to this. Because there's isolated studies. There's no additional copies of the same study. It's hard to say.

But the fact that they're all positive is positive information on genotoxicity.

Q. So, Doctor, based on your expert opinion, having reviewed the genotoxicity data, not just in humans but in all other species that you could find -- you said, like, 100 studies or so -- what is your opinion about the genotoxicity of -- let's break it down -- the genotoxicity of glyphosate?

A. Glyphosate is genotoxic.

Q. What about the genotoxicity of glyphosate formulations?

A. The glyphosate formulations that have been looked at are genotoxic.

Q. Are they more genotoxicity than just glyphosate?

THE COURT: Any objection on 1027?

MR. GRIFFIS: No objection.

THE COURT: Very well. You may proceed.

MR. WISNER: This one we have a board.

10:21:06 Q. All right, Doctor. What does 1027 show?

A. These are the various studies that were done. The first set are studies that were done in human cells, and the second set are studies that were done in mammalian cells.

10:21:21 Q. And, Doctor, these are all looking, at least in part, whether or not glyphosate or Roundup induced oxidative stress?

A. Well, let me correct something here.

Q. Sure.

10:21:34 A. The mammal *in vitro*, there are actually *in vivo* studies in there as well.

Q. Okay.

A. So those are mammal studies.

Q. Okay. Fair enough. Thank you.

10:21:51 Does that work (indicating)?

A. Yes, that works.

Q. Let's do this quickly. I don't want to go through each one of these. We will be here all day. But which ones of these showed oxidative stress and which

10:22:06 ones didn't?

A. Mladinic. I'm going to tear up these names.

Q. Read them off.

A. Positive.

Kwiatkowska was positive.

10:22:16 Chaufan did both glyphosate and a formulation. The glyphosate was negative, but the formulation was positive.

Coalova did three different formulations. It was positive.

10:22:25 Q. All three?

A. I'd have to look at my notes.

Q. I'll just do one check.

A. Gehin was positive. Elie-Caille was positive, but I think it was an inadequate study. It was

10:22:41 questionable as to what they did.

And George & Shukla was also positive, but it was questionable so I don't include it. I don't think it's an adequate study.

Q. Terrible question.

10:22:55 A. Bolognesi was -- that was done in mice. It was positive for liver cells in the mouse but negative for kidney.

Cavusoglu looked at a formulation. Liver and kidney were both positive for one of their markers and

10:23:17 negative for the other. No, it made sense. What they

saw made sense.

Jasper did it in mice. It was positive in the liver in both males and females.

Astiz did it in male rats. This was -- this is a study where they used a different chemical -- they used glyphosate to induce oxidative stress, and then they added another chemical to try to get rid of that oxidative stress. Remember I said cells have machinery for cleaning up oxidative stress? Well, you can add that stuff, and they did that and the oxidative stress went away. So that's a positive study.

Q. Are those substances called antioxidants?

A. Yes, they're antioxidants. Some people take them as vitamins.

Cattani exposed pregnant rats and looked at their offspring. It was positive.

And George looked at mice. This was a topical study. They measured proteins and oxidative stress, and I don't have a note here that says whether it was positive or not so I can't --

Q. Okay.

A. I can't be certain.

Q. Okay. We talked about the George study as related to the tumors; right?

A. The initiation promotion study.

Q. That's right.

A. Yes. Initiation promotion. This is the same study in the same animals. They measured oxidative stress using proteins. They did a proteomic evaluation.

10:24:42 Q. All right, Doctor, I'm looking at this chart. Almost everything is positive. What does that tell you?

A. That glyphosate can cause oxidative stress in mammalian systems.

Q. If you were to give an overall weight of the

10:24:57 characterization of the oxidative stress data, what would you say?

A. The evidence is strong in a positive direction.

Q. And would you have said the same about genotoxicity?

10:25:13 A. Yes. Very strong.

Q. All right. So look at that. We got through oxidative stress in like two. A first.

All right. So, Doctor, having looked at all three areas of science: We've looked at the animal data,

10:25:33 we've looked at epidemiology, now we've looked at mechanistic data, which included both oxidative stress and genotoxicity. What is your opinion about whether or not glyphosate, and then separately Roundup, whether or not they can cause cancer?

10:25:53 A. I believe glyphosate is a human carcinogen. I

used some word in my expert report that I'm not going to pull back. I don't remember what the exact wording was. It's not absolute, but in my opinion, 90 percent or higher, I believe glyphosate is a human carcinogen.

10:26:16 Q. What about Roundup?

A. Roundup has glyphosate in it. So by that argument, and you would say immediately that Roundup is also a human carcinogen. The question then becomes is the formulation stronger or not. I can't answer that

10:26:33 because the animal studies only did the glyphosate, and humans are only the formulations. So it's hard to make that decision. And the *in vitro* stuff only gives you some indication.

So they're just both human carcinogens.

10:26:48 Q. So to a reasonable degree of medical certainty, what is your opinion?

A. Well, I'm not a medical doctor.

Q. Scientific.

A. To a reasonable degree of -- a cancer risk

10:26:58 assessment expert, glyphosate is carcinogenic, causing NHL in humans.

Q. All right, Doctor. I want to ask you about a couple other things that I think are going to come up so I'd rather just talk about them now.

10:27:17 Let's start off with a document.

right there. What does that mean?

A. That's almost word-for-word a description of what I said with the human evidence, human epidemiology evidence, that there's an association. It's not definitely causal between human exposure and cancer.

Q. Okay. "In most cases, with some supporting biological experimental evidence, though not necessarily carcinogenicity data from animal experiments."

What does that second half of the sentence mean?

A. They want some laboratory evidence to support the positive finding. If it's -- if it's not animal carcinogenicity studies, then you're looking for strong data on genotoxicity or oxidative stress or some of the other potential links between chemicals and the creation of cancers.

Q. And in your opinion, based on the data we've shown this jury, is there some supporting biological experimental evidence?

A. Yes.

Q. Would you say it's a little bit more than some?

A. I'd say it's strong.

Q. Okay. All right. So based on what you've discussed today with this jury, would you agree that this exact example kind of fits what we're dealing with here with glyphosate?

A. Well, I think the next example does as well, but --

Q. We'll get to that in a second.

A. -- it doesn't quite fit glyphosate because you have carcinogenicity data from the animal studies for this one.

Q. So the data we have is actually stronger than this hypothetical right here?

A. Yes, it's somewhat stronger than the hypothetical.

Q. Okay. The next hypothetical is the agent has tested positive in animal experiments in more than one species, sex, strain, site, or exposure route, with or without evidence of carcinogenicity in humans.

So what does that mean in simple terms?

A. There's no epidemiology data that's worth bringing into the argument. It's just inadequate. Either there's none there or poor studies. There's lots of reasons that can occur.

And so all you've got is animal carcinogenicity studies, and so you want more than just one study. You want -- you want more than just one finding in one study. You want to see it in different species. That strengthens it. Was it in other species, both sexes, if you see that, it strengthens it, multiple strains, that

higher than this one because there is some evidence that makes you uncomfortable. So you still wouldn't put it in this category.

Q. Okay. Have you expressed your concerns about the EPA's analysis to the EPA?

10:47:53

A. Yes, I have.

Q. How have you done that?

A. During the first request for public comment on the draft proposal they were putting together, I sent them a formal set of comments about what they were doing, went through their document page by page and discussed what I was seeing that they were doing inappropriately.

10:48:11

Q. Did any lawyer ask you to do that?

A. No.

Q. Why did you do it?

10:48:26

A. As I said earlier, my entire career has been about using scientific evidence to make decisions primarily about the carcinogenicity of compounds. And we've worked for years and years to understand how to do that appropriately and how to do it so that you're really presenting good advice that can be used in policy decisions.

10:48:45

And this was just so amazingly wrong in the way they were doing it, not following their own guidelines, I just felt I had to say something about it.

10:49:04

Q. All right. Let's leave the United States. Let's go across the pond to Europe.

THE COURT: Mr. Wisner, before we move into a new topic, I think this is a good time to take the morning recess.

MR. WISNER: Sounds good, your Honor.

THE COURT: All right. So Ladies and Gentlemen, we'll be in recess for 15 minutes, and we'll return again at five after 11:00 on the wall clock. Please remember, do not discuss the case. Thank you.

(Recess.)

THE COURT: Welcome back, Ladies and Gentlemen. Dr. Portier remains under oath.

And Mr. Wisner, you may proceed.

MR. WISNER: Thank you, your Honor.

Q. Dr. Portier, just before the break I wanted to take us out of the United States and across the pond to Europe. I'd like to talk briefly about Europeans assessment of glyphosate and Roundup.

I understand you live in Europe.

A. Yes, I do.

Q. And have you been paying attention or been -- tried to look at the scientific assessments -- strike that.

The assessment of glyphosate that's being done

by the European authorities?

A. Yes, I have.

Q. All right. Briefly explain the process by which the assessments are done in Europe.

11:06:48 A. European Food Safety Agency is the authority in Europe on pesticide registration. The way it goes for renewal, which is what it is with glyphosate -- it was already on the market; they just want to review the literature again -- the industry puts forth a request for

11:07:11 renewal. They provide a document with their -- the science that's there and to some degree their interpretation of that science.

That document is taken by one of the member -- two of the member states, actually. One is the primary

11:07:27 lead. The member states in Europe are Germany, England, not too much longer, France, Belgium. Those are members of the European Union.

So in this case, Germany was the lead member state. They reviewed the document, they edited it, they

11:07:46 made some changes to it. They added some comments. Then that goes to the European Food Safety Agency, EFSA. And then EFSA brings together experts from all of the countries in the EU, who argue, review, decide, send it back to the Germans. They redo it. And then it comes to

11:08:07 them, and then EFSA puts forth a recommendation.

And then the European Commission takes that recommendation and makes a decision. And then that has to be accepted by parliament. That's my understanding.

Q. So at the beginning of the process, then, it looks like the industry actually prepares the first draft of the report; is that right?

A. Not always, but in this case, yes, as far as I understand it.

Q. So then it goes to the German authorities, they make edits; right?

A. Yes.

Q. Then it goes to EFSA. They discuss it?

A. Yes.

Q. And then it goes back to Germany, and then they make edits?

A. Correct.

Q. And at some point they issue a final report, and that goes to the EU, to the government?

A. To government itself, yes. And European Commission, which is the government, not the legislators.

Q. And they decide if they want to follow it?

A. And then they decide to either follow or not follow the recommendation.

Q. Now, the processes in the scientific approach that EFSA uses, is that in any way similar to IARC?

A. Their guideline document for human and animal evidence is identical to -- to that of IARC, with some minor wording differences in terms of who does it. Because at IARC it's the Working Group and at the EU it's someone else.

11:09:37

Q. So they apply the same standards. Did they come to the same conclusions as IARC?

A. EFSA came to the conclusion that the human evidence was very limited, is what they called it, but it's the same limited general area as IARC did. The animal evidence, they said, was suggestive of no effect. They called it completely negative. They called the genotoxicity data negative, and they said the oxidative stress was positive.

11:09:48

11:10:09

Q. Now, the animal data, did they do what the EPA did and exclude tumors over a thousand milligrams, kilograms per body weight?

A. They did almost identical what the EPA did in terms of all the problems they had in their evaluation.

11:10:26

Q. And do you know one way or the other whether or not EFSA or EPA had made a decision to disagree with IARC before they saw the Monograph?

A. I don't know that, no.

Q. All right. I understand that you also, like the EPA, but you expressed criticisms of EFSA's approach; is

11:10:43

that right?

A. Yes, that is correct.

Q. And I believe you said that to EFSA. They responded; is that right?

11:10:54 A. I sent a letter not to EFSA, but to the Commissioner of Health, which is -- EFSA is underneath them. And he instructed them to respond, and they did respond.

Q. And then you prepared a response to the

11:11:10 response; is that right?

A. Me and my co-authors prepared a commentary, a letter to a journal, which included our response.

Q. I'd like to talk about that letter. And was it published in a journal?

11:11:23 A. Yes, it was.

Q. Please turn to Exhibit 293 in your binder. It should be Volume 1.

A. I have it.

Q. Is this a fair and accurate copy of that letter

11:11:54 that was published in the journal?

A. Yes, it is.

MR. WISNER: Permission to publish, your Honor.

THE COURT: Any objection?

MR. GRIFFIS: No, your Honor. Oh, publish, no.

11:12:03 MR. WISNER: We're not putting these into

evidence.

THE COURT: Very well.

Q. BY MR. WISNER: So we're looking here at a copy of that letter; is that right, Doctor?

11:12:21 A. That is correct.

Q. If we look here at the title, "Differences in the Carcinogenic Evaluation of Glyphosate Between the International Agency For Research on Cancer, IARC, and the European Food Safety Authority."

11:12:36 Do you see that?

A. Yes.

Q. And as we can see right here, you are the first author; right?

A. That's correct.

11:12:45 Q. Let's start off with the conclusion that you guys came to. It's in the last page of the document. It says: "The most appropriate and scientifically based evaluation of the cancers reported in humans and laboratory animals as well as supportive mechanistic data

11:13:11 is that glyphosate is a probable human carcinogen. On the basis of this conclusion and in the absence of evidence to the contrary, it is reasonable to conclude that glyphosate formulations should also be considered likely human carcinogens."

11:13:26 And then you go into the CLP criteria. What is

that?

A. That's the criteria that's put forth by the European chemical agency on how to evaluate not just cancer studies, but the entire area.

11:13:44 Q. And their classifications, the highest one is 1A?

A. The highest one is 1A, correct.

Q. And the second one, which is the second highest is 1B?

11:13:54 A. Correct.

Q. It says: "The CLP criteria allows for a similar classification of Category 1B when there are studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in

11:14:07 experimental animals."

So this was the conclusion of this letter; is that right?

A. The first part.

Q. Yeah.

11:14:17 A. The second part -- yes, that's the conclusion.

Q. And that's the sort of conclusion about the issue of carcinogenicity?

A. Correct.

Q. And then after that, you actually have a summary

11:14:28 here. You go through all the different things that the

Working Group did at IARC and then what EFSA did; is that right?

A. Correct.

Q. Raising various concerns point by point about things that you thought were not scientifically valid; is that right?

A. That is correct.

Q. When I say "you," you were not the only author on this paper; is that right?

A. No. There were 94 authors, I believe. I don't remember the name -- number. 96, 94.

Q. All right. So we'll start here. We got Christopher Portier is the first one, and then we have all these different scientists that joined you in this letter regarding the relation that -- well, who's right, IARC or EFSA; is that right?

A. Correct.

Q. And some of these -- some of these scientists I think we've heard of, for example, Dr. De Roos.

Do you see that?

A. Correct. Yes, I see that.

Q. So Dr. De Roos joined you in concluding that glyphosate was a probable human carcinogen?

A. Yes. And that is the same De Roos who did the two studies.

Q. The same De Roos -- okay. Actually, look at that. We have Hardell. Do you see that? He joined you?

A. Yes.

Q. That's the Hardell that we've been hearing about in all these studies?

11:15:49

A. Yes, it is.

Q. There was some discussion that if there really was such a problem, all these authors would have said, hey, this stuff causes cancer. Isn't that what they're doing in this letter?

11:16:03

A. In essence, yes.

Q. I guess my only other question is -- is notwithstanding the fact that you and 94 other scientists have concluded that IARC was right, did EFSA change its position?

11:16:20

A. No.

Q. Did the European Commission agree to fully renew IARC based on EFSA's recommendation?

A. That's what they tried -- that's what they recommended.

11:16:34

Q. And what did the actual government end up doing?

A. They ended up renewing the registration I think for four years, and then I think they intend to phase it out, but I don't know the exact wording. I didn't look at the ruling.

11:16:50

Q. Phase out glyphosate in Europe?

A. Yes.

Q. Are you aware of any countries that have banned it in Europe?

11:17:04 MR. GRIFFIS: Objection, your Honor. May we approach?

THE COURT: Yes.

(Sidebar.)

MR. GRIFFIS: (Inaudible) -- has not been put

11:17:26 forward on this. So --

THE COURT: So now it's on. Okay. Dr. Portier has not been disclosed any opinion on this, has not relied on bans in his materials considered list. And the in the bans, as Mr. Wisner said in one of our early days,

11:17:47 are political, not scientific. He is a scientist and not qualified to comment on politics, nor should politics come into this, nor split decisions made come into this.

He's gone quite far enough by talking about this pursuant phase out of glyphosate in Europe, which is a

11:18:07 political not represented by, and the bans are going to quickly lead into some serious factual disputes about how no witness who has been named in this case is qualified to testify.

MR. WISNER: I thought the whole point was that

11:18:21 the foreign regulatory stuff was coming in, and so if

that's relevant, I have a right to say whether or not the countries that have actually commissioned that report agree with it.

THE COURT: So has he testified in his report or in any of his depositions about other countries that have banned it?

MR. WISNER: Not in his report, but I don't know about his other depositions. I would be surprised if it didn't come up. I'd have to look at his last deposition. It was all about the Green Party.

THE COURT: Let me ask you this: He's talked about EFSA, and I think in his disclosures he disclosed having reviewed or relied on other foreign regulatory reports. Right? So did any of those reports conclude that it should be banned?

MR. GRIFFIS: Any, no. No.

THE COURT: Or indicate that it was going to be banned?

MR. WISNER: It's a completely separate process. These are six reports by the regulatory agency. No regulatory agency has concluded they will be banned.

I'll withdraw this question.

THE COURT: Okay. All right. You may continue, Mr. Wisner.

MR. WISNER: All right. Thank you, your Honor.

EXHIBIT 4

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Tuesday, July 17, 2018, Volume 11, Morning Session, before the Honorable Suzanne R. Bolanos, at 9:27 a.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965314A

Pages 2423 - 2464

periods. Changing agricultural practices, such as pesticide application methods and use of protective" -- "personal protect equipment may impact actual exposure levels. In addition, if changing product formulations or amounts used are associated with risk, this may also impact results."

Do you see that?

A. Yes.

Q. Do we have any evidence that glyphosate had changing product formulations or amounts used during the study period?

A. I -- I'm not sure about formulations, but the amounts used have changed dramatically during the study period.

Q. And that was that diagram we showed of the country, where Iowa showed almost 20 times increased over -- between 1993 and 2015?

A. Yeah.

Q. Okay. Now, I understand you don't think that this study's data is particularly reliable, but let's assume for a second that Monsanto's right, okay, that this is the end-all-be-all of epidemiological studies, the most important one. Okay? Let's walk into that universe for a second, if we can.

I want to look at some of the data on here. So

Do you see how they're basically almost all at or below 1?

A. Correct.

Q. So we're not having any -- okay.

09:51:32 Does that in any way suggest anything to you about the quality of the study?

A. It's a consequence. It's an expected consequence of the exposure misclassification that is differential in this case.

09:51:46 Q. Okay. Now, here's one they didn't show you, non-Hodgkin's lymphoma T-cell.

Do you see this, Doctor?

A. Yes.

Q. And these risks are not below 1, are they?

09:51:57 A. No.

Q. In fact, for the middle exposure group, 4.25.

Do you see that?

A. Yes.

Q. And that's not statistically significant,

09:52:06 though, is it?

A. No. It crosses 1.

Q. But it's pretty elevated; right?

A. Yes.

Q. And if I were to pull out your plot chart and

09:52:16 lay it out for you, that would actually -- that number --

that point would be bigger than all the other ones on the chart, wouldn't it?

A. Yes.

Q. Now, if we actually go to the next page, there's a more comprehensive evaluation of a more deeper dive into non-Hodgkin's T-cell. And as you can see here, Doctor, for the first group, which is the less than five years of exposure, okay, we have a 1.86 for the middle group.

09:52:24

09:52:47

Do you see that?

A. Yes.

Q. So for the middle dose group, there's still an elevated, but it's not statistically significant.

Do you see that?

09:52:54

A. Yes.

Q. But for the 20-year lag -- well, before I ask you, what is a 20-year lag?

A. Basically if -- if -- they go back in time for 20 years and then start looking at your exposure and ignoring the exposure for the last 20 years.

09:53:09

Q. And so this would be -- you have had 20 years to, sort of, collect up cancers to look at; is that right?

A. Yeah.

09:53:22

Q. And so if you only looked at five years -- and

we talked about the bell curve of latency; right? If you look at only five years, you're looking at the first half -- the first part of the bell curve; right?

A. It's not latency here. It is lag time.

09:53:38 Q. Lag. You're only looking at the first part. Whereas for 20 years, you have more time to see more cancers to see if there's a risk?

A. Correct. And it changes where people go in what -- in which group.

09:53:50 Q. In this study, the one that Monsanto says is the greatest, there's actually a statistically significant, almost tripling of the risk for T-cell lymphoma; isn't there?

A. Yes, in the 20-year lag group.

09:54:02 Q. And, Doctor, mycosis fungoides, that's a T-cell lymphoma, isn't it?

A. Yes, it is.

MR. WISNER: No further questions.

THE COURT: Mr. Griffis.

09:54:12 MR. GRIFFIS: Yes. Thank you, your Honor.

RECROSS-EXAMINATION

BY MR. GRIFFIS:

Q. Good morning, sir.

09:54:18 A. Good morning.

cytotoxicity have been reported in rat or mouse study pathology reports, and as a follow-up to that, were those made available during review?

THE WITNESS: So typically, in an animal cancer
10:07:25 study -- we have to make sure we don't confuse the cancer studies with the genetic toxicology studies where they were looking at micronuclei. In the cancer studies -- because in those studies, the micronuclei studies, they seldom look inside the animals. They just take blood and
10:07:43 look to see if there's a problem in the blood in terms of DNA damage or specific tissue, but they don't do full pathology.

In an animal cancer bioassay, you look at every tissue and every organ, and if there is tissue
10:07:58 deterioration that appears to show up, regardless of the cause, it could be cell killing, it could be that the tissue is being invaded by parts of the immune system because it's beginning to look a little odd to the rest of the body, there's many reasons why you might have
10:08:16 tissue damage, but that tissue damage is indeed recorded.

For the evidence that I had in -- from those studies and the Greim papers, some of those papers included some information on non-cancer findings. Others only showed cancer findings, so it was mixed as to
10:08:37 whether I could see it.

EXHIBIT 5

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Wednesday, July 18, 2018, Volume 12, Morning Session, before the Honorable Suzanne R. Bolanos, at 9:25 a.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965316A

Pages 2512 - 2625

That's referring to confounding, is that right Doctor? The latter?

A. No, that's referring to exposure misclassification.

11:03:47 Q. Oh, sorry. Yes.

A. I think that's correct, that we don't measure exposure with great precision. When you ask someone how many are -- were you exposed to some exposure -- there's a high error rate in terms of -- it could be a random

11:04:06 error rate, but there's a high error rate, like what I was saying before with broccoli. You just don't get it right. No one does.

Q. They go on to say, "It is rare to find substantial confounding in occupational studies or in

11:04:20 other epidemiologic studies for that matter, even by risk factors that are strongly related to the outcome of interest. On the other hand, exposure misclassification probably occurs in nearly every epidemiological study. For nondifferential misclassification, the type of

11:04:35 misclassification most likely in cohort studies, the direction of bias is largely predictable. That is a bias of relative risks towards the null."

Do you see that?

A. Yes. So that's exactly what I was saying

11:04:50 before, that when you get random error in -- in measuring

the exposure, it will bias the estimate towards the null, towards 1. And by the way, exposure misclassification is going to be -- he says it in cohort studies, but exactly the same phenomenon will occur in case-control studies.

11:05:13 Q. And you would agree, Doctor, with Dr. Blair and his colleagues that the most -- the thing to be most concerned with in evaluating the methodological issues of epidemiology, you're most concerned with exposure misclassification, more so than confounding, although you

11:05:33 are concerned with both?

A. Well, that's the next sentence, if you read on to the next sentence.

Q. Okay. And you agree with that?

A. Yeah.

11:05:39 Q. Okay. Great.

MR. WISNER: Your Honor, it's probably a good time for a break.

THE COURT: All right. Ladies and Gentlemen, we'll take the morning recess now. We'll be in recess

11:05:47 until 11:20 on the clock. Please remember not to discuss the case, and we'll resume again at 11:20. Thank you.

(Sidebar.)

MR. LOMBARDI: Your Honor, I just want to put on the record the fact that counsel, out of everything on

11:06:24 Dr. Neugut's CV, called out studies related to Agent

not carcinogenic or probably not carcinogenic.

Q. Okay. I'll take this off the screen now.

I want to draw your attention to another section that also came up, incidentally, in Mr. Lombardi's opening statement. If you turn to page 8.

A. Page 8 in this document?

Q. Yes, that's right.

It reads: "Monograph evaluations take account of," quote, "real-world exposures by evaluations of epidemiological studies."

Do you see that?

A. Yes.

Q. All right. It reads: "A charge level at the Monographs is that evaluations are divorced from the real world, i.e., are made without taking account of realistic human exposures. However, epidemiological studies are an essential part of Monograph evaluations and by definition deal with people exposed in daily life, including at work. The studies frequently consider the gradient of risk observed with different levels of exposure. One part of the Monograph evaluation is specifically dedicated to describing the circumstances under which human exposure occurs and at what levels."

And then the last thing it says, "In light of the occurring," quote, "real-world human exposures,

Working Groups synthesize evidence in humans, animals and other model systems in reaching overall conclusions."

Now, Doctor, is it your understanding, as an epidemiologist who relies on IARC routinely in your practice, when IARC classifies something as a probable human carcinogen, does that mean it's not a real-world carcinogen?

11:34:29

A. Of course it's a real-world carcinogen. I mean, it would be nice, speaking as a scientist, to be able to do these studies the same way we do with animals and take 25 or 30 people and put them in a room and give them the maximum tolerated dose and see what happens, but I'm not allowed to do that.

11:34:43

So in essence, we use the -- obviously, the epidemiologic studies are relying on how people are really exposed in day-to-day life. All the studies that we're going to talk about or that we hear are, basically, asking farmers or agricultural workers or whomever how much they've been exposed to. What could be more real life? That's exactly what people are exposed to. That's what epidemiologic studies are.

11:34:58

11:35:16

Q. Now, if you look at the bottom of this page, the last bullet point, it reads: "In practice, by far the most frequent change in classification after re-evaluation is that the agent goes into a higher group,

11:35:29

for example, from Group 2A to 1. The fact that most reclassifications move into higher group is an objective indicator that the Monographs do not overstate the strengths of available evidence, but are, in fact, conservative in nature."

11:35:48

Can you explain what you understand that to mean?

A. So it's not uncommon -- again, I don't know the details of this. I'm relying on what they're writing in this document, but generally speaking, over time, of course, more evidence -- whatever classification IARC gives an exposure, things change, and 5, 10 years later, there's more evidence, so IARC may come back and do another Working Group or to -- re-evaluate an exposure.

11:35:59

11:36:20

And what it's saying is that when that happens, in the vast majority of instances, the reclassification increases the level of carcinogenicity that's assessed. It goes, for example, from a 2A to a 1, from a probable carcinogen to a definite carcinogen. It's very rare that it will go from a probable carcinogen to a less likely -- to a possible carcinogen, down, which tells you that they are very conservative, that they are modest in terms of how they decide on whether -- on the level of carcinogenicity that they assign to a certain exposure, that they usually end up making something even more

11:36:40

11:36:58

carcinogenic or assign -- reclassify something as even more carcinogenic than they started out with the first time.

Q. Now, Doctor, the reason why IARC classified it in 2A as opposed to 1 was because the epidemiological study was, in IARC's view, limited. Do you recall that?

A. Yes.

Q. Have there been examples in the past where something was originally classified by IARC as 2A because of limited epidemiology, but as time went on, they developed more epidemiology because people are using it in the world and they upped it to 1?

A. So an example of that is formaldehyde. Formaldehyde is a chemical that's used in the occupational setting for a variety of -- in construction, and it's used in the undertaking -- you know, in embalming and things like that.

So that was classified as a 2A originally, and based mainly -- just like glyphosate, based heavily on the toxicological evidence and with limited epidemiology, so it was initially classified as 2A, and then some years later, it had a re-evaluation when there was more epidemiology evidence, more studies had been done, and it got reclassified, and it's now classified as a definite carcinogen, as a Class 1 carcinogen by IARC.

above. Half should be below. That's what random means. Half should be above and half below.

And if you look, all of them are above 1. All of them. That's a phenomenon referred to in causal epidemiology as consistency. They're consistently elevated above 1. Whatever flaws, problems, issues we're all going to raise about these studies, one or the other, no studies are perfect, whatever things each study does, no study is identical. One does something. One -- each study does something differently. Each study -- but all the circumstances under which these six studies -- some of them control for different things, some of them are done in different populations. Some of them in Scandinavia. Some of them are in America. Some of them in Canada. Some of them are with farmers. Some of them are not.

But all of them are consistently above 1, and that's none random. And here -- this is what's called a meta-analysis, (inaudible) but it's not --

11:49:21
11:49:39
11:49:53
11:50:13
11:50:27

Q. Meta RR.

A. Meta RR.

So you get what's called a meta RR. So what happens here is a study was done by some scientists, by Cheng and Delzell. And what they did was they put together the risk estimates. Basically, they combined

statistically significant positive exposure.

The truth is that in the De Roos 1.6, they're using -- they took for this particular.

Q. You can cross it out and put in the right number.

11:52:23

A. They took a different -- the paper contains a whole slew of analyses. And probably they took a conservative estimate from it. They were trying to be conservative, like we always try to be, but they probably should have taken one where the risk estimate was .1. And so if they had taken that, it probably -- it would have been statistically significant -- De Roos would have been statistically significant on its own, and you probably would have had a somewhat higher risk ratio here.

11:52:38

11:52:53

Again, I'm not going to argue whether it's 1.3 or 1.4, et cetera. That's not really the issue. The point that we should walk away with is that overall, there's a statistically significant increased risk in the 1.3, 1.4, possibly 1.5, range. And that's basically what the case control studies are showing us.

11:53:06

Q. Thank you, doctor. Great. That was easy.

I want to point out a few things the jury should see, because I think it's a little different than -- they saw a plot summary earlier with Dr. Portier. I want to,

11:53:29

Q. So this is not reflecting if someone used it for, like, more than two days a year?

A. Correct.

Q. Now, some of the authors did actually look at, sort of, dosing or exposure effects; right?

A. Yes. Yes.

Q. And I believe it was in McDuffie and Eriksson; right?

A. Yes.

Q. And in both of those studies, both of the elevated exposure groups have statistically significant rates of NHL?

A. So while these overall analyses are, as I say, not statistically significant for the most part, that's because you're also including people who ever -- someone used glyphosate for two days, you know, and that was it, they're still included here as a positive glyphosate person, but they're -- obviously that level of exposure is not gonna make any significant contribution to the risk of getting lymphoma.

On the other hand, if you start to look at dose response of people who are really significantly exposed to glyphosate, got exposed in a more dramatic way, for longer periods of time, for higher doses, they're going to have a significantly higher risk.

And when you look in some of the papers, you see that dose response, and then you see much more significant levels of risk ratios that are statistically significant.

11:56:44 Q. All right. So we have on here De Roos 2005. And that's from the agricultural --

A. AHS study.

Q. Okay. Great.

They've heard a little bit about the AHS study, 11:56:55 but I want to hear from an epidemiologist. They published the new results, the new ones, last year; right?

A. Yes.

Q. You've reviewed them?

11:57:05 A. Yes.

Q. You considered it?

A. Yes.

Q. Do you think that that study is a reliable study?

11:57:10 A. No.

Q. Why?

A. For a few reasons. So -- so first, you have to appreciate that why -- what changed. So first of all, the level of use of glyphosate between the initial 11:57:29 exposure from -- let's say from 1993 to 1996, the people

were initially recruited in the 1993 to 1996 time frame.

What happened subsequent to 1993 to 1996 was that there was a dramatic rise in the use of glyphosate for various reasons, so that whatever was assessed in terms of the initial exposure of glyphosate really became almost useless information. I think we have a poster --

Q. A demonstrative. Do you want to show the jury that?

A. If we can.

Q. Yeah. Absolutely.

MR. WISNER: Permission to publish 1032?

THE COURT: Any objection?

MR. LOMBARDI: No objection, your Honor.

THE COURT: Very well.

THE WITNESS: So, again, we're talking now about a cohort study. So we're talking about people who were exposed -- who were recruited in 19 -- 50,000 people roughly. 50-something-thousand people who were exposed between -- who were recruited between 1993 and 1996 or so. And they were each given a questionnaire and asked about their usage of glyphosate and other herbicides.

And then what happened is -- you can see here, after 1996, there was a huge rise, almost tenfold, in the use of glyphosate.

So, basically, if you relied on the level of

glyphosate exposure that you had collected on the initial questionnaire back in 1993, '94, when you questioned them, it's totally useless. I mean, because their use of glyphosate has dramatically increased in between.

11:59:16 This doesn't usually happen with most exposures. If I ask someone, "How much do you smoke," and they said, "I smoke two packs a day," and then five years later you ask them how much they smoke, they're still smoking two packs a day. But here the glyphosate exposure went up

11:59:34 dramatically.

So basically what it says is you can't rely on the baseline questionnaire that was done in 1993, 1994, 1995, because the glyphosate exposure has dramatically changed. So, okay, that's no one's fault.

11:59:48 So the investigator said, "Okay. Here's what we have to do: We have to go back and reinterview everybody," which is exactly what they did.

So they went back and tried to reinterview everybody --

12:00:00 Q. BY MR. WISNER: And that was actually in 2001 and 2005; right?

A. Right. So around 2005, they went back and tried to reinterview the 50,000-odd, not odd, but, you know, 50,000-ish people who were in the study.

12:00:13 So now they run into what's a problem in cohort

studies. What's a problem in cohort studies is you've got to try to find them and get them to -- to go back and do the questionnaire again.

Well, I don't have to tell you, if someone
12:00:28 called -- this was by telephone. I don't know what you do. When someone calls me on the telephone and wants to interview me, I hang up. Or I don't answer the phone in the first place.

So what happened was they called the 50,000
12:00:43 people. Again, it's a little more than 50,000, but I'm just using rough numbers for our discussion. When they called the 50,000 people, they got a cooperation rate, if you want to call it that, a follow-up rate, of 62 percent. So 38 percent of the people that they
12:01:00 called -- I don't think anybody here will be surprised by that -- 38 percent of the people did not respond. Or they did not get follow-up from 38 percent of the cohorts.

Now they don't have information on 38 percent of
12:01:12 the cohorts in terms of their subsequent follow-up in terms of glyphosate.

Q. So, Doctor, let me just interrupt you before we get an objection.

A. Yes.

12:01:20 Q. For example, let's say they had been -- between

1992 and 1997, they'd never used glyphosate.

A. Right.

Q. Okay? And then in 2000, they start using it; right?

12:01:32 A. Yeah. And if you didn't interview them, you wouldn't know anything about it.

Q. And then let's say it's even worse. let's say -- 2000, they started using it for a couple of years. They died in 2004 from non-Hodgkin's lymphoma.

12:01:45 Okay?

A. Yeah.

Q. Let's say that happens. Then when they called, they obviously couldn't answer the questionnaire.

A. Because they'd be dead.

12:01:54 Q. Yeah. So that person, for purposes of the study, then, would be considered unexposed, and the cancer would then be assigned to the unexposed group?

A. Well, it's not clear what would happen. No, that person would have been imputed as being unexposed.

12:02:09 Yes, that's what you said.

Q. Yeah, that's what I meant.

A. Uh-huh.

Q. And that's exactly misclassification of exposure. That's the thing we were talking about with

12:02:18 Dr. Blair.

A. That's correct.

Q. So what happened?

A. So what happened is -- so, correctly, what they did was -- then you have several problems. So, again, this would not be a problem -- this would not be a problem if the risk ratio was high. If the relative risk was 10, like the tobacco and lung cancer -- again, these are errors that, kind of, would have been made -- instead of a relative risk of 10, maybe we'd have a relevant risk of 9 or a relative risk of 8 and -- who cares.

If we're talking about a relative risk of 1.5, then these kinds of errors are enormous and -- or potentially enormous. And so they -- they get thrown out in the wash, so to speak, so --

12:02:26 12:02:46 12:03:03 12:03:12 12:03:23

Q. Let's stop right there.

A. And there are several errors here.

Q. Let's stop right there.

MR. WISNER: Your Honor, it's probably a good time to take a break, so we can get a time check and make sure we don't run into the buzzer.

THE COURT: Okay. Great.

All right, Ladies and Gentlemen. Then we'll -- we'll break now for the lunch recess. Please remember: Do not discuss the case, do not do any research. And we'll see you again at 1:30. Thank you.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Wednesday, July 18, 2018, Volume 12, Afternoon Session, before the Honorable Suzanne R. Bolanos, at 1:31 p.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965316B

Pages 2626 - 2754

the issues that we were just discussing a minute ago or before lunch; is that right?

A. Correct.

Q. Okay. I want to go to the conclusion section here. Starting at the word "second."

13:39:48

Do you see that, Doctor?

A. Yes.

Q. "Second, except in situations where exposure estimation is quite accurate, i.e., correlations of .70 or greater with true exposure and true relative risks are 3.0 or more, pesticide misclassification may diminish risk estimates to such an extent that no association is obvious which indicates false negative findings might be common."

13:40:10

13:40:29

Did I read that right?

A. Yes.

Q. What does that mean?

A. So it's saying that if -- two things: If the exposure estimate is only 70 percent accurate in the first place, then you're going to have a random misclassification error that's going to lead to an error that's going to cause the relative risk estimate to be grossly inaccurate in the first place. But even more importantly, for our purposes, as I had said before, here it's saying that since we're talking in the context with

13:40:42

13:40:58

a relative risk estimate is putatively 1.5.

So they're saying if the true relative risk is 3 -- unless the true relative risk is 3 or more, pesticide -- the misclassification error is going to basically eliminate the observed risk estimate to the degree that basically you're going to miss a risk estimate entirely by the degree of error, that just the way people filled out the questionnaire is going to do it.

13:41:21

13:41:36

So basically in the AHS study, the exposure misclassification is basically going to make it impossible to see a relative risk of 1.5 in the first place.

Q. And, in fact, with the AHS article in 2017, we actually have a bit of both; right?

13:41:54

A. Yeah.

Q. We have poor imputation issues, and we have misclassification; is that right?

A. Well, I didn't get a chance to talk about the imputation error, but just the first -- we have misclassification error twice. We have the misclassification on the baseline interview which was measured at 10 percent or at least 10 percent, which is probably enough to obviate the risk to underestimate or eliminate the risk of 1.5 in the first place. Then

13:42:04

13:42:21

you're interviewing them a second time and getting a second misclassification error, then the point of the imputation, which is another error that we haven't talked about yet, but that's adding a third error.

13:42:38 So between all the errors, which are all going to be conservative, as I said, they're all going to reduce the observed risk ratio to 1 or below 1, so you're not going to see anything. That's why I think that the AHS study is really, to a large degree, uninterpretable

13:43:01 and really doesn't give us any information with regard to the association between glyphosate and NHL.

Q. Now, Doctor, AHS didn't just look at glyphosate; right?

A. No.

13:43:14 Q. And it didn't just look at NHL?

A. No. It looked at the basically multiple, multiple herbicides and fungicides and other things, and it also looked at the basically multiple, multiple, cancers, among them NHL.

13:43:30 Q. Just to be clear, would it ever be appropriate to call the AHS study, either the 2005 or the 2017 version of it, a "non-exploratory" study?

A. I don't know the term in this context. I mean, it's whatever it is. It's a study.

13:43:52 Q. I guess the question is: If someone were to say

all the case control studies they're exploratory, but the AHS, that's specifically glyphosate, would that be accurate?

A. Well, I suppose the last study is specific to glyphosate, because it only analyzes glyphosate as the exposure.

Q. But the AHS itself isn't about glyphosate?

A. The AHS study itself is not specific to glyphosate.

Q. So in all those case control studies that the authors had just published just the glyphosate results, then it would itself be a glyphosate-specific study; right?

A. Yes.

Q. All right. Now, because there was other pesticides tested in the AHS, wouldn't it be possible to see how the AHS did with other pesticides that we know cause cancer?

A. Absolutely.

Q. And I believe you prepared a demonstrative for that; is that right?

A. Yes.

MR. WISNER: Permission to publish, your Honor, Demonstrative 1034?

THE COURT: Any objection?

MR. LOMBARDI: No objection, your Honor.

THE COURT: Very well. You may proceed.

Q. BY MR. WISNER: All right. Doctor, we're looking at Exhibit 1034.

13:45:06 Do you see this, Doctor?

A. Yes.

Q. And this is from one of your reports that you prepared in this case; right?

A. Yes.

13:45:12 Q. Walk us through what we're seeing here.

A. Pardon me?

Q. Tell us what we see.

A. Oh, I'm sorry.

Q. What does this show us?

13:45:18 A. This is a table which looks at the -- basically, the results from the AHS study, and it's listing five pesticides or herbicides that were evaluated in the AHS study. And you can see the list in the first left-hand column, DDT, et cetera, et cetera, with glyphosate itself 13:45:42 on the bottom in bold. And you can see in the second column how they were each classified in the IARC classification, and you can see each of these is either a Class 1 or Class 2A carcinogen according to IARC and all of them being positively associated with NHL. So 13:46:06 basically they're all putatively like glyphosate.

And now if we look in the last column how the AHS study evaluated them or whether -- they were all evaluated by the AHS study. And while the AHS study did find an association between DDT and NHL and between lindane and NHL, it did not find an association with glyphosate as we know and as we're now saying, but it also missed diazinon and malathion, which are two other known carcinogens, 2A carcinogens, for NHL.

13:46:29

So basically, what we can say is that the AHS study -- I'll use the word "screwed up," not just once, but screwed up for several known 2A carcinogens. So it's not singular. It's not the only thing it missed. So we can say that the AHS study is, you know, insensitive or has problems and doesn't always -- it's not a perfect study in terms of being able to pick up 2A carcinogens that were identified previously. So the fact that it missed glyphosate is not remarkable. It goes along with its failures in other instances.

13:46:50

13:47:17

Q. All right. Doctor, we got ten minutes left. So let's end with Sir Bradford Hill. Who is Sir Bradford Hill, quickly?

13:47:37

A. Sir Bradford Hill was a statistician in the 1960s in Great Britain, basically an early epidemiologist, an early cancer epidemiologist involved in tobacco and lung cancer. These are the days of when

13:47:55

A. Yes. But that's -- that may or may not have anything to do with the glyphosate, but I'm talking about in the studies and in general.

And consistency is something I alluded to earlier, which is basically from the Forest plot, which is across the board in multiple studies, no matter how -- the studies that were done in different context, different populations, different countries under different circumstances, some of the studies were what are called a population-based context. Some of them were done with registries. Some of them were done among farmers.

But across all the studies, they were consistently positive -- or I say positive results. That's consistency. None of them, as I showed, were across -- were on the other side of the -- of one, so the results are consistent. That's a very important -- that's a very important criterion in causal associations. And so again, I gave it a fair high score, not quite four plus.

Dose response, you like to see a dose response. The more you're exposed, the higher your risk. Not all the studies assess this, but two or three of the six studies that were on that board did look at it, and they showed dose response relationships that those who were

exposed more had a higher risk of getting lymphoma. So I gave it a 2 to 3-plus which, again, is moderate or more than moderate but not super high 5, but I think there is certainly grounds for dose response associations here in relationships.

13:52:37

Biological plausibility, so, again, is there a biological reason or basis for assessing that glyphosate causes non-Hodgkin's lymphoma? So you've heard testimony from Dr. Portier -- and I'll leave it at that -- and the IARC Monograph discusses it at great length and gives it a high value, so I gave it a high score, and I won't discuss that at length. But certainly the biological plausibility that there are mechanisms by which this agent can cause malignancy, so that's biological plausibility.

13:52:52

13:53:11

Strength of association, strength of association is how strong is the relationship between the two. So here I would say it's modest, we're talking about a 1.5, not a 10 like in tobacco and lung cancer. But that's modest, so I didn't give it a very high score. But it is what it is.

13:53:23

Finally, there's a criterion called specificity. Specificity doesn't always come up in causal associations. We often ignore it, but here specificity is a very interesting one which applies in glyphosate and

13:53:38

non-Hodgkin's lymphoma, which is that as in the AHS study and in other studies, they looked at the relationship between glyphosate and multiple cancers.

There are multiple studies of glyphosate and every other cancer on earth: Prostate cancer, breast cancer, colon cancer, whatever you like. All the other studies are negative. I mean null, clearly null. And if you would do Forest plots for them, they would show up, you know, nicely distributed across 1 the way they should randomly associate across 1. The only one that comes up with a Forest plot that looks like the Forest plot we showed is NHL -- glyphosate and NHL. Very specific, it's NHL. All the time, it's glyphosate and NHL. That's specificity.

So it comes up as a powerful marker that whatever you do, it's NHL. So specificity in this particular instance applies, and I think that adds validity to our consideration that causality truly applies in this particular association, and that it's -- that there's truly a causal association and that's my ending conclusion and -- with regard to all of this is that there is indeed a causal association between glyphosate and NHL.

MR. WISNER: Thank you, sir.

No further questions, your Honor.

original.

Q. Okay. So what you did was you read the IARC Monograph which summarized papers?

A. Along with going back and looking at some of them. I'll confess I did not read every single one in depth, as I did later.

Q. You read a couple of them; right?

A. A few of them.

Q. Before you came to your conclusion; right?

A. That is correct.

Q. So if IARC was wrong in the way they summarized the papers, then your opinion could have been wrong because you relied on IARC; right?

A. And if I did, then I would have withdrawn from being a witness, because, yes, I do have integrity and I wouldn't have sat up there and lied after swearing.

Q. And so --

A. But, you're correct, I did not read every paper in depth at that point in time.

Q. And so, Doctor, let me just ask you a few points about glyphosate now that you have -- I mean, you've studied -- over the course of this case, you've studied glyphosate and the epidemiology certainly more than you did before this case; right?

A. Yes.

A. I wouldn't know.

Q. Well, wouldn't you say that every disease has a set of causes so that you would say almost perforce one would have to say that every subclass of disease has its
14:06:02 set of causes?

A. That's a complex question. And my answer is that by the definition that you're using for subtypes, that doesn't necessarily apply, because a subtype -- every disease splits into an absolute panoply of
14:06:25 multiple, multiple subtypes. There are more than 60 types of breast cancer. There are more than 60 types of colon cancer. And if you would split and lump into 60 types every disease, you would know absolutely nothing about any disease if you're going to argue that each one
14:06:44 has its own spectrum of causes or outcomes. To some degree, it is true that each one has a unique risk factor or a unique prognosis or a unique treatment, and to some degree one can make universal statements or integrated statements across the -- across the integrated group.

14:07:12 We talked about non-Hodgkin's lymphoma as a group. We treat them as a group. They all respond to the same -- for the most part, most of them respond to the same treatment, despite the fact that there are, as you say, 60 subtypes. By your definition, there should
14:07:30 be 60 different treatments for non-Hodgkin's lymphoma and

A. The confidence interval is a standard part of how you assess the risk estimate and it's always given together or it should be always given together with the risk estimate so that someone can assess the confidence with which they can look at that estimate.

14:38:17

Q. Okay. And when you're dealing with confidence intervals, you say that a result is not statistically significant if the bar overlaps 1.0; correct?

A. Yes.

14:38:33

Q. So, Doctor, in the Forest plot that you put up here, every single bar crosses 1.0; correct?

A. Yes.

Q. They are not statistically significant results; correct?

14:38:48

A. Yes.

Q. And, Doctor, from your point of view, you, you, Dr. Neugut, would not label an exposure as being associated with an outcome unless there is a finding of an increased risk that is statistically significant;

14:39:06

correct?

A. Why do you say I, I, I, Dr. Neugut?

Q. Because I'm asking you the question.

A. Oh. Again, if we're talking about one single study and only one study had ever been done on glyphosate

14:39:27

and non-Hodgkin's lymphoma, then you would probably be

correct. But if we're looking at a multiplicity of studies, as we are here, and they are all positive and some of them are pretty close to one, then I would say that that statement is not necessarily accurate.

14:39:49 And I would also say that, at least in more recent epidemiologic methodology, that the concept of statistical significance is becoming more flexible and not relying on P -- in .05 as a rigid tool for assessing statistical significance.

14:40:14 Q. Okay. Doctor, let me -- I'm going to ask you the question very precisely here.

A. Uh-huh.

Q. You would not label an exposure as being associated with an outcome unless there is a finding of

14:40:26 an increased risk that is statistically significant, correct?

MR. WISNER: Objection. Asked and answered. Improper hypothetical.

THE COURT: Overruled. You may answer.

14:40:37 THE WITNESS: It would depend on the circumstances.

Q. BY MR. LOMBARDI: Okay. Did you get asked that question under oath and give a different answer?

A. Again, I would have to say I don't recall.

14:40:50 Q. Okay. Let's look this time at a deposition from

You were asked this question and gave this answer under oath at your deposition; correct, Doctor?

A. Yes.

Q. "You would not label an exposure as being associated with an outcome unless there is a finding of an increased risk that is statistically significant; correct?"

Your answer was: "That's correct."

MR. WISNER: Again, objection. This isn't a -- hold on, Doctor.

THE WITNESS: And if that's the question, then my answer is twofold. One is, first of all, you have the metaanalysis, which is statistically significant. And, secondly, as I said before, if we're talking about a single study, that's accurate, but over the course of multiple studies, I would not say that that is -- that that would be my feeling. And if you're talking about it in the context of these studies, there are statistically significant findings in these studies as well aside from the overall findings.

Q. BY MR. LOMBARDI: Okay. Is that the answer you gave under oath, Doctor?

A. That is the answer I gave under oath.

Q. Thank you, Doctor.

Another area that epidemiologists consider when

of the National Cancer Institute article from 2018. You decided not to use that one as well; correct?

A. I explained that in my direct testimony this morning, so -- because I think that it's not up to the standards of being included.

Q. And we'll talk about that study in just a minute, Doctor. But as you look at this Forest plot and as you consider what you've seen in your review of the epidemiological literature related to glyphosate, it's true, isn't it, that there is no odds ratio anywhere in the epidemiological literature that reports for glyphosate and non-Hodgkin's lymphoma and adjusted odds ratio positive association that is statistically significant? That's true; isn't it?

A. First of all, I did not make up this metaanalysis. This is from a published study. So --

Q. I'm actually just asking about your knowledge. We can take this off the screen so it won't be a distraction. I'm asking your knowledge based on the epidemiology you've looked at.

A. De Roos.

Q. Okay. Let me ask you the question again just so we've got it clear.

Doctor, there is no odds ratio anywhere in the epidemiological literature that reports for glyphosate

and non-Hodgkin's lymphoma an adjusted odds ratio positive association that is statistically significant; correct?

A. That's not true.

15:22:32 Q. Okay. Could you refer to -- you were asked that question under oath, weren't you? Let's go to your deposition, your August 7th deposition at page 150.

MR. WISNER: Objection, your Honor. Sidebar.

(Sidebar.)

15:23:00 THE COURT: August 7th?

MR. LOMBARDI: Your Honor, page 158.

THE COURT: 158?

MR. LOMBARDI: Yes. Line 23. I read to him the exact question that he was asked at his deposition.

15:23:22 MR. WISNER: So he actually issued an errata correcting that sentence and he was cross-examined at length in Daubert where he explained he misunderstood the question. So he has to show the errata at the very least.

15:23:38 THE COURT: He corrected this?

MR. LOMBARDI: No, I don't have to show him the errata. He can show it to him. This is his sworn testimony. He corrected it after he realized it hurt his side after the Daubert hearing.

15:23:51 MR. WISNER: After he realized it was false,

MR. LOMBARDI: No objection.

Q. BY MR. WISNER: Mr. Lombardi raised an issue about how this De Roos study in 2003 was looking at studies in the 1980s. Do you remember that issue?

16:10:12 A. Yes.

Q. The 1980s, that doesn't have the problem change of Roundup use, does it?

A. No.

Q. So by actually focusing on earlier exposures

16:10:23 where it's more constant, you're actually able to parse out a difference?

A. It's easier.

Q. And that De Roos 2003 study, the one that has a 2.1, if this was the proper 2.1 this would be

16:10:41 statistically significant; right?

A. Yes.

Q. And that adjusted for like 69 pesticides, didn't it?

A. Yes.

16:10:46 Q. So even after adjusting for pesticides, studying a population that have consistent exposure, what did the results show?

A. Significant increase in glyphosate association with NHL.

16:10:58 Q. Now, Doctor, no one has said, not Dr. Portier

nor you, that the epi in this case is sufficient to show causation; correct?

A. That's correct.

Q. Would it be even remotely scientifically correct to just look at the policy?

16:11:16

A. No. I mean, not to make a causal link based solely on the epidemiology.

Q. You have to look at the totality of the evidence; right?

16:11:27

A. That's what I showed in the Bradford-Hill criteria at the end of my direct testimony, that you have to incorporate the dose-response relationship, the biological evidence like the toxicology that Dr. Portier spoke about. You have to think about it, you have to look at things, like I said, the specificity and the other factors, consistency the strength of association, et cetera.

16:11:49

Q. Now, you recall Mr. Lombardi raised some issues that IARC isn't doing a risk assessment; it's doing a hazard assessment. Do you recall that?

16:12:07

A. Yes.

Q. Now, a hazard assessment that's trying to answer the question that something causes cancer; right?

A. Yes. Sure.

Q. And after you decide that yes, sure, that can

16:12:16

EXHIBIT 6

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Friday, July 20, 2018, Volume 13, Morning Session, before the Honorable Suzanne R. Bolanos, at 9:17 a.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965317A

Pages 2755 - 2877

tell them a little about yourself?

A. Sure. My name is Chadi Nabhan. I'm a hematologist and medical oncologist. I've been so for the past 20 years. I live in Chicago in the northern
09:36:21 suburbs. I have twin boys turning 11, going on 25. So I'm sure you -- you can you understand the challenges.

Q. It's probably good to get at least a little break from them; is that fair?

A. Yes.

09:36:39 Q. You mentioned you're a hematologist medical oncologist. Do you specialize in any type of cancer?

A. Yes. I've focused my research and my clinical efforts on lymphoid malignancies and leukemia. I've had a small practice. Close to 15 percent of the patients
09:36:55 I've seen have prostate cancer. But the majority of my practice, with lymphomas and leukemias.

Q. When you say "lymphomas," does that include non-Hodgkin's lymphomas?

A. Yes. So Hodgkin lymphomas and non-Hodgkin's
09:37:07 lymphomas. Those are the two major types of lymphomas. And I specialize in both.

Q. I want to just run through, kind of, your educational background. You received your degree -- medical degree in 1991; is that correct?

09:37:18 A. Yes, in 1991. And this was followed by two

well as the fellows, to make sure the clinics are run on time, the educational agenda is being done properly and, you know, that sort of thing.

So I did a lot of administrative work for the fellows at the time.

09:40:11

Q. And were you actually treating cancer patients during your fellowship?

A. Yes. So my fellowship was in 1999 through 2002. And part of the fellowship training is you actually start treating cancer patients. So you have three half days of clinic, in general, as a first year. Second and third year, you have a little bit less of clinical time. So usually two half days. And you do more research.

09:40:23

So I did see -- started seeing cancer patients specifically in 1999. But, you know, in internal medicine residency, from '95 to '98, you do have a lot of oncology rotations. That's how, actually, I became fascinated by oncology. But obviously it was general internal medicine at the time.

09:40:42

Q. And you've been doing it ever since?

09:41:00

A. Yes.

Q. Are you Board-certified in any specialties?

A. I'm Board-certified in hematology, oncology and internal medicine.

Q. You are licensed in the State of Illinois; is

09:41:09

throughput for patients that come in in making sure that the patient experience is actually good, but at the same time trying to make sure that, you know, the care is being delivered in a very concise way between various attendings and various faculties.

09:43:59

Q. While at Advocate Lutheran and University of Chicago, were you treating non-Hodgkin's lymphoma patients?

A. Yes. As I said, my -- again, the majority of my practice was focused on lymphoid malignancies. So non-Hodgkin's lymphoma, Hodgkin lymphoma and some forms of leukemias.

09:44:10

Q. Can you give us an estimate as to how many non-Hodgkin's lymphoma patients you'd be seeing per week?

A. It's very tough. I think I saw more non-Hodgkin's lymphomas -- more lymphomas in the University of Chicago versus the Advocate system. I would say on average would be somewhere between 30 to 40 a week. Obviously this is not new patients. It's all patients. Some of them are returns and follow-ups and others are new. And these are all types of lymphomas.

09:44:26

09:44:42

Q. And that 30, 40, was that at University of Chicago?

A. Right.

Q. Did you see more or less at Advocate Lutheran?

09:44:53

A. No. About -- I mean, the total number of patients was a little bit more in the Advocate system because I had less administrative work. More administrative work at the University of Chicago.

09:45:06 But in terms of the number of lymphoid malignancies patients, about the same.

Q. We've heard some in this case about a subtype called mycosis fungoides. Did you ever treat mycosis fungoides at either Advocate Lutheran or University of

09:45:21 Chicago?

A. I did in both institutions. And I just want to make sure everybody understands that while we keep saying mycosis fungoides, it is non-Hodgkin's lymphoma. It's a form of non-Hodgkin's lymphoma. Sometimes the name might

09:45:35 mask the fact that this is a lymphoid malignancy. Especially it involves the skin, but this is non-Hodgkin's lymphoma. And yes, I have.

Q. And while you were busy treating patients, you actually went and got a Master's; is that right?

09:45:47 A. Yes. To add to the pain, I did decide to go back to school. And in 2014, I went back to graduate school, and I got an MBA in healthcare management, graduating in 2016.

Q. Why did you decide to go back and get your

09:46:02 Master's?

you when I took care of this patient that was very similar to the one we saw before.

Q. And in that teaching role in teaching the residents in a clinical standpoint, were you teaching the diagnosis and treatment of non-Hodgkin's lymphoma?

09:51:31

A. Yes. By default, I mean, this is the most of the patients I obviously see. And so that those were the patients that were seen in my clinic.

And not to brag about, but I also won an award as teacher of the year when I was an advocate, which was a good honor to receive.

09:51:51

Q. That's not too much bragging.

With respect to journals, have you ever published any journals or abstracts?

A. Yes. So I've written a lot of peer reviewed original research, original manuscripts, as well as abstracts and book chapters. In totality, over 300. And they are all listed in the résumé.

09:52:03

Q. How many of those relate to cancer, generally?

A. Hundred percent are cancer.

09:52:18

Q. How many relate to non-Hodgkin's lymphoma?

A. The majority. I would say about close to 80, 85 percent. Over the past year to year and a half, I've published a little bit in about healthcare in general that affect cancer patients, but they may not be specific

09:52:38

lymphoma, there would be no point of looking at any other subtitle, including cutaneous T-cell lymphoma.

Q. What types of materials did you undertake and actually review in rendering or reaching an opinion as to whether or not Roundup or Ranger Pro can cause non-Hodgkin's lymphoma generally?

09:57:00

A. So you really look at the literature, you know, what is published in the literature. You look at epidemiologic studies that have been published in the literature.

09:57:18

You have to keep in mind there is absolutely no perfect epidemiological studies. There's no perfection in these studies whatsoever. There are some that may be better than others, but there is no perfect epidemiologic.

09:57:33

I'm not an epidemiologist, but I can assure you there is no epidemiologist that will ever tell you there is a perfect epidemiologic study.

Nonetheless, I reviewed the epidemiologic studies. Some of them were positive in terms of association and causality; some of them were negative in terms of association or causality. So you have to look at the total body of evidence, the positive and the negative.

09:57:47

09:57:56

I reviewed some of the animal studies and

toxicology studies. I'm not a toxicologist, but again, you just try to review some of the things that were available.

And then you have to really try to put your clinical hat on. Ultimately, I don't treat numbers, I don't treat Excel spreadsheets, I don't treat P values or none of these things.

When you treat people, when you look at a patient in the eye, you're not going to look at, well, I'm sorry, this is not really a problem because the odds ratio is not over a certain limit.

From a patient perspective, as a clinician, you have to take all of this body of evidence in context of what's impacting patients, and then you have to figure out whether this is positive or negative.

So if you recall, it took me several months before I said yes. I reviewed the evidence, and I believe that there is causality before I accepted.

Q. And have you ever testified at a trial before?

A. This is my first time in trial so if I'm a little bit nervous, I apologize.

Q. In reviewing or deciding whether something can cause something, why did you review more than just the epidemiology if you're just treating humans?

A. Well, I mean, again, you just have to -- I think

to be fair, you have to review whatever is available, and you have to try -- you have to put the clinical hat on at the end of the day because, again, you are the one in front of a patient who is going to ask you these questions.

So, you know, some of -- some human studies are just not going to be perfect. So you may be able to support these human studies by animal studies that were done.

09:59:56 I mean, you're never going to find a randomized control trial where you take a hundred patients and they say I'm going to actually expose you to Roundup. And a hundred patients and say I'm not going to expose you to Roundup.

10:00:10 Q. And why is that, Doctor?

A. It is unethical. This is not something that you would do because there's a potential harm. I mean, when you do a randomized control trial, even if you don't believe that the harm exceeds whatever threshold, if

10:00:23 there's a potential harm, you can't really put patients and say, you won't be exposed, you would be exposed, we'll see what happens in two years or three years and see what happens. That doesn't happen.

And I'd like to see anybody in this room who

10:00:38 would be willing to volunteer for a trial like this.

Nobody would volunteer for a trial like this, even the manufacturer of Roundup.

So again, I think it's important to look at that in context; right? So in the absence of randomized control trials to tell you, you go into epidemiology studies, case-control studies, et cetera, and animal studies and toxicology studies.

10:00:53

Q. And that's something you would do just in your general practice for patients; right? You wouldn't just look at the epidemiology?

10:01:07

A. Yeah, I mean, sometimes in general practice you may not know. I mean, a patient can ask you a question. I mean, no physician should ever claim that they know everything. You get asked a question, and you say, you know, I'm not 100 percent sure, but let me look it up. Let me just check and -- I mean, I would hope that you one day ask a physician, hey, you know what, I'm not 100 percent certain, but look things up and I'll research for you, I'll get back to you in a couple of days. I'll give you a call.

10:01:18

10:01:33

This happens a lot because we don't claim that we know every single thing.

So it's appropriate not to know, but I don't think it's appropriate not to research and figure it out and try to come up with a conclusive answer because

10:01:45

ultimately we just -- we all have to remind ourselves what's at stake here is patients who could be involved with deadly cancer. That's really what's at stake. We're not dealing with anything short of that.

10:02:02 Q. In addition to your own review of all those materials, did you review any conclusions by any types of agencies or organizations?

A. Yeah, I mean, there was -- I mean, I presume this has been covered with prior witnesses. I reviewed

10:02:17 the IARC, obviously. I looked at some comments that came from the EPA, which I wholeheartedly disagree with.

But these are organizations that have actually looked at the evidence critically and they came up with the conclusions of association between -- of pending

10:02:40 hazard compound and cancer.

Q. And after your review of those materials, did you reach a conclusion or an opinion as to whether or not Roundup or Ranger Pro can cause non-Hodgkin's lymphoma?

A. It can cause non-Hodgkin lymphoma. It doesn't

10:02:59 you cause all non-Hodgkin lymphomas, and not every patient who is going to use the compound is going to develop non-Hodgkin lymphoma. But it absolutely can cause non-Hodgkin lymphoma.

Q. Is the same true with respect to we talked about

10:03:10 the subtype mycosis fungoides. Is that the same true

with respect to mycosis fungoides?

A. Again, remember what mycosis fungoides is, as I said, as much as we keep saying mycosis fungoides, it is non-Hodgkin lymphoma. It is non-Hodgkin lymphoma.

10:03:26 So what applies to the general umbrella of non-Hodgkin lymphoma -- and there are so many types of non-Hodgkin lymphoma, which I have always told my fellows, and I always joke with them, and I say, it's job security because not everybody is going to know all types

10:03:42 of non-Hodgkin lymphoma. That's why I was getting referrals from all over Chicago area.

But everything from an epidemiology standpoint and etiology standpoint, there are certain things that may apply to all non-Hodgkin lymphomas and certain things

10:03:56 may apply to subtypes of non-Hodgkin lymphomas.

When you look at some of the etiologic factors, that epidemiologies to T-cell non-Hodgkin lymphoma as well.

Q. And that's an opinion you hold to a reasonable

10:04:07 degree of medical certainty?

A. Every opinion I'm stating today I hold with a reasonable degree of medical certainty.

Q. We talked generally. What types of materials did you review specific to Mr. Johnson and whether or not

10:04:22 Roundup or Ranger Pro caused his cancer?

A. Well, thousands of medical records. I reviewed the medical records of Mr. Johnson's here at Kaiser, at Stanford, and UCSF, University of California at San Francisco. I reviewed some of the correspondence with his employer in terms of what has happened during his employment, a little bit of employment history, but essentially really the medical records, the treatment, and his exposure to Ranger Pro.

Q. You reviewed all those medical records, thousands of them?

A. I did.

Q. Were you able to read all the handwriting, Doctor?

A. It took many hours, and I had to get a new pair of contacts after that because my computer.

Q. Did you do anything else prior to rendering or reaching a final opinion with respect to Mr. Johnson?

A. Well, I also had a chance to meet him in person. Mr. Johnson was able to fly to Chicago, and we met in October of 2017. And we talked for an hour, two hours about his case, his condition, what he has gone through, as well as the chance to do a brief physical examination.

Q. Is that the type of meeting consultation and examination you would have done generally for a patient of yours?

what it currently is. It doesn't change my ultimate impression of the prognosis; it just probably shifts the curve differently.

Q. After all of your review and your examination and your meeting with Mr. Johnson, did you reach an opinion to a reasonable degree of medical certainty as to whether or not Mr. Johnson's, specifically his non-Hodgkin's lymphoma, was caused by his exposure to Roundup and Ranger Pro?

10:10:18 A. Roundup and Ranger Pro are a major contributing factor to the development of Mr. Johnson's cutaneous T-cell lymphoma or mycosis fungoides.

Q. You said major. It's a substantial contributing factor, in your opinion?

10:10:39 A. Yes.

Q. Maybe we should take a step back. We've heard a lot about non-Hodgkin's lymphoma, and it sounds like you're the one to ask. Can you just describe: What is non-Hodgkin's lymphoma?

10:10:47 A. You know, I'm going to step back and just explain what cancer is in general. Just in general; right?

Cancer is overgrowth of cells. So every organ in our body, every single organ in our body is composed

10:11:06 of cells. If these cells grow in an uncontrollable

indolent. It is behaving in an aggressive manner. It is not responding very well to therapy, and even with the treatments that he has responded to, the response duration is short.

10:20:02 You would like to have someone who responds to treatment and go on for one to two years, not requiring any therapy. And then they come back maybe, and then you do another treat, and it just goes back for two years and so forth. This is not what's happening.

10:20:17 So generally speaking, it should be indolent, but his particular case is far from indolent.

Q. And if we look at the demonstrative here, I've highlighted mycosis fungoides. That's just one of those 70 subtypes; correct?

10:20:30 A. Yes.

Q. That's a T-cell lymphoma?

A. Yes. In fact, yeah, you will see -- if you scroll, you will see that it's listed see here, mature T and NK neoplasms. So it is under T-cell lymphoma. So

10:20:42 from here on, in the second part of the table and so forth. So yes, it is a T-cell lymphoma.

Q. And I want to take a step back to something you said earlier with respect to reviewing epidemiology for all of these different subtypes.

Do we need actual epidemiology on subtypes to

know if it causes cancer?

A. You know, we would like to if we can. I mean, at the end of the day it would be wonderful if we are able to do many epidemiologic studies for every single subtype of these 70 types of non-Hodgkin lymphoma.

10:21:12

The reality is number one, we can't, for a couple of reasons. Because as I told you, the classification has changed. So how do I know that if the type of disease that I thought I was looking at in 2005 is the actual disease. Because my ability to diagnose that disease has changed. It's not actually the same. So the accuracy is not going to be there.

10:21:31

At the same time as I told you, when you look at specific etiology or causality or contributing factors, you can, from an epidemiologic standpoint, look at the entire category of diseases in its entirety as non-Hodgkin lymphoma.

10:21:49

No one will be able to tell for every single subtype design specific epidemiologic studies, because the classification has changed. The classification has changed.

10:22:07

This is 2016. I promise you it's going to change in the next couple of years. You know, we have in December -- every December we have the American Society of Hematology meeting coming up in December, and I'm

10:22:21

speaking at that meeting. And you will see some new data that tell me we can even diagnose differently. So you can't. And I gave you an example of breast cancer or prostate cancer that we study the etiology differently.

10:22:37 Now there are some studies that attempt to do that. I mean, there are some studies that looked at specific categories to see if, you know, you're able to link an occupation to a particular subtype and so forth. And these studies are excellent, and they're commended, you know, the authors to be able to do this.

10:22:52 But I don't think it's a realistic expectation to say I'm not going to believe the epidemiology literature because it did not look at this specific subtype. Because that subtype did not exist ten years ago so how could they look at it?

10:23:08 Q. So with that said, how did that affect your review of the literature in this particular case when you're trying to determine out can Roundup or Ranger Pro cause cancer?

10:23:20 A. It did not change my conviction.

Q. So you can rely on the epidemiologic studies of non-Hodgkin's lymphoma generally?

A. And you should.

Q. And that's what you did?

10:23:29 A. Yes.

And frankly, a lot of these studies -- and you're going to hear a lot about odds ratios and P values and all of these things, but how would anyone feel if you are talking to a physician and the physician said you know what, the P value in the study of this thing that you were telling me about is not significant. I don't -- I'm not going -- I'm going to dismiss this because the P value is not significant.

10:41:06

Not every single thing that is clinically significant has to be statistically significant. The statistics are numbers. These are numbers. Somebody many years ago said in order for us to believe that statistical significance is appropriate, the P value, it's random. It has to be less than 0.05. So if it's less than 0.06, then it's not -- it just doesn't work like this when you're talking to patients.

10:41:20

10:41:40

So the American Statistical Association actually has a statement, and that statement says: Not every single thing that is clinically significant has to have a P value less than 0.05. And vice versa. Not everything, single thing that is statistically significant may have any meaning to the clinic. It may have no impact to clinic. And I have examples of both.

10:41:59

But if the folks who are the statistics, the American Statistical Association comes out and says, you

10:42:14

know what, not every single thing has to be about the P value, we have to take things in clinical context, how what we see affects patients. Because ultimately we are clinicians. We're treating patients; we're not treating Excel spreadsheets.

10:42:31

Q. And in looking at those studies, then, are you looking at things such as dose response or, you know, how big of a risk it is, is it doubling or more?

A. Yes. You look at that, and there are several studies that I looked at that doubled the risk of developing non-Hodgkin lymphoma.

10:42:45

Q. And what were those studies that you reviewed and said these are actually showing a fairly large risk?

A. There's a study published by McDuffie and colleagues in 2001. There's another one in 2003 by De Roos and colleagues. There's another one by Eriksson and colleagues that also published in 2008. All of these showed doubling the risk.

10:43:01

And there are some others that didn't show doubling necessarily, but they still showed there's an actual risk. It may not have been doubled, but again, metaanalysis showed, you know, doubling and a half of the risk.

10:43:19

And you look at the trend. You look at, you know, what is the actual trend that you are seeing. At

10:43:31

the end of the day, it may not always be statistically significant, but the trends don't lie. Because again, all of these P values is a matter of what? Is a matter of numbers. Is a matter of number of patients.

10:43:47 So if I'm able to find something that is statistically significant with a low number of cases, that is very meaningful; right?

Q. Very meaningful to you as a clinician actually treating patients?

10:44:00 A. Absolutely. If it didn't take me thousands of patients to find something statistically significant and I was able to find something statistically significant with 20 or 30 cases, do I dismiss that? No. In fact, the power of this is significantly high because I didn't

10:44:16 need large numbers to show statistical significance.

Q. Rather than going to the actual studies, and we've already seen those and talked a lot about those, I just want to highlight what you had mentioned. You mentioned the De Roos of 2003; is that correct?

10:44:29 A. Yes.

Q. And what did that show with respect to the risk estimate?

A. So you will see that it says 2.1. So it doubles the risk. And this study adjusted for other pesticides

10:44:45 exposure as well as other factors.

Q. And that's one of the studies that you specifically said that you relied on maybe more than others because of that doubling the risk; is that right?

A. Yes. Again, I looked at all of the studies, but you know, anything -- it will catch your attention when you see these higher numbers.

10:44:58

You don't -- in my view as a clinician, I don't think you need to see all of these high numbers all of the time. To me, it's -- you know, when you're dealing with human life, when you're dealing with patients with cancer, I don't need to see triple or quadruple the risk for me to catch my attention. Any type of risk is important. Because we're all at the end, we're all current or future patients, at the end of the day.

10:45:12

10:45:26

So but, you know, doubling the risk obviously catches my attention.

Q. And you mentioned McDuffie as well?

A. Yes, I did.

Q. It says something here. It looks like greater than two days. What does that mean?

10:45:34

A. It just -- this study looked specifically at patients who were exposed -- unexposed, as you see, or exposed less than two days or more than two days. And if you're exposed more two days, you also have double the risk of developing non-Hodgkin lymphoma.

10:45:51

Q. And the last one I believe you mentioned was Eriksson; is that correct?

A. Yes.

Q. Let's go to Eriksson. Here's the chart from IARC with respect to Eriksson. Is this the Eriksson study you're referring to?

10:46:13

A. Yes, it is.

Q. And I do want to direct your attention -- I put a random highlight on there. But why don't we turn your attention down to the bottom the chart.

10:46:28

Do you see that, Doctor?

A. I do.

Q. It says T-cell lymphoma; correct?

A. It does.

Q. What's the risk estimate there for T-cell lymphoma?

10:46:35

A. It says 2.29.

Q. But to be fair, that's not statistically significant; correct?

A. It's not.

10:46:45

Q. What does it mean by unspecified NHL in Eriksson?

A. You know, this -- and again, I will always commend authors for trying to subclassify the type of lymphoma. As you see here, these authors, to their

10:47:00

credit, they went ahead and they said let's take a look at the subtypes of lymphomas at the time that they published and see if we see any particular trend and so forth.

10:47:12 And look at this. It says unspecified non-Hodgkin lymphoma. It just tells you that you can't -- you can't make that diagnosis accurately all the time. And that's exactly why you cannot have an epidemiologic study for every single subtype of

10:47:26 non-Hodgkin's lymphoma. It's just simply impractical, not doable. It's never going to happen.

And so for the unspecified, which some of them could be T-cell, some of them could be B-cell, the risk is five times, five times, 5.63. And again, I don't --

10:47:44 as I told you before, I don't necessarily need to see the subclassification. This is not something I necessarily need to see. All what this tells me is the challenges in making the diagnosis. It actually illustrates that very nicely.

10:47:59 Q. Okay. And does Eriksson actually show a dose response, the more you use it, the likelier you develop cancer?

A. It does. If you please highlight "more than ten days per year use," you'll see that these authors looked

10:48:13 at less than ten days per year and more than days, and --

yeah, and more than -- more than -- no. The one on top. It's more than ten days.

Q. It's -- that's the next one.

A. Yeah. So it's more than ten days. It says 2.36, so more than double the risk.

10:48:28

Q. I'm learning as I go here, Doctor.

A. I told you anybody can be a lawyer.

Q. You're right about that. You sound like my wife.

10:48:42

I do want to direct your attention down here. It says, "NHL, 1 to 10 years and greater than 10 years." I just want you to remember this. We're going to come back to this, Doctor, with respect to Eriksson. Okay?

A. Sure.

10:48:54

Q. If I don't get there, you remind me.

How many of these actual studies studied mycosis fungoides specifically?

A. To my knowledge, none of these studies looked specifically at cutaneous T-cell lymphoma, for the many

10:49:10

reasons that were decided and listed.

Q. And for these many reasons, you still feel like you can say to a reasonable degree of medical certainty that Roundup and Ranger Pro can cause cancer?

A. Absolutely. Non-Hodgkin's lymphoma.

10:49:23

Q. Okay. We talked generally about your opinions.

I want to talk specifically with respect to Mr. Johnson.

A. Sure.

Q. You said you reviewed his entire medical chart.

A. I did.

10:49:36 Q. And you also personally examined him.

A. I did.

Q. Okay. With respect to Mr. Johnson specifically, did you take into consideration how much exposure he had prior to his diagnosis?

10:49:58 A. I did, yes. I was able to get that from him as well as from reading the charts. It's not always very easy to discern the charts, as I mentioned, in terms of dates, but to the extent I was able, I did.

Q. And it's my understanding you also came -- 10:50:16 prepared a demonstrative with respect to Mr. Johnson and his history.

A. Yeah. I mean, there are a lot of dates, lots of events. Again, I reviewed thousands of pages, but I just wanted to list, I guess, some -- just a legal bit of -- 10:50:33 you know, some particular dates that may be relevant.

MR. DICKENS: I jumped the gun, your Honor. Permission to publish Plaintiff's Exhibit 1039?

MR. LOMBARDI: And I had no objection, your Honor.

10:50:43 THE COURT: All right. Very good. But perhaps,

Roundup prior to that date.

Q. And did you consider the amount of exposure Mr. Johnson had to Roundup and Ranger Pro in reaching your decision as to whether or not it was a substantial contributing factor to his cancer?

11:09:00

A. Yes, of course I did.

Q. And how did you go about doing that?

A. I'm not a toxicologist. Again, as you know, I'm a physician, clinician that has treated patients for years, so, you know, just the simple math of asking a patient, "Tell me what you do when you mix and how do you do it?" And, you know, he told me that he would -- he -- he would spray in the morning, usually during the summer months, June, July and August. And he would spend several hours in the morning, and he told me specifically he would to that, you know, before kids come in and so forth.

11:09:15

11:09:35

And it's five locations for five schools in the school district, and it's about several hours, two to five hours every single day, about four days a week, in general. And sometimes he told me he would do the weekends. It wasn't very detailed as why sometimes weekends, why not, but he would just say, again, four days a week, every week for several months during the summer. And he did that -- again, if you look here, I --

11:09:50

11:10:08

he was diagnosed sometime in the summer of 2014, so he did that for two summers in a row.

Q. Did you reach an opinion as to whether or not the amount of exposure he had was sufficient in order to
11:10:22 cause his non-Hodgkin's lymphoma?

A. Yes, I did. And again, I mean, you know, you have to correlate things, because just one time or twice exposure, minimal exposure may not be that significant, but at least from reviewing the literature -- and some of
11:10:39 this is common sense. Again, common sense. If you smoke two cigarettes a day, you're unlikely to get a particular cancer, but if you keep smoking, smoking, smoking, you're more likely than not to increase the risk of developing a particular cancer. So, yes, there were studies that
11:10:55 suggested that the more exposure you have to Roundup, the more likely you are going to develop non-Hodgkin's lymphoma, and I think we reviewed these studies before the break.

Q. Did you consider whether or not -- or what he
11:11:07 was wearing, whether or not he was covered up when he was doing the spraying?

A. He did tell me that he would wear a Tyvek suit most of the time. He said he followed the instructions in terms of how he mixes the compound with water, about
11:11:28 50 gallons, and there was a -- he described a motor pump

connected to a hose, and so, yes, I took that into consideration.

He also mentioned every time he mixes, no matter what, he gets a lot of drifts into his face. I mean, the -- despite everything that he tried to take precautions, he did get a large risk and this exposure that hits his skin and his face, and had a couple of acute spilling events that had a lot of exposure to his skin allover that he described to me, and they're documented in the medical records.

Q. Okay. The next entry you have there is for late May, early June 2014. What happened at that point in time?

A. Looks to me that -- again, from reviewing the records, that he started developing a rash, and, again, we all know that you probably -- you're not going to run to the doctor the first time you get the rash, right? I mean, just common sense. You just try to think if things will just go away for a couple of days, maybe a couple of weeks, and then if things get worse or just don't work, you just call the doctor or the nurse and get an opinion.

Looks like sometime in -- sometimes in May or June where he developed a rash, because when he went to see one of his physicians in late July 2014, he describes that he started having a rash about a month before, so I

Q. And that was a record close in time to his doctor visits at one point in time; correct?

A. Yes. He saw the doctor in July, as you can see.

Q. Doctor, if we can put this aside. I want to talk about how you went about reaching your opinion that Roundup was a substantial contributing factor for Mr. Johnson, and we actually have a demonstrative with respect to this.

MR. DICKENS: If I can publish Plaintiff's Exhibit 1031, your Honor.

THE COURT: Yes. Any objection?

MR. LOMBARDI: No objection, your Honor.

THE COURT: Very well. You may proceed.

MR. DICKENS: And may I ask Dr. Nabhan to come down into the well, your Honor?

THE COURT: Very well.

Q. BY MR. DICKENS: So, Doctor, you discussed just generally what a differential diagnosis is; correct?

A. Yes.

Q. And can you explain that to us again?

A. Really, in any particular case, you can never be 100 percent that this is the one sole reason that is contributing or the most substantial factor in developing or in making the cancer worse. So we -- I would oftentimes have to throw everything that is possible or

plausible and then take a look at what of these factors may apply to a particular patient to a particular condition. And almost I would say it's process of elimination or process of exclusion.

11:19:21 Q. And is that something that you did in evaluating Mr. Johnson's case and whether or not it caused his cancer?

A. Yes. And I think it should be done in every case.

11:19:30 Q. Okay. So what I want to do is I'm going to hand you a marker, and I want to go through some of the risk factors and causes that you considered for Mr. Johnson, so --

THE COURT: Excuse me, Mr. Dickens, do you mind 11:19:43 pushing your exhibit a little further back?

MR. DICKENS: No problem, your Honor.

THE COURT: Okay. Very good. Thank you.

THE WITNESS: You do realize the handwriting of physicians is very limiting, so I'm now under a lot of 11:19:57 pressure.

Q. BY MR. DICKENS: Do it nice and neat.

A. I will try my best.

Q. So what kind of risk factors did you consider?

A. So, you know, I mean, the first -- the first 11:20:04 thing when a -- when a patient comes in, common sense;

right? I mean, you look at the age and race.

So I look at the age, and generally speaking, just in general, in any textbook, when you look at non-Hodgkin's lymphoma, the median age of diagnosis of 11:20:23 patients with non-Hodgkin's lymphoma is anywhere between 62 to 70, but in T-cell lymphoma, in cutaneous T-cell lymphoma, the median age is between 55 to 60, so at least for me, as a oncologist, when you meet a patient that is not within the age bracket that most patients with 11:20:47 cutaneous T-cell lymphoma or non-Hodgkin's lymphoma develop, it raises a red flag.

I mean, you know, if you -- if a woman at the age of 35 walks in with breast cancer, God forbid, a physician would have a red flag. I mean, why is breast 11:21:04 cancer developing in the age of 35? You look at genetic factors. You look at other things that may cause it, and sometimes you may not have the cause.

So for me it was a red flag. Let me just put this here (indicating). So red flag, and what I mean by 11:21:20 that is -- what I mean by this is just it warrants further investigation, right?

I mean, if somebody has a heart attack where they have all the risk factors in the world and the same age group, you may not really think about it twice, but 11:21:39 if somebody who is an athlete and exercises, doesn't

smoke and have a heart attack at the age of 38, you say, "Well, let me think. Is there other reasons?" So that's really for me, as an oncologist, what I think.

Q. Okay. We've heard some here with respect to idiopathic cancer. What does idiopathic mean?

A. Idiopathic is a word that physicians try to use so they don't appear dumb, but basically, it is like to say, "We really don't know, so it's idiopathic." So it's, like, "Wow. I have an idiopathic" -- simply we don't know.

Q. And when you say "a red flag," does that, you know, mean I'm flagging this, because maybe it isn't idiopathic? Maybe there's something there?

A. Yeah, maybe there is something in this. Again, I contrasted the example with breast cancer. We don't know all the causes, but when you have a very young woman who gets diagnosed with breast cancer, you think, you know, "This just doesn't add up. Let me investigate that further."

Q. Okay. And so were you able to rule out age as a risk factor or cause for Mr. Johnson?

A. I mean, you will see patients with younger age. All I'm saying is -- all this age told me is I can't say that just because of the aging process -- I mean, we all age, and the aging process by itself could cause some

disruption and so forth. I can't blame age on this case. That's really all that tells me.

Q. Okay. So if you can't blame age in this particular case for Mr. Johnson, you can go ahead and

11:23:03 put -- your handwriting's wonderful, but --

A. Or the marker's bad.

Q. We'll blame it on the marker, Doctor. If we can go -- just write a little bigger, for those in the back, just so they can see it.

11:23:17 A. Sure.

Q. Age isn't. What else did you consider?

A. I think the second thing is race, and I think race is important, because there are certain cancers that develop in particular ethnic -- ethnicities, in

11:23:30 particular racial groups than others. I can give you examples. There's a form of leukemia called acute promyelocytic leukemia or APL. It's more common in Hispanic patients. There is -- this type of disease is more common in African American patients. There are

11:23:48 certain cancers more common in Asians. Others more common in Caucasians. We don't always know why. We don't know how much of this is actually a surrogate for other things versus the genetic makeup of a particular race. We really don't know yet. Sometimes we do.

11:24:04 Sometimes we do not.

But this particular disease, or what we call CTCL or MF non-Hodgkin's lymphoma, is more common in African American. So it is not surprising to see -- it doesn't mean you don't see it in Caucasians, by the way. It just means it happens more commonly in this particular racial group.

11:24:18

I've taken care of many patients who are Caucasians who have this disease, but you're more likely to see this disease in African Americans.

11:24:32

Q. And I just want to point out, as I believe in opening statements, my co-counsel made an accidental misstatement with respect to mycosis fungoides, but I just want to be clear because of that. African Americans are at an increased risk; is that right?

11:24:42

A. They are at an increased risk of this disease.

Q. Other than age and race, is there anything else that you considered in rendering an opinion as to whether Mr. Johnson's --

A. Yeah, so you look at -- you look at immunosuppressive drugs, so patients who are on immunosuppressive therapies. So just to -- just to explain -- to explain: If you have somebody who gets an organ transplantation, so liver transplant or kidney transplant, they're usually put on immunosuppressant therapy so they don't reject the organ that got

11:25:02

11:25:22

transplanted into them. This immunosuppressant therapies suppresses the immune system, so patients could have increased risk of developing lymphoma in general, specifically non-Hodgkin's lymphoma, if they are on immunosuppressive therapy.

11:25:36

Q. Was there any evidence that Mr. Johnson was on immunosuppressive therapy prior to his diagnosis?

A. He was not.

Q. Anything else you considered?

11:25:47

A. You look at autoimmune diseases, and these are patients who have lupus, something called Sjögren syndrome, if you've heard about that, rheumatoid arthritis. These are diseases that actually common. They happen. And what they do, they occur because the

11:26:15

immune system of the patient is not as strong. So we call it autoimmune. It's not something that is because of drugs that you receive or -- or therapies. It's just simply a disease that affects the immune system.

And because the immune system is affected, there

11:26:33

are increased risks of developing non-Hodgkin's lymphoma. And Mr. Johnson does not have any autoimmune diseases.

Q. Okay. Anymore things that you considered here?

A. Obviously here we look at the occupation.

Q. And what was Mr. Johnson's occupation?

11:26:51

A. Insecticides/pest manager. And he was spraying,

which we just talked about excessively, with Roundup. So he had an occupation or exposure to an agent that has been determined by the International Agency of Research on Cancer as a human carcinogen. So there's nobody that could logically exclude this, and you have to put a checkmark as a possible substantial contributing factor.

Q. Now, Doctor, we said "occupation." You're not saying his actual job, though?

A. No. It's what you do with the job. As we said -- I think I gave you the example of coffee. It's not the coffee, it's the temperature. If you boil the coffee to over 150 degrees and you drink it, it's not the coffee, it's the actual temperature.

So you have to think beyond what the occupation is. It's what's the surrogate? What are you doing with this occupation?

As you know, I offer examples. Discussed night shift working. So patients who have night shift, they are at increased risk. Now, why is that? Let's think about it. Does this mean that everybody who works at night has an issue? No. It's just possible it's diet related when you are working at night. Maybe you are not exercising when you're working at night. Maybe that your circadian rhythm is completely out of -- out of context.

And, in fact, this type of evidence is making

employers figure out ways of: What can we do for night shift workers when we need? How can we make things better, in terms of exercise, switching shifts and so forth? It's not really their thing. It's -- you have to look beyond. We can't -- we can't be short-sided.

11:28:25

Q. Is there a difference here -- and you have race and Roundup. Is there a difference between risk factor and cause?

A. I mean, risk factor puts you at an increased risk of developing a particular disease. But if you don't get exposed -- I mean, in other words, could Mr. Johnson have had this disease without being exposed to Roundup? We don't know the answer to that. I mean, it could have developed in the next 10 years or 15 years. Nobody has a crystal ball.

11:28:37

11:28:55

But you can be very certain that if he had not been exposed, he would have not had it today.

Q. Okay. So you say "very ceratin." Is it more likely than not Mr. Johnson would not have cancer had he not been exposed to Roundup?

A. Today, yes.

Q. With respect to his occupation, did you look at his full occupational history from, you know, his adult life?

A. To the extent he was able to remember and told

11:29:16

me. He did work a little bit in the school where I think he cleaned the school and bathrooms and so forth. He worked in a winery at some point. That's really what I can recall. And he took several years off to take care of his grandmother. I recall that.

11:29:39

Q. Do you -- you mentioned Roundup here. Did you take into consideration possible other occupational exposures, other chemicals or pesticides or anything else?

11:29:49

A. But he was not exposed to any other pesticides. I think he -- what we know is with certain occupations, that -- farmers, for example, and agricultural workers are at increased risk. Nobody -- I mean, everybody knows that. But, again, it's not the fact that you're farming. It's what you do on the farm is really what matters.

11:30:07

Q. So you did consider other occupational exposures?

A. Yes. And he doesn't have any.

Q. All right. So why don't we write "other occupational exposures" underneath.

11:30:18

A. (Witness complies.)

Q. Now, you said he doesn't have any. Were there any other type of herbicides that he used, in addition to Roundup, during his job at the school?

11:30:36

A. To my knowledge, none.

Q. What else do we have on your differential diagnosis?

A. Well, I mean, I think, obviously, you know, from sun exposure standpoint, I don't believe that sun exposure has a role in developing this type of lymphoma.

11:30:49

In fact, we treat this type of lymphoma with UV -- with light therapy, with forms of radiation therapy. Mr. Johnson had several courses of radiation therapy. So it's not the type of -- it's not the other skin cancers. Not the melanomas.

11:31:07

Again, this is not skin cancer. This is -- it's in the skin, but it's lymphoma. It's like the lymphoma that we talked about earlier. Extranodal could affect any organ in the body.

11:31:20

So it's not the melanomas or the squamous cell or the basal cell that could occur from the sun. This is not sun exposure.

So I can put "sun" here, and I can actually cross it.

11:31:32

Q. You mentioned squamous cell carcinoma. Isn't it true Mr. Johnson at one point had squamous cell carcinoma?

A. He did have squamous cell carcinoma. I believe in the right knee. And he had surgery for this. These

11:31:45

are completely two separate entities. And I don't

believe the squamous cell carcinoma is related to Roundup.

Q. Can viruses cause non-Hodgkin's lymphoma?

A. Usually you put viruses, in general, for non-Hodgkin's lymphoma. There are certain subtypes of non-Hodgkin's lymphoma that are affected or could be caused by viruses.

HIV positive patients are at increased risk of developing non-Hodgkin's lymphoma. There are some forms of non-Hodgkin's lymphomas that could occur because of exposures to certain viruses.

There's the human herpesvirus 8, or what we call HHV8, and so forth. There's one bacteria, Helicobacter pylori. I don't know if you know about this. But it's H. Pylori. It's usually in the stomach. People usually treat it with antibiotics. This is well known to be causing a disease of lymphoma called M-A-L-T or MALToma. It's a B-cell lymphoma. It's associated with headache or back -- MALToma, yeah.

And, you know, there's a form of virus called HTLV-1. This happens more in the Asians and folks in the Caribbean. It is implicated with T-cell lymphoma.

But, again, Mr. Johnson actually was tested for all of these viruses. Some of them I wouldn't have tested myself, because there's clearly -- this is not

adult T-cell leukemia. I wouldn't have tested for HTLV, for example. But he was tested for that. And all of the viruses came back negative.

Q. Anything else you considered?

11:33:26 A. No. I mean, I think -- you know, I don't recall there's -- to my knowledge, there is no evidence that alcohol or tobacco are associated with this type of lymphoma.

Now, I will never endorse tobacco. But to my 11:33:42 knowledge, tobacco does not actually cause this particular type of lymphoma. And Mr. Johnson is/was never a heavy smoker. And alcohol is not implicated also with this type of disease.

So I usually don't put them under non-Hodgkin's 11:33:58 lymphoma, frankly, because, again, as a lymphoma specialist, I don't actually believe that they are implicated at all. So I didn't even list them.

Q. Fair enough.

So after you did your whole differential 11:34:08 diagnosis, you put everything in and ruled everything out, what were you left with as possible risk factors or causes?

A. Race and Roundup.

Q. And so based on your review, you can say that -- 11:34:22 can you say that Roundup was the most substantial

contributing factor for Mr. Johnson's --

A. Yes, I can.

Q. Thank you, Doctor. You can go back and sit.

Now, Doctor, I do want to address one more thing. And we'll bring up your -- your chart again.

11:34:48

Mr. Johnson's first exposure was in June 2012; correct?

A. Yes.

Q. And he was actually -- had his first rash in late May or early June 2014; correct?

11:35:03

A. Correct.

Q. Was that rash in June 2014, in your opinion, cancer?

A. Yes.

Q. So, Doctor, it was approximately two years from the time of his exposure until he got cancer. How can it happen that quickly?

11:35:15

A. Well, it can. I mean, it can. I think what you're probably referring to is something called, in medicine or epidemiology, latency period.

11:35:28

And, you know, it's basically you're trying to say, well, from the time you get exposed to an offending hazard or an offending agent to the time of developing a particular cancer.

11:35:45

There is no agreed upon latency period with

these types of exposures or anything in cancer. So it's not a binary -- and what I mean by binary, it's not like you have to be exposed five years in order for me to even be convinced. Or ten years or one year. There's no such
11:36:06 a thing. There's no such a thing when you are dealing with patients, when you are in clinic, and when you are talking to partners.

Latency periods could be short and could be long. So there's no such a thing. And we can keep
11:36:25 talking about this for the next two years. There's no such a thing.

In fact, there are so many examples of particular cancers that occur very shortly after an offending agent. They may not be Roundup or glyphosate,
11:36:42 but, again, it's analogous. It's an example; right? You can't always have the same exact example.

Q. Are those the examples --

A. I'll give you an example, if it's okay.

Q. That's what I was going to ask, Doctor.

11:36:53 A. There's a form -- there's a disease called PTLD, which is -- which stands for post-transplant lymphoproliferative disorder. Basically, think of it: A patient gets a transplant -- gets a liver transplant or kidney transplant. We just talked about that. Then they
11:37:12 are put on an immunosuppressant therapy. So that's an

offending thing that happened. This patient, before they received immunosuppressant therapy weren't on anything. They just got the transplant. And then the doctor says, "I'm going to prescribe these drugs so you don't have the organ rejected."

11:37:27

These patients could develop non-Hodgkin's lymphoma as early as one month after being exposed to this particular immunosuppressant therapy or as late as three years. And I have seen that, because, again, I actually had several clinical trials in this particular disease, PTLD. So you do see that.

11:37:42

There are patients who actually develop the lymphoma in a short period of time after being exposed to an offending hazard. Patients could develop leukemia several months after undergoing chemotherapy for something else.

11:37:57

So in non-Hodgkin's lymphoma, we give chemotherapy for some patients. And they could develop leukemia, which is a form of blood cancer, a month or two months, up to several years after, from being exposed to these chemotherapies or chemicals.

11:38:10

So, again, the examples are numerous. But at the end of the day, from a latency perspective, from the time you're exposed to something until the time you actually could develop the disease, there is never an

11:38:26

actual threshold that you have to meet and -- that's from a clinical perspective.

And as you know, the World Trade Center, after the terrorist attack, attempted to figure out how can they actually look at latency from the first responders and people who lived in that area who developed cancers after the terrorist attack because -- so they can compensate them and pay for the medical bills and so forth.

11:38:41

11:38:57

And they started looking at the different diseases that they are seeing for patients. And, basically, in their latest publication they said the latency period for these types of lymphomas is as early as 146 days.

11:39:09

So it does happen a short time or a long time. This is exactly what happens in clinical practice. As a clinician, you should never dismiss a complaint or a possibility just because you believe it has to be five years.

11:39:25

So if a patient comes in after four years, you say, "You know what, Mr. Johnson? I'm not going to listen to it. It's not five years yet. It's not related." This doesn't -- it's not how it works. It's not always this binary threshold that you need to fulfill.

11:39:40

Q. So is it fair to say that latency can vary by individual?

A. Yes, of course.

Q. If you can turn to Exhibit 820 in your binder. Do you have that there, Doctor?

A. I do.

Q. Can you identify what that document is?

A. This is the World Trade Center Health Program, which is actually the one I was just citing. It's a document that was written in October 2012 and updated in January 2015 and discusses minimum latency and types or categories of cancer.

MR. DICKENS: Permission to publish Plaintiff's Exhibit 820, your Honor.

THE COURT: Any objection?

MR. LOMBARDI: No objection, your Honor.

THE COURT: Very well.

Q. BY MR. DICKENS: And, once again, this is the 911 minimum latency and types or categories of cancer. That's the document you're referring to?

A. Yes, it is.

Q. Okay. And I'm going to draw your attention down to Number 3. It says, "Lymphoproliferative and hematopoietic cancers, including all types of leukemia and lymphoma."

Is it your understanding this includes non-Hodgkin's lymphoma?

A. Yes. I'll have to tell you, even if this document never existed, I don't care. It's what I see in clinical practice. You know, if anything, this document solidifies what you see in clinic.

So it's great, it's wonderful, that obviously it solidifies what I see. But even if they didn't say this, what I actually see in real life -- and in clinic practice, you see patients could have shorter exposure or longer exposure. But I like the fact that it at least confirms what we, as clinicians, see in clinic and in practice.

Q. Okay. So this wasn't the basis of your opinion for latency?

A. No --

Q. This just backed it up?

A. -- it was not.

Again, what you see in real life, and there are so many examples -- I cited just two. And there are tens of these examples that absolutely show time from offending hazard to development of disease or cancer could be short, could be long.

Q. I'm going to show you a slide that was used by defendants in their opening statement.

A. Yes.

Q. What's the significance of him being soaked, you know, over his whole body?

A. Your -- I mean, your exposure is now magnified significantly. I mean, it's all over your skin. So, you know, there's no -- there's no protective layer between you and an offending hazard. So, I mean, the significance is very high, because now you're -- you know, the impact of how much you got exposed is substantially increased.

Q. Do you understand that that happened on more than one occasion for Mr. Johnson, prior to his diagnosis of cancer?

A. I saw it happened twice.

Q. And I think you mentioned before, were those his only exposure, those two incidents?

A. No. These were -- to my knowledge and to my recollection, these were the two acute high-level exposure. But he was obviously exposed constantly and chronically through his job. But these were, like, an aberration. These were just out of the norm of his job.

Q. Okay. It states: "His entire body is covered in this now and doctors are saying it's skin cancer."

A. It's not skin cancer. Obviously it's lymphoma. Again, this is -- tells you obviously the misnomer that

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Friday, July 20, 2018, Volume 13, Afternoon Session, before the Honorable Suzanne R. Bolanos, at 1:03 p.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965317B

Pages 2878 - 3069

One of them was financial. And subsequent to that, he was started on additional chemotherapy in November of 2018, as you see.

Q. Doctor, have you reviewed a recent or the most recent scan of Mr. Johnson?

13:08:32

A. He had a PET scan done in June 2018. A PET scan lights up in the areas where there's actual disease, especially if it's getting worse, and when you look at the PET scan from last month, it is much more than the one before, showing progressive disease and showing the disease has taken a turn for the worse.

13:08:52

Q. Okay. And in your binder, Exhibit 1019, is that the latest scan for Mr. Johnson?

A. Yes.

13:09:05

MR. DICKENS: Permission to publish Exhibit 1019, your Honor?

THE COURT: Any objection?

MR. LOMBARDI: No objection.

THE COURT: Very well. You can proceed.

13:09:12

Q. BY MR. DICKENS: Doctor, based on this scan, it's from June of 2018, what is Mr. Johnson's prognosis?

A. You know, I'll always say I don't think any physician should ever play God. I mean, we just don't know, but clearly the prognosis is bad. He has a disease

13:09:32

that is progressing rapidly. The PET scan is showing

is that right?

A. I believe it's a substantial risk factor to causing non-Hodgkin's lymphoma in general, which would affect any of the subtypes that are listed on the table that I showed.

13:23:01

Q. Okay. But it may be the case that glyphosate is causally associated with every single type or not associated with every single type. We just don't know right now; is that right?

A. What we know, it's associated with non-Hodgkin's lymphoma, as I said. The classification of non-Hodgkin's lymphoma continues to change. But as a disease, it's a large umbrella. It's like breast cancer or prostate cancer. So we know the association between glyphosate and non-Hodgkin's lymphoma.

13:23:11

13:23:28

In a few years, if this classification I showed today changes again, it's hard for me to go and say, "Well, it doesn't cause the new classifications that were added." Because they existed. We just now knew that they -- we knew how to diagnose them.

13:23:42

All of these classifications change just by virtue of us being able to diagnose better. That's really what. They obviously were there 20 years ago. We didn't discover them. We just were able to diagnose them better.

13:23:58

Q. Okay. All right. And then there was a second one where he was wearing a backpack; right?

A. Right.

Q. Okay. So that gives us some way of distinguishing it.

14:34:42

So let's go to exhibit -- and I hope I wrote this down right, because my writing's bad. Doctor, 2294.

A. Yep, I'm here.

Q. Okay. 2294. And let's go to page 57.

14:35:08

A. Okay.

Q. And do you have that? I actually think you saw this one this morning, didn't you?

A. I think I did.

MR. LOMBARDI: Okay. Well, I'll ask to publish

14:35:20

it, your Honor.

THE COURT: Any objection?

MR. DICKENS: No objection.

MR. LOMBARDI: Okay. Let's put this up on the screen, 2294, 57.

14:35:27

And just to orient everybody, this is, again, at the Permanente Medical Group.

Q. Do you see that?

A. Yes.

Q. And it's -- the provider, the doctor, was

14:35:37

Carrie Chanson; is that right?

A. Yes.

Q. All right. And if we go down --

A. I think that's the Workers' Comp. When you have incidents, that's who you see.

14:35:48 Q. Okay. And that's probably -- is that your understanding, this incident happened, and Mr. Johnson went to the doctors that are provided through Workers' Comp?

A. Yes.

14:35:56 Q. And this is the record of that; is that right?

A. Correct.

Q. All right. And so this was -- this says --

A. It seems that they thought -- the injury date, though, it says, "April." I think the encounter file, if 14:36:08 you look, it's July 23rd, of '14. But at least they're reporting that the injury was April 2014, as you see.

Q. Yes. Yeah. Okay.

And that's about when he placed -- when Mr. Johnson placed the Mary Farmar situation; right?

14:36:25 A. I -- I honestly don't remember those dates, but I -- if you show me, I'm pretty sure that's correct. I told you the dates exactly I struggle with.

Q. That's okay. Understood.

But anyhow, he said -- he's clearly describing 14:36:37 an accident; right?

what the cause was, one category is unknown causes; right?

A. That's implied. Like I said, I prefaced this with -- I put in here the known causes.

15:24:00 Q. Now, there are people -- well, right. But if you want -- it could be -- it could be that the cancer was caused by an unknown cause?

A. Not in his condition. Not in somebody who has now been exposed to an agent of known carcinogen causing

15:24:15 non-Hodgkin's lymphoma.

Q. And you make that assumption based on your review of IARC and the literature; right?

A. Yes, of course.

Q. That you undertook after you were retained in

15:24:24 this case?

A. Yes.

Q. Okay. And so -- so you've heard it said, haven't you, that non-Hodgkin's lymphoma is idiopathic 80 to 90 percent of the time?

15:24:33 A. I have cared for patients -- hundreds of patients of non-Hodgkin's lymphoma where I've told them I don't know why the disease happens, so, I mean, I know that for sure.

Q. Okay.

15:24:43 A. But there are situations that are different.

Q. And was the trend -- did you see a trend in all --

A. Yes, there was a trend.

Q. Okay. I'll turn your attention to the next page, 1662, and the conclusion in the particular article.

15:58:11

It says, "Glyphosate was associated with a statistically significant odds ratio for lymphoma in our study, and the result was strengthened by a tendency to dose response effect, as shown in Table 2."

15:58:32

Do you see that?

A. Yes.

Q. What do they mean by that, Doctor?

A. It means that patients who were exposed to glyphosate have an increased risk of developing non-Hodgkin's lymphoma.

15:58:44

And what they actually saw is that the more exposure they get, the more likely that they are going to develop the disease. That's what they mean by a dose response effect.

Q. Okay. And in this study, there was a lot of talk about other pesticides and adjusting for those. And it's true, some farmers, some occupational workers, have multiple exposures; right?

15:58:55

A. Absolutely. It's -- I mean, again, it's -- that's what happens. You can't -- in every single

15:59:12

Q. Mr. Johnson had his first exposure June 2012?

A. Yes.

Q. So even if it was September 2013, that's more than a year; right?

16:24:26 A. Yes, it was not less than a year.

Q. And so once again, regardless of whether we're talking early May, late June 2014 or September 2013, your opinion does not change in any way, shape or form; is that right?

16:24:41 A. It does not. And I think what's also important is recognize that the disease course that this patient had was very aggressive compared to any type of TCTL, or cutaneous T-cell lymphoma, that you would read about, and the fact that it behaved aggressively would tell you that 16:25:00 the latency or that lag time is not going to be long, and this is really consistent with what we usually see.

MR. DICKENS: No further questions.

THE COURT: All right. Thank you.

Thank you, Dr. Nabhan --

16:25:09 THE WITNESS: You're welcome.

THE COURT: -- you may be excused.

All right. Ladies and Gentlemen, we're going to adjourn for today. I do have some special instructions for you on Monday.

16:25:24 On Monday, we are expecting a large attendance,

EXHIBIT 7

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Monday, July 23, 2018, Volume 14, Morning Session, before the Honorable Suzanne R. Bolanos, at 9:05 a.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965319A

Pages 3070 - 3196

okay, strike that.

So Doctor, I want to focus in on that first email we read, which was him feeling foolish about spraying chemicals at the school.

10:44:44 A. Uh-huh.

Q. Did this conversation prompt you to do anything on behalf of Mr. Johnson?

A. Yeah. You know, when he had said that he was really worried that spraying this was worsening his

10:44:58 condition or may have been causing his condition, I did write a letter to the School Board, and I requested that he not be exposed to any airborne environmental allergens as that could exacerbate his condition.

Q. And specifically that was referring to the

10:45:16 Ranger Pro and chemicals that he's talking about?

A. Correct.

Q. Do you know if at this time in March of 2015, do you know if he reached out again to Monsanto to see if there was any relationship between Roundup and cancer?

10:45:44 MR. GRIFFIS: Objection. This has been asked already.

THE COURT: Overruled.

You may answer.

THE WITNESS: I'm not familiar. I really do not

10:45:52 recall whether or not he told me about reaching out to

THE COURT: Very well.

MR. DICKENS: "Admission Number 13. Request: Admit that Monsanto has never warned any consumers that glyphosate-containing products can cause non-Hodgkin's lymphoma.

"Response. Admitted. Monsanto denies its glyphosate-containing products can cause non-Hodgkin's lymphoma.

"Admission Number 14. Request: Admit that
11:45:13 Monsanto never warned Dewayne Lee Johnson prior to August 2014 that glyphosate-containing products could cause cancer.

"Response. Admitted. Monsanto denies that its glyphosate-containing products can cause cancer."

11:45:39 THE COURT: Call your next witness, Mr. Dickens.

MR. DICKENS: Thank you, your Honor.

At this time, we call Mr. Dewayne Lee Johnson to the stand.

THE COURT: Mr. Johnson, if you'd please step up
11:45:48 here, and remain standing while the clerk swears you in.

MR. DICKENS: Your Honor, if I may approach?

THE COURT: Yes.

DEWAYNE LEE JOHNSON,

having been first duly sworn, was examined

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Monday, July 23, 2018, Volume 14, Afternoon Session, before the Honorable Suzanne R. Bolanos, at 1:28 p.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965319B

Pages 3197 - 3356

And that's what you -- you know, when you get to the laws and regulations, you learn the laws and regulations to get that license -- to get your certification.

Q. And did you get that certification?

13:54:07 A. I did.

Q. But had you been spraying Roundup or Ranger Pro before obtaining, kind of, certification or license?

A. Yes.

Q. Did you need a license or certification in order

13:54:20 to spray Roundup or Ranger Pro?

A. Well, the way that works is that, no, you don't need a license to spray Ranger Pro or Roundup. But if -- if you did, my supervisor at that time, Roy Owens, he had a license. So just like if I have a license, people can

13:54:37 spray under me. They are under my license. Just like I was under his license in the beginning, is the way he looked at it.

Q. All right. Did you spray any other chemicals -- did you spray them while at Benicia -- other than the

13:54:50 Roundup or Ranger Pro?

A. No.

Q. Prior to getting your job as integrated pest manager, did you ever spray chemicals at home or in any other capacity?

13:54:59 A. No. I used to even have my own landscaping

Pro from?

A. It was my responsibility to purchase it. I purchased it from a store in Concord called Horizon. Horizon Irrigation & Landscaping.

13:56:21 Q. Were you involved in the process of deciding to use Ranger Pro or to use that kind of an herbicide to spray for the school?

A. What I had decided is that those bottles were too small. So then that's when my supervisor suggested,

13:56:38 "Well, maybe we should get a 50-gallon drum of Ranger Pro. It's stronger anyway." So I'm, like, "Yeah. We might as well." Because other than that, we're going to keep going and buying bottles. Maybe twice a week, you know, so -- no, we don't want to do that. So it saved

13:56:50 time.

Q. So you'd buy huge 50-gallon barrels of Ranger Pro? Is that --

A. Yes.

Q. And what did you do? Would you use it right

13:56:59 from the 50-drum barrels to mix it with?

A. No. So when we get those bottles of -- we started out with the bottles of Ranger Pro. And they were just a small -- they're bigger than a gallon of milk. There must be a couple of gallons in there. Maybe

13:57:15 five. And it's, you know, a small, little bottle. And

A. Only other things that I had a little splash of -- or a -- Henry's roofing patch got on my pants, and it just -- I had to throw the pants out because it's like tar, so I couldn't get it out of my pants.

13:59:18 Q. I'm sorry.

With the Roundup and the Ranger Pro, did you receive any type of training specific to the spraying of Roundup or Ranger Pro?

A. There was a lady named Leanne Schroeder that 13:59:32 used to come from Horizon. And she would come, you know, every year. And she would sit us down at the table at the maintenance yard, and she had her little papers, and she went over some facts and some -- and some safety training and some options that you might have and things 13:59:47 like that. And what you should do and where you shouldn't spray stuff and how to protect drains. And she just gave us a little general safety training.

And at the end, you signed a paper, and she certified you as able to spray Ranger Pro.

14:00:01 Q. Do you remember anything about that training or what you were told with respect to the safety of Roundup or Ranger Pro?

A. The funny thing about it that I will never forget is she said that it's safe enough to drink. You 14:00:13 know, she told us that in training. Said, "Oh, don't

worry. It's safe enough to drink. But don't drink it, you know. And, you know, be careful. It's not something to play with. But you don't have to worry too much about it."

14:00:23 Q. Was there any discussion at those training sessions with respect to whether or not Roundup or Ranger Pro could cause cancer or any health effect to you, as a human?

A. Not at all.

14:00:35 Q. So Roundup -- well, let's talk Ranger Pro. You used more Ranger Pro. Just so we don't get confused.

The Ranger Pro that you used, did that come with any type of warnings?

A. It came with a label, you know. And they come

14:00:48 also with a safety precaution sheet, which you have to check out and have handy to show when you need to.

Q. And that -- you said it comes with a label. Did you actually review that labeling prior to spraying the pesticide?

14:01:01 A. The requirement of the laws and regulations is that you must keep that instruction manual in -- it's like a little -- I don't know how -- it's about the size of this phone (indicating), and it flips. So imagine this being a flip -- a paper that you can open up, and

14:01:17 you have your instructions and your -- and your manual.

It's a portable manual, really, of everything that's going on with Ranger Pro.

Q. And how often would you review that?

A. Every time I sprayed.

14:01:31 Q. You reviewed the label every time?

A. Every time.

Q. And why would you review it every time?

A. Because it's important that you get the same mix every time that you're looking for, because 1 percentage

14:01:42 more could kill a tree or it could kill something that you want, so you want to use the exact percentage.

And I've had that training way back in the day. I was a prep cook trainer for Applebee's, and I would train managers that were going the open up new stores.

14:01:57 So this is actually a good example, because the Applebee's manual -- I mean recipe book is like this, and bigger, right? So if you're making pico de gallo or you're making guacamole or -- you've done it a thousand times, right, you have to have that recipe out. And that

14:02:15 was a part of the rules of Applebee's, and it was something that I learned, because the managers were watching me in training, and my manager that ran the restaurant was watching, so it's just one of those things.

14:02:25 And you forget, so I just kept that with me all

Do you see that?

A. Yes.

Q. And it says it causes eye irritation.

Do you see that?

14:04:26 A. I do.

Q. And then it has some numbers there; correct?

A. Yes.

Q. At any point in reviewing the label, did you see anything other than, you know, general caution

14:04:40 information? Did you see anything else about the side effects it could cause to you as a sprayer?

A. No, not at all.

Q. Did you ever see anything in the labeling that you reviewed every time about whether or not Ranger Pro

14:04:54 was associated with cancer?

A. No.

Q. Did you ever see anything that it was associated with non-Hodgkin's lymphoma?

A. No, I didn't.

14:05:04 Q. Had you seen something, that Ranger Pro could cause non-Hodgkin's lymphoma or cancer, would you have sprayed this product?

A. I would never have sprayed that product on school grounds or around any people if I knew it would

14:05:19 cause them harm.

Q. And why is that?

A. It's just unethical. It's not what you would do. It's wrong. I have children that go to school, and I've been in schools, and people just don't deserve that. They deserve better.

Q. Mr. Johnson, didn't you keep spraying after you had been diagnosed with cancer?

A. Yes.

Q. At that point, when you continued the spraying even after cancer, were you aware that this Ranger Pro could cause cancer?

A. I wasn't aware, but I started to, kind of, have a feeling.

Q. Well, did you ever tell your employer? Did you ever ask them to stop spraying?

A. Yeah, I went to Mr. Owens, and I spoke to him about it, and it was weird. He told me, you know, "It takes, like, two years for you to get cancer from that stuff." I'm, like, "What?" I said, "You can get cancer from it?" He said, "Yeah, you didn't know?" I said, "No, I didn't know that." You know, so that was my first time finding out when he told me, "It takes years for that stuff to give you cancer." I'm like, "Oh, come on, man. It gives you cancer eventually?" So I wasn't happy about that at all.

Q. And once again, Mr. Owens was your supervisor; right?

A. He was.

Q. Did you -- and Dr. Ofodile testified she actually wrote a letter on your behalf; right?

A. She did.

Q. Did the school eventually allow you to not continue spraying?

A. After I refused to totally stop spraying. They didn't do anything until I told them I refused to spray.

Q. So once you received more information, you actually refused to -- stopped spraying this stuff?

A. Definitely.

Q. If we can keep looking in this particular document. Did you take any other precautions when you were spraying the Ranger Pro?

A. Yeah. There's something called PPE, which is your personal protection equipment. And I wore a full body Tyvek suit. I wore chemical-resistant rubber gloves, chemical-resistant rubber boots, eye goggles and a paper mask.

Q. And if you go look at the actual labeling on your screen there, there is a section with respect to personal protective equipment; correct?

A. Yes.

the forklift, and hope that it worked that day, and pull it out, and then go and get this one, wherever I had it sitting, lift it up and place it in the back of my truck, and then put tow ties and keep it in the truck.

14:26:39 Q. Okay. And, Mr. Johnson, there's a large tank here.

Do you see that?

A. I do.

Q. And so what would be in that large tank?

14:26:45 A. That would be my juice. That would be my solution of Ranger Pro and water and sometimes surfactant.

Q. And so would you mix it directly into the big tank?

14:26:56 A. Yes. I would put my measured amounts of Ranger Pro into the tank first, and then my antifoam, because Ranger Pro foams up a lot when you put the water pressure in there, and then you take a water hose and you fill it up to your 50 gallons.

14:27:14 Q. Okay. And so this tank held 50 gallons?

A. Yes.

Q. And would you, at any given time, spray that full 50 gallons?

A. I would use that in an hour. Sometimes I'd have

14:27:25 to go remix and then get some more before, you know -- I

would get two or three tanks sometimes in the morning, like 150 gallons sometime, yeah.

Q. How many hours per day were you spraying out of this --

14:27:39 A. During the school year, we would spray no more than three hours, two to three hours. Three hours was the max. We would be pushing it, because people were coming soon, so we -- we started very early. We'd show up when it was dark, you know what I mean, and use
14:27:55 the lights from our truck and whatever else, and by 6 o'clock, the sun starts to come up, so we would get out there right when the sun -- and that was the plan, why we came in early, is to be mixed, ready and at your site by 6:00 when the sun rises, so -- yeah.

14:28:06 Q. And you mentioned, you know, you'd spray three hours. Were there ever days that you'd spray longer than three hours?

A. On the weekend, when there's nobody around and there wasn't children around or if there wasn't a school
14:28:18 event, we would try to hit sites, and we would get some good overtime. Four or five hours sometimes in the summer.

Q. Okay. Four or five hours of overtime?

A. Yeah.

14:28:24 Q. So there -- would there be days that you'd spray

up to seven, eight hours a day?

A. No, that's impossible.

Q. Okay. So at most you'd talk -- you know, maybe five, six hours, but on average, between three and six; is that fair?

14:28:35

A. Exactly, yeah.

Q. And so, you know, we talked about how many times you sprayed per year. That's -- was that about 20 to --

A. Twenty, thirty times a year, yeah. Or more, depending on if something pops up.

14:28:45

Q. And during those times, you -- you know, in three hours, you'd spray about 150 gallons worth?

A. Yeah.

Q. There's a tube here, if you see that, a yellow tube?

14:28:56

A. Uh-huh.

Q. What is that?

A. That's just a feeding tube that's going to take air from that engine and shoot it into this thing. The green tube at the bottom is the one that's going to suck the juice out of the tank and give it to the hose reel.

14:29:05

Q. Okay. And so this is actually motorized; correct?

A. Yeah, it's motorized, with a basic Honda lawnmower engine, very good engine, but yeah.

14:29:23

Q. Okay. And you'd crank that up and then -- this is -- is that a hose over there?

A. Inside those two circles, there's 250 feet of green hose and a wand. It's sort of, you know, like, a wand, like a -- with a pistol grip and it sticks out.

14:29:39

Q. Okay. And so would that be approximately four feet, three feet long?

A. I would say the wand is about three feet, and then with the handle, it would be four feet, but the wand itself -- you know what I mean. Not even four feet. I guess the handle would be five, six inches, so maybe three and a half.

14:29:54

Q. So anyone who's ever power washed a house, is it kind of similar to that?

A. It's totally similar to that.

14:30:05

Q. And so the hose would connect directly into, you know, your nozzle, or, you know, as you referred to it, the gun --

A. The -- what comes out of the big hose reel, it comes down into the nozzle. It's got a little pull-down clamp. You pull it down. You clamp it into the nozzle, and it, you know, has a little -- a way where it won't come out of that wand. It locks. You either have to pull that down and pull it off or pull it down and pull it up to lock it.

14:30:17

14:30:31

Q. Okay. Were you -- on your actual gun with the handle, were you able to control the pressure on how hard it was coming out?

A. The only thing you can do is you can change nozzles. Like if you feel like you're getting too much, you can change to a blue or pink or red or different color nozzles, and those nozzles had sizes, of course, and it gave you less spray at the time, but there was no dial to say, you know, "Give me moderate spray today," or "Give me high spray today." There's no dial for that. Just -- you have to dial that in through nozzles and your trigger control.

Q. Okay. So the trigger control, I mean, you couldn't really necessarily control the amount of pressure in which the Roundup was coming?

A. Not really. It's, like, either a squeeze or a not squeeze. So you squeeze it as much as you can and try to go light or whatever, but it doesn't really stop. It stops when you left off, and it goes when you squeeze.

Q. At any point when you were spraying over 150 gallons of Ranger Pro, did you ever get Ranger Pro on your skin?

A. Yeah. I had pretty bad exposure with that tank right there spraying at Mary Farmar.

Q. Okay. And what was Mary Farmar again?

A. Mary Farmar's an elementary. It's in between a high school, and then -- the high school's right on this side, and Mary Farmar's up here (indicating). And it's just baseball fields and soccer fields in between the two schools.

14:31:55

Q. Okay. Do you recall at all when that actual incident occurred?

A. No. It's been a long time. It's really hard for me with dates and stuff and remembering things, but I don't remember the exact date, no.

14:32:04

Q. Was it at least before you were diagnosed with cancer?

A. When this happened?

Q. Correct.

A. Yes.

14:32:12

Q. And I want you to walk us, kind of, through that incident. You went to the school. Where were you located? Did you park the truck, and how did you go about spraying?

A. So I'd already done the bottom of the hillside, so my truck was -- at that point, it was inside and at the bottom of the hillside. So when I went into Mary Farmar, I went up this hill, which has a really big hill that leads up to the school, and I parked my -- turned my truck around and parked it where it was facing downhill,

14:32:22

14:32:37

and then I took my hose reel out and extended it as far as I could and started to spray back to the truck, because, of course, you spray away from where you are. You don't spray into it and then walk out. You spray backwards. Like, you -- if I was going to spray that side of the wall or this side of the court, I would start over there and end up over here, like you're painting. You know what I mean? So -- yeah. I remember that I turned my truck around, parked it and started spraying -- and started spraying the top of the hillside down.

14:32:54

14:33:10

Q. And what do you remember next?

A. I remember getting my hose caught in a gap in between the sidewalk and the asphalt, and my hose got detached from the reel.

Q. Okay. And when you say "the reel," what are you talking about here?

14:33:24

A. That's the two silver wheels you see there. That thing rolls like this. You know, it reels in, and it reels out. I have to take it by hand and take the 250 out and -- I mean, in, but I could pull it out.

14:33:36

Q. And when it became detached, what happened? I mean, was the engine still running?

A. Yeah, the engine -- I'd just started it up and went over there and started dealing with stuff. So the engine was running, and the juice was coming right out of

14:33:49

the side of the side -- the side -- inside the hose reel, there's a little place where you hook that hose in inside there. It's kind of hard to explain if you've never seen that, but there's a place where the juice comes right into this, and it connections into there, and that became detached.

14:34:10

Q. And once again, when we say "juice," we're not talking --

A. Orange juice.

Q. Yeah, you're talking --

A. I'm talking Ranger Pro. My bad. I should really be saying Ranger Pro.

Q. No. That's fine.

And so what happened? What was the Ranger Pro doing when that became detached? Was it spraying?

14:34:25

A. Yeah, because there's no control on the engine or safety switch to turn it off, so I -- it just was shooting up. The grill was just shooting fluid everywhere. It was just an open wound almost. So I had to get in here and -- I don't know if you can see that on there. It's a little -- right by that red filter right there, there's a switch. I had to go in the back of that switch by that gas tank and turn it off. It's a red off and on over there. It's kind of blurry by the corner.

14:34:42

14:34:56

Q. And so during that time when you had to go in to

shut it off, Ranger Pro was shooting out into the air; right?

A. Definitely, yes.

Q. Did it get on you at all?

14:35:05 A. Yes. That's when it got inside of my Tyvek. It went down my back -- as I reached in, it went down in there, got in the Tyvek, got on my clothes, got on everything down inside there, down to my waist again.

Q. And after it got on you, what did you do then?

14:35:22 A. That was the first time. So the first time that happened to me, I immediately had to shut down the situation and not let this herbicide get into the drains. So once I got the tank stopped, I took some dirt and I stopped the flow of the Ranger Pro that was going

14:35:39 downhill probably into a drain. So I stopped it with dirt and stopped that whole spiel. And then I got my hose reel back rolled in and headed back to the yard to take off the stuff. I took off the Tyvek right there and then when I got back to the shop, I took off my shirt, my

14:35:59 work shirt and my T-shirt and tried to clean up as best as possible.

Q. Okay. And how long was it from the time you got drenched with the Ranger Pro until you got back to the shop?

14:36:10 A. I would say about 20, 25 minutes to clean that

situation up.

Q. And you said when you got back, you took off at least the top part of your clothing?

A. Right.

14:36:19 Q. And you said that you tried to clean off as best possible.

Did you take a shower?

A. No. Sort of like a sink bath. We had a little sink in our maintenance yard and we did everything there.

14:36:30 We always would come in after we sprayed because you knew you would get it on your face every day. So the routine was take your stuff off at the maintenance yard across the hall, get rid of your dirty Tyvek, and then go in and wash your face immediately. Because you know we're not

14:36:43 going home. We're going now to weed or rake and do painting or whatever a maintenance guy does. You clean up your face or whatever. So that day I had to clean more than my face. I cleaned my face, my neck, my back, my shoulder. And I just tried to do what I could.

14:36:57 Q. So you didn't have an option to take a shower at that point?

A. No.

Q. And was that in the beginning of the day?

A. Yeah, early in the day.

14:37:04 Q. So you went and just tried to rinse off in a

Q. And if Monsanto had told you at that time that Ranger Pro could have caused cancer, would you have kept spraying their product?

A. Absolutely not.

15:12:08 Q. Even if Monsanto had said, "Mr. Johnson, we're not entirely sure, but your cancer might be related to your Ranger Pro exposure," would you have continued to spray the product?

A. If they said it might be?

15:12:19 Q. Even if they said "We're not entirely, but it might be," would you keep spraying?

A. No.

Q. But nobody ever told you, did they?

A. No.

15:12:29 Q. Was that the only call you ever made to Monsanto?

A. No, I believe I called again.

Q. Do you know who you called that next time?

A. I don't.

15:12:36 Q. Do you know where you got the number from?

A. I think I got that one from online or from Ms. Biehl. I know she said something about a poison control. I'm not sure. I was doing so much research and numbers at that point, I'm not sure where the number or the

15:12:54 person came from or the source.

Q. Okay. And part of the training you had and part of the information on the label, was to make sure you were spraying when other people weren't around; right?

A. Exactly.

15:44:39 Q. And that includes children at schools; right?

A. People, period. In general, any human. Not spraying around humans or animals.

Q. Okay. And I think you said during the spray seasons you typically sprayed about 20 to 30 days a year; is that right?

A. Sometimes.

Q. Roughly?

A. Roughly.

Q. Okay. You mentioned on direct that there was

15:44:56 one season where the truck-mounted sprayer that we saw a picture of, that it wasn't working; is that right?

A. Correct.

Q. And I think you said you nearly lost a whole season. What did that mean, sir?

15:45:07 A. Well, we lost a whole season of spraying, almost.

Q. Okay.

A. So we -- that's what I mean when I say we almost lost a whole season. The weeds, you know, they have a

15:45:17 cycle. So if you miss it, it will be even harder next

time. There will be more weeds.

So the thing is to stay ahead of the weeds. And that's why people, you know, use a pre-emergent eventually.

15:45:28 Q. Okay. So when the truck-mounted sprayer broke, that was the sprayer that you used most of the time; correct?

A. Correct.

Q. All right. So whatever period of time that 15:45:35 wasn't working, is it fair to say you weren't spraying?

A. At first we weren't spraying. But then we went and got the backpacks to start spraying. Because we had to. It's a part of our job requirement, when we signed up, and we're paid a little more to do that. So we have 15:45:49 to spray. It's part of it.

Q. Okay. And was the -- the period where the truck-mounted sprayer broke, was that prior to your cancer diagnosis?

A. No. It was after.

15:45:58 Q. It was after? Okay.

So up until your cancer diagnosis, you were using the truck-mounted sprayer primarily?

A. Yes, ma'am. Yes.

Q. And then the -- then the backpack sprayer?

15:46:09 A. I only used the backpack, during my whole

EXHIBIT 8

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Thursday, July 26, 2018, Volume 17, Morning Session, before the Honorable Suzanne R. Bolanos, at 9:08 a.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965331A

Pages 3553 - 3666

A. It's a very specific field. We are the ones who determine causation, what chemicals, pharmaceuticals, environmental substances can do to the body. And physiologically and mechanistically how they operate.

09:54:03 Q. After graduating with your Ph.D. in toxicology, what did you do next in your career?

A. I worked for five years as a governmental toxicologist in Syracuse, New York. I was responsible for assessing the environmental exposures, forensic

09:54:21 matters, in general Public Health. Everything from lead in water to hazardous chemicals from, I think, almost 18 different Superfund sites in the area.

Q. You said that was through the Department of Health?

09:54:39 A. Yes.

Q. After -- how long were you with the Department of Health?

A. Five years. And during that time, I started consulting and developed my own consulting business in, I

09:54:48 think, 1990, which I am still with today.

Q. Okay. And what's the name of that consulting business?

A. Toxicology Consultants and Assessment Specialists, LLC. And I do work throughout the US and

09:55:02 also internationally.

Q. And from 1990 to the present, you've had that sole business as a toxicology or consulting toxicologist; is that right?

A. Correct.

09:55:12 Q. And you said "consulting." Who do you consult with in that role for your actual business?

A. Civil matters, which about -- 60 percent are plaintiff, about 40 percent defendant. Also a number of governmental agencies, the United States Attorney's

09:55:29 Office, US Navy, various prosecutors, Attorney State General of Montana, New York, New Jersey and other states.

Q. So you said both plaintiffs' and defendants' side. Have you ever served as an expert for a

09:55:44 manufacturer?

A. Many times. And currently.

Q. So it's not just on the plaintiff's side of claiming a chemical caused an injury. You've also served as an expert for the defendant saying it didn't?

09:55:58 A. Oh, yes. I have some very good defense experts who have true, good defense cases. I'm very selective in what cases I take.

Q. Now, there's a term "forensic toxicologist." Are you a forensic toxicologist?

09:56:11 A. Yes, I am.

Q. Can you explain what a forensic toxicologist is?

A. My training was in forensic toxicology. Forensic toxicology is simply application of science to the law. The word "forensic," the Latin root stems from debate, as we are debating today. This is a forensic matter.

Q. And so, you know, based on that, you're involved in a lot of cases, both civil and criminal; is that fair?

A. That's correct.

Q. And so you've probably done this a lot, depositions and trial testimony. Is that fair?

A. Yes. When I looked at my list of cases and trials, I testify in court, in trials, about six times per year on the average.

Q. And, once again, that's both for plaintiff and defense side?

A. That's correct.

Q. Other than your work for the Department of Health that we talked about and your own company as a forensic toxicologist, what else have you done in the field of toxicology?

A. I've served as a peer-reviewer for the Forensic Examiner, which is a peer-reviewed journal. In the past, I've directed various laboratories as a licensed lab director in multiple states, including clinical, forensic

and environmental analyses. And probably other things, but I don't have my CV in front of me.

Q. That fine. You mentioned a laboratory director. Who were you a laboratory director for?

09:57:33 A. Oh, for Express Laboratories in Rochester, New York, Public Health Laboratory in Syracuse, New York, Lozier Laboratory in Rochester, New York. Possibly others.

Q. Are you Board-certified in anything?

09:57:52 A. Yes. American Board of Forensic Medicine in 1996, I believe.

Q. Do you also teach in the field of toxicology?

A. Yes. I've taught medical students at the State University of New York, Upstate Medical Center in

09:58:09 Syracuse for, I think, 22 years, as an adjunct assistant professor in the Department of Medicine.

I specifically taught a portion of the clerkship toxicology course, as well as a portion of the second-year students in Public Health.

09:58:31 Q. With respect to -- you mentioned in your work, you know, both in your actual business and otherwise, you've worked for government agencies. What have you been doing for those government agencies?

A. Oh, a wide variety of cases. I've worked in

09:58:49 criminal cases, in terms of cause of death from

intentional poisoning with arsenic thallium. In fact, the movie was produced on my original work in 1993 called "The Black Widow."

I've worked on prosecution cases involving drugs and alcohol, which are quite common. I've worked on large chemical case matters, worked on the BP Oil release. There's just numerous cases.

09:59:13

Q. Have you, in the cases you've worked on, established causation analysis for chemicals or pesticides?

09:59:28

A. Yes.

Q. How often have you done a chemical analysis with respect to causation for chemicals?

A. Really, continuously since the last -- about the last 30 years. That's how I started in the Health Department.

09:59:44

Q. Have you ever published in any peer-reviewed journals?

A. Yes.

09:59:53

Q. How many?

A. Not a lot. Maybe -- probably about 8 or 10 original articles. And then probably about 25 review articles.

Q. With respect to those articles, those are in the field of toxicology?

10:00:11

A. Yes.

Q. In some of the cases you've worked on, have you ever done anything with respect to 911 and the World Trade Center?

10:00:18 A. Oh, yes. I was called on that shortly after it occurred and wrote a report, which was very extensive, including all of the chemicals that were released, including volatiles, such as benzene, even dioxin. And probably nuclear aromatic hydrocarbons and other

10:00:45 carcinogens, which led to a much broader investigation ultimately.

Q. In your work, have you ever been involved in preparing product labeling or material safety data sheets?

10:01:01 A. I'm sorry, I didn't quite hear that.

Q. Yeah, no. I'm sorry. I'll be louder for you.

Have you ever been involved in -- in product labeling or material safety data sheets?

A. Oh, yes. I have prepared material safety data

10:01:11 sheets for corporations, yes. And product labels as well.

Q. And can you tell us a little bit about that? You know, what type of corporations were these?

A. Well, one -- the first one I ever did was a --

10:01:25 actually, a corporation that made a bookbinding spray for

libraries. And, unfortunately, their original spray had carbon tetrachloride in it, which is a very dangerous liver carcinogen. And then they had switched to a chemical, which was highly volatile. And I actually
10:01:47 remember doing a flame test with it. I could shoot a flame about 10 feet with it. And they reformulated. And then I wrote a material data safety sheet and label for that product, which is still in use.

Q. And --

10:02:01 A. Using a non-flammable propellant. Because it was designed for use in close quarters, in offices and closets.

Q. And what was your particular role in that process?

10:02:17 A. Safety. I had to be certain that a number of characteristics were met, that the international guidelines for safety were met in terms of warnings for each of the chemicals in the product.

And, also, with respect to the label -- labels
10:02:37 are interesting. You actually have to have labels in a certain format of certain size, letters and displays that are easily understood and read. And there's actually standards for this. There's a big volume of documents which we use to write labels and material safety data
10:02:55 sheets that follow strict guidelines.

Q. And who ultimately is responsible for the warnings in the product labeling?

A. Well, the manufacturer.

MR. DICKENS: At this time, your Honor, we'll tender Dr. Sawyer as an expert in toxicology, forensic toxicology and exposure assessments.

10:03:05

THE COURT: Any *voir dire*?

MR. LOMBARDI: No objection, your Honor.

THE COURT: All right. Very well. Then I will accept Dr. Sawyer as an expert in toxicology and forensic toxicology and related assessments.

10:03:16

You may proceed.

Q. BY MR. DICKENS: Okay. Doctor, you're here today in your role as an expert; is that right?

A. Yes.

10:03:27

Q. And you've reached some opinions in this case?

A. Yes, I have.

Q. And the opinions that you're going to be expressing here today, do you hold those to a reasonable degree of scientific certainty?

10:03:39

A. Yes.

Q. And did you review your role in this case from the experience of a toxicologist?

A. Yes.

10:03:49

Q. And did you reach an opinion to a reasonable

degree of scientific certainty that Roundup and Ranger Pro can cause non-Hodgkin's lymphoma?

A. Yes. I have been following the peer-reviewed literature on glyphosate since mid-1990s.

10:04:06 Q. And what is the opinion you've reached, generally?

A. That, clearly, glyphosate and with its combinations of adjuvants, is a known carcinogen.

Q. You just used the word "adjuvants." Can you

10:04:23 tell us what that word means?

A. Well, glyphosate is the -- the primary -- the principal ingredient in Roundup and Ranger Pro. And glyphosate is roughly 41 percent of the product in Roundup and about 51 percent, I believe, in Ranger Pro.

10:04:46 However, there are additional chemicals and chemical -- what we call reactants, by-products, within the Roundup and Ranger Pro. It's not just glyphosate and water.

Q. There is water in Roundup and Ranger Pro; right?

10:05:06 A. Right. But there's more than just water in glyphosate.

Q. And we'll get to some of those in just a little bit. But did you also reach an opinion, to a reasonable degree of scientific certainty, that glyphosate

10:05:19 formulations have a greater potential to cause cancer

than glyphosate alone?

A. Yes, I did. Yes.

Q. And what is that opinion?

A. That glyphosate, based on animal test data, is carcinogenic by itself. However, there are additives to the product which increase and enhance its carcinogenicity by several mechanisms.

Q. And one of those that we'll talk about is surfactants; is that correct?

10:05:56 A. That's correct.

Q. Okay. And those are your general opinions. Did you also look at Mr. Johnson's case specifically?

A. Yes, I did. In fact, I early on interviewed Mr. Johnson by telephone.

10:06:08 Q. And did you reach an opinion, after your review of this case, as to whether or not Mr. Johnson's Roundup and Ranger Pro exposures substantially contributed to his diagnosis of non-Hodgkin's lymphoma?

A. Yes.

10:06:22 Q. And what is that opinion?

A. That Mr. Johnson, and I'll explain in detail when asked, was heavily exposed, far more than the individuals in the Monsanto UK POEM studies, for example. He was heavily exposed. He had a wet face. He had

10:06:48 exposures in which he was notably damp or wet with the

material. And his --

Q. And based -- I'm sorry.

A. -- and his use of the product was extraordinarily heavy, approximately 50 gallons per hour.

10:07:04 Q. And is that a lot?

A. Yes. Backpack sprayers put out between 4 and 24 gallons per hour, on the average about -- about 16 gallons per hour, and he was spraying at 50 gallons per hour through a rigged system, which operated at an

10:07:23 uncontrolled pressure. It was either on or off.

Q. And you know, based on Mr. Johnson's testimony, you understand, you know, he had roughly a 50-gallon tank he'd been spraying out of, is that what you're basing that 50-gallon number on?

10:07:43 A. Right. And that he -- he actually would go through as much as 150 gallons of this stuff in one day.

Q. Can you -- you mentioned Mr. Johnson and speaking to him, can you tell us what types of materials you reviewed before reaching your opinions in this case?

10:07:56 A. Certainly. I initially reviewed a very large quantity of medical records on Mr. Johnson from -- some records dating prior to his diagnosis and then up at his diagnosis, including pathology results in August of 2014, and then his treatment records.

10:08:27 I also reviewed several of his depositions.

When I say "several," there was a Worker Comp deposition, and I believe there were two depositions following that. I also reviewed -- I had a file box, a full file box, of studies that I reviewed, which would be approximately 10:08:48 5,000 pages. I brought with me today what I could handle on the airplane, which is a good amount of material, but just a variety of documents also from Monsanto, in fact, memorandums, emails, official documents, including reports that were issued by Monsanto.

10:09:15 Q. You mentioned studies, were those both published studies and internal Monsanto studies?

A. Yes. When I say "studies," my large file box is primarily published studies from the generally accepted period of the literature, but I also have a large volume 10:09:31 of inhouse studies from Monsanto, many of which were never provided to the EPA or any regulatory agency.

Q. Those studies, were those both epidemiological studies and the animal studies that you reviewed?

A. Primarily the animal studies or the -- what we 10:09:51 call the *in vitro* studies.

Q. And -- did what did those studies entail? Did you review any studies with respect to exposure of individuals or animals to Roundup and how that affects carcinogenicity?

10:10:07 A. I certainly did. The key studies that I

reviewed with respect to exposure were actually Monsanto-published studies.

Q. You mentioned some internal correspondence, emails, other types of documents with Monsanto. Are those documents you reviewed and relied upon in reaching your opinions?

10:10:27

A. Yes.

Q. And these documents that you reviewed, the internal documents for Monsanto, are those types of documents that are reasonably relied upon by experts in your field as a toxicologist?

10:10:45

A. Yes. All the time, yeah.

Q. And what do you mean all the time? How do toxicologists rely on that information?

10:10:56

A. Well, a toxicologist is sort of like a detective. Okay. We look hard and deep to try to find all the evidence we can, whether it is helpful for the client or adverse to the client. It doesn't matter. The objective is to look at every possible piece of evidence and then assemble it into a conclusion based on the merit of that evidence.

10:11:14

Q. And is that what you did in this case?

A. Yes.

Q. And what in particular were you investigating?

10:11:27

A. A number of factors. To start with, the

exposure dose, which was very thoroughly calculated by Monsanto in their operator exposure studies.

Q. And can I just stop you right there. Can you define what "exposure dose" means?

10:11:50 A. Yeah. Okay. Exposure is, in this case, how much material gets on the body. Okay. The dose, however, is how much gets into the body, in the systemic circulation or into the tissue target, so there's a big difference. If, for example, the dermal absorption was

10:12:12 only 1 percent, only 1 percent of that material would make its way to the target organ, whether it be the dermis, the skin or the liver or internal organs, that's what we call the internal dose.

Q. Is that also referred to as systemic dose?

10:12:26 A. Yes.

Q. So systemic or internal, it means the same thing?

A. Yes, yeah. It means -- the bottom line is the target organ.

10:12:35 Q. And so you were discussing what you were investigating in this case, and so one of the first things you did was investigate all of the materials to try to figure out exposure and internal dose; is that fair?

10:12:47 A. Yes. The first step was to determine whether

Mr. Johnson was significantly exposed, that is, did the exposure at work actually make it into his systemic circulation? Did it make it into the blood and impact any of the stem cells that ultimately developed into a T-cell lymphoma? So really the question for Mr. Johnson was: Was he significantly exposed, and if so, was that exposure dose substantial and significant enough to cause damage to his stem cells.

10:13:13

Q. And based on your experience, education, review of all of the materials, you reached an opinion that, in fact, it was enough of an exposure dose to cause his non-Hodgkin's lymphoma?

10:13:36

A. Much so.

Q. Now, to be clear, Doctor, you don't believe that Roundup or Ranger Pro needs to be taken off the market for all purposes; correct?

10:13:56

A. No. If there were proper warnings, if an individual knew that they were dealing with a carcinogen and it was used in a limited fashion without producing what we call aerosol, that is aerosol that drifts and gets all over the body, it could be used.

10:14:11

Q. And, in fact, like many people here in this room, you've used Roundup; correct?

A. I believe it is fairly popular.

10:14:27

Q. And what do you mean by that?

A. Well, I think it's used both over the shelf. You can buy it at Walmart or Home Depot. I buy it at the Bailey's Hardware Store in Sanibel, Florida.

Q. And so you believe that Roundup and Ranger Pro could potentially be used properly; correct?

10:14:44

A. Yeah. There is a proper way of using it, yes.

Q. Okay. And so do you take any precautions in your use of the Roundup?

A. Yes. I've used it several times per year. The first time I ever used it was about 20 years ago, and I was absolutely disgusted, because I had bought a backpack, and I used it on spot weeds, and the wind blew it all over my legs. I immediately washed with soap, and I actually went into my swimming pool after that and --

10:14:56

10:15:16

Q. And why did you do that?

A. Well, because it produced an aerosol mist that the wind would uncontrollably blow back on the body.

Q. Did you try to prevent that drift?

A. I sure did.

Q. Okay. But you weren't able to?

10:15:27

A. No, I did. I drilled with about a 30-thousandths drill into my orifice in my workshop and turned it into, basically, a squirt gun, where I can directly squirt weeds. I have mulch. I don't have grass, and I have -- occasionally I have weeds shoot up

10:15:45

in that mulch, and I can direct it right on those weeds with no aerosol production, and I wear heavy rubber gloves, and I have zero exposure.

Q. Okay.

10:15:59 A. So, I mean, the -- I think that -- I don't think that the material necessarily needs to be completely banned, but there are a lot of things we use that are dangerous, but it's a matter of how you handle it and the warnings.

10:16:09 Q. Okay. And so you -- you made that modification to the actual hose. Was that after your first time of spraying?

A. Yes.

Q. And was that because of your first experience

10:16:18 with the drift?

A. Yes. And I knew at that time it had carcinogenic potential.

Q. So you had already known that?

A. Yes.

10:16:27 Q. And did you take that into consideration in your choice to use it?

A. I did.

Q. So you actually made the choice, you had the choice whether or not to use the product?

10:16:36 A. Yes.

Q. How much -- you mentioned your use. How large of an area are you actually spraying?

A. Well, I have nearly an acre, but as I say, it's almost 100 percent mulch. I don't have grass, but I do get occasional weeds.

10:16:56

Q. How does your exposure, when you do that, how does that compare to Mr. Johnson?

A. Mr. Johnson was using a higher pressure system, which was on or off. He had no controls to reduce it, and he was, based on his testimony, as I understand, about 50 gallons in an hour, which is several times what would normally come out of a --

10:17:16

MR. LOMBARDI: Your Honor, may we approach?

THE COURT: Yes.

(Sidebar.)

10:17:37

MR. LOMBARDI: He had no nothing in his expert report about Mr. Johnson's use of this -- I don't know what the right term is -- the 50-gallon pump and the details of how that worked or a comparison between that and the way that he used the product, so this is beyond the scope of his opinions.

10:17:57

MR. DICKENS: Your Honor, they're the ones that brought it up. We weren't going to get into how he uses it.

THE COURT: I know. Was there anything -- did

10:18:09

he review any materials that indicated how Mr. Johnson used it?

MR. DICKENS: Absolutely. He knew he used his truck sprayer.

10:18:19 THE COURT: He knew all of that and that was -- whatever reports he read about Mr. Johnson was all disclosed?

MR. DICKENS: Absolutely. He went into detail about how he used that, how he used the truck sprayer --

10:18:36 67-page report that goes -- that all the details -- all of the evidence Mr. Johnson has given (inaudible).

THE COURT: So what is it that's new?

MR. LOMBARDI: What's new is that he -- I don't dispute that he talked about he used a backpack sprayer

10:18:51 or that he used the pump in the back of the truck. I don't dispute that, but now we've had discussion about it's an unregulated pump. It was out of control, the way it sprayed, you couldn't control the way it's spraying. That stuff I don't believe was in his report. And there

10:19:09 certainly wasn't any comparison between the way Mr. Johnson did it and the way Mr. -- Dr. Sawyer did it. And this did come up at his deposition. Dr. Sawyer's use of Ranger Pro did come up at his deposition. There was no comparison of that at all. But no detail other than

10:19:26 he used the pump in the back of the truck, is my

recollection.

MR. DICKENS: We wouldn't -- he can include any use by Dr. Sawyer. We have to explain how his exposure compares to Mr. Johnson.

10:19:44 THE COURT: I'll allow it.

(End sidebar.)

THE COURT: You may continue, Mr. Dickens.

Q. BY MR. DICKENS: Okay. Dr. Sawyer, we were just discussing how your exposure compared to the exposure of 10:20:04 Mr. Johnson. Can you explain to us, again, how that -- your exposure in your one-acre yard compared to Mr. Johnson?

A. Well, what I explained was I experienced what we call drift. That's aerosol droplets that the wind blows 10:20:18 back onto the body. Now, I never experienced any drift above my knees, but Mr. Johnson experienced drift that -- in fact, to his entire body, including even face. And he was using an application rate about three times above that which is that which was used in the Monsanto 10:20:43 operator exposure assessment study. Thus, his exposure from the standpoint of the dose I relied on from the Monsanto study was severalfold higher than that.

Q. And so, you know, based on that, once again, you believe that there's appropriate uses for Roundup or 10:21:10 Ranger Pro, if used in small quantities?

A. Yes, with appropriate warnings and the proper equipment.

Q. And because you were aware of the carcinogenicity potential of Roundup and Ranger -- or Roundup when you used it, you were able to take that into consideration?

10:21:24

A. Yes. I'm an extreme outlier. I mean, I've been following -- I looked at the original hairy cell leukemia studies back in the '90s. I've been following it for years. I know what it does. That's why I was rather disgusted when I got it on my lower legs.

10:21:38

Q. And that's why you immediately stopped, went, washed it all off and got in the swimming pool?

A. Yeah.

Q. Now, what type of glyphosate products did Mr. Johnson spray, based on your understanding?

10:21:53

A. Primarily, he initially worked with what we call Roundup, which is 41-percent glyphosate, with a number of other chemicals in it, and then later, he worked more often with Roundup, which is basically the same mixture, but simply a higher concentration, 51 percent -- or 52 percent versus 41 percent in the Roundup.

10:22:15

Q. Other than the concentration, is there any difference between Roundup that you can buy in stores that ordinary consumers like us and the Ranger Pro that

10:22:35

Mr. Johnson used?

A. No. The concentration is the difference. Now, if you were to go to Home Depot or Lowe's, you would find that there's Roundup and -- which they call Roundup Concentrate, and there's also a Roundup Super Concentrate, which is 51 percent, and the instructions simply -- state simply dilute it more when you buy the Super Concentrate, so it's basically the same material.

Q. Does Monsanto sell glyphosate by itself?

10:23:20 A. No. However, they license it to other corporations, such as Syngenta and a number of other corporations, but they don't sell it to consumers as pure glyphosate, no.

Q. Monsanto -- is Monsanto the manufacturer of both

10:23:39 Roundup and Ranger Pro?

A. Yes.

Q. Did Mr. Johnson use any glyphosate formulations by any other manufacturer?

A. Not that I found in the records or his

10:23:50 deposition.

Q. And was Mr. Johnson ever exposed to any other chemicals, pesticides or herbicides that had been associated with non-Hodgkin's lymphoma?

A. Not to my knowledge, no.

10:24:02 Q. And you reviewed that, his chemical exposure;

correct?

A. That's correct.

Q. You mentioned, kind of, the makeup of Roundup and Ranger Pro, and you said water and glyphosate and some other stuff. What are some of those other chemicals?

A. Well, propylene glycol. Propylene glycol is used to help emulsify the material. Remember, the product works by gaining entry into the plant leaf, and the absorption of that chemical into the plant leaf is very critical in terms of operating and knocking out the ES -- or the EPSP enzyme, which permits plant growth in light.

So some of these additives, propylene glycol, dipropylene glycol, tallow amine, which is what we call a POEA, a polyethoxylated ethyl amine, are all used to help the penetration of the product either spread onto the leaf or penetrate into the leaf and work more efficiently. It's a very clever design, really, in terms of how this product works.

And so there are also what we call co-contaminants that -- for example, when the POEA is made, whether it's tallow amine or another POEA, there's oxidation reactions in preparing that, which result in ethylene oxide, 1, 4-Dioxane, and those two chemicals are

known confirmed Class A human carcinogens. In fact, ethylene oxide is one of the most potent carcinogens known to man, and it's highly volatile, so when it is used -- whenever ethylene oxide is present, it's volatile as it's inhaled.

10:26:12

So there are co-contaminants. There's even some additional co-contaminants that form during the production process, called N-nitroso compounds, which are also known human carcinogens, which generally cause cancer in humans, so --

10:26:30

Q. And, Doctor -- I'm sorry.

A. Yeah, I mean, it's a mixture of adjuvants, surfactants, glyphosate, and then trace quantities of these other carcinogens, which act in an additive and in some cases synergistic effect to cause cancer, along with glyphosate.

10:26:51

Q. You just mentioned surfactant. We've heard some of that here in this case so far. What is a surfactant?

A. Well, a surfactant is -- think of -- think of water on a freshly waxed car and the water droplets bead up. If you were to add surfactant to that rain water, it would spread out over that waxed car, and a surfactant is -- in a sense, it's a detergent. It's a soap. But in this case, they generally use what we call non-ionic surfactants, but the fact is the surfactant is simply

10:27:10

10:27:35

DNA, the molecular code material in our body, in our cells, which determine whether we produce normal skin or carcinogenic skin. That DNA can be damaged by what we call these adducts, that is the binding of the POEA, the tallow amine, to the DNA, and when the DNA is read, it is misread and becomes corrupted. There's also oxidative damage done to the DNA from tallow amine and other POEAs.

Q. Has Monsanto ever conducted any carcinogenicity studies on the surfactant such as POEA?

10:32:43 A. No, they have not.

Q. Has the EPA ever reviewed the carcinogenicity of surfactants?

A. No. No. I've researched that. The only thing EPA has done is what's called an SAR, a structural

10:32:58 activity relationship by computer.

Q. And what is that? Can you explain it? You say by computer. How do they test that? How does that related in any way to carcinogenicity?

A. Well, there are certain classes of compounds

10:33:11 that are generally carcinogenic. For example, let's take chlorinated hydrocarbons, such as trichloroethylene, TCE, or DDT or dioxins or PCBs. They're all chlorinated hydrocarbons, and they have certain chemical configurations with chlorine that are very often

10:33:34 carcinogenic.

So by performing an SAR analysis, one is simply looking at the configuration of the chemical. In this case, it's an organic phosphate. It's not a neurotoxic organic phosphate, but it is an organic phosphate, and the SAR did not find that chemical to be -- likely to be carcinogenic. That is the EPA position.

10:33:55

Q. Okay. And so that's based on a computer model, but they haven't actually looked at any testing as to carcinogenicity?

10:34:09

A. No, it's never been tested.

Q. And has Monsanto ever submitted any testing at all with respect to the carcinogenicity of their surfactants?

A. No. However, Monsanto has documented and recommended that such evaluations be performed. That's very clear.

10:34:24

Q. And did they ever perform them?

A. No. What has been performed are university studies showing, you know, the DNA adduct formation and DNA oxidative damage. That's been published in the peer-reviewed scientific literature.

10:34:43

Q. Okay. And so Monsanto themselves never conducted any testing, but you mentioned universities. So those are third parties?

10:34:54

A. Correct.

absorption studies conducted by Monsanto and others in reaching your opinion as to the dermal absorption rate; correct?

A. Yes.

11:34:38 Q. And you reached an opinion as to what the dermal absorption rate for Ranger Pro and Roundup is; correct?

A. That's correct.

Q. And what is your opinion with respect to the percentage of dermal absorption of Roundup and Ranger Pro

11:34:50 in the human skin?

A. Based upon the studies conducted by Monsanto or their contractors, 10 percent. 10 percent of the dose is absorbed systemically.

Q. Okay. And can you put that in context? What

11:35:05 does that mean, 10 percent?

A. Well, it mean that 90 percent of it can be washed off after a sustained period of time. It does not -- or 90 percent of it does not penetrate through the epidermis into the dermal area, but 10 percent does make

11:35:28 it into the skin, into the body.

Q. And what is the significance of that?

A. It's important in calculating the dose. The dose for a worker handling either a backpack sprayer or a hose, hydraulic hose unit as Mr. Johnson did, has been

11:35:50 carefully assessed in the Monsanto operator exposure

see here, "Comfort fit design based on the wearer input to provide our most comfortable garment."

It allows moisture to go in and out. So you -- so you don't basically turn into a horrible, overheated, sweaty mess, which happens when one wears the more sophisticated suits, which I've worn many times.

Q. So there's different types of Tyvek?

A. Yes.

Q. And you wear them in different situations?

A. Correct.

Q. This one you referenced as a dust suit. Are there some that wouldn't be permeable to liquids?

A. There are suits that are completely impermeable to organic solvents, liquids, glyphosate, water, yes.

Q. Well, which suit does the Roundup or Ranger Pro product labeling instruct its -- its users to use?

A. The actual label from Roundup and Ranger Pro does not require any suit. It's rather strange. When they ran their own operator exposure study, they recommended waterproof jacket, pants, faceplate, et cetera. But none of that is on the warning of Roundup that was used by Mr. Johnson.

Q. Well, it protects against particles down to 1.0 micron in size. With the Roundup and Ranger Pro Mr. Johnson was spraying, was that -- would that have

permeated? Is it of the sufficient size?

A. No. It's not designed as a water or solvent-proof suit. It's the wrong suit for the -- it's not the right suit for the job. Let's put it that way.

11:53:31 This is the suit that's designed -- for example, spreading the talc material on the baseball field. This would be a great suit for keeping the talc dust off Mr. Johnson. But it's not the right suit for spraying Roundup.

11:53:47 Q. Okay. I'm going to turn your attention to page 3 of this document. And it actually has "Herbicides." And it says, "General." Then it says, "Solid form."

Do you see that?

11:54:00 A. Certainly. In a solid form, it would be acceptable. The solid form means particles. And particles of herbicide are generally greater than 1 micron in size, and they would not make it through the pores.

11:54:13 Q. Okay. And there is solid herbicides sold out there?

A. Oh, absolutely. Yeah. You can put them in these lawn spreaders, for example, that you push.

Q. Now, some of these other examples actually say

11:54:28 it's, you know, suitable for use for liquid.

Do you see that, Doctor?

A. Yes, I see that.

Q. But there's no mention of it being suitable for herbicides that are liquid like Roundup or Ranger Pro; is that right?

11:54:46

A. Correct.

Q. And, once again, Monsanto's labeling doesn't warn you or tell you to wear any type of Tyvek or other permeable suit, does it?

11:54:57

A. That's correct.

Q. And so Mr. Johnson, even though he was wearing, you know, this Tyvek suit, that was above and beyond the labeling requirements?

A. That's correct.

11:55:08

Q. But, you know, it wasn't keeping him completely protected from the Roundup and Ranger Pro that he was spraying?

A. No. It did very little.

Q. With respect to Mr. Johnson's spraying, do you

11:55:34

have an understanding how he was spraying the Roundup and Ranger Pro?

A. Yes.

Q. Okay. And what is your understanding of the different manners in which he would spray?

11:55:45

A. Primarily he was using a large hydraulic nozzle

hose, which was connected to a hose reel, which was connected to a pressurized pump, and then a 50-gallon reservoir tank on the truck.

And he was able to reel out the hose line and walk around and spray with it. It was an uncontrolled pressure. In other words, he couldn't turn the pressure down or up. It was either on or off.

Q. And you mentioned aerosol earlier today. Was his type of spraying, would that create an aerosol?

A. Yes. He was using a -- interchangeable colored spray heads consistent with that used in pressure washers.

Q. Have you ever used spray heads similar to that?

A. Yes. I have a pressure washer I use on my boat.

Q. Okay. So Mr. Johnson, unlike the way you did it with a long hose that you modified, was actually using a pressure hose gun, essentially?

A. Yes.

Q. Is that a type of spray that you would expect to be smaller or greater than the way in which you do it?

A. Well, a pressure washer nozzle produces a huge aerosol. If you've ever used one, just one trigger would literally fill this courtroom with mist. I mean, it's not -- not the right nozzle for application by any means.

Q. Based on your review of the materials, was

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Thursday, July 26, 2018, Volume 17, Afternoon Session, before the Honorable Suzanne R. Bolanos, at 1:31 p.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965331B

Pages 3667 - 3811

you sweat, sometimes sweat profusely.

Q. How does sweat affect --

A. It means that the undergarments, the shirt, pants and so on, are moist. So when that glyphosate and surfactants, adjuvants, contact the moist clothing, it has an immediate diffusion pathway to the skin. Because you have damp skin against damp clothes against a damp Tyvek suit, so you have an immediate pathway. So it actually enhances the sweating, enhance -- plus it opens the pores, plus there's vasodilation when a person is hot and sweaty.

13:34:19

13:34:38

Q. Do you have an understanding as to whether or not Mr. Johnson was able to shower immediately after he got it on himself? "It," Ranger Pro?

A. Based on my review of his depositions, in most cases, he did not immediately shower. Rather, he would go back to work and finish his functions, and then shower at home.

13:34:54

Q. And do you have an understanding -- did he do anything to try to wash it off after being exposed to the Ranger Pro?

13:35:17

A. Well, I know he talked about washing his hands and arms and forearms, and I believe he even wiped himself at times.

Q. Would that have gotten all the Ranger Pro off of

13:35:32

him so that there wouldn't be any more absorption?

A. No. And the other thing to remember is that the studies have shown that the first hour of exposure shows the greatest degree of absorption, and then it falls off each hour -- less absorbed, less absorbed, and so on -- so that the first couple hours are critical.

Q. What facts did you consider in determining the total amount of Mr. Johnson's exposure?

A. Well, as I said, I compared him to what's in the literature, in terms of workers who were wearing patches that were measured. But I also compared him in terms of his gallon per hour. You know, he's testified that he's used up to 150 gallons a day, and even 50 gallons in an hour, which is 3 times above the rate. Even if he used the backpack sprayer and held it on non-stop, it would only be about 16 or 15 gallons per hour, and he was running 50 gallons per hour with a spray head that produces a horrible aerosol.

So based on his testimony description in terms of the drift, the fact that his face actually was wet, based on the quantity used, he is an outlier. He's -- beyond the worst case that I've found in the literature which I used as my basis of calculations. So my dose calculation's actually another underestimate.

Q. Based on his exposure and the 10-percent dermal

absorption rate that you testified to, is that enough to cause a carcinogenic response?

A. Yes, absolutely. He is -- I can say that emphatically, and base it on the peer-reviewed literature, in that his exposure -- his levels of exposure were far higher than that in the literature, but its duration of 2.25 years of exposure, or three seasons of exposure, was less than the average in the peer-reviewed epidemiologic studies who developed T-cell lymphoma. So it puts him approximately in the middle of the human epidemiologic studies that show human cancer. He falls in the middle of the exposure categories, not at the extreme low end, not at the extreme high end. And I say it again, because his exposure days were far less than that in the human literature. However, his intensity of exposure was actually higher.

Q. So did you consider the total number of days that he sprayed in consideration of your opinions in this case?

A. I did. I calculated ninety, based on his testimony. Ninety days of spraying.

Q. And that was based on 20 to 30 times of spraying per each year?

A. Twenty to thirty, although he did testify that perhaps it was more. It could have been as high as

forty.

Q. And you mentioned three spraying seasons. That's from the date of his first use until the date of when? Was that date of diagnosis?

13:38:44 A. August of 2014. The date of diagnosis was when the pathology was taken and he was diagnosed with lymphoma.

Q. Did you consider whether or not 2.25 years, as you state, was long enough for non-Hodgkin's lymphoma to

13:39:02 form?

A. Yeah. I have -- for many years, have searched the literature and have kept track of latencies for different cancers. Different cancers have different -- very different latencies. You know, mesothelioma has the

13:39:18 longest latency of any. Lymphoma has the shortest latency period of any known human cancer, as short as eight weeks. When a drug called Cyclosporin A -- some of you may have heard of it. That's a drug used for tissue transplant recipients. For example, if I were to have a

13:39:43 kidney transplant, I would have to have Cyclosporin A to suppress the immune system to not reject that organ. In that case, that particular drug has a side effect of non-Hodgkin's lymphoma developing in as short as eight weeks.

13:39:56 Now, that's not the case here. We're not

dealing with Cyclosporin A. We're dealing with another chemical, and, therefore, I've used other literature studies to determine the shortest latency period.

Q. In studies, how is latency looked at? How is it considered?

13:40:13

A. Very specifically. The rule is -- it's a standard worldwide international rule: It's from the time of first exposure until the time of diagnosis. When that pathology sample is collected, that person is diagnosed. That is how all the studies in the epidemiologic literature work. It's from time of first exposure to time of diagnosis.

13:40:28

Q. So if Mr. Johnson was considered in that study, his latency would have been that 2.25 years that you mentioned previously?

13:40:44

A. That's correct.

Q. I want to turn your attention to one exhibit.

MR. DICKENS: Permission to publish Plaintiff's Exhibit 880?

13:40:52

THE COURT: Any objection?

MR. LOMBARDI: No objection, your Honor.

THE COURT: Very well. You may proceed.

Q. BY MR. DICKENS: Doctor, I'll point this out: This is an article by Dennis Weisenburger, "Pathological Classification of Non-Hodgkin's Lymphoma For

13:41:05

Epidemiologic Studies."

Have you reviewed this previously, Dr. Sawyer?

A. Yes.

Q. And I want to turn your attention to a chart on page 6 of this study. Do you see that there?

13:41:20

A. Yes.

Q. And this has -- it says "latency curve." Can you explain what a latency curve is?

A. Yes. Latency is generally found to exhibit what we call a bell-shaped curve. We'll have some individuals who develop it very early, and then a mean peak value, which typically, for lymphomas, is about a ten-year mean, and then some people that don't develop it for 20 or 25 years, and they're at the other end, at what we call the tail. So this diagram, Figure 4, shows two latency curves for non-Hodgkin's lymphoma, based upon a high acute exposure versus a steady, long-term, low exposure, and it makes a difference on the latency curve.

13:41:39

13:42:00

Q. And so the A, the first one we see there, that is the short-term high dose; is that right?

13:42:21

A. That's correct.

Q. And what's your reading of this particular latency curve with respect to short-term high dose versus the long-term low dose?

A. Well, this is typical for most chemicals with

13:42:35

respect to chemical carcinogenesis, that if the person is receiving the sustained high dose, the latency is generally much shorter. And that's what we have in this case. We have a person who received very high dosage but for a shorter period of time, only 2.25 years, prior to the diagnosis.

13:42:53

MR. DICKENS: Thank you, Doctor. I have no further questions. If I may pass the witness.

THE COURT: Thank you.

13:43:04

MR. DICKENS: Can I approach? Dr. Sawyer left his binder behind.

THE COURT: Yes, of course.

THE WITNESS: Thank you very much.

THE COURT: Counsel, Mr. Dickens, would you mind

13:43:31

getting some water for Dr. Sawyer?

MR. DICKENS: Not a problem.

MR. LOMBARDI: May I approach?

THE COURT: Yes.

CROSS-EXAMINATION

BY MR. LOMBARDI:

Q. Good afternoon, Doctor. I'm going to try to moderate my voice to fit the room and move the podium also. If you have any trouble understanding me or

13:44:18

hearing me, you'll let me know; right?

dermal absorption takes place, so the washing has to be rather immediate.

Q. Okay. But if you -- assuming you do an immediate washing, that's an effective way of preventing dermal absorption of Roundup or Ranger Pro?

A. Well, it's not going to prevent it, but it's certainly going to reduce it.

Q. Okay. Substantially; is that correct?

A. Yes.

Q. And that's why you do it?

A. Well, I have.

Q. Yeah.

A. You know, I -- there was one exception where I had to scrub my legs, the first time I ever used the darn stuff.

Q. Yeah. And you scrubbed your legs, I assume, with soap and water; is that right?

A. That's correct.

Q. All right. Now, you did not yourself, Doctor, perform any calculation of the amount of glyphosate that penetrated Mr. Johnson's clothing; is that right?

A. I relied on the Monsanto official studies that show how much the impact is on an average worker.

Q. Yep. And --

A. And realizing that that underestimates his

A. Of course not.

Q. Okay. Thank you. You didn't do any calculation of the amount that penetrated Mr. Johnson's chemically-resistant boots; is that correct, sir?

13:57:47 A. No. I used the Monsanto figure for boots --

Q. You didn't --

A. -- rubber boots, which is 0.

Q. I apologize. Did you finish your answer?

A. Yes, sir.

13:57:55 Q. You didn't calculate the amount that penetrated Mr. Johnson's mask; is that correct? You know he wore a mask; right?

A. Yeah, I -- I actually did, in terms of I used the 100 percent value. I did not -- I did it two ways,

13:58:17 actually, in our report. I did one with a zero inhalation, assuming 100 percent was captured by the mask, and I did it a second measure using the Monsanto figure of inhalation. So I did it two different ways, and it had hardly any impact on the dose level at all.

Q. Okay.

A. And per page -- Table 26, 27 of my report.

Q. But my question, again, sir, is: Did you do any calculation of the penetration of Mr. Johnson himself of his mask by glyphosate?

13:58:44 A. Of course not. That could not be replicated for

Mr. Johnson.

Q. Thank you.

And you didn't do any calculation yourself of the amount of drift that Mr. Johnson was exposed to; correct?

13:58:56

A. Of course not. There was no way to go back in time and measure that.

Q. Okay. Thank you.

Now, you have said, Doctor, that it's important also -- in addition to protect equipment, exposure is also determined in part by the way you spray; correct?

13:59:11

A. Yes.

Q. All right. And you told us about the way you spray at home, and you've studied Mr. Johnson's testimony and the records about the way Mr. Johnson sprayed; correct?

13:59:26

A. Yes.

Q. And Mr. Johnson indicated that he was very aware of the problem of drift; is that right?

A. Yes.

13:59:36

Q. And you don't want -- he indicated you don't want to spray when the wind is too great; correct?

A. Are you asking me about his testimony?

Q. Yes.

A. He testified that it was unpredictable on any

13:59:48

given day.

Q. Right. But he made an effort not to spray if the wind was too great, didn't he say that?

A. Yes.

13:59:59 Q. Okay. And that's -- and you agree with that, you shouldn't try to spray when the wind is too great?

A. Correct.

Q. And one of the things you should do when you spray, is you should, for instance, not spray into the

14:00:11 wind; right?

A. Of course.

Q. Because that would just bring the spray right back at you?

A. Correct.

14:00:19 Q. And Mr. Johnson understood that as well?

A. I don't remember his exact testimony, so I'd rather not --

Q. Okay. That's fine. And if you have that situation, please just tell me, and we'll move on. But I

14:00:36 understand you don't remember that specifically; is that right?

A. Not exactly.

Q. Okay. Thank you.

And do you recall that Mr. Johnson knew that

14:00:43 it's better to spray in a way that the wind was going to

blow the aerosol away from you?

A. I believe so. But I know he also testified that it was very unpredictable. The wind could be moving one way and then switch to the other, depending on what buildings were, you know, in the area.

14:01:05

Q. Sure. Okay. Sir, and you understand that Mr. Johnson used a wand when he sprayed; correct?

A. Yes.

Q. Whether it was with the backpack or the -- I'm not sure what we call it -- the pump or -- the pump that he had on the back of the truck, both -- in both instances, he would use a wand; is that right?

14:01:18

A. Yeah, it's got -- termed a hydraulic nozzle, yes.

Q. Okay. And the wand -- or I should call it a hydraulic nozzle; is that --

14:01:31

A. Correct.

Q. Okay. The hydraulic nozzle, that's a good idea to help control your exposure; is that right?

A. No. It's a terrible idea. I drilled a hole in mine. I wouldn't use it again. That creates a dangerous aerosol.

14:01:42

Q. Okay. So -- and -- so by using a wand, he actually was doing the wrong thing, as far as you're concerned?

14:01:58

A. Well, he didn't know any better.

Q. I'm not blaming Mr. Johnson. I'm just -- it was not helpful, I guess, to avoiding exposure?

A. Certainly not.

14:02:06 Q. Okay. So -- but the wand at least -- it helps extend the spray away from your body? That's the idea of using a wand; correct?

A. Yeah, it moves it approximately 30 inches.

Q. Okay. And is that the length of your wand.

14:02:23 A. I have several wands. I have pressure washer wands, which I use with water only, of course, and I have my backpack wand, which measures about 30 inches.

Q. Okay. So the wand that you use for -- you use Roundup when you use a herbicide, not Ranger Pro; is that

14:02:44 right?

A. That's right.

Q. So when you use Roundup, you use about the same wand that Mr. Johnson was using; is that right?

A. Yes, except mine has a hole drilled in it, and

14:02:53 it shoots out like a squirt gun, not an aerosol.

Q. Okay. Yeah. Understood.

Now, the other thing that Mr. Johnson wore -- we've talked about the boots and the gloves and the mask. I forgot -- he also wore goggles; is that right?

14:03:10 A. Yes -- well, not --

Q. Thank you.

A. For example, like a dust sample and then calculated from that dust how much chemical was in it and knowing how much dust a person takes in each day.

15:29:01 Q. And you've done that calculation many times?

A. Certainly.

Q. All right. Thank you. Now, in addition, Doctor, just to confirm, I think you said this, but I just want to make sure I had it clear. You didn't

15:29:15 compute an actual dose for Mr. Johnson in this case; is that right?

A. I did compute it using the literature values, and I substituted a higher dermal absorption rate of 10 percent and made the computation.

15:29:31 Q. But, Doctor, I'm asking you specifically about -- specific to Mr. Johnson, you didn't calculate -- we went through this before, I think. You didn't calculate the drift that he was exposed to, how much got in through his gloves?

15:29:46 A. No, I did. I can take you to the actual page for his hands, the actual page for his back. I could show you all that data, if you wish. I used the published data for those skin sites for a 60 kilogram individual using a hydraulic nozzle, wearing a waterproof

15:30:09 jacket, waterproof pants, rubber boots, impermeable

gloves and a face shield.

Q. Doctor, what you used to calculate dose here was days of exposure. Isn't that what you just told us on direct?

15:30:28 A. No. I actually calculated the dose in milligrams per kilogram per day as well.

Q. You calculated a dose based on a generic model; isn't that right, Doctor?

A. Oh, I wouldn't call it generic. It's a tested

15:30:41 model.

Q. But it's a model; isn't that right?

A. It's the best model, yes, available.

Q. What you didn't do was sit down and compute an actual drift based on Mr. Johnson himself and based on

15:30:54 exactly what he was wearing, exactly what he was doing; isn't that true, Doctor?

A. I did. I just erred in the direction of assuming that he was wearing more protective gear than he had on, so my dose is an underestimate.

15:31:14 Q. Doctor, would you refer to page 293 of your deposition. Tell me when you have that, Doctor.

A. Okay.

Q. And, Doctor, it's a fact that you did not perform any calculation of the amount of glyphosate that

15:32:04 penetrated Mr. Johnson's clothes, isn't it?

A. It can be developed much shorter than two years, actually.

Q. Okay. And the same is true with respect to the other document that you were shown in the Portier documents; correct?

A. Yes.

Q. And that was a median of 6.7 years?

A. Right. That was a median. Not a -- it's either an early or late extreme.

Q. So nothing in that article says, "You have to have 6.7 years from exposure to diagnosis"?

A. That's correct.

Q. And nothing you saw in that article or from Dr. Portier's opinion suggests that you cannot develop non-Hodgkin's lymphoma from glyphosate or Roundup exposure in two years or less?

A. Correct.

Q. And your opinion in this case is that Mr. Johnson's non-Hodgkin's lymphoma was caused by his exposure to Roundup or Roundup formulations; correct?

A. Yes.

Q. And that's despite the fact that it developed in 2.25 years --

A. That's correct.

Q. -- from exposure to diagnosis?

and they use the word "extraordinarily" or "exceedingly" definitive data can demonstrate otherwise.

And in this and other studies on glyphosate, almost always there's some unaccounted for material. And it should be added into the absorbed dose. Because there are studies that show that glyphosate forms a reservoir in the skin over time and it builds up in the skin.

Q. Now, you mentioned that -- or you were asked whether or not you did a specific analysis of Mr. Johnson's exposure. Do you recall that?

A. Yes.

Q. And would it be possible to come up with an exact amount of Mr. Johnson's exposure to Roundup or Ranger Pro?

A. Yes, it is possible if we use that original equipment under similar environmental conditions and set up monitoring patches on his clothing and let him re-expose himself.

Q. And rather than exposing Mr. Johnson to that again, you indicated that you -- there was another study that you used to generate the information; correct?

A. Yes. Where actual laboratory testing was done of the collection patches placed on various parts of the body among applicators using what we call the nozzle, which is used in field work as opposed to pulling a

tractor.

Q. Okay. Now, Mr. Johnson -- well, first of all, in that study, the comparison you made were to workers who were actually using nonpermeable or impermeable clothing; correct?

16:25:06

A. Well, as the document stated, waterproof. Waterproof jacket, waterproof pants, rubber boots, gloves and a face shield.

Q. And Mr. Johnson wasn't wearing a face shield or waterproof clothing, was he?

16:25:18

A. No.

Q. And so Mr. Johnson's exposure would actually be greater than those applicators that you used in your comparison to come up with the exposure now?

16:25:23

A. Much so. And also remember that the amount used in the applicator studies was approximately a third of what he was using per hour.

Q. So, in fact, your exposure estimate or analysis was underestimated for what Mr. Johnson's exposure truly was?

16:25:40

A. It was.

Q. And that's a conservative number. But still based on that, you found that it was sufficient to cause cancer in Mr. Johnson?

16:25:49

A. Yes.

EXHIBIT 9

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Friday, July 27, 2018, Volume 18, Morning Session, before the Honorable Suzanne R. Bolanos, at 9:11 a.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965334A

Pages 3812 - 3943

discuss the change in pesticide use?

A. Yeah, I did.

MR. WISNER: Your Honor, permission to publish Exhibit 1043?

11:49:15 THE COURT: Any objection?

MR. GRIFFIS: No objection.

THE COURT: Very well. You may proceed.

Q. BY MR. WISNER: All right. Doctor, this is the demonstrative that you've prepared; right?

11:49:40 A. Yes.

MR. WISNER: Your Honor, permission for him to come down and walk us through what this says?

THE COURT: Yes, that's fine.

THE WITNESS: Is that all right?

THE COURT: Yes.

Q. BY MR. WISNER: Doctor, before you go, if you want to mark it, here's a marker. And use this one (indicating). And stand on this side, so you don't block her view. Okay?

11:50:07 Doctor, what is this document? Explain it to the jury.

A. So over the years, the EPA puts out every few years a report on pesticide use in the United States. So just the volume. So scientists can understand what

11:50:18 pesticides are widely used, which ones are being used

more or less.

And they put this information out in a ranking. They rank the top -- they list 25 pesticides that account for the highest volume of use in agriculture. And they 11:50:36 put out reports in '87, '93, '95. All of these years.

So the -- this is the first one they did. And glyphosate, in 1987, which is fairly early in the history of glyphosate use, it ranked number 17. And this is 6 to 8 million pounds used by US farmers and ranchers. All of 11:50:59 these numbers are the range that EPA reported in agriculture.

In the first year they did it, this is a -- atrazine's a corn herbicide. It has been, you know, way up in the ranking all throughout, as you can see. I mean 11:51:15 it's still -- it's still number 2 all the way to there.

So you see the use of glyphosate, it climbed up the ranking fairly quickly, from 17 to 11 to 7 to 5th. And then we see a much -- pretty big jump here to number 2, where it's only about 10 million pounds behind 11:51:38 atrazine, 1999.

In the 2001 ranking, it reached the number 1 spot. It might have happened in 2000. It certainly happened by 2001.

And as you see, it passed atrazine. Atrazine 11:51:56 was used -- there was 74 million to 80 million pounds of

atrazine used and 85 million to 90 million of glyphosate used.

Pretty impressive increase in the popularity and -- and use of Roundup-based herbicides. And this applies by glyphosate -- it's a glyphosate-based herbicide. It could be a subjective herbicide. It could be Roundup. Or any other company that had a -- had a label.

But I really want to direct your attention to what happened, you know, after 2001. So glyphosate is -- this is just -- this is being repeated here. Glyphosate stays at the top. It's ranked number 1 in 2001, between 85 million and 90 million pounds.

Look what happens. It rises 40 million pounds in two years. So just think about that. It rises 40 million pounds. That's half as much of what atrazine was used at in a year. This is the rise in glyphosate.

By 2007, only six years later, the use had more than doubled, to 170 million to 190 million pounds.

By 2007, no pesticide in the history of the US has been used that heavily that much in one year. And the use continued to go up.

And by 2012, according to the EPA, 270 million pounds to 290 million pounds were applied by US farmers. Let's just wrap our minds around this growth from 2001 to

2012. So 11 years.

So there was -- let's just say 90 million pounds applied in 2001. Eleven years later, three times as much. So that's --

11:53:53 You know, the other pesticide most heavily used, atrazine, throughout this whole period, it went from 70 to 80 million pounds. The increase in Roundup use -- glyphosate use, from 2001 to 2012, was double that amount.

11:54:13 So there's never been a pesticide really in the US or globally whose use has gone up as dramatically as the case with glyphosate-based herbicides.

And you've heard a lot about different studies that have assessed -- say, the epidemiology. Well, there 11:54:41 are very few epidemiology studies that -- that take into account the uses and exposures to glyphosate-based herbicides in this part of the history of the use of that product.

So we -- scientists will be continuing to study 11:54:59 glyphosate-based herbicides and their impacts on the environment and the public health for years to come. And one of the major reasons is how much is used.

This -- so American farmers harvest about 310, 315 million acres of crops a year. So this is wheat, 11:55:19 corn, soybeans, potatoes, et cetera. You know, the

harvested crops. About 310 billion acres. 290 -- well, today, it's higher than that. 290 million pounds.

So there's really over three quarters of a pound of the glyphosate-active ingredient applied on every 11:55:42 cropland acre in America if you spread it out equally.

Now, that's not the way it is. Not every crop gets treated with a glyphosate-based herbicide, but it's a volume of use that we've never had any experience with. EPA hasn't had any experience with something used that 11:56:01 widely. And it -- the change came so fast that we're still playing catch-up.

Q. Thank you, Doctor. That was really helpful. Please take a seat.

I'm going to ask a few follow-up questions to, 11:56:16 sort of, explore some aspects of this. All right, Doctor?

A. Yeah, sure.

Q. The first issue is -- you know, I want to get a sense of how glyphosate use has changed in the real world 11:56:28 between 1987 and 2012.

So in 1987, what was the general distribution of Roundup use amongst the world? In the US, sorry, I should say.

A. Well, there were -- at that time, there was 11:56:47 about two-thirds of it were applied by farmers to control

EXHIBIT 10

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Monday, July 30, 2018, Volume 19, Afternoon Session, before the Honorable Suzanne R. Bolanos, at 1:34 p.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965337B

Pages 4126 - 4175

and things like that, but it's not really a commercially viable option.

Q. So you studied this issue?

A. Well, I -- this is what all my life, I --

13:48:13 Q. Right.

A. Before you born, I was working with weeds.

Q. That's what I'm thinking. I mean, you're the guy who knows how to control weeds; right?

A. Yeah. Yeah.

13:48:24 Q. Okay. And it's your testimony to this jury that they haven't effectively used steam to control weeds at the school district of California?

A. They can use it. I'm not saying you don't use it, but I'm talking about why it's not adopted as a

13:48:38 means. Because of all the things I've mentioned.

Q. You are familiar with other alternatives, like acids and stuff; right? And those are not --

A. Yeah, I --

MS. EDWARDS: Your Honor, may I renew my

13:48:48 objection? This is going well beyond the scope of my direct.

THE COURT: All right. Mr. Wisner, he may answer this question.

THE WITNESS: Can I answer?

13:48:56 THE COURT: Yes, you may answer this question.

THE WITNESS: Yeah. There are other alternative herbicide. Mostly acid, you know. For example, acidic acid, vinegar, you want to use it in your kitchen. It's 5 percent acidic acid. You want to use it for herbicide, it's a 20 percent acidic acid. It's -- it's -- it's not very effective. Because, again, for the same reason. It's a contact herbicide, kills the part which is in contact with. If it doesn't contact it, it doesn't kill it. If the weed has underground part, it would be safe, and they will regrow out of it.

13:49:15

13:49:34

In addition to that, the acid is 20 percent acid. It's not easy to use. I mean, it can burn the skin. It can melt sometimes the hose. So, you know, it's not -- it's used in organic setting on smaller scale, but it's not widely adopted because of the reason I mention here.

13:49:49

But you can use it, if you want to use it.

Q. BY MR. WISNER: Doctor, you testified on direct --

13:49:59

A. I'm sorry, can you --

Q. Sorry. I don't want to shout at you, but I've also got to get heard. So no problem.

You know, you testified on direct that you supervise your students spraying glyphosate; right?

13:50:12

A. Yeah. I trained them.

EXHIBIT 11

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Tuesday, July 31, 2018, Volume 20, Afternoon Session, before the Honorable Suzanne R. Bolanos, at 1:31 p.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

Job No. 2965340B

Pages 4311 - 4467

Where are we?

Here we go. "Similarly, increased NHL risk in men was associated with having ever used glyphosate."

And it gives the 2.1 ratio, doesn't it?

14:45:20 A. Yes, it does.

Q. And it says, "After adjustment for the other commonly used pesticides in a pooled analysis of National Cancer Institute's sponsored case-control studies conducted in Nebraska, Iowa and Minnesota"; correct?

14:45:35 A. Yes.

Q. And you assume Dr. De Roos, when she said this, she knew what she was talking about?

A. Yes. Actually, so that really does help clarify it.

14:45:43 Q. Okay. So we agree -- interestingly enough, when she decides to relate the results in the next published literature on this area, she doesn't mention any hierarchical analysis, does she?

A. No, she does not.

14:45:55 Q. She represents the logistical regression; right?

A. Yes, she does.

MR. WISNER: Okay. We can take a break, your Honor.

THE COURT: All right. Ladies and Gentlemen,

14:46:01 let's take the afternoon recess. We'll be in recess

EXHIBIT 12

Johnson v. Monsanto

Goldstein, Daniel A. (Vol. 01) - 02/27/2018 [No Timestamp]

1 CLIP (RUNNING 02:01:54.939)

QUESTIONS BY MR. MILLER: ...

DG-0227-0000708 271 SEGMENTS (RUNNING 02:01:54.939)

1. PAGE 7:08 TO 8:02 (RUNNING 00:00:28.065)

QUESTIONS BY MR. MILLER:
Q. Good morning.
A. Good morning.
Q. And please state your full name.
A. Daniel A. Goldstein.
Q. And you're a medical doctor?
A. I am.
Q. I will refer to you then as Dr. Goldstein.
A. Thank you.
Q. Okay. And you work for the Monsanto Company?
A. I do.
Q. And how long have you worked for the Monsanto Company?
A. It will be 20 years in May.
Q. Okay. Part of your job responsibility at Monsanto is to deal with complaints and consumer safety; is that fair?

2. PAGE 8:05 TO 9:11 (RUNNING 00:00:57.425)

THE WITNESS: I would narrow that somewhat. I -- being a physician, I'm more focused on concerns and complaints related to human health.
QUESTIONS BY MR. MILLER:
Q. Excuse me, I have the hiccups, and I'll try to get rid of them as we go along.
You're also a toxicologist?
A. Yes, an MD toxicologist or a clinical toxicologist, that is correct.
Q. All right. And so you review complaints of human health that would come to Monsanto from people that perceive rightfully or wrongfully that a product of Monsanto has caused them an ill effect; is that a fair statement?
A. I would review some of them. I may not see all of them.
Q. I understand.
And how long have you generally speaking been performing that job function at Monsanto?
A. The entire time that I've been with the company.
Q. Okay. And it's a full-time position at Monsanto?
A. It is.
Q. So you have not been in the clinical practice of treating patients, if ever, and how long?

Johnson v. Monsanto

having spoken with him. It would be my custom and practice to try and do so, and I've seen documents that indicate that I had an intention to do so, but I don't recall a conversation.

37. PAGE 28:18 TO 28:21 (RUNNING 00:00:15.258)

All right. Exhibit 4 and a copy for counsel. This was produced to us in

0332 -

discovery, Doctor, from Monsanto, and it's an e-mail, isn't it?

38. PAGE 29:01 TO 31:18 (RUNNING 00:02:59.379)

00029:01 THE WITNESS: It is an e-mail, yeah.
QUESTIONS BY MR. MILLER:
Q. And it's an e-mail that begins at the bottom from a Patricia Biehl, she's a contractor, on Tuesday, November 11th at 2:12 in the afternoon.
She sends it to who, Doctor?
A. To me.
Q. Daniel Goldstein, right, concerning the subject of what?
A. Was Ranger Pro exposure.
Q. Now, you and I both know that Ranger Pro is a Monsanto product, right?
A. That is correct.
Q. And it also -- like Roundup, it has the active ingredient glyphosate?
A. Correct.
Q. And like Roundup, it has a surfactant in it, right?
A. It does.
Q. Okay. So what do you understand Patricia Biehl's job function to be, sir, at this time?
A. So Patricia Biehl is a
00030:01 long-term Monsanto individual who works in our -- in our consumer response center as a product support specialist. So they take a wide range of calls regarding our products, some subset of which could sometimes be medical in nature.
Q. Okay. So she's a product support specialist, right?
A. That is correct.
Q. And she's employed by Monsanto, right?
A. She's marked as a contractor and so I don't know who her actual legal, nominal employer is. She has worked in the safety center for many, many years, and so for practical purposes from my standpoint, she is functioning as a Monsanto employee.
Q. Yes, sir. I understand.
So let's see what this is about then. Ranger Pro exposure is the subject matter, right, sir?
A. Yes.
Q. "Spoke with Dewayne Johnson," that's Lee's first name, and it gives

Mr. Johnson's phone number and tells us this is his story, right?
A. That is what the document says.
Q. Okay. So on November 11, 2014, Lee Johnson told Patricia he "works for a school district in California and about nine months ago he had a hose break on a large tank sprayer."
That e-mail was forwarded to you, wasn't it, sir?
A. Yes.
Q. "This resulted in him becoming soaked to the skin, on his face, neck and head with" --
What, sir?
A. The document says Ranger Pro.
Q. "He said he was wearing a white exposure suit and it even went inside that."
Do you see that, sir?

39. PAGE 31:24 TO 32:11 (RUNNING 00:00:30.719)

Q. Well, let me read it again. "He" meaning Lee Johnson, "he said he was wearing a white exposure suit and it even went inside that," end quote.
Did I read that correctly, sir?
A. Yes, you did, that is what the document states.
Q. Okay. "A few months after this incident, he noticed a rash on his knee, then on his face and later on the side of his head."
Did I read that correctly?
A. You did.

40. PAGE 32:12 TO 32:16 (RUNNING 00:00:15.053)

Q. "He said he changed his laundry detergent, dryer sheets and used all creams available to him but nothing seemed to help."
What's the medical significance of that, sir?

41. PAGE 32:20 TO 33:01 (RUNNING 00:00:21.736)

THE WITNESS: I don't know. Not being his treating physician or seeing his medical records, typically when you see that, that is someone who is trying to address the possibility of a skin allergic or irritant condition from some type of product.

42. PAGE 33:03 TO 33:04 (RUNNING 00:00:03.219)

Q. As a physician, would you have said that patient had anxiety?

43. PAGE 33:08 TO 33:12 (RUNNING 00:00:10.979)

THE WITNESS: I can't speculate as to -- as to anxiety. I've never spoken with the patient that I can recall, and I am not his treating physician.

Johnson v. Monsanto

44. PAGE 33:14 TO 33:17 (RUNNING 00:00:15.663)

Q. Have you ever spoken to a patient who his entire body covered and doctors were telling him it was skin cancer who didn't have anxiety?

45. PAGE 33:20 TO 34:07 (RUNNING 00:00:25.405)

THE WITNESS: I don't think I've ever spoken to a patient that has made that particular claim or had that particular presentation.
QUESTIONS BY MR. MILLER:
Q. Okay. Let's look at exactly what the document says.
He tells Patricia on November 11, 2015, quote, "His entire body is covered in this now and doctors are saying it is skin cancer."
It's a pretty serious call, isn't it?

46. PAGE 34:10 TO 35:04 (RUNNING 00:00:45.279)

THE WITNESS: Well, it is first and foremost a call that makes no sense to me from the strictly medical standpoint. That's not an attempt to be critical in any way of Mr. Johnson's [sic]. Patients don't always fully understand their medical condition, but as a physician looking at this, skin cancer does not present that way. And so I am looking at something, which as noted in my response, makes no sense to me from a medical standpoint.
QUESTIONS BY MR. MILLER:
Q. Now, there are doctors called cancer doctors or oncologists, right?
A. Yes.
Q. And you're not one of them, right?
A. That's correct.

47. PAGE 35:05 TO 35:07 (RUNNING 00:00:06.501)

Q. Okay. And as a non-Hodgkin's lymphoma that started in the skin, this makes perfect sense, doesn't it?

48. PAGE 35:11 TO 35:19 (RUNNING 00:00:24.386)

THE WITNESS: I have not seen him, but at the -- just at a superficial level, I can say that being covered extensively is consistent with a T cell lymphoma of the skin, but that is not the subject that was raised in this e-mail. In the e-mail it's stated to be a skin cancer.

49. PAGE 35:21 TO 35:23 (RUNNING 00:00:05.641)

Q. But this description, you and I agree, is consistent with a T cell lymphoma in the skin, right?

Johnson v. Monsanto

50. PAGE 36:01 TO 36:12 (RUNNING 00:00:25.405)

00036:01 THE WITNESS: Without seeing
02 the rash and knowing the details of
03 the clinical presentation, I can't
04 purport to make a diagnosis on a
05 patient I have never seen. A T cell
06 lymphoma of the skin can certainly
07 present with widely disseminated rash.
08 QUESTIONS BY MR. MILLER:
09 Q. Well, then I assume you did the
10 right thing and asked Patricia to get you the
11 information you needed in order to help
12 Mr. Johnson out; is that true?

51. PAGE 36:15 TO 37:07 (RUNNING 00:00:31.085)

15 THE WITNESS: I don't recall
16 what happened at that time.
17 QUESTIONS BY MR. MILLER:
18 Q. Well, let's see what happened.
19 I didn't mean to interrupt you.
20 Are you finished?
21 A. No, my custom and practice, as
22 indicated here, would be to try and contact
23 the patient myself rather than to have
24 Patricia Biehl do so because Patricia Biehl
25 is not someone with medical background.
00037:01 Q. Now, have you read Dewayne
02 Johnson's repeated depositions?
03 A. No.
04 Q. This is a man that's been told
05 he's dying from cancer and he's testified
06 under oath that you never called him.
07 Are you aware of that?

52. PAGE 37:10 TO 37:14 (RUNNING 00:00:09.133)

10 THE WITNESS: No, I'm not.
11 QUESTIONS BY MR. MILLER:
12 Q. As Mr. Johnson has stated under
13 oath that you never called him, can you sit
14 here and say, "Oh, no, I did call him"?

53. PAGE 37:17 TO 37:17 (RUNNING 00:00:02.073)

17 THE WITNESS: I do not recall.

54. PAGE 37:19 TO 38:08 (RUNNING 00:00:34.685)

19 Q. Okay. Here's what record we
20 have of Patricia sharing this information
21 with you. This is from you, an e-mail,
22 right, from Daniel Goldstein, right, sir?
23 A. Yes.
24 Q. And this is about six hours
25 after she sent you her e-mail, right?
00038:01 A. Yes.
02 Q. Okay. And it's, again,
03 about -- it's to Patricia and it's about
04 Ranger Pro, right, sir?
05 A. Yes.
06 Q. You told her you would call
07 him, but there's no record of you ever
08 calling him, right?

55. PAGE 38:11 TO 39:09 (RUNNING 00:01:00.296)

11 THE WITNESS: I don't recall

whether I called him or not. That would normally have been my custom and practice, but I have no record or recollection that I did, in fact, speak with him at that time.
QUESTIONS BY MR. MILLER:
Q. Okay. You say to the e-mail to Patricia, "The story is not making any sense to me at all," right?
Is that what you said?
A. Well, that is, in fact, what I said. Those are the words in the -- in the e-mail. What I meant by that is what I had referred to previously. It states his entire
00039:01 body is covered with skin cancer, and that is not a presentation that you will see with what I would consider to be a true skin cancer. So it's not making sense to me from that standpoint.
Q. So you would need more information to be able to help Mr. Johnson as he struggles to find out why he has this -- this cancer all over his body?

56. PAGE 39:12 TO 40:06 (RUNNING 00:00:43.130)

THE WITNESS: Well, it's doubtful that I could help him to answer that question. The science is fairly sound that this product would not be expected to cause either a skin cancer or a T cell lymphoma, so I doubt that I can help him in that sense. Nor can I treat him; he's out of state, so I'm not his treating physician.
But to answer the question, it would certainly be helpful to have spoken with him, and I don't recall whether I did.
00040:01 QUESTIONS BY MR. MILLER:

-KE0332 - Clear Attached Exhibit 0332

Q. Dr. Goldstein, you just said there was no scientific evidence that glyphosate increases the risk of non-Hodgkin's lymphoma.
Did I hear you correctly?

57. PAGE 40:10 TO 40:12 (RUNNING 00:00:06.981)

THE WITNESS: I said that sound science supports the contention that glyphosate does not cause cancer.

58. PAGE 40:14 TO 40:24 (RUNNING 00:00:24.055)

Q. You've known since -- more than ten years before Lee Johnson reached out to you for help that there was credible, scientific evidence in the peer-reviewed journals showing a significant association between the exposure to Roundup and a patient then getting non-Hodgkin's lymphoma.
Sir, you've known about it and wrote about that for over ten years before you talked to Lee Johnson; that's true, isn't

it?

59. PAGE 41:03 TO 41:12 (RUNNING 00:00:25.060)

THE WITNESS: There are epidemiologic, you know, human publications that span that time frame. The weight of the scientific evidence has been that glyphosate is unlikely to cause cancer, and that conclusion has been reached by regulatory agencies around the world, including our own Environmental Protection Agency.

60. PAGE 41:17 TO 41:23 (RUNNING 00:00:16.729)

Q. But, in fact, Doctor, the Environmental Protection Agency has a textbook out that says chronic exposure to herbicides like glyphosate, even specifically mentioning glyphosate, increases one's risk of non-Hodgkin's lymphoma.
Are you aware of that?

61. PAGE 42:02 TO 42:03 (RUNNING 00:00:02.067)

THE WITNESS: I'm sorry, no, I'm not.

62. PAGE 42:05 TO 42:11 (RUNNING 00:00:13.414)

Q. Okay. And you're aware that a scientific advisory panel has many members that have concluded that IARC was quite correct when they said glyphosate is a probable human carcinogen for a very specific cancer called non-Hodgkin's lymphoma, are you aware of that?

63. PAGE 42:15 TO 43:02 (RUNNING 00:00:28.198)

THE WITNESS: I have not reviewed the scientific advisory panel.
QUESTIONS BY MR. MILLER:
Q. Sir, at the time that you wrote this e-mail on November 11, 2014, you already knew that IARC was going to have a meeting in March of 2015 and look at this issue, whether glyphosate -- whether the science showed that glyphosate increased the risk of non-Hodgkin's lymphoma.
00043:01 You knew about that meeting already, didn't you?

64. PAGE 43:06 TO 43:16 (RUNNING 00:00:22.771)

THE WITNESS: We were aware that IARC was going to take glyphosate into consideration, yes.
QUESTIONS BY MR. MILLER:
Q. And you had said to your other colleagues that you expected IARC to either classify glyphosate as a possible human carcinogen or if things are really bad, a probable human carcinogen.
Do you remember having that general conversation?

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65. PAGE 43:19 TO 43:19 (RUNNING 00:00:03.389)

19 Q. With your coworkers in e-mails?

66. PAGE 43:22 TO 44:01 (RUNNING 00:00:10.622)

22 THE WITNESS: I stated in a
23 number of places and in conversations
24 that that was my expectation; however,
25 that conclusion is not supported by
00044:01 the science.

67. PAGE 45:06 TO 45:08 (RUNNING 00:00:03.927)

06 Q. Doing that with other
07 individuals isn't much help to Lee Johnson,
08 can we agree on that?

68. PAGE 45:11 TO 45:17 (RUNNING 00:00:17.773)

11 THE WITNESS: I think it
12 depends what you mean by "help."
13 There's nothing I could provide him in
14 the way of information that would
15 modify his condition in any way. If
16 he's seeking information, that
17 information can be provided.

69. PAGE 45:19 TO 46:01 (RUNNING 00:00:24.126)

19 Q. But, Dr. Goldstein, let me ask
20 you if you're aware of this, sir: When he
21 wrote you on November 11, 2014, he was not
22 terminal yet. He continued to spray
23 glyphosate. He got no information from
24 anyone at Monsanto. He later became terminal
25 after continuing to spray the glyphosate.
00046:01 Are you aware of that, sir?

70. PAGE 46:05 TO 46:06 (RUNNING 00:00:02.615)

05 THE WITNESS: I have not seen
06 his medical records.

71. PAGE 47:03 TO 47:04 (RUNNING 00:00:02.164)

03 Have you seen this before, sir?

0333 -



04 A. Yes, I have.

72. PAGE 47:09 TO 47:13 (RUNNING 00:00:19.972)

09 Q. Explain to us what this is.
10 A. This is an e-mail. It is from
11 Joy Thompson at the Missouri Regional Poison
12 Control Center to Monsanto. Subject of this
13 is March 2015 FIFRA 6(a)(2) reports.

73. PAGE 47:17 TO 47:25 (RUNNING 00:00:25.852)

17 Q. Now and the attached reports
18 we're going to mark as Exhibit 6. Let me
19 give you a copy of those as well and a copy
20 for counsel.
21 All right. So Exhibit 5 is a
22 list of reports that come, and they come to
23 you, right, sir?
24 A. I am copied on the
25 communication, yes.

74. PAGE 48:01 TO 48:08 (RUNNING 00:00:18.861)

00048:01 Q. All right. And let's look from
02 the top.
03 Who is Joy Thompson?
04 A. Joy Thompson is a nurse at the
05 Missouri Regional Poison Control Center.
06 Q. And they're under some sort of
07 contract with Monsanto to do these intakes,
08 or what's the process?

75. PAGE 48:11 TO 49:06 (RUNNING 00:00:51.327)

11 THE WITNESS: We have an
12 agreement with them to provide case
13 consultation and medical response on
14 individuals who contact us regarding
15 our products.
16 QUESTIONS BY MR. MILLER:
17 Q. Okay. So here we have
18 Mr. Johnson who -- well, let's first look at
19 the e-mail and then we'll go to the report.
20 Okay. So she sends that to
21 Matthew Graneto, who is an employee at
22 Monsanto, right, sir?
23 A. That is correct.
24 Q. On April 15, 2015, right, sir?
25 A. Yes.
00049:01 Q. And you are copied, Daniel
02 Goldstein, right, sir?
03 A. Yes.
04 Q. And attached to this is a list
05 of people who have called asking questions,
06 right, sir?

76. PAGE 49:10 TO 49:16 (RUNNING 00:00:16.432)

10 Q. And we'll put Exhibit 6 up
11 which you're now looking at. It's the "Human
12 Exposure/Adverse Effect Incidents Involving
13 Monsanto Lawn & Garden Products."
14 Have I read that correctly?
15 A. Yes, but there's an unanswered
16 question pending.

77. PAGE 49:20 TO 50:03 (RUNNING 00:00:23.692)

20 Q. And this is for the period
21 between March 1, 2015 - March 31, 2015,
22 right, sir?
23 A. Yes, it is.
24 Q. Which ironically is the period
25 when the 17 scientists who compose the IARC
00050:01 committee held their vote to determine that
02 glyphosate was a probable human carcinogen.
03 It was during that same time frame, right?

78. PAGE 50:06 TO 50:11 (RUNNING 00:00:15.072)

06 THE WITNESS: Yes, that's
07 correct.
08 QUESTIONS BY MR. MILLER:
09 Q. All right. And so during that

10 time period, go with me, please, to page 5395
11 in the numbers on the bottom right. Here's

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79. PAGE 50:12 TO 52:06 (RUNNING 00:01:51.478)

another call, Ranger Pro, herbicide from Monsanto.
That's the substance that the caller is calling about, right?
A. Yes.
Q. And it says, "Medical outcome, major effect H-B."
And what does that mean?
A. So EPA in its reporting requirements asked us to classify outcomes according to a categorization scheme. H-B would indicate a serious or persistent medical effect that is being stated by the individual.
Q. All right, sir.
So the active ingredient of this Ranger Pro is 41 percent glyphosate, right?
A. That is correct, yes.
Q. And the caller lives in California, right?
A. Yes.
Q. Where Lee Johnson lives, right?
A. Correct.
Q. "Caller states he has been using Ranger Pro as part of his job for two to three years."
Did I read that correctly?
A. Yes.
Q. "He has recently been diagnosed with cutaneous" --
And you and I agree that means skin, right?
A. Yes.
Q. -- "T cell lymphoma. He has concerns about continuing to use Roundup as part of his job and questions if Roundup could be a source of his cancer."
Do you see that?
A. Yes.
Q. What effort did you make to get back to Mr. Johnson and tell him whether there had been an association between glyphosate and non-Hodgkin's lymphoma after receiving this, sir?

80. PAGE 52:09 TO 53:01 (RUNNING 00:00:33.543)

THE WITNESS: Well, this was a call to the poison control center, not to Monsanto or to me personally.
I don't necessarily follow up on calls to the poison center if the poison center has discussed the product with the individual.
QUESTIONS BY MR. MILLER:
Q. We've just shown how this document was sent to you, right?
A. Yes.
Q. Okay. So this was sent to you.
Do you read them when they're sent to you?
A. I don't necessarily read all of them.
Q. Would you read the ones about a

00053:01 fatal form of cancer?

81. PAGE 53:04 TO 53:17 (RUNNING 00:00:36.432)

04 THE WITNESS: If I would miss
05 it on the monthly reporting, I would
06 see it in the annual reporting. So at
07 some point, yes, I would see anything
08 that was a serious outcome.
09 QUESTIONS BY MR. MILLER:
10 Q. But you don't remember ever
11 getting back to Mr. Johnson and telling him,
12 "Hey, this group of scientists have just
13 concluded there is a probable association
14 between glyphosate and non-Hodgkin's
15 lymphoma."
16 Nothing like that ever
17 happened, right?

82. PAGE 53:20 TO 54:10 (RUNNING 00:00:38.006)

20 THE WITNESS: I don't recall
21 speaking with him.
22 QUESTIONS BY MR. MILLER:
23 Q. I see.
24 As the call progressed, "Caller
25 said that doctors are unsure how to treat his
00054:01 condition, and they are not even sure if it
02 is cancer. Caller states he works with
03 Ranger Pro using a 50-gallon tank and also
04 using a backpack sprayer."
05 Did I read that correctly?
06 A. Yes, you did.
07 Q. So if you would have read that
08 in March of 2015, you would have known that
09 he's still using Ranger Pro, still using it
10 in a backpack sprayer, fair?

83. PAGE 54:14 TO 54:22 (RUNNING 00:00:19.087)

14 THE WITNESS: That is what the
15 document states.
16 QUESTIONS BY MR. MILLER:
17 Q. He goes on to say, "He dilutes
18 10 ounces of Roundup per gallon for the
19 50-gallon tank and 4 ounces of Roundup per
20 gallon when using the backpack sprayer."
21 Nothing out of the ordinary
22 there, right?

84. PAGE 55:02 TO 55:13 (RUNNING 00:00:30.898)

02 THE WITNESS: Nothing out of
03 the ordinary in terms of the use,
04 that's correct.
05 QUESTIONS BY MR. MILLER:
06 Q. "He recalls having been exposed
07 to Roundup twice in the past two to three
08 years, both from the backpack
09 leaking/malfunction. In one case he was
10 wearing personal protective equipment but it
11 soaked through the PPE and his clothing."
12 You're aware that can happen,
13 right?

85. PAGE 55:17 TO 55:18 (RUNNING 00:00:01.844)

17 THE WITNESS: It can happen,
18 yes.

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86. PAGE 55:20 TO 55:23 (RUNNING 00:00:08.529)

Q. "The caller's level of fear is rising over his continued use of Ranger Pro."
Why didn't somebody call him back?

87. PAGE 56:02 TO 56:05 (RUNNING 00:00:05.765)

THE WITNESS: He spoke to individuals at the Missouri Regional Poison Control Center about his concerns.

88. PAGE 56:07 TO 56:10 (RUNNING 00:00:10.906)

Q. Did you tell anybody at the Missouri Poison Control Center when people call, tell them to stop using Ranger Pro because it's been associated with cancer?

89. PAGE 56:14 TO 56:20 (RUNNING 00:00:11.092)

THE WITNESS: No, and I would have no basis for doing that looking at the science.
QUESTIONS BY MR. MILLER:
Q. So even if you had talked to Lee Johnson, you would not have told him to stop using Ranger Pro?

90. PAGE 56:24 TO 57:04 (RUNNING 00:00:05.708)

THE WITNESS: No, I would not.

00057:01 QUESTIONS BY MR. MILLER:
Q. You think he could use it tomorrow and that would be good? That would be okay?

91. PAGE 57:11 TO 57:19 (RUNNING 00:00:26.905)

THE WITNESS: Sorry. Yes.
QUESTIONS BY MR. MILLER:
Q. "He states he continues to get unexplained rashes and nodules over his body. Missouri Regional Poison Control discussed the product toxicity. The symptoms are not an expected response from the product."
That's just not true, is it, Dr. Goldstein?

92. PAGE 57:24 TO 58:03 (RUNNING 00:00:04.472)

THE WITNESS: Yes, it is true.

-KE0334-005 - Clear Attached Exhibit 0334-005

00058:01 QUESTIONS BY MR. MILLER:
Q. So IARC got it wrong?
A. Yes.

93. PAGE 60:24 TO 61:05 (RUNNING 00:00:13.123)

Q. Two members of the Environmental Protection Agency for the United States Environmental Protection Agency were on the IARC panel that concluded glyphosate is a probable form of human

even though the reference to glyphosate wasn't removed entirely, there was a substantial reduction in emphasis, including, but not limited to, removal from the abstract."
Did I read that correctly?
A. You did.

128. PAGE 91:12 TO 91:15 (RUNNING 00:00:08.481)

Q. Why was it such a big deal to make it so people couldn't search abstracts and find the association between glyphosate and non-Hodgkin's lymphoma?

129. PAGE 91:18 TO 91:18 (RUNNING 00:00:01.650)

Q. Why was that important?

130. PAGE 91:21 TO 92:02 (RUNNING 00:00:17.227)

THE WITNESS: Honestly, I don't know what the writers were thinking at the time. What matters to me is the data and so I don't know what the individuals who were making those statements at the time were trying to imply.

131. PAGE 92:04 TO 92:07 (RUNNING 00:00:11.590)

-KE0313 - Clear Attached Exhibit 0313



Q. In 2003, more independent, scientifically published data came out showing the association between glyphosate and non-Hodgkin's lymphoma, true?

132. PAGE 92:10 TO 92:14 (RUNNING 00:00:07.768)

THE WITNESS: I don't remember the exact dates for the various publications. If you have a document that would refresh my memory, it would be helpful.

133. PAGE 92:18 TO 92:20 (RUNNING 00:00:08.778)

Q. I do. Let's look at

0314 -



Exhibit 16, an e-mail from John Acquavella to you in 2003.

134. PAGE 92:21 TO 92:21 (RUNNING 00:00:00.820)

A. Yes.

135. PAGE 92:22 TO 93:25 (RUNNING 00:01:00.491)

Q. So let's take a look at this e-mail. This is again from the epidemiologist at Monsanto, John Acquavella, right?
A. Correct.
Q. And it's in September of 2003?
A. Yes.
Q. And it's sent to you, Donna Farmer and others at Monsanto, right, sir?

A. That's correct.
Q. And it's regarding -- an article that is regarding non-Hodgkin's lymphoma and glyphosate and some other chemical, right?
A. That is correct.
Q. All right, sir.
And it states that it's about the De Roos paper, which is -- we'll call that 2003 De Roos.
Okay?
A. Yes.
Q. Okay. And it says in pertinent part that this paper -- this is a paper from investigators at the National Cancer Institute, right?
A. Correct.
Q. All right. If my math is right, this is 11 years before Lee Johnson reached out for information from Monsanto?

136. PAGE 94:05 TO 94:05 (RUNNING 00:00:00.911)

Q. Is that right?

137. PAGE 94:07 TO 94:23 (RUNNING 00:00:41.855)

THE WITNESS: Yes, it would be 11 years from 2003 to 2014.
QUESTIONS BY MR. MILLER:
Q. Right.
And what John Acquavella, the epidemiologist at Monsanto, tells us here is that, "Strangely glyphosate looks to be one of the pesticides most associated with non-Hodgkin's lymphoma in this analysis."
Did I read that correctly?
A. You did, and then he goes on to explain the reasons why he finds that to be unusual.
Q. And he also states that this is going to "add more fuel to the fire for Hardell."
Who is Hardell?

138. PAGE 95:02 TO 95:05 (RUNNING 00:00:07.657)

THE WITNESS: Hardell is a scientist who had previously published on the topic of non-Hodgkin's lymphoma and glyphosate.

139. PAGE 95:07 TO 95:09 (RUNNING 00:00:07.927)

Q. And Hardell had found an association in his study between glyphosate and non-Hodgkin's lymphoma?

140. PAGE 95:12 TO 95:15 (RUNNING 00:00:06.427)

THE WITNESS: It was reported in that study. Without looking at the study, I don't remember the statistical significance.

141. PAGE 95:17 TO 96:03 (RUNNING 00:00:33.502)

Q. John Acquavella, Monsanto's epidemiologist, closes with, "It looks like

non-Hodgkin's lymphoma and other lymphopoietic cancers continue to be the main cancer epidemiology issues for both glyphosate," and the other drug, right?
A. The other herbicide.
Q. Yes, another herbicide.
"We're assembling a panel of experts to work on this."
Did I read that correct?
A. Yes, you did.

142. PAGE 96:04 TO 96:08 (RUNNING 00:00:12.570)

-KE0314 - Clear Attached Exhibit 0314

Q. I'm no scientist, but one way a chemical can cause a cancer is by damaging the DNA of a cell.
Is that a fair understanding that us lay people should have?

143. PAGE 96:11 TO 96:18 (RUNNING 00:00:16.893)

THE WITNESS: That is one mechanism by which a chemical could contribute to risk of cancer.
QUESTIONS BY MR. MILLER:
Q. Yes, sir.
And by 2007, you knew it was old news that glyphosate damaged the DNA of cells, right, sir?

144. PAGE 96:21 TO 97:02 (RUNNING 00:00:16.292)

THE WITNESS: No, that would be counter to all of the regulatory determinations that I'm familiar with. There certainly is an extensive body of genotoxicity data, but my belief is that the weight of the evidence supports nongenotoxic effect.

145. PAGE 98:14 TO 99:20 (RUNNING 00:01:38.513)

Q. And I can highlight that. "DNA damage may activate genes associated to the development of cancer, lead researcher Cesar Paz y Miqo told sciencedevelopment.net."
A. You had stated it's called the Miqo study. I don't know if that is the correct first citation for this. I'm not sure which of several studies it actually is making reference to.
Q. All right, sir.
In any event, you commented on the study in the e-mail chain that is

0315 -

Exhibit 17. I just want to ask you a few questions about that, sir.
You state -- actually, Eric Sachs.
Now, who is Eric Sachs?
A. Eric Sachs in 2007, well, he would have an individual in our scientific outreach group I believe at that point in

time.
Q. And what he's telling other employees is -- as he copies you and Donna Farmer, "Darren and Andy," these other employees, he says, quote, "Please engage Donna and Dan as this is an old issue and they have extensive experience and information on this topic."
Right?
A. Yes.
Q. You had been dealing with this

-KE0315 - Clear Attached Exhibit 0315

issue for a while, fair?

146. PAGE 99:23 TO 99:24 (RUNNING 00:00:04.447)

THE WITNESS: It had certainly come up before, yes.

147. PAGE 100:03 TO 100:08 (RUNNING 00:00:21.109)

Q. I want to talk to you now about the new Hardell paper in 2008 on these issues and ask you about some e-mails that you sent or received on the issue, if I can. I have

0316 -

copies for you. I'll mark them as Exhibit 18.

148. PAGE 100:09 TO 100:11 (RUNNING 00:00:12.338)

Sir, here are copies of 18 and 19, the article that these e-mails are referencing.

149. PAGE 100:12 TO 101:03 (RUNNING 00:00:45.842)

All right, sir. Here we are in 2008, and Andy Hedgecock, that's an employee at Monsanto, right?
A. Yes.
Q. Is e-mailing you and others about the Hardell, the new Hardell paper, right?
A. He's actually e-mailing us about a variety of articles in the scientific literature that had come out in the preceding week, among them is this particular paper.
Q. Sure.
He attached the new Hardell paper. He attached something about The Chicago Tribune raising a global stink, issues, management, Argentina, and other issues, right?

150. PAGE 101:06 TO 101:10 (RUNNING 00:00:06.420)

THE WITNESS: That's correct.
QUESTIONS BY MR. MILLER:
Q. And the importance was high, right?
A. That's what he indicated, yes.

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00113:01 And obviously something was forwarded to her,
02 and she is asking John and myself whether we
03 have done an assessment on the paper.
04 At that time, you know, we were
05 both covering various issues, so we would be
06 the appropriate people to ask, and that's
07 about all I can tell you about the e-mail.
08 Q. That's fair enough.
09 Whoever wrote this e-mail, it
10 says about the Shinasi paper, "The data on
11 glyphosate is also worth looking over.
12 Table 4, page 4505, summarizes six studies on
13 glyphosate and non-Hodgkin's lymphoma, three
14 or four of which report significant increases
15 in the risk ratio."
16 Did I read that correctly?
17 A. You did, but there was some
18 serious issues with the quality of work in
19 this paper. And this data was reanalyzed by
20 Delzell, and they found a number of
21 significant statistical errors in their work
22 and -- recalculating it in accordance with
23 their own analysis plan, these relationships
24 were no longer anywhere near as statistically
25 significant.
00114:01 Q. You know that the Shinasi paper
02 of 2014, this meta-analysis, was one of the
03 pieces of scientific evidence upon which IARC
04 concluded that glyphosate was a -- probably
05 associated with non-Hodgkin's lymphoma. It
06 was one of the pieces of evidence used;
07 you're aware of that, right?

160. PAGE 114:10 TO 114:21 (RUNNING 00:00:29.221)

10 THE WITNESS: It was cited in

-KE0319 - Clear Attached Exhibit 0319

11 their document, so they had looked at
12 it, that is correct. I don't think
13 they looked at everything, but they
14 had looked at that.
15 QUESTIONS BY MR. MILLER:
16 Q. And the date of this is
17 significant for me to ask this. This is in
18 June of 2014. This meta-analysis was done
19 before Lee Johnson first reached out to
20 Monsanto, right, sir?
21 A. Yes, that is correct.

161. PAGE 119:24 TO 120:03 (RUNNING 00:00:21.652)

24 Q. And once the IARC decision came
25 in, you recommended that Monsanto fund money
00120:01 to them so that they would write articles
02 saying IARC was wrong about glyphosate. That
03 was part of the IARC strategy, right?

162. PAGE 120:07 TO 120:16 (RUNNING 00:00:22.029)

07 THE WITNESS: No, you've
08 mischaracterized that.
09 We support and had supported
10 ACSH on and off over the years with
11 various grants. What I believe I
12 proposed that we do at the time was to
13 provide them the scientific literature

so that they can create whatever documents and responses they choose to create.

163. PAGE 120:20 TO 120:22 (RUNNING 00:00:06.702)

Q. All right. We're going to mark

0321 -

this as Exhibit 24 to your deposition. I'm sorry, Exhibit 22.

164. PAGE 120:23 TO 120:24 (RUNNING 00:00:06.440)

It's an e-mail that you send in February 2015 I want to ask you about.

165. PAGE 120:25 TO 121:16 (RUNNING 00:00:34.534)

All right, sir. So this is an e-mail from you on February 26, 2015, right, sir?

A. Correct.

Q. To other employees at Monsanto, right?

A. To my leadership in the regulatory and scientific affairs group, yes.

Q. Okay. Regarding ACSH, right?

A. That is correct.

Q. And what does that stand for again?

A. The American Council on Science and Health, I believe.

Q. And they were working with you to respond to IARC if IARC came out with a decision Monsanto didn't like, right?

166. PAGE 121:21 TO 122:13 (RUNNING 00:00:45.653)

THE WITNESS: They were working with us only in the sense that I had raised this issue with Gil Ross, who was at ACSH, and asked him if they would be interested in receiving information regarding IARC so that they can prepare to respond.

So we don't decide whether they respond. If they do respond, we do not generate that content, and they're quite adamant about those parameters.

So, you know, my point here really was a plea for funding. I wanted to keep our funding to ACSH. I believe that they do a lot of good work. We don't dictate what they respond to, and we don't dictate what they say.

167. PAGE 122:15 TO 123:02 (RUNNING 00:00:28.125)

Q. Let's see what you said in February of 2015.

What you stated, sir, were, quote, "They are working with us to respond, if needed, to IARC." True?

A. That is correct, it is what I had said previously. I had contacted Gil, knowing that the IARC decision was coming,

and offered to provide him a complete set of information around the glyphosate and cancer issues.
Q. He wanted you to feed him information, right?

168. PAGE 123:05 TO 123:15 (RUNNING 00:00:28.943)

THE WITNESS: I raised the issue with him and offered to provide the scientific information to ACSH.
QUESTIONS BY MR. MILLER:
Q. And you stated about whether or not the financial reward would be there with ACSH for Monsanto, quote, "While I would love to have more friends and more choices, we don't have a lot of supporters and can't afford to lose the few we have."
Did I read that correctly?

169. PAGE 123:24 TO 124:18 (RUNNING 00:00:58.820)

A. Well, as I stated earlier, this is an argument for continued funding. I was essentially making the case internally at that point in time in our budget cycle that we needed to support ACSH.
Q. You go on to say, quote, "I am well aware of the challenges with ACSH and know Eric has valid concerns, so I can assure you I am not all starry-eyed about ACSH. They have plenty of warts."
What are some of their warts?
A. Well, if you look back at them historically, some of their positions on tobacco, some of their positions on lead, are not positions that I would agree with. So, you know, this is an organization that I think at least in the recent past has done good quality, science-based work, and I felt it was useful for us to continue to support them.

170. PAGE 124:19 TO 124:20 (RUNNING 00:00:07.090)

0321-006 -

Q. Let's go a couple pages back, if we could, sir, to page 9478.

171. PAGE 124:21 TO 125:13 (RUNNING 00:00:44.082)

This is an e-mail from you to Tracey about the glyphosate IARC assessment, right, sir?
A. Yes.
Q. This was about eight hours before the one we just read, right?
A. Yes.
Q. Okay. "Per my discussion with John, we had some money set aside for IARC."
What's that mean?
A. I had a budget line in the proposed budget to continue to support ACSH in relation to IARC.
Q. Right.
So you thought that you should

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1 CLIP (RUNNING 00:41:38.691)

You know that I'm William ...

DG-0118-0028517 17 SEGMENTS (RUNNING 00:41:38.691)

1. PAGE 285:17 TO 285:20 (RUNNING 00:00:07.082)

You know that I'm William Cople, and I'm an attorney that represents Monsanto in this case, right?
A. Yes.

2. PAGE 286:10 TO 297:25 (RUNNING 00:12:19.347)

Now, you went to college where, Doctor?
A. Undergraduate, University of Wisconsin at Madison.
Q. And you studied what there?
A. My undergraduate degree ended up being in molecular biology.
Q. When did you graduate?
A. Actually December of 1976.
Q. From there you went to graduate school?
A. I was in graduate school concurrently for my last semester of undergraduate school, and I remained in grad school for that year, the spring of 1977, and then went on to medical school.
00287:01 Q. And the graduate school was the same institution that you were concurrently in for undergraduate?
A. Yes. The University of Wisconsin-Madison in -- the graduate school was actually genetics.
Q. Did you get your graduate degree?
A. I did not.
Q. Why not?
A. I had decided at that point in time to pursue medical school, and I went off in that direction.
The concurrent registration really just allowed me to take a graduate-level biochemistry and other graduate courses despite my undergraduate status.
Q. So you did go to medical school, though?
A. I did.
Q. And where was that?
A. Johns Hopkins in Baltimore.
Q. At Johns Hopkins did you study or focus your curriculum on anything in
00288:01 particular?
A. Well, it was obviously a general medical curriculum, at least for the first several years. I knew within the first few years of medical school that I was interested in pediatrics, and so I had a focus interest in pediatrics.

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really could expand my horizons in toxicology.
Q. In that first position at Monsanto, did you have occasion to deal with glyphosate-related issues?
A. I did, yes.
Q. And of what kind?
A. Initially, most of my role was related to product specifications and formulations, to material safety data sheets, both of which I review. And to any medical cases which required my attention, that would include management of Monsanto's relationship with the Missouri Region Poison Control Center, which receives any of the phone calls that come off the telephone number on our packages of consumer use products as well as agricultural products.
Q. How long were you in that initial position you occupied at Monsanto?
00297:01 A. I came in, I believe, in May of '98, and in October of '99, they reorganized, and at that point in time, I was actually moved into what was then global regulatory affairs.
Q. Did you become at some point the director of medical toxicology?
A. Titles are kind of a funny thing at Monsanto.
So I was at one point in time referred to as director, medical toxicology. I'm now titled lead medical sciences and outreach.
Q. Did you continue in that new or next position dealing with glyphosate issues?
A. I did.
And, in fact, after that transition -- I guess originally when I came in, I had pharmaceutical responsibilities as well because we had a pharmaceutical subsidiary. Those responsibilities were, after several years in that new position, were removed from me because we spun out in a merger the pharmaceutical division. At that time I took on more responsibility for

3. PAGE 298:01 TO 298:01 (RUNNING 00:00:02.703)

00298:01 glyphosate-related issues. Also began to

4. PAGE 298:05 TO 304:02 (RUNNING 00:06:43.997)

the restructuring process. And so at that point in time, the breadth of my activities expanded, and I began to become more involved in communication issues.
Q. And these glyphosate issues relate to human health?
A. Yes.
Q. And that was your responsibility?
A. Yes.
Q. How long were you in this position where you had the role of directing medical toxicology?
A. I was the only medical toxicologist inside Monsanto up until very recently; we just had a new toxicologist join

are familiar with our earlier products that were only based on glyphosate.

So as we've added some breadth to the product line, we've incorporated other active ingredients in some of the consumer Roundup products. I would actively communicate with the medical toxicologists and poison control centers, usually at our annual meeting, occasionally in an e-mail conversation, just to communicate with them and make them aware of changes in our product line.

Q. Are these medical toxicologists individuals that you know personally or professionally?

A. I know the vast majority of them. It's not a large group. I certainly know my generation of contemporaries better than the younger trainees, but I know many of them, yes.

Q. Let's talk about science for just a bit.

Does science in its broadest context for you have a role at Monsanto?

A. For me, and I think for the entire technology organization and regulatory affairs is part of technology at Monsanto, for the whole technology organization, it's really all about science.

Q. Does Monsanto follow the science or make decisions based on science?

A. It does both. I mean, we have internal science, we follow external science, and we make decisions on a scientific basis.

Q. Now, as a medical toxicologist, Dr. Goldstein, are you a scientist?

A. I am, yes.

Q. What is your role at Monsanto as a scientist?

A. So I don't do experiments. I don't do research. I primarily look at a range of potential exposures for our employees as well as the formulation of our products which our customers then, in turn, can be exposed to. And I pay careful attention to the safety issues that may evolve around our various products.

Q. Do other scientists at Monsanto or in addition other professionals at Monsanto turn to you for advice on science?

A. Yes, they frequently do. Some of that is simply consultation. Some of it is built in structurally in the sense that, for instance, for product formulations, I have final sign-off on the formulation of any product going out of Monsanto. I have final sign-off on any materials coming into all of our manufacturing facilities around the globe.

So some of that consultation, if you will, is structured.

Q. Now, Monsanto -- well, does Monsanto have scientific expertise in-house?

A. Yes, it does.

Q. And that includes yours?

A. Yes, that's correct.

EXHIBIT 13

Johnson v. Monsanto

Martens, Mark A. (Vol. 01) - 04/07/2017

1 CLIP (RUNNING 02:25:53.247)

Dr. Mart- -- can you please state your ...

MM-0407-0001018 277 SEGMENTS (RUNNING 02:25:53.247)

1. PAGE 10:18 TO 11:08 (RUNNING 00:00:26.676)

Q Dr. Mart- -- can you please state your name for the record.
A Mark Martens.
Q Okay. And you're a doctor; is that correct?
A I'm a Ph.D. in pharmaceutical sciences and toxicology.
Q Okay. Would you prefer I call you Dr. Martens or Mr. Martens?
A Whatever you like.
Q Which would you prefer?
A Oh, you can call me Mr. Martens. That's fine with me.
Q Okay. So, Mr. Martens, have you had your deposition taken before?
A No.

2. PAGE 12:19 TO 12:22 (RUNNING 00:00:11.167)

Q Okay. So what I've given you is marked

MARTENS 1 -

as Exhibit 9-1 is your CV. Is that an accurate version of your CV?
A Yes, it is.

3. PAGE 13:01 TO 14:07 (RUNNING 00:01:03.015)

So it looks like you have some -- some areas of expertise; is that correct?
A That is correct.
Q Okay. And what are your areas of expertise?
A My areas of expertise throughout my career are, you know, toxicology in all its forms. That means as well experimental, regulatory, as evaluative toxicology.
Q Okay. And it looks like you had marked down "experimental toxicology, regulatory toxicology" -- I missed one -- "hazard and risk assessment, and preclinical development" as your past and current fields of expertise, correct?
A Yes. I can add that when I was at the university, I was also involved in forensic toxicology.
Q Okay. So an update to this would be that you're also an expert in forensic toxicology?
A Yes.
Q Okay. Excellent.
And it looks like -- like you mentioned you've gotten your Ph.D. in the school of pharmacy in 1976; is that correct?
A Yes.
Q And a rough math is around 40 years ago, right?

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A Right.
Q And so you --
A Yep, 45 years ago, yeah.
Q 45 years ago?
A Yes.

4. PAGE 14:14 TO 15:01 (RUNNING 00:00:32.773)

Q Okay. And right now, if you move to the

MARTENS 1-002 -



next page, it looks like your current position is a consultant in preclinical development and toxicology; is that correct?
A That is correct.
Q Okay. So can you tell the jury a little bit about what -- what your -- what that means, your current job right now.
A That means that as an independent consultant, I'm asked as well by pharmaceutical companies, chemical companies and agrochemical companies to -- to provide them support in interpreting and in analyzing toxicology studies.

5. PAGE 15:08 TO 15:14 (RUNNING 00:00:12.357)

Q Okay. And is -- is Monsanto one of the companies that has hired you as a consultant in that past seven years?
A Yes.
Q Okay. And Monsanto has paid you for that consulting position over the last seven years?
A Yes.

6. PAGE 15:16 TO 16:11 (RUNNING 00:00:45.899)

A It's actually the last five years, because I was actually contacted by Monsanto in 2011 for a first contact.
Q Okay. So, just so we're on the same page --
A Mm-hmm.
Q -- in 2011, Monsanto contacted you --
A Mm-hmm.
Q -- to consult for them; is that --
A Right.
Q -- correct?
And what -- what sort of consulting job were you contacted for in 2011?
A That was actually for the analysis of mechanistic studies on another compound than glyphosate for Monsanto.
Q Okay. And have you done consulting work for Monsanto since 2011 on glyphosate?
A Only the last year.
Q Okay. So, yes, you have?
A Yes, I have.

7. PAGE 17:01 TO 18:08 (RUNNING 00:01:21.130)

Q So it goes on, your -- your CV goes on to talk about your current and previous positions. And if you go through it, it says here that -- and this

MARTENS 1-003 -



is on page 3 of your CV, it says that you were

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promoted to a Monsanto Science Fellow in 2002; is that correct?
A That's correct.
Q And can you tell the jury what that -- what a Monsanto Science Fellow means?
A A Monsanto Science Fellow is a distinguished degree as a scientist in the Monsanto organization.
Q Okay. So it's a distinguished scientist within Monsanto, you were promoted to that?
A Yes. Right.
Q Okay. And is that a position within Monsanto?
A That is not a position. That is a kind of a degree which should be considered as a parallel type of career path next to the managerial career path and which is reserved for people who are continuously involved in scientific projects and scientific research.
Q So when you were promoted to a Monsanto Science Fellow in 2002, were you a current Monsanto employee at that time?
A Yes.
Q Okay. So is -- are the Monsanto Science Fellow promotions just for Monsanto employees?
A That is just -- well, that is a system that exists in every chemical, agrochemical and pharmaceutical industry which allows career paths for people who want to stick to scientific career paths.

8. PAGE 18:09 TO 18:13 (RUNNING 00:00:17.622)

Q Okay. You were a toxicology director in Europe and Africa for Monsanto starting in 1992 and ending in 2004; is that correct?
A Actually, I started with Monsanto in 1989.

9. PAGE 18:15 TO 19:03 (RUNNING 00:00:28.744)

A And then I was hired as a manager of toxicology, and then afterwards I was promoted and I graduate to director of toxicology, Europe and Africa, yeah.
Q Okay. So that's a good clarification. You began working for Monsanto in 1989?
A Yes.
Q And when did you quit working for Monsanto?
A At the end of 2003.
Q Okay. So then between 2003 and when they hired you to be a consultant in 2011, did you do any work with Monsanto?
A No.

10. PAGE 19:09 TO 19:12 (RUNNING 00:00:08.606)

Q Okay. And you were actually, it looks like, a professor or assistant professor at the -- at St. Louis University in St. Louis, correct?
A Yes.

11. PAGE 19:16 TO 19:23 (RUNNING 00:00:18.381)

Q Okay. And you were teaching toxicology to college students.
A No, no, not college students.
Q Okay.

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A I was teaching toxicology to medical postgraduates, and those were two branches that was experimental and occupational and forensic toxicology.

12. PAGE 20:05 TO 20:10 (RUNNING 00:00:17.679)

Q And then you go on to list a few other of your toxicology positions, but the bottom line is that you have been working in toxicology for 45 years, and there would be few people that wouldn't consider you an expert in toxicology; is that correct?

13. PAGE 20:12 TO 20:12 (RUNNING 00:00:02.042)

THE WITNESS: Yes.

14. PAGE 20:22 TO 21:08 (RUNNING 00:00:38.406)

MARTENS 1-005 -

On page 5 of your CV, you also have a lot of experience with international and national organizations. Then you list a couple of pages of those, the EU Commission and Council, the OECD chemicals group. You go on to list -- list a bunch, right?
On the next page, you have experience

MARTENS 1-006 -

with IARC, right?
A (The witness nods.)
Q You have experience with the European Council for the chemical industry, if you go down there.

15. PAGE 21:09 TO 21:17 (RUNNING 00:00:20.496)

MARTENS 1-007 -

You also have experience on the next page with the European Crop Protection Association where it looks like you were participating as a representative of Monsanto, correct?
A Yes, correct.
Q So sometimes you engage with regulatory or international associations on behalf of Monsanto; is that correct?
A Yes.

16. PAGE 21:18 TO 21:21 (RUNNING 00:00:09.931)

Q Okay. And you list -- you go through and there's ten organizations that you list, so you have experience with international organizations, correct?

-KEMARTENS 1-007 - Clear Attached Exhibit martens 1-007

A That's correct.

17. PAGE 23:10 TO 23:14 (RUNNING 00:00:06.863)

Q Okay. And you lived in the United States for two years; is that correct?
A Two years, yes.
Q And then back to Belgium, correct?

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14 A Yes.

18. PAGE 23:20 TO 24:01 (RUNNING 00:00:15.244)

20 Q Okay. So you also lecture on toxicology
21 and related sciences, correct?
22 A Yes.
23 Q And I counted up really quickly that you
24 have lectured at about seven institutes or
25 universities. Does that sound correct?
00024:01 A That sounds correct, yeah.

19. PAGE 24:06 TO 24:09 (RUNNING 00:00:09.662)

06 Q Okay. So you've authored -- coauthored a
07 book on -- is that on toxicology as well?
08 A This is on preclinical development of --
09 and toxicology is a part of preclinical development.

20. PAGE 24:13 TO 24:15 (RUNNING 00:00:07.143)

13 And then very impressively you speak four
14 languages as well, correct?
15 A Yes.

21. PAGE 24:24 TO 25:08 (RUNNING 00:00:37.916)

24 What is oxidative stress?
25 A Oxidative stress is a state of a cell
00025:01 where there is a production of free oxygen radicals,
02 which are inclined actually to damage several
03 molecules in the cell of which DNA.
04 Q Okay. And how long has the scientific
05 community known about oxidative stress?
06 A I think that from 1990, '92, there was
07 science developing in that direction as a possible
08 mechanism of carcinogenicity.

22. PAGE 25:16 TO 25:24 (RUNNING 00:00:23.730)

16 Q Okay. So in the early 1990s, it's fair
17 to say that the scientific community was aware that
18 oxidative stress could increase -- could -- could
19 lead to an increased risk of cancer; is that correct?
20 A That was in the beginning, and, you know,
21 there was more and more information that these were
22 possible mechanisms for carcinogenicity, yes.
23 Q Sure. And what is the mechanism of how
24 oxidative stress can increase the risk of cancer?

23. PAGE 27:07 TO 27:22 (RUNNING 00:00:55.911)

07 A Right. So oxidative stress is a state of
08 the cell where there is a production of free oxygen
09 radicals. Now, free oxygen radicals are a very
10 reactive species, molecular species, and they bind to
11 the oxidized molecules in the cell of which DNA. So
12 oxidation of DNA and there is oxidation of the
13 nucleotides in the DNA can lead, after cell division,
14 to mutation, which can be a permanent change in the
15 gene, and a permanent change in the gene can also
16 make changes in gene transcription, which can lead to
17 phenotypic change of the cell leading to cancer.
18 Q Excellent. Thank you.
19 One other question I -- I have for you is
20 the -- the concept of hazard assessment versus risk
21 assessment. Are you familiar with those two terms?
22 A Absolutely.

24. PAGE 28:02 TO 29:17 (RUNNING 00:01:17.690)

Q Okay. And is it fair to say that a hazard assessment is considering whether an effect can happen under any circumstance; is that fair?
A That's fair.
Q Okay. And is it fair to say that a risk assessment is considering under what specific circumstance that effect will happen.
A Yes.
Q Okay. I just wanted to make sure I had those -- those straight in my head before we started going.
The first topic we're going to get into is, do you know Dr. James -- the late Dr. James Parry?
A Yes.
Q Did he go by Jim Parry or James?
A That was Jim.
Q Jim? Okay.
A Yeah.
Q Dr. Jim Parry. And were you friends with him?
A Oh, we knew each other from scientific congresses. Friends is a little bit too close.
Q Okay. You were professional
00029:01 acquaintances?
A Yes. Put it that way.
Q And what was -- was Dr. Parry a toxicologist?
A He was a toxicologist specializing in genetic toxicology.
Q Okay. And was he an expert in his field?
A Yes.
Q Okay. He was a good scientist, correct?
A He was a good scientist, yes.
Q Okay. And are you -- he has since passed away. Has --
A Mm-hmm.
Q -- has -- am I correct?
A Yes.
Q I believe sometime in around 2010, '11.
A I don't remember.

25. PAGE 30:12 TO 31:07 (RUNNING 00:00:38.219)

Are you familiar with the Bolognesi paper from 1997?
A Yes.
Q Okay. Am I pronouncing that right?
A Bolognesi.
Q Bolo -- okay. Bolognesi. The American way I'm pronouncing it.
A That's okay.
Q Okay. Are you familiar with the Peluso paper --
A Yes.
Q -- from 1998?
A Yes.
Q Okay. And are you familiar with the two
00031:01 Dr. Lioi papers from -- both from 1998?
A Yes, I recall that these have been in our -- are considered, but I -- I didn't actually look at the papers themselves recently.
Q Okay. But you're familiar with all four of those papers --
A Yes. I know about them, yes.

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26. PAGE 31:17 TO 32:05 (RUNNING 00:00:30.743)

Q Okay. So all four of these papers deal with the genotoxicity of glyphosate and/or Roundup, correct?
A Correct, yes.
Q Okay. And you put ourselves -- if we transport back to the 1999 time period right before the turn of the century, all four of those papers came out, correct?
A Yes.
Q They were all 1997 to 1999, correct?
A Yeah, yeah.
Q Okay. And these papers weren't good for the genotox profile of glyphosate and Roundup, correct?

27. PAGE 32:07 TO 32:09 (RUNNING 00:00:07.087)

THE WITNESS: I will phrase it this way: They were not in concordance with the existing results on genotoxicity with -- on glyphosate.

28. PAGE 33:13 TO 33:21 (RUNNING 00:00:26.492)

So did you go to Monsanto with these papers or did Monsanto come to you, or do you not recall because it's been so long?
A Well, I don't recall that detail, but -- but we both were aware at the same time that these papers had been published and these needed attention.
Q Okay. Excellent.
I'm going to hand you what's been -- what

MARTENS 2 -

we are going to mark as -- I guess this will be

29. PAGE 33:22 TO 33:22 (RUNNING 00:00:05.826)

Exhibit 2. No, not Exhibit 2. I need 5.

30. PAGE 34:04 TO 34:10 (RUNNING 00:00:16.925)

Q And when I hand you e-mails, Mr. Martens, feel free to take all the time you need to read them, and if we need to go off the record to give you more time, we certainly can. Okay? I'm not trying to rush you through any documents.
A Okay. Can I read them now?
Q Sure.

31. PAGE 35:04 TO 36:13 (RUNNING 00:01:31.955)

So this is a -- these are what the e-mails from the 19 -- late 1990s look like when they're printed out. The first e-mail was from Donna Farmer, and it was written on December 27th, 1998, which is two days -- two or three days after Christmas back in 1998.
And who is Donna Farmer?
A Dr. Farmer is a product toxicologist located in St. Louis at that time.
Q Okay. And she still is employed with Monsanto, correct?
A I believe so, yes.
Q And at this time was Dr. Farmer your boss?
A No.

Q No. Was Dr. Farmer on the same sort of level as you within the hierarchy of Monsanto?
A At about the same level at that time, yes.
Q Okay. And did you and Dr. Farmer work a lot together at this point?
A We had for this type of project
00036:01 communications.
Q Okay. And did you and Dr. Farmer get along?
A Yeah.
Q Okay. So this looks like Dr. Farmer was talking about a meeting that y'all had had on December 17th on mutagenicity; is that correct?
A That is correct, yes.
Q And the reason why I think that you were at this meeting is that you write back to her two days later, is that -- or -- yeah, two days later; is that correct? If you look above.
A Yeah, it seems to be correct, yes.

32. PAGE 36:18 TO 37:03 (RUNNING 00:00:42.486)

Q So you had a meeting on December 17th of 1998, and ten days later she writes an e-mail to y'all, probably slowed down with the holidays, of course, and about what had happened on December 17th.
And so she has action items from -- "Action items from the meeting, from today's call." So it looks like she had written that simultaneously, and then just circulates that later.
00037:01 So MON 35050, what is that?
A That is a formulation that has been used by Peluso and Bolognesi for their test system.

33. PAGE 37:04 TO 37:07 (RUNNING 00:00:09.652)

Q Okay. So would it be fair to call those the Italian papers? Are they both from Italy?
A It would be fair to call it the Italian formulation.

34. PAGE 37:13 TO 40:03 (RUNNING 00:02:27.673)

Q Okay. So this is the -- this is the formulation that was used in the Italian papers, correct?
A Yes, correct.
Q Okay. So you guys are now knowing about this, this is in late 1998, and you are talking about doing tests on formulation blanks of the Italian formulation, correct?
A Yes. That was the idea, yeah.

MARTENS 2-002 -



Q Okay. And if you turn to the next page, and if you go down, we talk about -- this is where Dr. Parry is first talked about.
A Mm-hmm.
00038:01 Q You have other topics, as you can see, as the jury can see, that they had talked about, but in relative part, it says that: "Agreed that an external global network of genotox experts need to be developed."
Do you see that?
A Yes.
Q Okay. "As EU has an immediate" --

03 one of the Italian papers, which is Bolognesi, and

0217-006 -

04 that was from a couple of years later in 1997, right?
05 A Yes.

65. PAGE 62:13 TO 62:16 (RUNNING 00:00:10.796)

13 And his conclusions were Dr. Parry found
14 a positive response in vitro SCE for both compounds.
15 And the both compounds being glyphosate
16 and Roundup, correct?

66. PAGE 62:20 TO 62:20 (RUNNING 00:00:01.368)

20 THE WITNESS: Yes.

67. PAGE 62:22 TO 63:08 (RUNNING 00:00:26.566)

22 Q Okay. So in -- in the Bolognesi test,
23 the authors were studying both glyphosate and
24 Roundup, correct?
25 A That's correct.
00063:01 Q Okay. So when Dr. Parry is talking in
02 his conclusions about, quote, both compounds, he's
03 referencing glyphosate and Roundup, correct?
04 A Yes.
05 Q Okay. So Dr. Parry -- Dr. Parry
06 concluded that there was a positive response in vitro
07 SCE for both glyphosate and Roundup, correct?
08 A That's what it says.

68. PAGE 63:15 TO 63:17 (RUNNING 00:00:09.262)

15 Q And SCE is another marker looking at the
16 structure of genetic material, correct?
17 A That is sister chromatid exchanges.

69. PAGE 63:18 TO 63:23 (RUNNING 00:00:14.854)

18 Q Okay. And it --
19 A This is an indicator top of test of which
20 the biological mechanism is unknown and with some
21 kind of experimental endpoint which was not accepted
22 by regulatory authorities for assessment of
23 genotoxicity.

70. PAGE 64:07 TO 64:10 (RUNNING 00:00:08.793)

07 Q Dr. Parry concluded that the response was
08 at ten times lower concentration for Roundup mixture,
09 correct?
10 A That's what he said, yes.

71. PAGE 65:03 TO 65:14 (RUNNING 00:00:33.828)

03 Q Dr. Parry concluded that both glyphosate
04 and Roundup mixture produced an increase in DNA
05 strand breaks in mouse liver and kidney, correct?
06 A That's what he says, yes.
07 Q Okay. And next he found that glyphosate
08 increased 8-OHdG in mouse liver, which is a marker of
09 oxidative stress, correct?
10 A Yes.
11 Q Okay. And then he found that the Roundup
12 mixture increased O dash -- or 8-OHdG in mouse liver
13 and kidney, correct?
14 A Yes.

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72. PAGE 65:20 TO 66:21 (RUNNING 00:01:06.328)

Q So he concluded oxidative stress -- Dr. Parry concluded oxidative stress with respect to glyphosate and with respect to Roundup, correct?
A Yes, that was what he concluded, yes.
Q Okay. And this was in 1999, correct?
A Yes.

0217-007 -



Q Okay. Next we're moving to the Peluso paper, which was one of the Italian papers we discussed, and we talk about the conclusion that Dr. Parry found for the Peluso paper. And that is that Roundup mixture produced an increase in DNA adducts in the mouse liver and kidney, correct?
A Yes, that was what he concluded.
Q Okay. And then let's move over to --
A May I -- may I say --
Q Sure.
A -- something?
He also concluded that there was no increase in the production of DNA adducts in the presence of glyphosate.
Q Sure.
A And that's important.
Q That's fair. Okay. Sure.
So -- so what you're saying is that he -- he determined that with glyphosate there wasn't, but with Roundup mixture there was?
A Yes.

73. PAGE 66:23 TO 67:11 (RUNNING 00:01:07.824)

Next if we turn to the Lioi 1998 paper,

0217-008 -



and if you turn the page to 00 and you look at conclusions there, it looks that Dr. Parry found -- or Dr. Parry concluded that there was an increase in the chromatid aberrations of SCE following glyphosate exposure, correct?

0217-009 -



A That is what he concluded, yes.
Q Okay. Now if you turn to 01, we're talking about his conclusions still, and he found -- Dr. Parry found sister chromatid exchanges induced in human lymphocytes by both glyphosate and Roundup mixture, correct?
A That's what he found -- that's what he concluded, yes.

74. PAGE 67:13 TO 67:23 (RUNNING 00:00:25.134)

And he also concluded that the Roundup mixture produced a positive result at a lower concentration, correct?
A That is what he concluded, yes.
Q So Dr. Parry concluded that the Roundup mixture and the glyphosate alone would often produce different results, correct?
A That indeed, yes.
Q Okay. And this was back in 1999 that this was concluded, correct?

Q Okay.
A So we cannot change it.

78. PAGE 71:25 TO 73:03 (RUNNING 00:01:15.597)

0217-011 -

Q Okay. Next page, if you go to 03, it says: "The overall" -- are you there?
A Yeah.
Q Okay. "The overall data provided by the four publications produce evidence to support a model that glyphosate is capable of producing genotoxicity, both in vivo and in vitro, by a mechanism based upon the production of oxidative damage."
Is that Dr. Parry's conclusion in 1999?
A Yes.
Q That was given to Monsanto, correct?
A Yes.
Q Okay. And the question raised by these studies are that the -- this is what Dr. Parry is telling you and some of your toxicology expert colleagues, correct?
A Mm-hmm.
Q Is that the role of components of mixture which leads to high levels of activity of Roundup, he is questioning the genotoxic activity observed due to oxidative damage, correct? And the genotoxic -- and can that activity be reduced by anti -- antioxidants, correct?
A Yes.
Q So his recommendations and questions were kind of similar to what you said earlier was that these studies raised new questions that needed to be studied, correct?
A Yes, that's correct.

79. PAGE 73:04 TO 73:06 (RUNNING 00:00:04.403)

Q So you were in agreement with Dr. Parry that that's sort of what needed to happen, correct?
A Right. Can I point --

80. PAGE 73:09 TO 73:22 (RUNNING 00:00:19.360)

THE WITNESS: Can I point to a sentence which is important --
BY MS. WAGSTAFF:
Q Sure.
A -- which you didn't mention?
Q Sure.
A That he said -- you know, after you mentioned the sentence: "Based upon production of oxidative damage" --
Q Yeah.
A -- he said, "If confirmed."
Q Mm-hmm.
A So that means that he has a hypothetical conclusion and he was seeking confirmation.

81. PAGE 73:25 TO 74:09 (RUNNING 00:00:12.121)

Q Doctor, that's fair, because -- and that's confirmed when it says raised -- questions raised by the study --
A Mm-hmm. Right.
Q -- he is saying that there is more

14 A Not that I recall.

202. PAGE 169:15 TO 169:16 (RUNNING 00:00:04.880)

15 MS. WAGSTAFF: Yeah, and this is what

0209 -



16 we're going to label Exhibit 12 and --

203. PAGE 171:20 TO 171:23 (RUNNING 00:00:10.798)

20 Q So this appears to be a PowerPoint that
21 you've created. Do you remember this PowerPoint?
22 A I -- I recall the images when I see them
23 now, yes.

204. PAGE 172:05 TO 174:06 (RUNNING 00:02:08.909)

05 Q So do you remember making this
06 PowerPoint?
07 A Yes, yes. I remember the -- some of the
08 pictures, yes.
09 Q All right. And so when you made this,
10 you were not an employee of Monsanto, correct?
11 A I was an employ -- employee of Monsanto
12 at the time when I made this presentation.
13 Q Oh, you were. Okay.
14 A Yeah.
15 Q So you made this presentation before
16 2003?
17 A Yes.
18 Q Okay. And -- and what did you make this
19 presentation for?
20 A That presentation was given at the
21 occasion of an internal technology meeting of
22 Monsanto Europe.
23 Q Okay. And so just help me understand,
24 who was the audience that you were presenting to?
25 A It was all European Monsanto technology
00173:01 researchers.
02 Q Okay. And do you remember why you gave
03 this presentation?
04 A This presentation -- well, Monsanto
05 Europe organizes on a regular basis scientific
06 meetings to educate their personnel and to put them
07 aware of new findings in -- in science that is of
08 application to the agricultural products of Monsanto.
09 And at the tech days 2001, which were organized in
10 Brussels, the theme was surfactants.
11 Q Okay. At the what days? I just didn't
12 hear what you said.
13 A Well, there was internal technology
14 meeting days were called the tech days.
15 Q Oh, tech days. Okay. Got it.
16 So tech days 2001 was in Brussels --
17 A Yes.
18 Q -- and the theme was surfactants.
19 A Yes.
20 Q And this was your presentation at that.
21 A Right.
22 Q You remember that?
23 A Right.
24 Q Okay. And so you put this data together
25 at that point, right?
00174:01 A Right.
02 Q Okay. And this isn't a PowerPoint
03 someone else made and gave to you, correct?

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A No, no, this is my PowerPoint.
Q You made it, this is your thoughts?
A Yes.

205. PAGE 174:10 TO 174:25 (RUNNING 00:00:52.679)

Q Okay. So, unfortunately, there aren't names -- or page numbers on it, but I will kind of guide you by picture. Okay?
A Okay.
Q Okay. If you go to the thing that says

0209-015 -



"Surfactant Technology, Specific Toxicity Cases." It's kind of far back, and then it will be easy from there. It looks like this (indicating).
A Yes.
Q Okay.
A I have it.
Q And these are all slides from your PowerPoint, right?
So it looks like you were educating your audience about the toxicology of surfactants, right?
A Yes.

206. PAGE 175:03 TO 175:13 (RUNNING 00:00:31.127)

In doing so, you noted the Peluso case, right?
A Yes. One -- well, the results of our additional research were available at that time, and one of the initiatives was actually to inform personnel -- technology personnel in Monsanto about the results.
Q Mm-hmm.
A And also at the same time in parallel, we were preparing the poster for the Society of Toxicology meeting in San Francisco.

207. PAGE 175:18 TO 177:11 (RUNNING 00:01:50.709)

Q My question was, in educating these folks, you noted the Peluso case, right?
A Yes.
Q Okay. And you talk about the Peluso case and you talk about MON 35050, which is what we've been talking about all morning, the Italian formulation, right?
A Yes.
00176:01 Q And that's the -- MON 35050 is also the formulation used in the Peluso and the -- the --
A Bolognesi.
Q -- Bolognesi paper.
A Yes.
Q Right?
A Yes.
Q Okay. And it says: "The in vivo genotoxicity finding was cause of concern to regulatory authorities."
Correct?
A Yes.
Q Okay. So now these are your thoughts that the genotoxicity finding in vivo was of concern, correct?
A Yes.

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0209-016 -

Q Okay. And this is -- then you're -- you're going on to educate these people who are listening to your presentation about the toxicity of surfactants, and you said: "To better understand the significance, Monsanto undertook research to examine the role of intraperitoneal versus oral, DMSO olive oil versus saline, and then the Italian formulation with and without glyphosate." Right?
A Yes, exactly.
00177:01 Q So I just want to make sure that I understand what additional research Monsanto undertook. Was that the 2008 article that we've been talking about?
A Yes.
Q And was there any other research Monsanto undertook?
A No. That was that research.
Q Okay. And do you remember about what month this presentation occurred in 2001?
A That must have been very early 2001.

208. PAGE 177:22 TO 178:03 (RUNNING 00:00:14.417)

Q Okay. And so your -- the -- the results from your new study weren't finalized at this point; is that correct?
A I think they were known by that time, yes.
00178:02 Q Okay. So do you include them in this PowerPoint?

209. PAGE 178:05 TO 178:06 (RUNNING 00:00:03.888)

Yeah, the conclusions of that study were mentioned on a slide.

210. PAGE 178:14 TO 179:02 (RUNNING 00:00:36.698)

Q Okay. So this is -- these are your conclusions --
A Mm-hmm.
Q -- from the MON 35050 case.

0207 -

So the MON 350 case is your 2008 study, correct?
A Yes.
Q Okay. And just so we're clear, this is the -- this is the 2008 study that Bill Heydens is the lead coauthor, right?
A Mm-hmm.
Q And it's called "Genotoxic Potential of
00179:02 Glyphosate Formulations: Mode-of-Action Investigations," correct?

211. PAGE 179:10 TO 179:21 (RUNNING 00:00:38.183)

Q If this was done in 2001, previous to -- to this research, why did it take seven years to publish it in a journal?
A Well, we were very fast in actually bringing it into the open because we communicated the results via a poster on the -- at the Society of Toxicology meeting in San Francisco. So those

recent methodology in order -- in a very sensitive and specific way to identify oxidative stress.

243. PAGE 218:18 TO 219:04 (RUNNING 00:00:28.749)

Q Now, you mentioned -- you talked earlier about how once these results came out, they were provided to the authorities and they were part of a poster presentation in San Francisco; is that right?
A Yes, that's right.
Q And when something is published as a poster presentation, is it available to the general scientific community to see and review?
A Yes. Exactly.
Q And the same results were also published in 2008 in a paper that you were a coauthor on?
A Yes.

244. PAGE 219:22 TO 220:02 (RUNNING 00:00:15.066)

0214 -



Q I have marked as Exhibit 18 a February 19th, 2001 e-mail from Bill Heydens to Larry Kier, and you're copied on some of the rest of the thread.
Go ahead and take a look at that, sir, and tell me when you're ready?

245. PAGE 220:04 TO 220:04 (RUNNING 00:00:02.074)

Yes, I'm ready.

246. PAGE 220:14 TO 220:19 (RUNNING 00:00:22.441)

0214-002 -



Q And on the second page of the two pages of this exhibit is an e-mail from Richard Garnett dated February 16th, 2001, to you and to Donna Farmer, Bill Heydens and Bill Graham, reporting on your meeting with Dr. Parry, correct?
A Yes.

247. PAGE 221:04 TO 221:14 (RUNNING 00:00:24.178)

Q Then "The presentation of the results of the MON 35050 study changed the mood because it clarified certain effects found in the Bolognesi and Peluso papers." Correct?
A That's correct.
Q And the MON 35050 study is the one that we were just talking about --
A Right.
Q -- that you performed improving on those earlier studies; is that right?
A That is correct.

248. PAGE 224:10 TO 225:15 (RUNNING 00:01:22.915)

Q Okay. Since our -- I'm reading again from Exhibit 18. "Since our previous discussions with him, Professor Parry had begun to comprehend the complexity and range of glyphosate formulations. We clarified this by reviewing the brands, formulations and surfactants used in Europe and the rest of the world. Then reviewed the mutagenicity studies available for the surfactants used in glyphosate

EXHIBIT 14

Johnson v. Monsanto

Azevedo, Kirk J. (Vol. 01) - 06/08/2016 [No Timestamp]

1 CLIP (RUNNING 00:15:07.977)

Good morning, Dr. Azevedo. Is that a ...

KA-0608-0000424 15 SEGMENTS (RUNNING 00:15:07.977)

1. PAGE 4:24 TO 6:22 (RUNNING 00:02:09.445)

Q. Good morning, Dr. Azevedo. Is that a comfortable --
A. Good morning.
Q. -- title for me to call you?
A. Oh, yeah. Kirk is fine, too.
Q. All right. Could you state your full name for the record.
A. Kirk Joseph Azevedo.
Q. Okay. And do you have a -- do you have a title or a degree that goes with it?
A. Doctor of chiropractic.
Q. Okay. Dr. Azevedo, where are we today for this deposition?
A. We're in Cambria, California.
Q. And is that where you live?
A. Yes, it is.
Q. Is this where you have your medical or chiropractic practice?
A. Yes.
Q. Dr. Azevedo, where did you grow up?
A. In Los Banos, California. I was born in Chico, just for a couple years, lived there, but I was quite young, but Los Banos, California.
Q. Okay. And is that considered part of the Central Coast area?
A. It's Central San Joaquin Valley.
Q. Okay. Is that an agricultural area?
A. Yes. It's agriculturally based.
Q. Tell us, if you would -- well, scratch that. Did you grow up on a farm or in a very agricultural part of the --
A. Yes. I grew up on my family farm, and continues to farm.
Q. What type of farming do they do?
A. Diversified farming from row crops to trees and into cattle now, also.
Q. And you understand we're here today to talk mostly about your experience working at Monsanto?
A. Yes.
Q. Okay. Before we get into that, I'd like to talk about your background some, but focusing now on your childhood, did you ever have any exposure or experience with Monsanto products growing up on the farm?
A. Yes, I did.
Q. Okay. Could you tell us about that?
A. Gosh. Probably some of the earliest memories of Monsanto's Roundup was as if it were a miracle-type product to control some of the more difficult weeds,

2. PAGE 7:01 TO 7:11 (RUNNING 00:00:34.243)

later on, working on the farm, you know, I grew up using Roundup quite regularly and doing things like wicking weeds, like Johnson grass, a difficult-to-control weed

did the perception of Roundup products around this time, were they perceived, in your experience, to be safer with that downgraded signal?
A. Yeah. And that's what we spoke about, like, at these continuing education seminars is things that change, we would go ahead and educate the PCAs as to what those changes are, and in this case, it was the -- you know, a safety difference.

8. PAGE 48:24 TO 49:12 (RUNNING 00:00:45.096)

Q. Okay. So it was able to get you into a different level of the market share?
A. Different price point, yes.
Q. Were there other products at the time you were there that Monsanto made, glyphosate products, that didn't contain the word "Roundup"?
A. Yes. You know, one of which is like Rodeo. Rodeo was used mostly around aquatic areas and it had different types of, once again, less or no surfactant in it that could be dangerous to those -- the organisms that are living inside an aquatic environment.
There might have been other products, too, that were glyphosate-based, but the main one was Roundup itself, and so that's what I stewarded the most.

9. PAGE 49:25 TO 50:02 (RUNNING 00:00:09.850)

When you worked at Monsanto, did you develop an impression of the company's attitude toward profits versus safety?

10. PAGE 50:04 TO 50:08 (RUNNING 00:00:09.048)

THE WITNESS: So it sounded like the question is did I have an impression of product sales versus safety?
MR. LITZENBURG: Yeah. And the company's attitude or philosophy.

11. PAGE 50:10 TO 51:25 (RUNNING 00:01:55.011)

THE WITNESS: That changed as I worked for Monsanto, to add some of the experiences that kind of changed my idea on that, where there were some disconnect with, you know, like with Robert Shapiro's vision with what was actually done in the field, and I know it's nearly impossible for it -- big corporations to, you know, bring their vision all the way down to the sales force, but I saw some things that were incoherent -- weren't consistent with some of the safety protocols that I had experienced with some of the other companies.
BY MR. LITZENBURG:
Q. Okay. Did you have any interactions that seemed to contradict in any way those visions that Robert Shapiro set forth?
A. Yeah. There's a couple experiences that I had that really kind of changed my mind on some of these things --
Q. Okay.
A. -- for safety, one of which was -- well, the first one was doing local market manager training in St. Louis, Missouri, and at some point during that time, had a meet-and-greet with the vice presidents of the company and different managers and so forth, and in sharing, you know, some of this information with one of the vice presidents, I remember, you know, talking about

the vision of Robert Shapiro, like talking about reducing in-process waste and the factories of the future not being these spewing pollution factories, but, you know, being these plants that are going to be green and we can, you know, help, you know, save the world in this regard.

And in speaking of this vision, really kind of quoting from the prospectus where Robert Shapiro is speaking on, one of the vice presidents pulled me aside and says, Hey, you know, we don't know what Robert Shapiro is really talking about here. He's just kind of this visionary guy. This sort of thing isn't really what we're about. We're about making money, so get it straight." And that kind of made me feel like, "Oh, man, jeez, I'm here to save the world," but I -- you

12. PAGE 58:01 TO 58:12 (RUNNING 00:00:24.745)

00058:01 Q. Where did that happen? Was it in St. Louis or --
A. St. Louis, Missouri. That's where we get local manager -- market manager training.
Q. And I'm sorry. You were talking to -- it was a meet-and-greet-type event with senior vice presidents?
A. Yes. We had -- I don't know just vice presidents, and we had regional managers there, too.
Q. Okay.
A. Like, my regional manager was there, also.
Q. Okay.
A. Yeah.

13. PAGE 59:04 TO 59:12 (RUNNING 00:00:22.948)

Q. Okay. And I didn't mean to mischaracterize it. Did that give you any misgivings at the time?
A. Oh, sure because I joined the company based on these visions of Robert Shapiro of reduce in-process waste, et cetera.
Q. And do you know who that was that made that statement to you?
A. Yeah.
Q. Who was that?

14. PAGE 59:14 TO 59:15 (RUNNING 00:00:05.804)

THE WITNESS: Brett. The same name as my brother, Brett Bergmann or Bregemann.

15. PAGE 77:07 TO 79:09 (RUNNING 00:02:34.786)

Q. What is involved in becoming a pest control advisor?
A. At the time, it was, in general, having met certain requirements, and that led to mostly a bachelor of science in that, but then further studies in, you know, pest control and so forth, and then there was, you know, a rigorous exam in order to become a pest control advisor and continuing education that was consistent with that to be able to stay educated in the field to protect people and animals in health.
Q. So pesticide control advisors, then, are experts in the field of pesticide applications; is that fair to say?
A. I believe so. It may have a new term now. I think they may have changed it and incorporate even more fertilizers and how to manage these things so that it's helpful for the environment or not as detrimental.
Q. So when you were working for Monsanto, in your

EXHIBIT 15

Johnson v. Monsanto

Farmer, Donna (Vol. 01) - 01/11/2017

1 CLIP (RUNNING 01:08:13.101)

Good morning. ...

DF-0111-0001321 120 SEGMENTS (RUNNING 01:08:13.101)

1. PAGE 13:21 TO 14:18 (RUNNING 00:00:28.847)

Good morning.
A. Good morning.
Q. What is your name?
A. Donna Farmer.
Q. Donna Farmer, by whom are you employed?
A. Monsanto Company.
Q. And how long have you, Donna Farmer, been employed by Monsanto Company?
A. Since September of 1991.
Q. Okay. Don't make me do the math.
How many years have you been with Monsanto?
A. 25 years.
Q. 25 years continuously employed with Monsanto?
A. Yes.
Q. And as we sit here today, still employed by Monsanto?
A. Yes, I am.
Q. Okay. And what would you describe your title as?

2. PAGE 14:23 TO 15:19 (RUNNING 00:00:43.706)

THE WITNESS: I'm a toxicologist in our product safety center.
QUESTIONS BY MR. MILLER:
Q. Would you -- is it fair to say that you're the lead spokesperson for Monsanto and Roundup?
A. I have been one of the spokesperson for the safety of Roundup when it comes to the toxicology.
Q. Ma'am, who is Christophe Gustin?
A. Christophe Gustin is the head of our regulatory affairs for chemical products in Europe.
Q. And how long, approximately, has he been with the company?
A. I don't know. I've known him for many years.
Q. And you work together with him as the job requires?
A. Yes.

3. PAGE 18:22 TO 18:24 (RUNNING 00:00:06.760)

Q. Okay. So because of your knowledge and experience with Roundup, you were selected to defend Roundup, weren't you?

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4. PAGE 19:02 TO 19:21 (RUNNING 00:00:39.290)

THE WITNESS: I have been involved with glyphosate since 1996, so as this indicated, I had a lot of knowledge. And so based on that in depth knowledge for over those many years, yes, I was asked to be -- help defend glyphosate.

QUESTIONS BY MR. MILLER:

Q. Okay. And that's your job, defend Roundup, right?

A. No, that's not my job. I wouldn't agree with that.

My job is to make sure as a regulatory toxicologist for glyphosate that we meet all the requirements by the regulators. And then there are times when there are questions that are asked about the molecule that we need to do responses for.

So it's more than just, as you say, defending the molecule.

5. PAGE 23:11 TO 23:24 (RUNNING 00:00:37.258)

Now the truth is as early as 2004, your job was to defend the glyphosate business, right?

A. Yes. And again, I want to put that in context, that it's not just about defending glyphosate; it's about being technically correct. And so to be the toxicologist for glyphosate, you need to know the toxicology database, you need to know what the regulatory agencies' reviews are thinking about them; and then when there are questions or allegations about it, then we go back and we put those into context and support the product, yes.

6. PAGE 24:03 TO 24:07 (RUNNING 00:00:09.840)

Q. Here is what we're going to mark as 1:3, ma'am, produced from your file, and it's a document with your name on the top, produced again from your file, Donna Farmer.

7. PAGE 24:16 TO 24:21 (RUNNING 00:00:13.228)

Q. Donna Farmer, do you see that on the top left-hand corner?

A. Uh-huh.

Q. And it says your number one goal, "Defend and maintain the global glyphosate or Roundup business," right?

8. PAGE 24:25 TO 25:22 (RUNNING 00:00:43.830)

THE WITNESS: It does say that, but, again, that's the phrase that was used. But it's more than just doing that. It's about being technically aware of what is going on with this.

So when you look on the other side, you will see that it talks about technical expertise and deliverables that then would come into the position of helping to defend glyphosate.

paragraph, "The overall data provided by the four publications provide evidence to support a model that glyphosate is capable of producing genotoxicity both in vivo and in vitro by a mechanism based upon the production of oxidative damage," right?
A. He says that, but, again, I want to remind you that there were some that were negative. And then again, oxidative damage can be due to cytotoxicity.
In many of the studies where we see these kinds of responses, it's secondary to cytotoxicity, not a primary oxidative response.

0264-012 -

Q. He recommended on page 2104, paragraph B at the top there, ma'am, "an assessment of the individual components of Roundup mixture to determine whether there is any components which act synergistically to increase the potential genotoxicity of glyphosate," right?
A. He did, and it was a basis for a study that we actually did.

-KE0264-012 - Clear Attached Exhibit 0264-012

Q. What study?
A. It was with Heydens, et al.
Q. Can you spell that, please?
A. It was Bill Heydens, H-e-y-d-e-n-s.
Q. Oh, your boss?
A. Uh-huh.
Q. And he did the study?
A. No, there was a group of us. We had some -- because we are not in a laboratory. We worked with some laboratory people to look at this exact question because, again, we did not believe that these findings were related to a genotoxic effect but secondary to some cytotoxicity.
So we did a study doing an oral route of exposure, which would be more relevant, and we didn't reproduce the same findings. We did an intraperitoneal injection and got the same findings but not an oral one.

45. PAGE 153:13 TO 155:15 (RUNNING 00:01:51.467)

Q. All right. Excuse me. What is the date of that study, and was it published?
A. It was a series of studies, so I don't remember exactly when they were, and I think it was in 2008 or '9.
Q. Were they published?
A. It was published in one publication.
Q. Which publication?
A. I don't remember what the journal was.
Q. Were they ever submitted to Dr. Parry?
A. I would believe based on what I

EXHIBIT 16

Johnson v. Monsanto

Heydens, William (Vol. 02) - 01/24/2017

1 CLIP (RUNNING 01:43:43.892)

Can you tell the jury what your ...

WH-0124-0028919 81 SEGMENTS (RUNNING 01:43:43.892)

1. PAGE 289:19 TO 298:23 (RUNNING 00:08:33.720)

Q. Can you tell the jury what your profession is, Dr. Heydens?
A. Yes. I'm a toxicologist by profession.
Q. And what is your current title at Monsanto?
A. Currently I'm product safety assessment strategy lead.
Q. And can you tell the jury what you do in that role?
A. In that role, my job is to work with other scientists as we get new products that come in that would need to be tested for safety to work on, devise the overall testing strategy and sets of studies that we would do to support the safety of that product.
Q. Are there standard studies or a guide to what kind of studies need to be done for a new product?
A. There are for some -- for the traditional pesticides, there are a set of guideline studies. A couple different sets of guideline studies that we can use and we can -- if necessary, we can adapt those for a different product concept.
Q. Are there any required studies that would have to be done for a new herbicide or pesticide?
A. For new pesticides, for which herbicide is one, yes, there's a whole set of studies, a very comprehensive set of studies that need to be done, all way from acutes, subchronics, gene tox studies, reproductive toxicity, developmental toxicity, cancer, metabolism, just -- neurotoxicity, everything.
Q. Who specifies what studies need to be done?
A. Here in the United -- that's by regulatory agency. So here in the United States, that would be the Environmental Protection Agency.
Q. I want to briefly review your background.
Can you tell the jury where you went to college?
A. For undergraduate, I went to Grand Valley State.
Q. And what state is that in?
A. That's in the state of Michigan.
Q. And what degree did you receive from Grand Valley State?
A. My degree was a bachelor's

that's addressed by this report that we've marked as 3-44?
A. Yes, it is.
Q. Okay. Can you turn to page 4 of this report that we've marked as Exhibit 3-44, please, and ask you to read for the jury under the Executive Summary, this paragraphs that starts "the toxicology database"?
A. "The toxicology database is adequate to support the use of alkyl amine polyalkoxylates when used as inert ingredients. The AAPs are not acutely toxic by the oral and dermal routes of exposure or via inhalation under normal use conditions. Concentrated materials are generally corrosive, eye and skin irritants and may be dermal sensitizers. There is no evidence that the AAPs are neurotoxic, mutagenic or clastogenic."
Q. And now let's turn to page 15 of the report. There's a heading 4.4. It says "Classification of Carcinogenic Potential," correct?
00364:01 A. Correct.
Q. And can you read the first sentence of that section?
A. "There is no evidence that the AAPs are carcinogenic."
Q. Do you agree with that finding of EPA that's set forth in 3-44?
A. Yes, I do.

20. PAGE 365:02 TO 365:08 (RUNNING 00:00:12.289)

Q. Has Monsanto ever conducted any research on the genotoxic potential of glyphosate formulations?
A. Yes, we have.
Q. Were you involved in that research?
A. Yes, I was.

21. PAGE 365:12 TO 368:18 (RUNNING 00:03:37.895)

2601 -

Q. Hand you what's been marked as Exhibit 3-45.
Can you tell the jury what this document is?
A. Yes. This is the results of work that we conducted on formulated product and this was published in the peer-reviewed literature.
Q. It was published in the Journal of Agricultural and Food Chemistry, correct?
A. That is correct.
Q. And it was published in 2008, correct?
A. Yes, it was.
00366:01 Q. And can you tell the jury the title of this paper?
A. The title is, "Genotoxic Potential of Glyphosate Formulations: Mode-of-Action Investigations."

Q. And you were the first author on this paper, correct?
A. Yes, that is correct.
Q. Why did Monsanto undertake to write this paper?
A. We undertook this investigation because there were some reports in the open literature which suggested that glyphosate formulations were genotoxic. And it was our hypothesis that those studies had problems with them, which led to improper conclusions, and so we wanted to test to see if that was true or not.
Q. Can you generally describe the methods that you employed in doing this study?
A. Yes. Basically what we did was we selected two of the main studies that were done in the open literature and then we basically did the same study design as they did. So we replicated the study design and then went on to investigate in more detail what the relevance of the findings were.
Q. And what were the results of your experiments?
A. So the results of our experiments were basically that we -- for the most part, we could replicate what they had done. There was one important difference. There was one major finding that they reported that we could not reproduce, but basically we saw the same things that they saw.

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

The other thing that we found was we added a component to the study -- in the studies that they did, these were studies where the test material was injected directly into the abdomen of the animals, and in some -- in one case, the study added a bunch of additional material to those test material that they injected. We added another component where we exposed the animals to that same test material with the additional materials via the oral route of exposure, which would be relevant for humans. And when you do that, you don't see any of the effects that they reported.
Q. And what conclusions can you draw based on those results, those findings?
A. Our conclusion is that those formulations do not produce genotoxicity.

EXHIBIT 17

Johnson v. Monsanto

Jenkins, Daniel (Vol. 01) - 03/21/2017

1 CLIP (RUNNING 01:07:16.557)

Okay. But my question is related to ...

DJ-0321-0003401 114 SEGMENTS (RUNNING 01:07:16.557)

1. PAGE 12:01 TO 12:02 (RUNNING 00:00:03.731)

00012:01 Q Okay. So when did you start working for
02 Monsanto?

2. PAGE 12:04 TO 12:20 (RUNNING 00:00:56.693)

04 THE WITNESS: My recollection is I
05 started working for Monsanto sometime in -- oh,
06 probably early 2007.
07 BY MS. ROBERTSON:
08 Q Do you recall what your position was at
09 that time?
10 A Yes. I was a regulatory affairs manager
11 when I started working for Monsanto.
12 Q Well, what does it mean to be a
13 regulatory affairs manager?
14 A A regulatory affairs manager is a person
15 who served as project management for a project. In
16 this case it was biotechnology. And so what I would
17 do is try to direct the project and -- and move
18 things along.
19 Q Okay. And in 2007, was there a specific
20 project you were assigned to?

3. PAGE 12:22 TO 14:10 (RUNNING 00:01:46.594)

22 THE WITNESS: Yeah, at the time I was
23 working on a biotechnology project in Sweden, and
24 that's what I was doing.
25 BY MS. ROBERTSON:
00013:01 Q And did you always remain a regulatory
02 affairs manager focused on biotechnology during your
03 employment at Monsanto?
04 A No. I was a regulatory affairs manager
05 for several years, and then I -- I took on a new role
06 here in Washington, D.C., for Monsanto.
07 Q And what was that new role?
08 A That role was U.S. agency manager for
09 regulatory affairs, and -- and then later became the
10 lead.
11 THE REPORTER: Became what? I'm sorry.
12 THE WITNESS: The lead.
13 BY MS. ROBERTSON:
14 Q And do you recall what year that was?
15 A I came to Washington, D.C., for Monsanto
16 sometime in early to mid-summer, I would say, of like
17 2010.
18 Q And when you first moved to Washington,
19 D.C., do you recall who your supervisor was at
20 Monsanto?
21 A Dr. Russ Snyder was my supervisor at that
22 time.
23 Q And as U.S. agency manager for regulatory
24 affairs in 2010, when you made the move to
25 Washington, D.C., what type of work did you do for
00014:01 Monsanto? Was there a project -- or a product you

had knowledge of any other regulatory agency desirous of reviewing carcinogenicity related to glyphosate --

20. PAGE 34:07 TO 34:07 (RUNNING 00:00:00.654)

Q -- in Roundup?

21. PAGE 34:10 TO 35:18 (RUNNING 00:02:09.988)

THE WITNESS: I recall around that time that ATSDR had announced in the Federal Register that they were going to be looking at glyphosate as well. But again, Monsanto's concern is about good scientific process.
BY MS. ROBERTSON:
Q And what does ATSDR stand for?
A I don't recall what ATSDR stands for.
Q Just one of those common acronyms that we --
A I'm sure it's common.
Q Probably just regulatory speak. You're probably right there.
Can you explain for me what you mean, and I will read back the question -- or the answer. Excuse me.
"I recall a concern at Monsanto that, you know, with the scientific process that took place. And again, Monsanto doesn't have any issue with a good scientific process taking place and giving the data and sharing it with them so it can be looked at and evaluated in an independent process."
Can you explain for me what you mean by "scientific process"?
A I think for me, and I don't offer it as a scientist, that -- that there is an objective -- objective evaluation by qualified scientists, and they're the best people to figure out what that means and what they need to look at. That's the best I could probably do to describe it.
Q What about -- I mean, I guess, you don't have any other recollection aside from ATSDR of any other government agency that had interest in reviewing the carcinogenicity of Roundup?

22. PAGE 35:21 TO 36:03 (RUNNING 00:00:32.857)

THE WITNESS: Yeah, I think I've responded to that. I -- my answer is the same.
BY MS. ROBERTSON:
Q So ATSDR and EPA are the only two you recall?
A Yes, that's -- that's correct.
Q Did Monsanto prepare any new data for these EPA submissions in and around March 2015?

23. PAGE 36:06 TO 36:14 (RUNNING 00:00:30.894)

THE WITNESS: I -- so for me in my role, I couldn't speak to the age of data. I -- what I would do is, is talk to a government agency in the U.S. and -- and ask, What do you need? They would say that they see a need for data here or there, they've got questions. I would turn back to the scientists and say, Well, what do we have? But I didn't keep track of what was new and what wasn't. That wasn't for me to do.

Johnson v. Monsanto

24. PAGE 36:16 TO 36:18 (RUNNING 00:00:14.236)

Q I'm going to hand you now what we will

0371 -



mark as Jenkins Exhibit 7-2. MONGLY03555680 is the first control number.

25. PAGE 36:21 TO 37:04 (RUNNING 00:00:19.742)

THE WITNESS: (Perusing document.)
Okay.
BY MS. ROBERTSON:
Q Please identify for the record the type of document that is Exhibit 7-2.
00037:01 A This is an e-mail exchange between Monsanto and EPA.
Q And you're a party to this e-mail chain?
A Yes, I am.

26. PAGE 37:08 TO 37:11 (RUNNING 00:00:24.491)

0371-002 -



Q If you could look at the second page at MONGLY03555681.
After your review of this exhibit, do you recall the content?

27. PAGE 37:14 TO 38:20 (RUNNING 00:01:29.432)

THE WITNESS: The content of what?
BY MS. ROBERTSON:
Q Well, could you read for me the content of the e-mail starting with "I asked Dan..."
A "I asked Dan about e-mailing the prepublication of the peer-reviewed paper to you. We can't do that because it will make it public property before its publication. We are therefore going to burn a CD this afternoon, and Natalie will deliver it to your attention. Trust this is OK."
Q And who is Khue, K-H-U-E?
A Khue Nguyen -- I'm not sure of her last
00038:01 name -- was the person who was working at EPA at the time in the pesticide reregistration division.
Q And what is the -- what is the e-mail referring to when it's saying "prepublication of the peer-reviewed paper"?
A I don't recall what this information is, so I couldn't tell you that. But this is -- this is a case where EPA is requesting something, and we're perfectly willing to give it to them.
Q Well, the subject reads: "A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment."
Does that refresh your recollection?
A Yes, but I -- I couldn't tell you the details of the -- the study.
Q Do you know whether this was a Monsanto study?
A I don't recall.
Q Could it have been a JGTF study?

28. PAGE 38:23 TO 39:04 (RUNNING 00:00:17.115)

THE WITNESS: I honestly don't know.

APPENDIX B

SURFACTANT TOXICOLOGY

[redacted]

Toxicology, Europe/Africa



SURFACTANT TOXICOLOGY

Outline

- *Toxicity related to surfactant action*
- *Specific cases of toxicity*
  - *Genotoxicity*
  - *Oestrogenicity*

SURFACTANT TOXICOLOGY
Toxicity related to surfactant action

Skin	• Corrosion (tissue destruction) • Irritation (inflammation) • Sensitisation (allergy) • Irritative dermatitis
Eyes	• Corrosion (tissue destruction) • Irreversible corneal lesions (blindness) • Irritation (inflammation eye lids)
Intestines	• Necrosis • Inflammation • Water retention $\rightarrow$ hypovolemic shock
Kinetics	• Poor skin absorption • Poor intestinal absorption • Enhancement of skin absorption of other chemicals

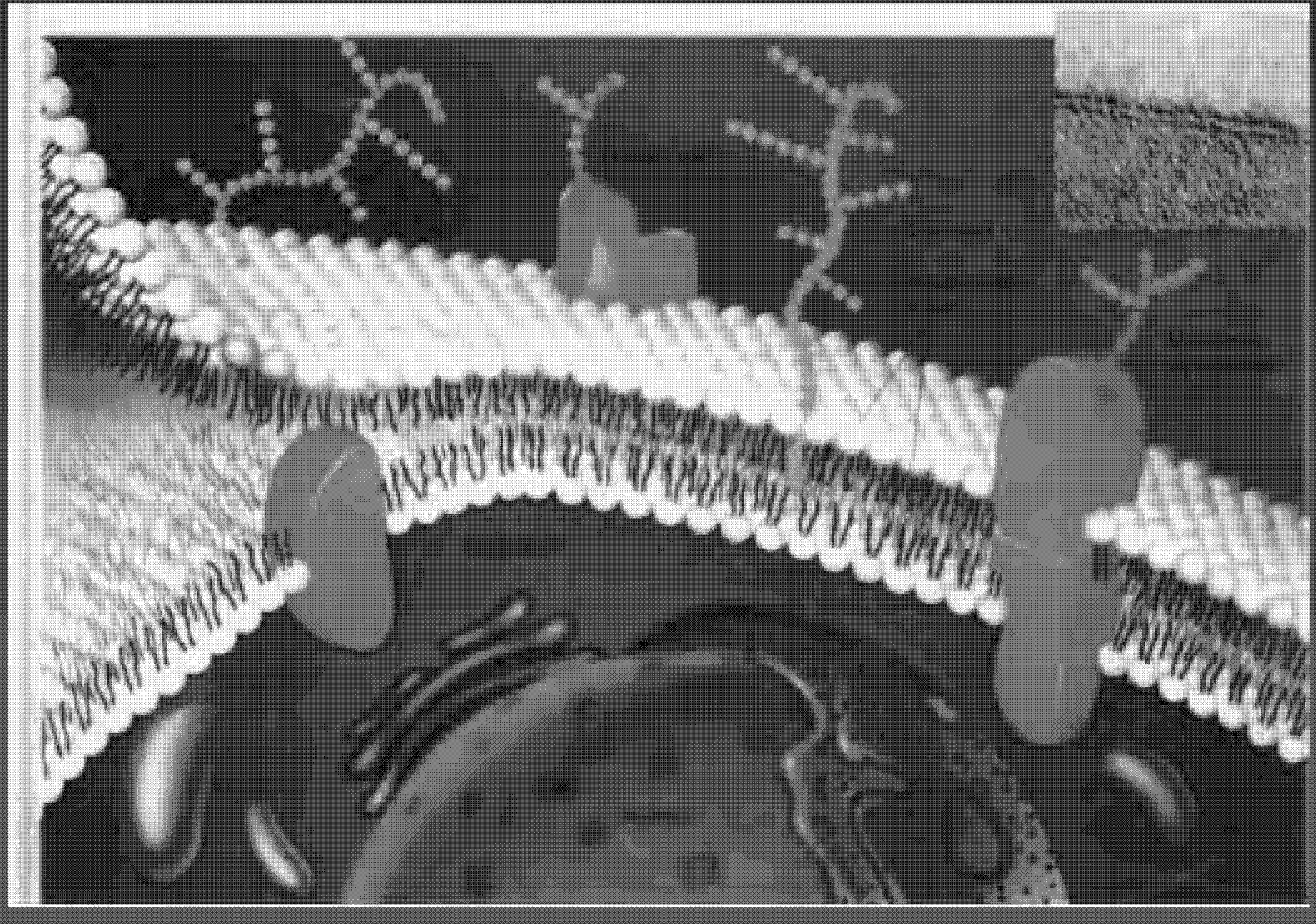
SURFACTANT TOXICOLOGY
Toxicity related to surfactant action

Common toxicologic mechanism:

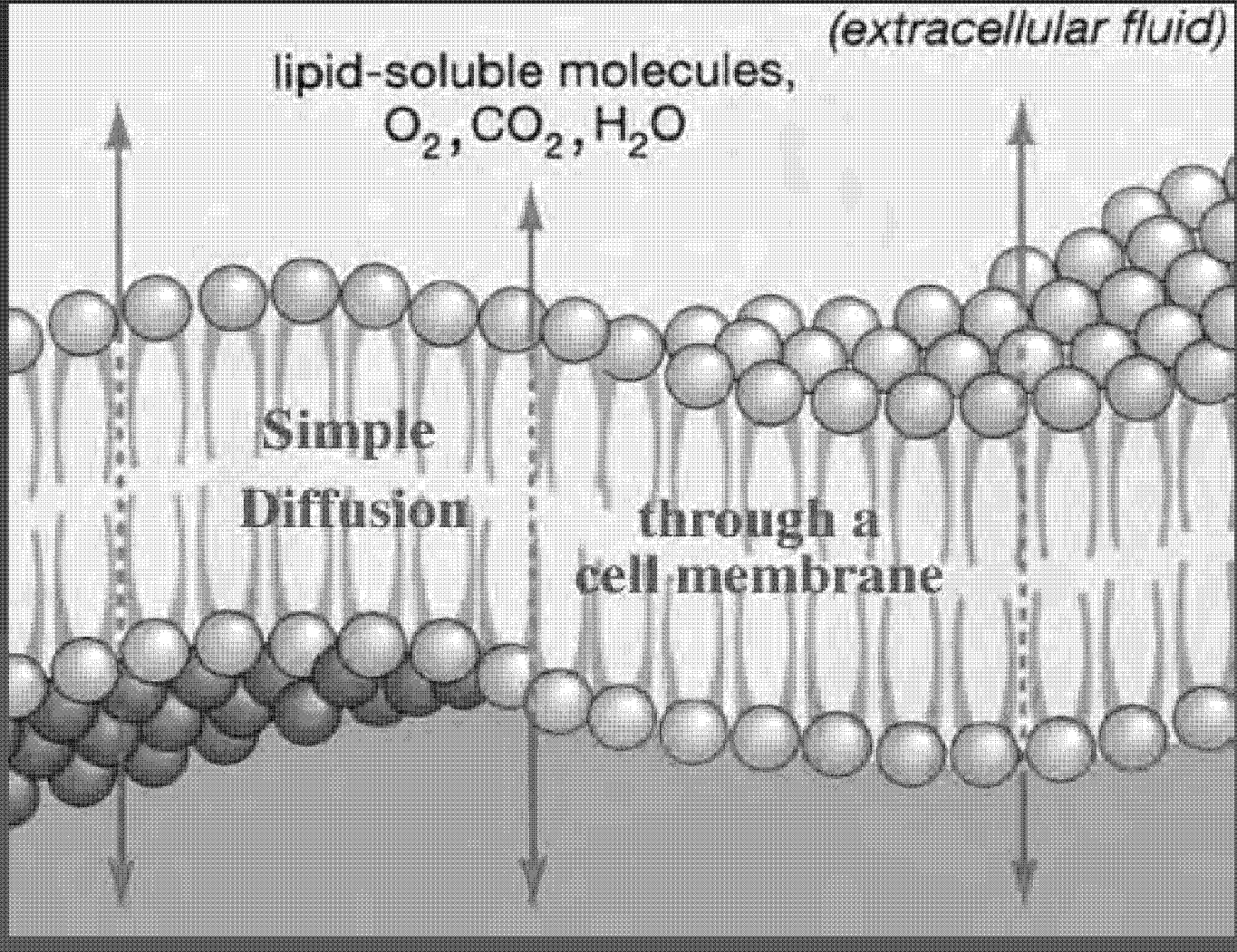
Disturbance of cell membrane integrity

SURFACTANT TOXICOLOGY

Toxicity related to surfactant action

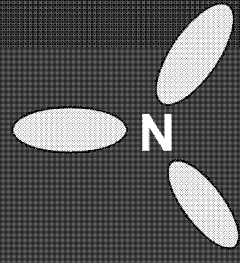


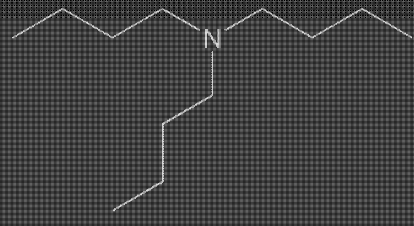
SURFACTANT TOXICOLOGY
Toxicity related to surfactant action

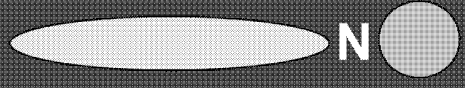


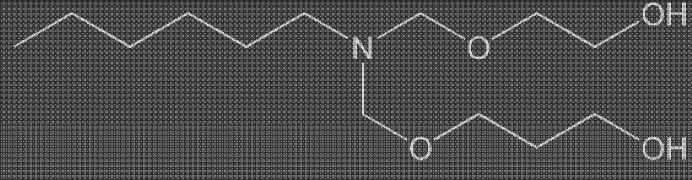
SURFACTANT TOXICOLOGY

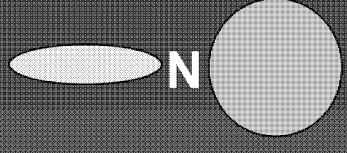
Poly-ethoxylated fatty amines

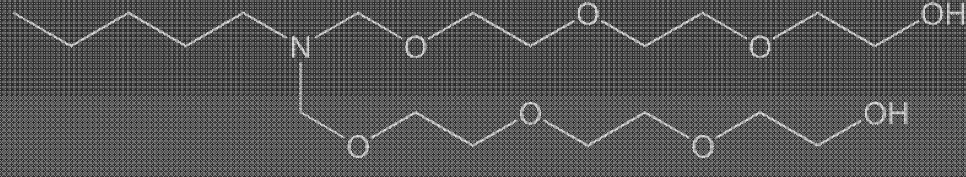


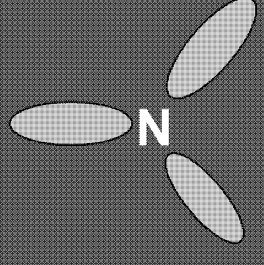


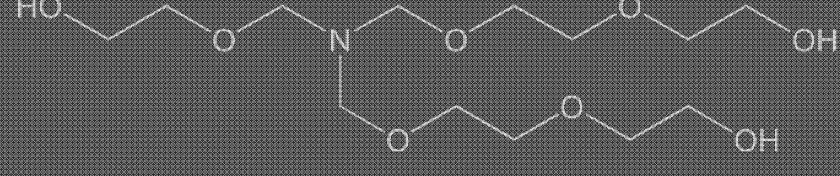






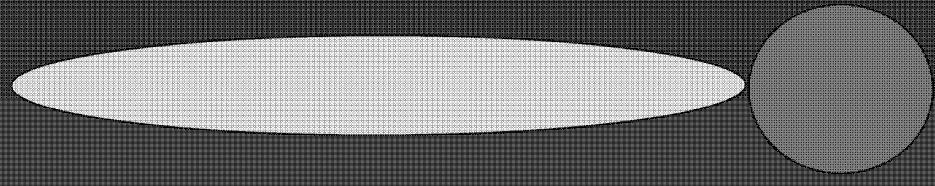




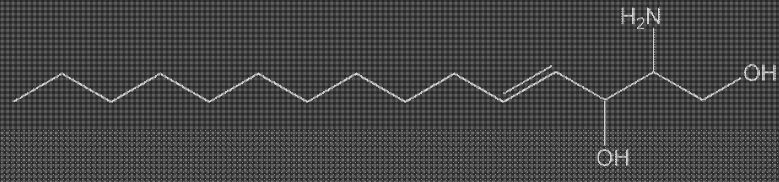


SURFACTANT TOXICOLOGY

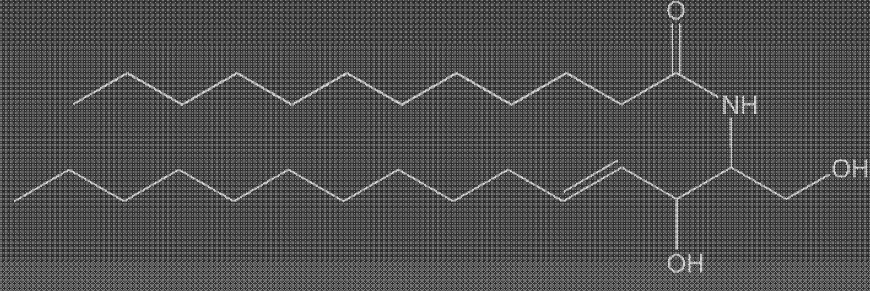
Sphingolipids of the cell membrane



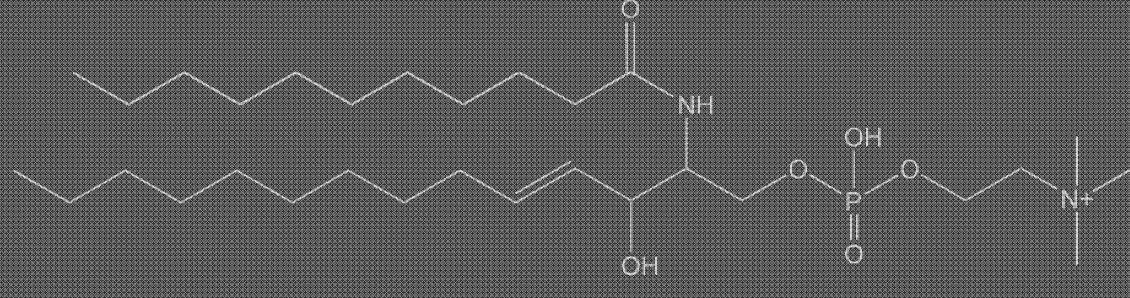
Sphingosine



Ceramide

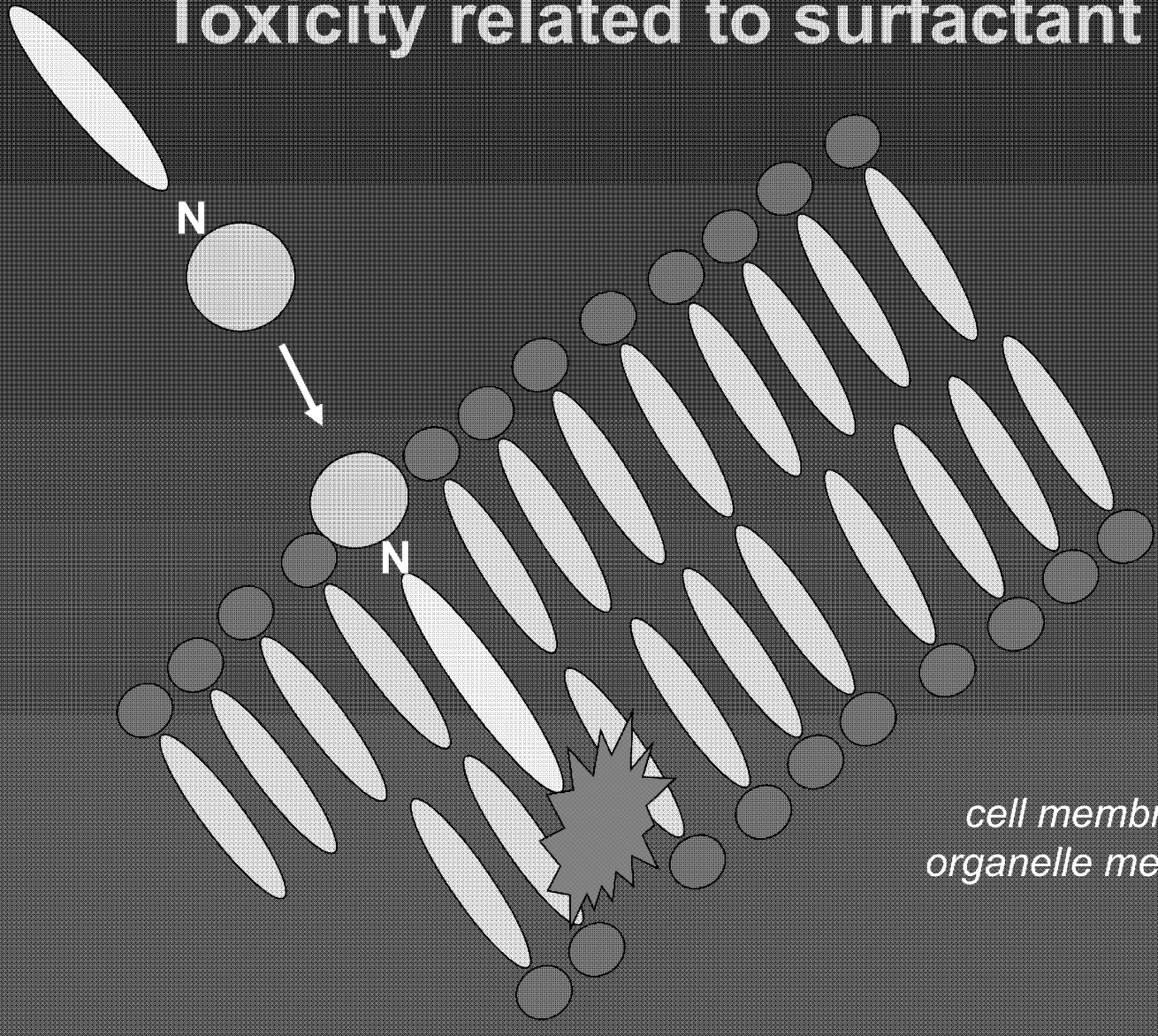


Sphingomyelin

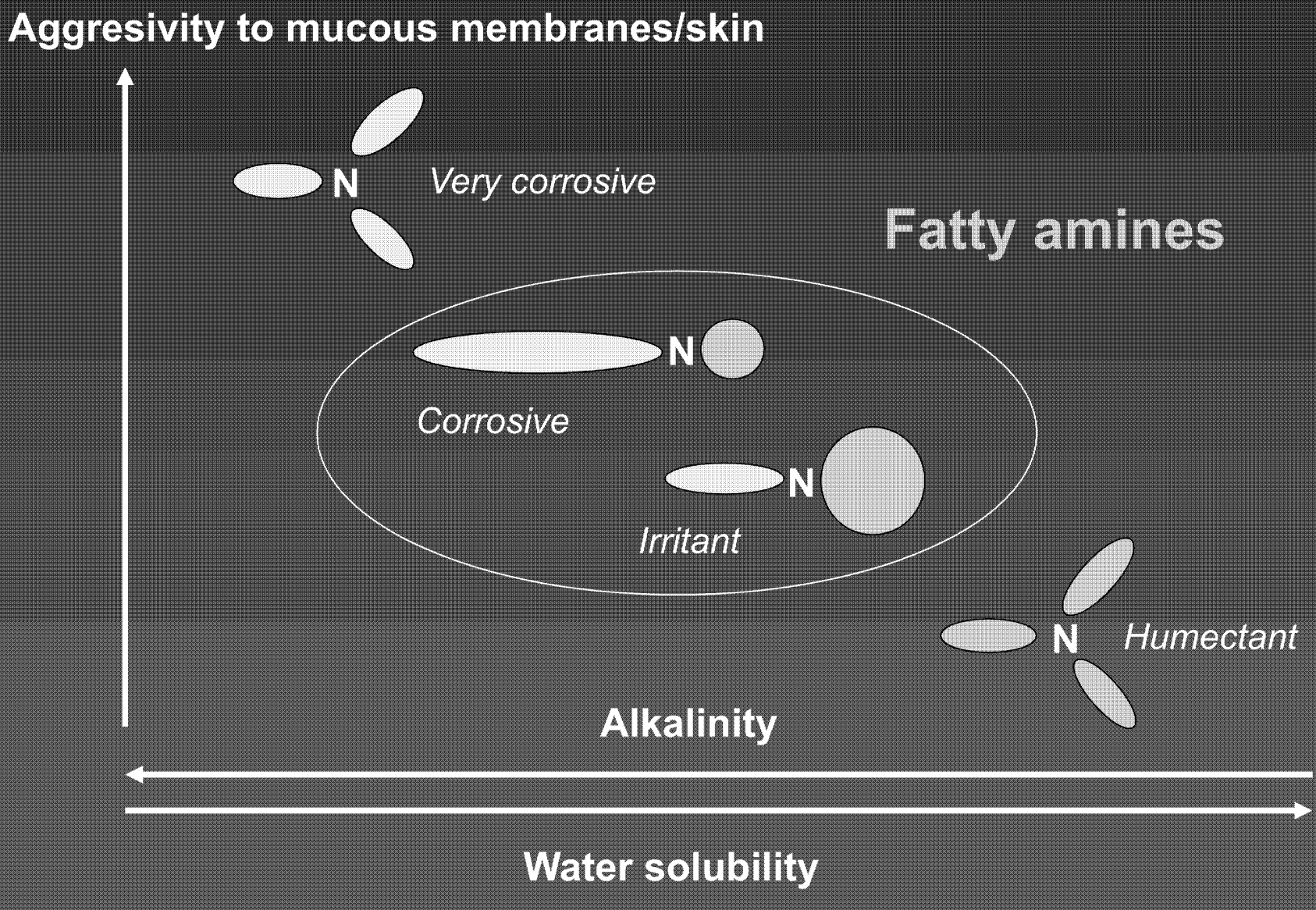


SURFACTANT TOXICOLOGY

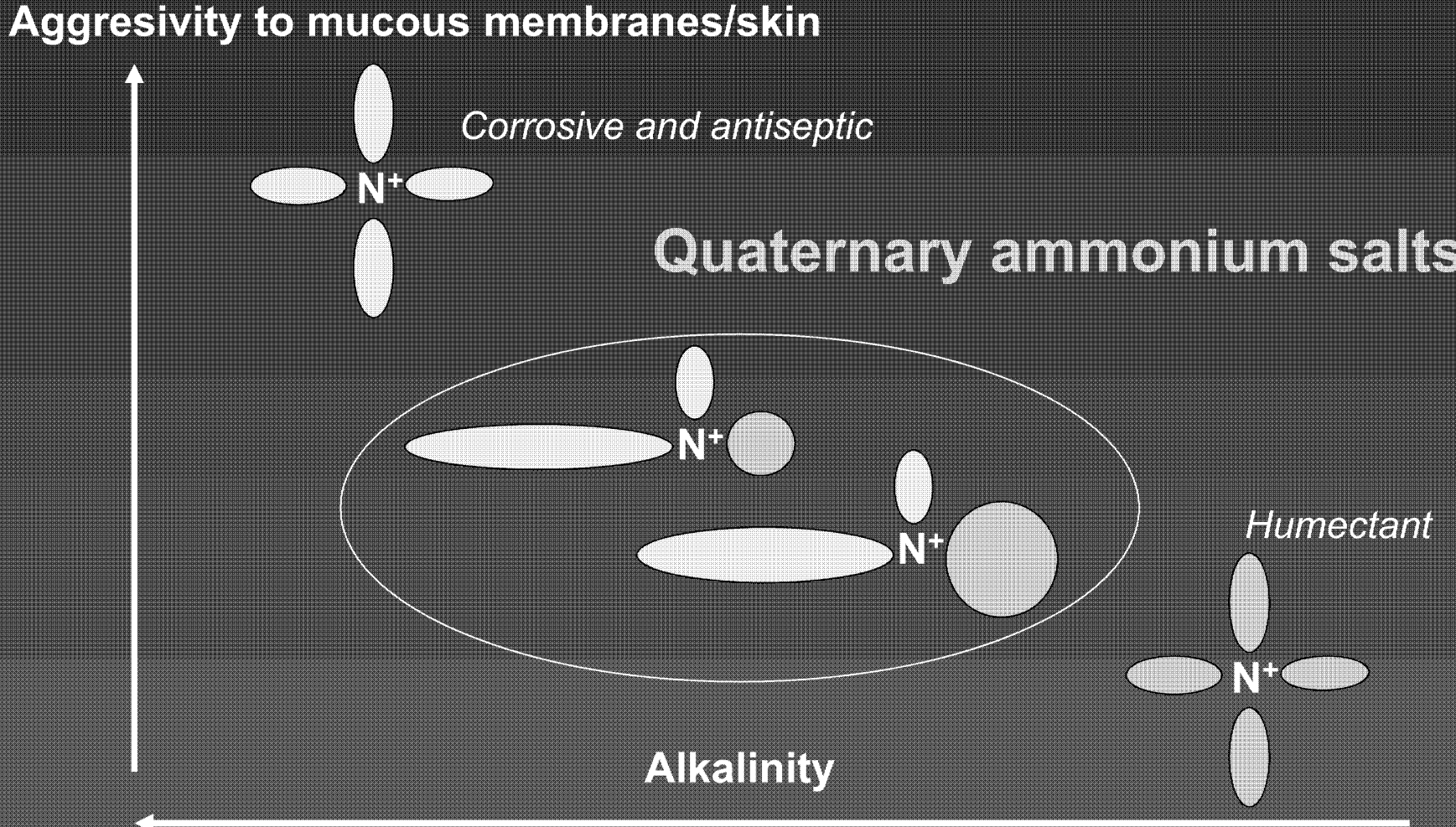
Toxicity related to surfactant action



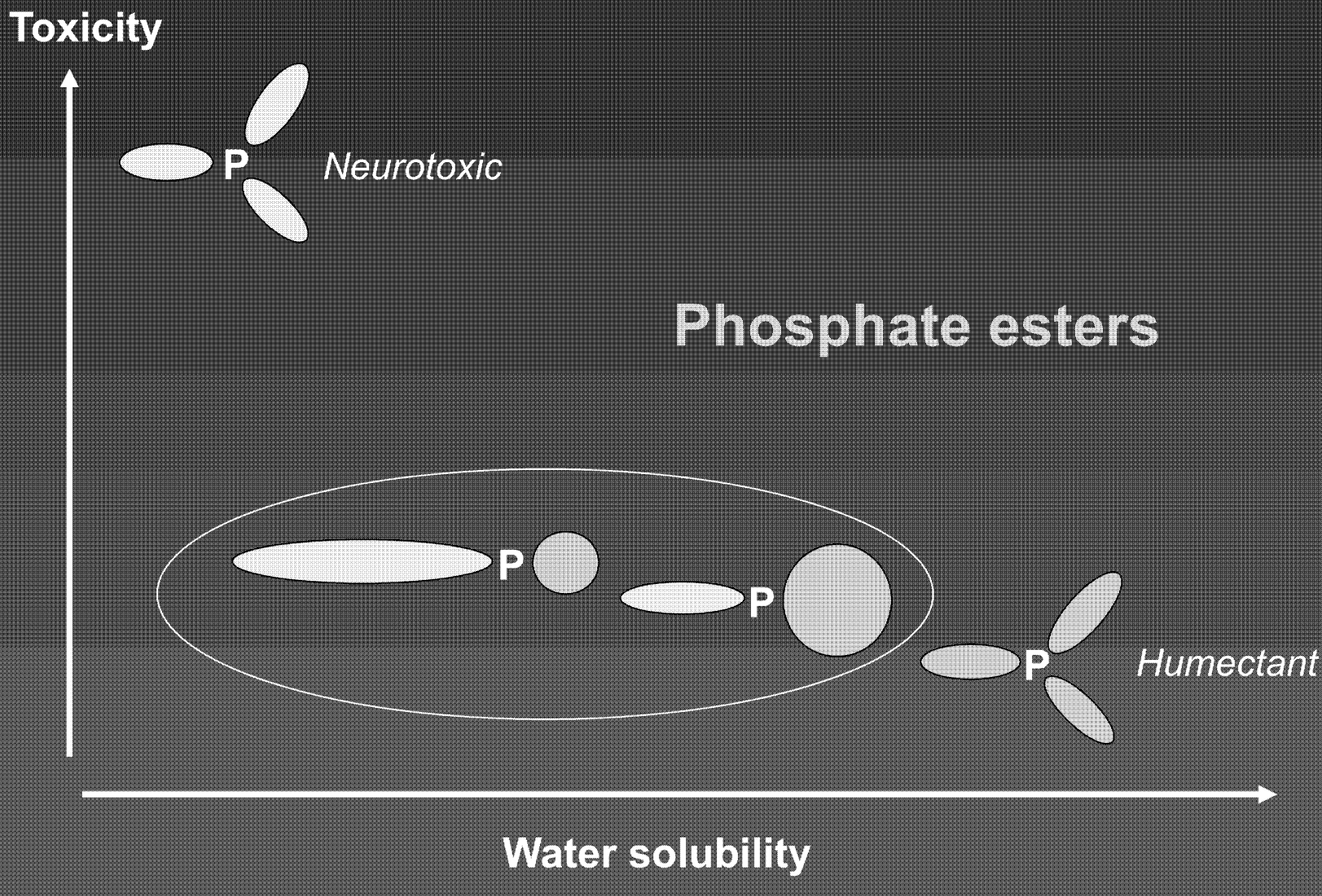
SURFACTANT TOXICOLOGY



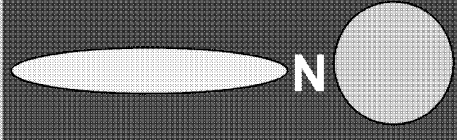
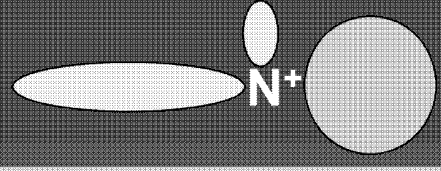
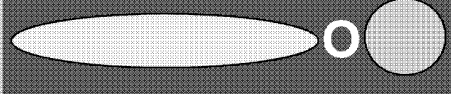
SURFACTANT TOXICOLOGY



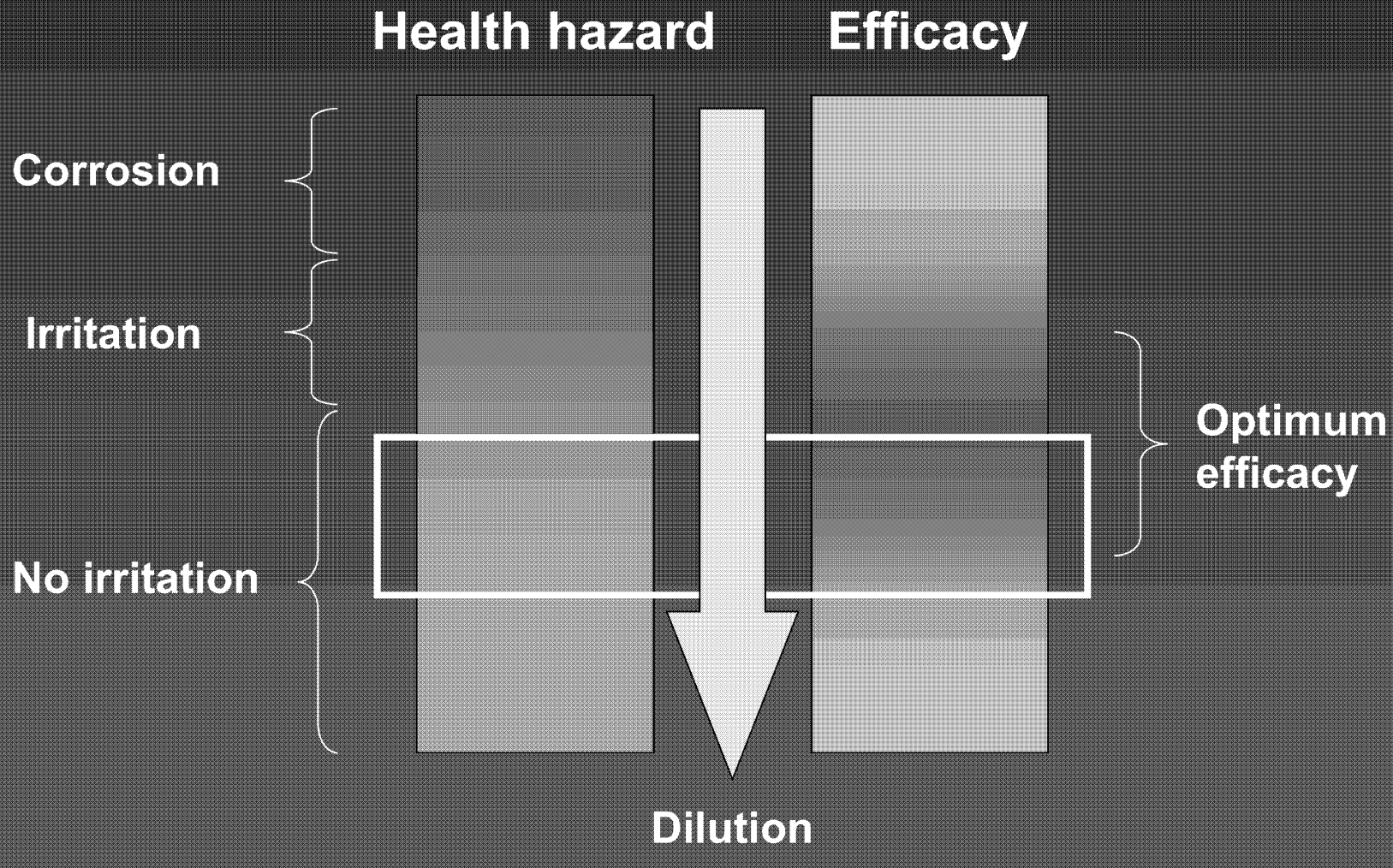
SURFACTANT TOXICOLOGY



SURFACTANT TOXICOLOGY

Surfact.	Type	Cyto-toxicity (EC50, ug/mL)	Eye irritation (EU class)	Fish toxicity (LC50, mg/L)
HOE T 3329		28	Xi, R41	0.1-1
MON 0818		26	Xi, R41	1.3
Dodigen 4022		233	< Xi	> 500
Tween 20		695	0	216
G3 mix	Dodigen 4022 + Tween 20	2068	< Xi	500-1000

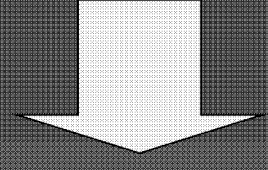
SURFACTANT TOXICOLOGY
Toxicity related to surfactant action



SURFACTANT TOXICOLOGY
Specific toxicity cases: DNA adducts

Peluso et al., 1998:

Increase of DNA adducts in liver and kidneys of mice after intraperitoneal injection (I.p.) of Italian Roundup (MON 35050, not anymore commercial) dissolved in DMSO/olive oil



This in-vivo genotoxicity finding was cause of concern to regulatory authorities

SURFACTANT TOXICOLOGY
Specific toxicity cases: DNA adducts

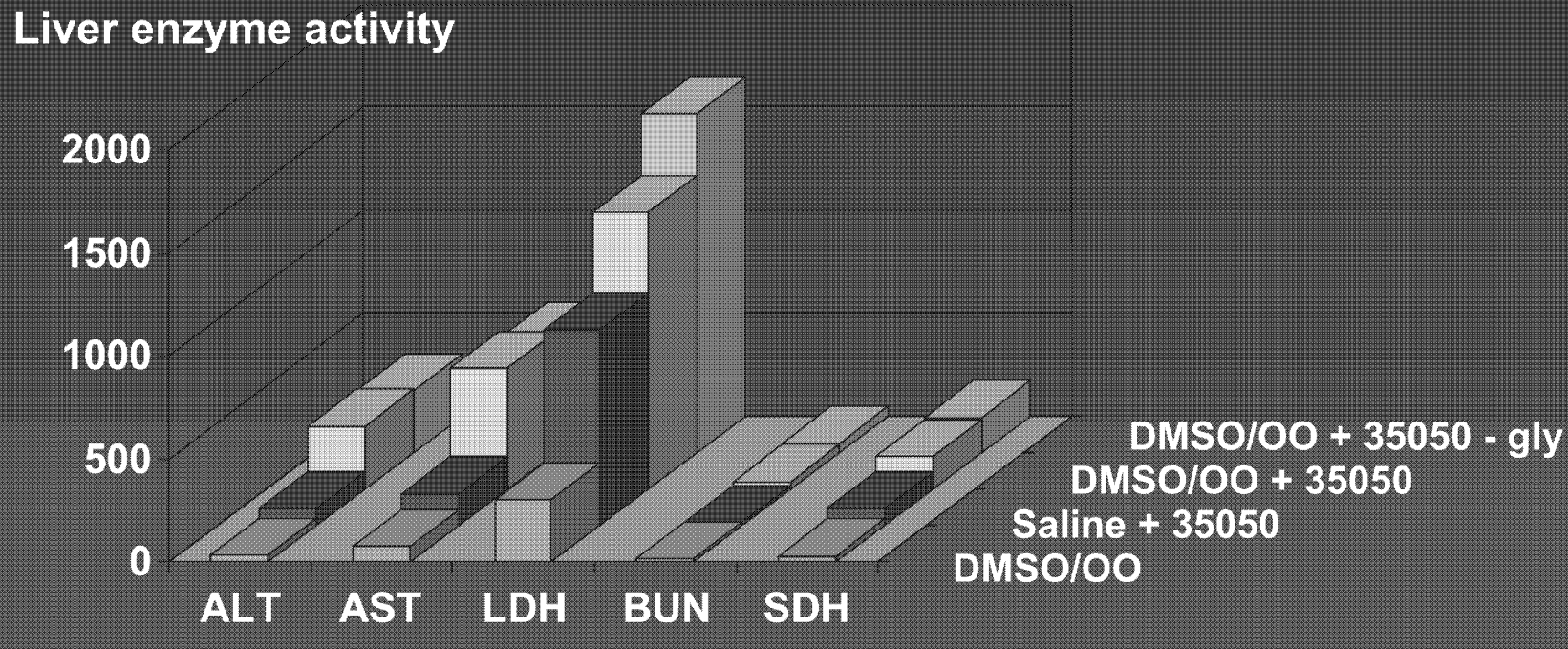
To better understand the significance of these findings Monsanto undertook research to examine the role of:

- *The route of administration (I.p. vs oral)*
- *The vehicle (DMSO/olive oil vs saline)*
- *The surfactant (MON 35050 with and without glyphosate)*

SURFACTANT TOXICOLOGY

Specific toxicity cases: DNA adducts

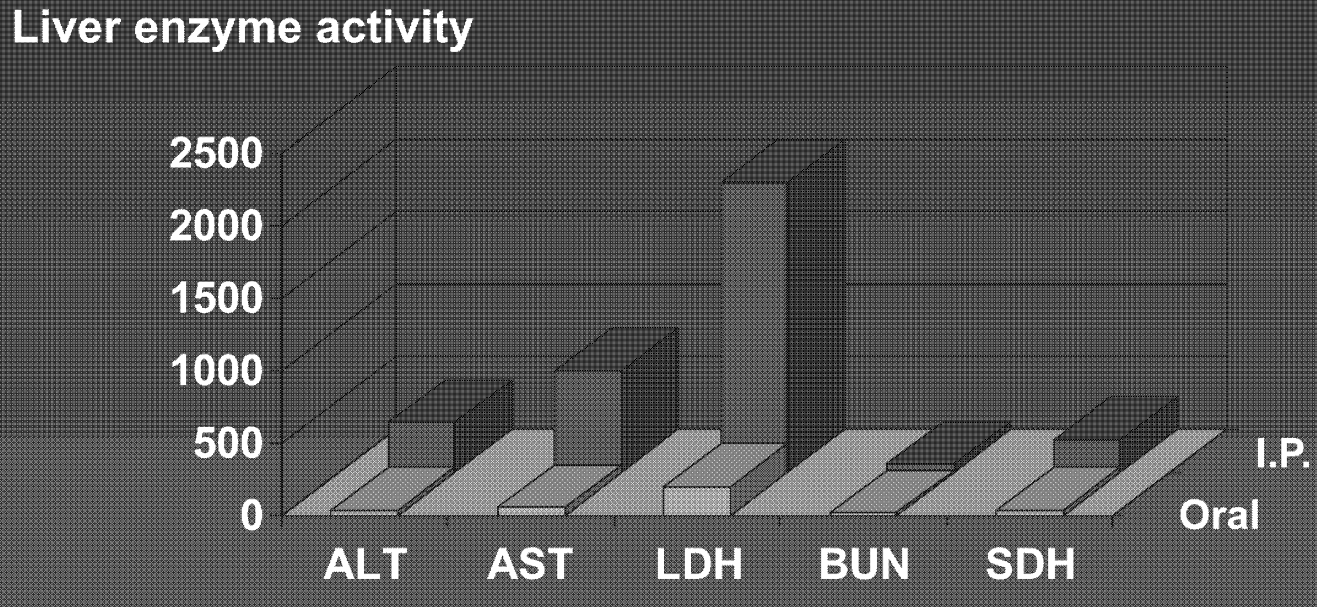
Liver toxicity in the CD-1 mouse: influence of surfactant and vehicle after I.P. administration



SURFACTANT TOXICOLOGY

Specific toxicity cases: DNA adducts

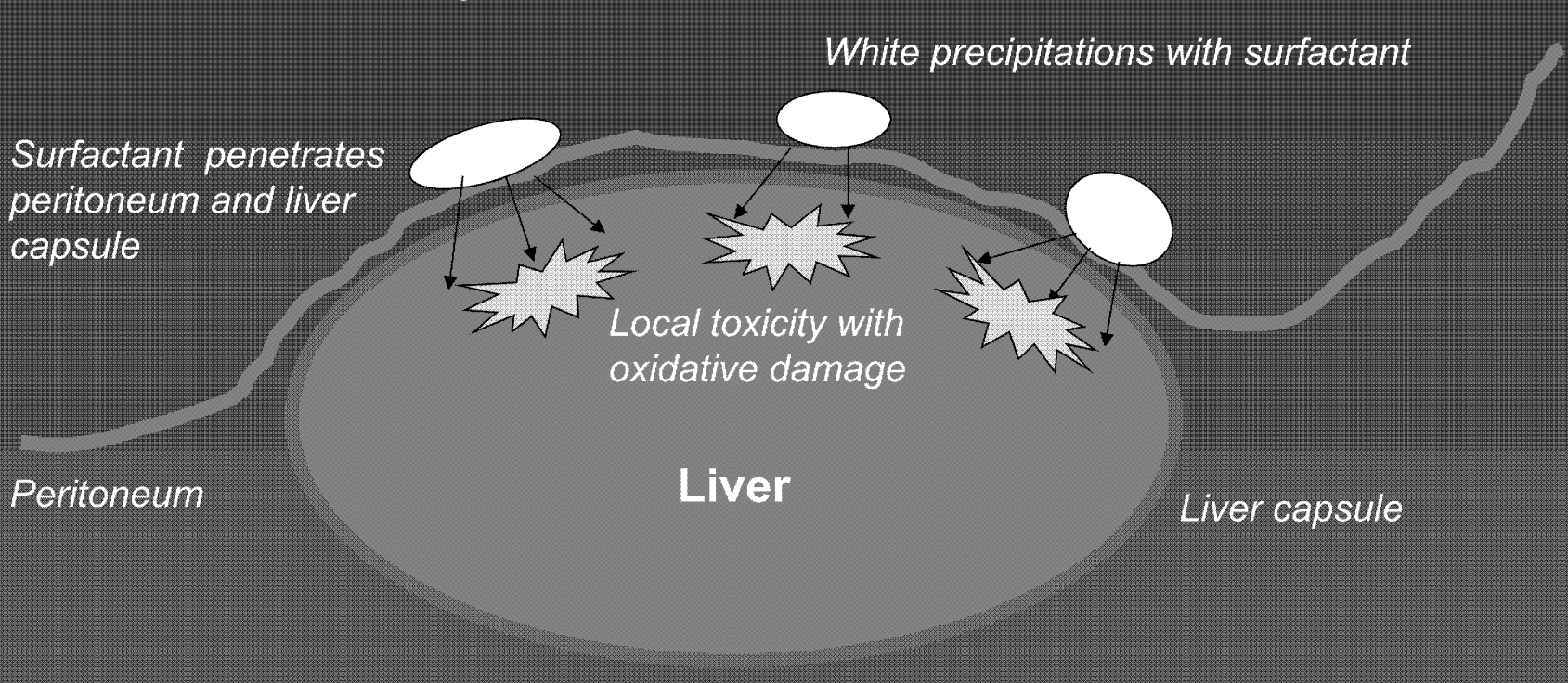
Liver toxicity in the CD-1 mouse: influence of route of administration



SURFACTANT TOXICOLOGY

Specific toxicity cases: DNA adducts

Mechanism



SURFACTANT TOXICOLOGY

Specific toxicity cases: DNA adducts

Conclusions of MON 35050 case

- *The I.P. route is an inappropriate route of administration*

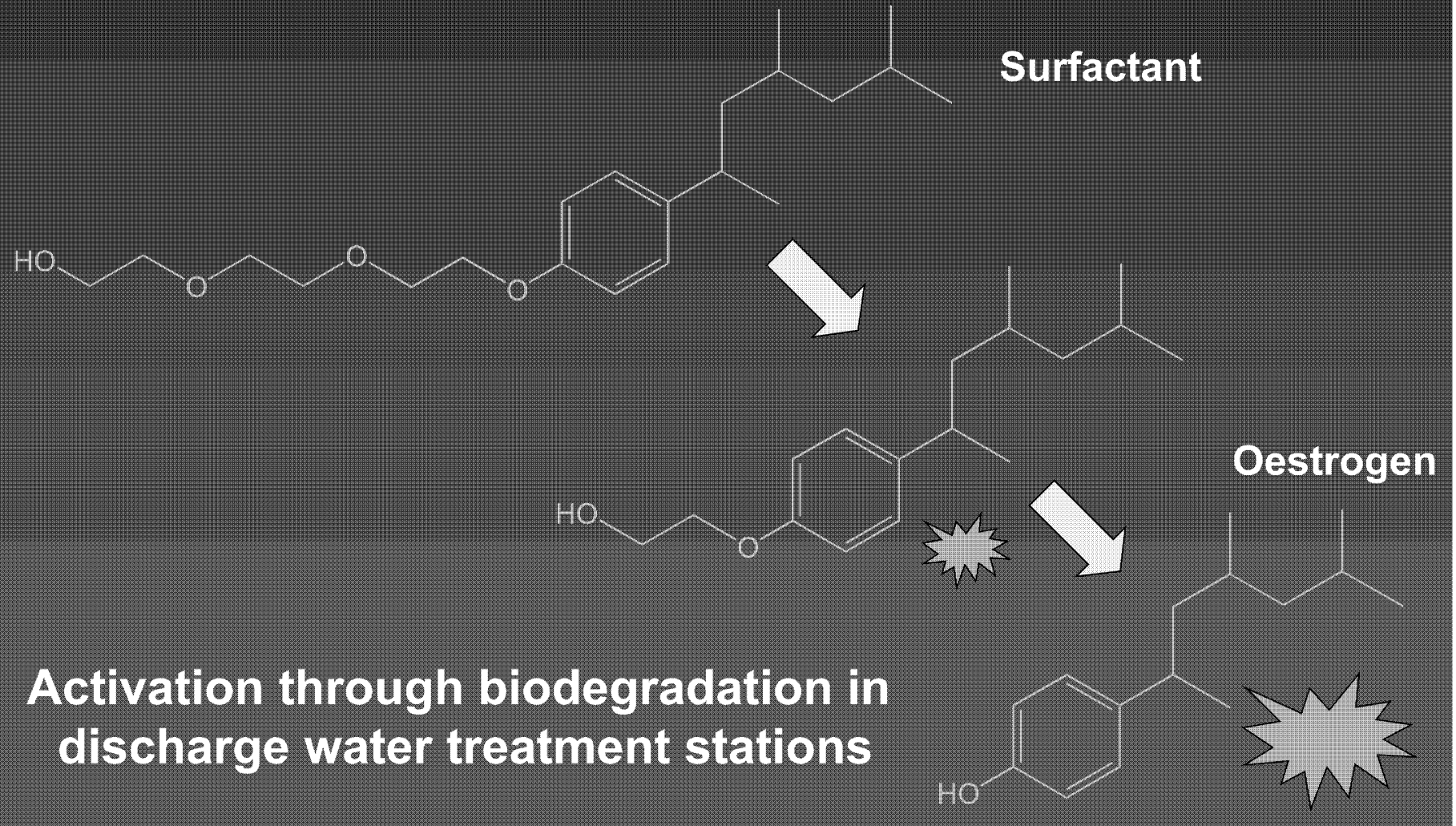
- *The vehicle (DMSO/olive oil) produces precipitates onto the peritoneal membrane with very high local concentrations of surfactant as a consequence → inflammation in underlying organs!*

- *The surfactant (alkyl sulphate) is the cause of the oxidative damage of DNA in liver and kidneys and not glyphosate*

- *The observation of the EU/BBA on the Peluso et al. paper was: " …some indications of DNA damage have been observed…rather due to cytotoxic properties of the formulation …"*

SURFACTANT TOXICOLOGY

Specific toxicity cases: Oestrogenicity

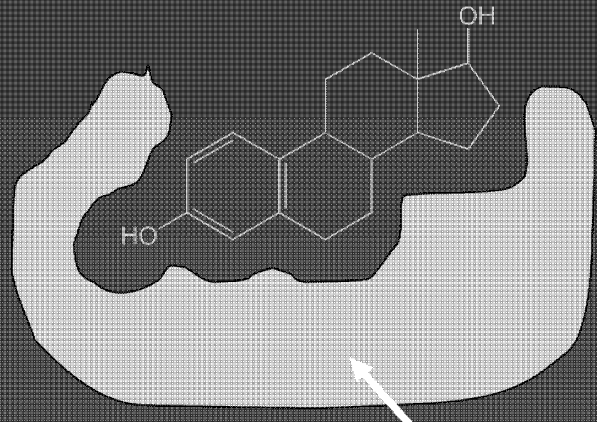


Activation through biodegradation in discharge water treatment stations

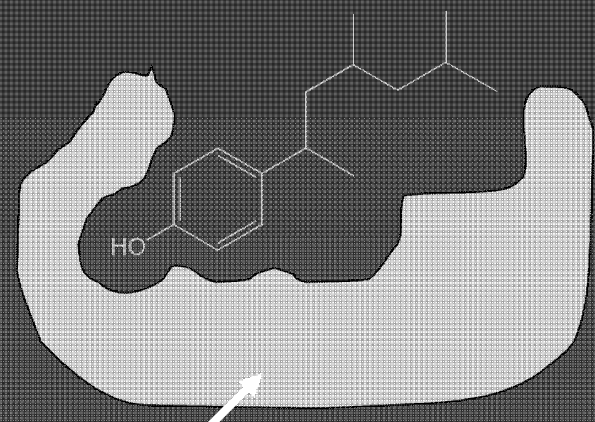
SURFACTANT TOXICOLOGY

Specific toxicity cases: Oestrogenicity

17β-oestradiol



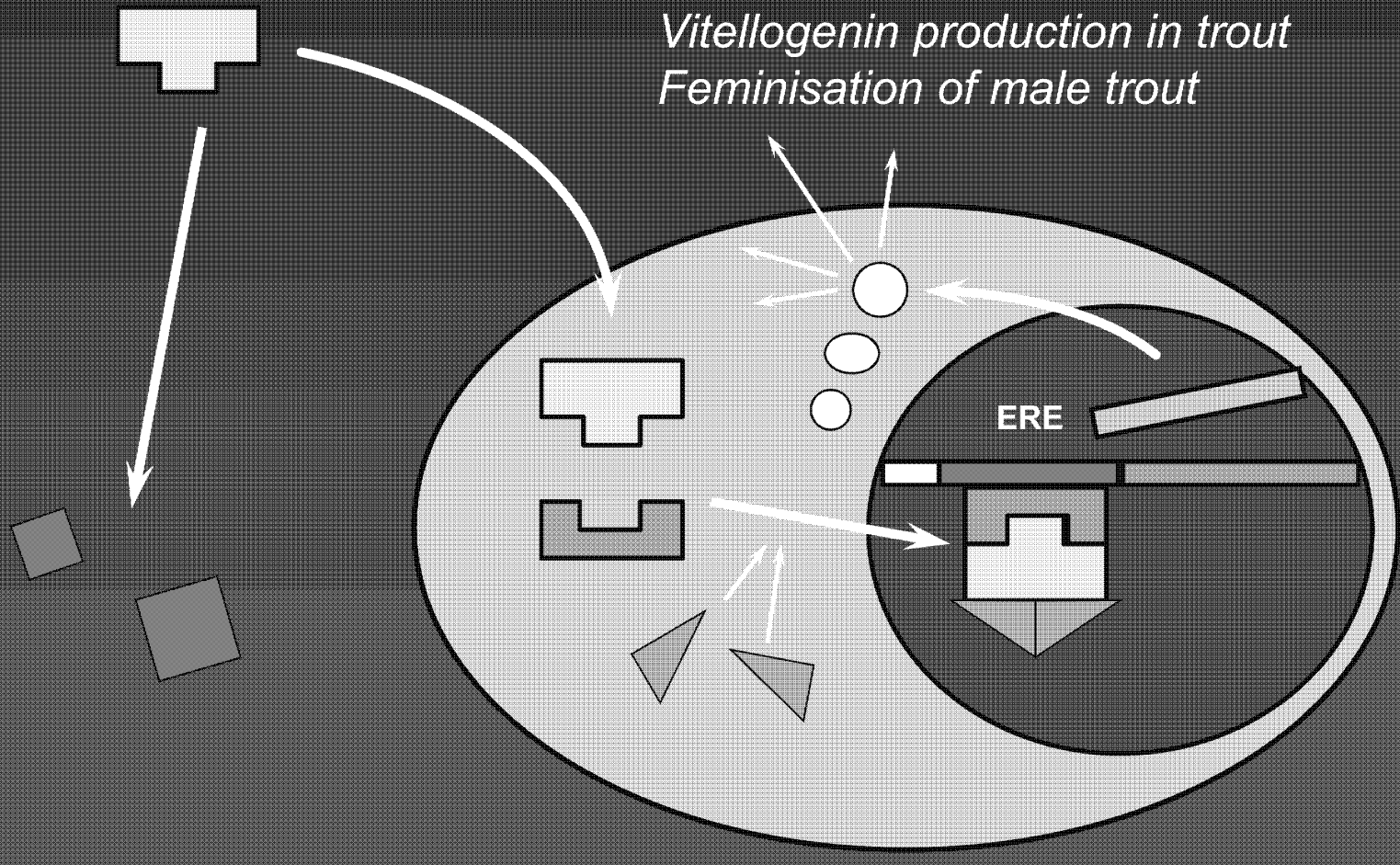
4-nonyl phenol



Oestrogen receptor

SURFACTANT TOXICOLOGY

Specific toxicity cases: Oestrogenicity



SURFACTANT TOXICOLOGY

Specific toxicity cases: Oestrogenicity

	In-vitro			In-vivo		
	Recept. binding	Prolifer.	Transcript.	Uterotr.	Hersh-berger	Reprotox. 2-gen
BBP	ER	ER	ER		Peripu-bertal	
DBP	ER	ER	ER			Sem. Ves. Penis (F1)
NP	ER	ER	ER			Vaginal opening
BPA	ER	ER	ER		Peripu-bertal	

SURFACTANT TOXICOLOGY

Specific toxicity cases: Oestrogenicity

Conclusions of the case the polyethoxylated nonyl phenol surfactants (1)

- *Polyethoxylated nonyl phenol (and octyl phenol, decyl phenol, undeceyl phenol, dodecyl phenol) surfactants biodegrade to form oestrogenic chemicals (mimic female hormones).*

- *Nonyl phenol has been shown to be oestrogenic in mammals in-vitro and in-vivo, however, the potency is approx 1,000-10,000 times lower than that of natural oestradiol.*

- *Nonyl phenol has been shown in-vitro, in vivo and in the field that it can feminise fish at environmentally relevant concentrations*

SURFACTANT TOXICOLOGY

Specific toxicity cases: Oestrogenicity

Conclusions of the case the polyethoxylated nonyl phenol surfactants (2)

- *An effort will have to be done by the pesticide industry to avoid using these surfactants in new formulations and whenever practically possible to replace them in existing formulations*

- *Monsanto Europe successfully undertook research to find a suitable replacement for polyethoxylated nonyl phenols. The new surfactant mix has similar technical properties and does not biodegrade into oestrogenic molecular species. It has already been proposed to replace surfactants in triallate formulations.*

SURFACTANT TOXICOLOGY
General conclusions

- *Surfactants are biologically not "inert", they can be toxic and this must be addressed*
- *Part of the toxicity of surfactants is related to the surfactant action which destabilises cell membranes*
- *Part of the toxicity of surfactants can be specific (skin sensitisation, oestrogenicity)*
- *The toxicity of surfactants depends of their concentration in the formulation*
- *The high added value of herbicide formulations containing surfactants resides in the optimal compromise between efficacy and safety for man and the environment*

Message

From: DONNA R FARMER
Sent: 12/29/1998 9:59:24 AM
To: WILLIAM F HEYDENS; LARRY D KIER; [redacted]
CC: [redacted]
Subject: Re[2]: Actions from12/17 Meeting on Mutagenicity

[redacted]

What is your schedule for the week of the 11th? We can discuss both of the topics below at that time.

Donna

_____ Reply Separator _____
Subject: Re: Actions from12/17 Meeting on Mutagenicity
Author: [redacted]
Date: 12/29/98 9:34 AM

Donna,

Thanks for the report.

Could we include in the micronucleus testing of the MON 35050-glyphosate the histopath of liver and kidneys? This could give us some idea of the pathology of these organs in the test conditions of the Peluso test.

For the meeting on the testing programme of the detergent molecules I would prefer the week of Jan 11th since then I can attend the meeting in St Louis. I would also like to meet with you, Bill, Alan and Larry to discuss what we are going to do with Parry in Europe.

Regards, [redacted].

_____ Reply Separator _____
Subject: Actions from12/17 Meeting on Mutagenicity
Author: DONNA R FARMER [redacted]
Date: 12/27/98 1:31 PM

Below please find:

1) Actions from 12/17 meeting on Mutagenicity
2) Recommendations for the Lioi papers

Thank you all for your participation and especially to Larry for his continued support!

****

1)Actions from todays conference call:

a) Agreed to conduct guideline AMES and Mouse Micronucleus Tests (i.p. route of exposure) on the following "formulation blanks' (all components present except glyphosate):

MON 35050 - glyphosate = MON 8081 (IPA salt of C8-10 Alkyl Sulfate), KTS, Antifoam SF and Debubbler Bevaloid 680

Plaintiff Exhibit
0215

MON 52276 - glyphosate = MON 8151 (Dodigen 4022) and Tween 20

MON 35012 - glyphosate = Cocaoamine and Antifoam RD

- Donna - will contact the lab, get protocols, request test material etc.

- We will target to start the studies mid-January. But recognize we may alter the studies/and or test materials based on receipt of german amendment on mutagenicity

b) Agreed to further discuss and develop "detergent molecule" testing program

- Donna will arrange this discussion. Timing after the receipt of the german amendment. Please let me know your availability for the following days (we can always cancel the meeting if we have not heard yet):

AM of:

1/11
1/12
1/15
1/18
1/19
1/21
1/22

c) Agreed an external global network of genotox experts needs to be developed.

As EU has an immediate need and is a critical area now it was agreed that [redacted] would contact Dr. Parry next week to discuss with him his participation in the support of glyphosate, glyphosate-based ***formulation*** gentox issues.

After initial contact, if Dr. Parry is agreeable than Larry will be included in discussion to outline issue/needs etc.

For North America - Gary Williams will be here in early February as part of the CANTOX project. Larry Kier as graciously agreed to join in those discussions.

****

2) Unfortunately our time rain out but Larry, Bill and Donna stayed a little while longer and dicussed the Lioi papers:

- The data are very unusual and suspect (i.e. the results may reflect an artifact of some procedural error and/or inexperience in scoring) but may be extremely difficult to refute based simply on the contents of the paper.

- It is a real concern that these papers may create an even bigger problem for us than the Peluso paper. Therefore we do some things quickly!

- The results of the human lymphocyte test by Lioi do not agree with the toxicity and data in the human lymphocyte study conducted by Agrichem at NOTOX.

Recommendations:

Contact the authors. Have a letter sent from Monsanto Italy or Brussels and saying something about:

- The data doesn't agree with other data we have - the agrichem study
- Therefore we are interested in investigating the discrepancy
- We would like samples of what they tested for evaluation.

- Are the concentrations correct?
- Was it the acid or salt that was tested?
etc.

In addition, before this letter is sent we may want to contact the manufacturers of vinclozolin and atrazine and inquire if they have seen the papers, do they have data from similar assays for their products, are they planning on responding, contacting the authors etc.

Please let me know if you disagree with this proposal and/or have some other recommendation on how to proceed.

"official request by the Italian Government"

2) Donna will discuss the mutagenicity issue with Kerry Preete/Mike Sterns

3) The group recommended testing the full formulations

- However before any testing begins on a formulation, generation and/or review of the mutagenicity data on each of the individual components must be completed first. If the individual component data is not sufficient it was recommended that studies be conducted on the individual components prior to initiating any testing on the full formulation.

- MON 52276 - Larry Kier will review results of mutagenicity tests on each of the components (MON 8151/Dodigen 4022, and Tween 20). [Donna will get references to Larry.] If the data look reliable - recommend beginning the following tests on the formulation ASAP (Results of the mutagenicity tests are needed by 4/26 in time for the ECCO Tox evaluations):

AMES assay
In vivo Mouse Micronucleus assay
In vitro human lymphoctye cytogenetic assay

* Donna will contact Hema Murli at Covance for cost and starting dates for the studies

- MON 35012 - as no mutagenicity data could be found on the cocoamine surfactant it was recommended to put the cocoamine surfactant into the following screens:

MicroAmes
- MicroMicronucleus

*Donna will contact Monsanto's Investigative Tox Group regarding cost and starting dates

- MON 35050 - this is the Italian formulation used in the Peluso and Bolognesi papers. While it is no longer on the market it was deemed valuable to conduct an in vivo mouse micronucleus study.

* Donna contact Hema Murli at Covance regarding study cost and starting date

4) The development of a "positive" press release was requested. Please comment on the DRAFT below.

DRAFT DRAFT DRAFT DRAFT

"Several genotoxicity studies have been conducted on glyphosate, the surfactants in glyphosate formulations, and other closely-related surfactants. Studies have also been performed on Roundup herbicide and other glyphosate formulations. None of these studies have shown any adverse findings. Based on all these results, we are confident that glyphosate herbicide products are not genotoxic and therefore to not present a mutagenic or carcinogenic risk to humans and animals. We will continue to diligently consider concerns raised in this area and will support our conclusions on the safety of Roundup herbicides with appropriate scientific

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information and studies."

5). A "detergent molecule" testing program was recommended to better understand and address the SCE (sister chromatid exchange) findings in some of the studies. Further meetings will be necessary to work out the details, however a 6/99 start date was projected.

6). External global network of genotox experts:

- EU
  - While Dr. Parry is a recognized genotox expert what is not known is how he views some of the "non-standard endpoints" (such as SCE, DNA P-32 postlabling, Comet assays etc) evaluated in the genotox articles by Rank, Bolognesi etc.
  - Therefore it was recommended that before we ask him to get more deeply involved (reviewing all the literature, glyphosate data; represent us as a consultant with regulators, etc) we would ask him to review a subset of the articles.
  - It was proposed that [redacted] would contact Dr. Parry and ask him for a written review the articles by Rank, Bolognesi, Peluso & Lioi
  - Based on his critique of the the genotox papers a decision would be made as to expanding or terminating his involvement.
  - Regarding [redacted], no further contact will be made at this time. When a clear role has been identified for [redacted] Alan will contact him.
  - Money for this initial consultation will come from [redacted] budget. A bigger initiative will require additional funds to be located.
- NA
  - Expanded discussions with Dr. Gary Williams on genotox issues will occur as part of the CANTOX meetings (2/5,6&7). Dr. Williams is recognized internationally as a genotox expert and might be used in Europe on a contingency basis.
- LA/SEA - no action at this time

7). There is a concern that the papers by Lioi et al, may present an even bigger problem because the studies are with glyphosate and are on a more standard endpoints. The results of the human lymphocyte test by Lioi do not agree with the toxicity and data in the human lymphocyte study by Agrichem at NOTOX therefore it was recommended that:

- Larry Kier will finalize his rebuttal
- Include the Lioi papers in the articles to be reviewed by Dr. Parry
- Bill/Donna will draft for Larry a letter to the editor or a short publication to be submitted to the journal upon receipt of Parry's evaluation

8). While there is $90K in the glyphosate toxicology testing budget for mutagenicity testing, this may not be enough. Further

Author: [redacted]
Date: 1/28/99 3:50 PM
Priority: Normal
TO: ALAN G E WILSON at MONSL125
TO: LARRY D KIER at MONSL701
TO: DONNA R FARMER at MONSL125
TO: WILLIAM F HEYDENS at MONSL216
Subject: Re[8]: DRAFT of Minutes - 1/15 Meeting
---------- Message Contents ----------

Bill,

That's true, let's have a look at it.

Regards, [redacted]

---------- Reply Separator ----------
Subject: Re[7]: DRAFT of Minutes - 1/15 Meeting
Author: WILLIAM F HEYDENS at MONSL216
Date: 1/28/99 7:34 AM

[redacted]

I hear you. But that's what we said about alachlor (UDS follow-up), and look what we got after 12 hours.

Bill

---------- Reply Separator ----------
Subject: Re[6]: DRAFT of Minutes - 1/15 Meeting
Author: [redacted]
Date: 1/28/99 2:05 PM

Bill,

I wonder whether we would already see important changes in serum enzyme levels after such a short time.

Regards, [redacted]

---------- Reply Separator ----------
Subject: Re[5]: DRAFT of Minutes - 1/15 Meeting
Author: WILLIAM F HEYDENS at MONSL216
Date: 1/28/99 6:40 AM

All,

I have no problem examining liver and kidney on MON 35050 as [redacted] suggests. In concept, this is what we did with alachlor and were somewhat surprised and delighted that we found such a marked response. Would we want to include serum enzyme analysis too as long as we are going this far?

Bill,

Reply Separator

Subject: Re[4]: DRAFT of Minutes - 1/15 Meeting
Author: [redacted]
Date: 1/28/99 11:51 AM

Donna,

Sorry to jump in so late but I had first to get a triallate problem in the UK out of the way.

I reviewed the minutes and find the text in agreement with the discussions we had in St Louis. Something for which we didn't formulate a conclusion during the meeting was whether we shouldn't look in the histopathology of the liver and the kidneys in the I.P. micronucleus test of MON 35050. If we would find severe lesions (e.g. infammatory) then this could help us in putting the Peluso findings in a better context.

I fully support the text that was prepared for the public statement (brochure) in Denmark.

In the meantime I contacted Parry and a letter of authorisation with the papers is underway to him. A report is expected by mid February. As soon as I get it I will submit it to you for critical review and assessment of further action.

Regards, [redacted]

Reply Separator

Subject: Re[3]: DRAFT of Minutes - 1/15 Meeting
Author: DONNA R FARMER at MONSL125
Date: 1/27/99 3:03 PM

Please find revised minutes with comments incorporated from Alan, Larry and Bill.

If there are no more comments/changes etc. I will distribute them in the morning to Hjelle, Fuhremann, Fuller, [redacted] Preete/Stern (have asked to meet with them no time set up yet), Dirks, Wratten, GGRST? others add/delete?

Donna

****

In attendance:

Donna Farmer
Bill Heydens
Larry Kier
[redacted]
Alan Wilson

1) Donna will ask [redacted] for clarification on exactly what was the

Monsanto Technical Center

Rue Laid Burniat 5
Parc Scientifique Fleming
B-1348 Louvain-la-Neuve
Belgium

TELEPHONE: [redacted]
TELEFAX : [redacted]

03E

MONSANTO TELEFAX TRANSMITTAL SHEET

TO	ALAN WILSON, DONNA FARMER & BILL HEYDENS
LOCATION	MONSANTO STL CC CASE
FAX NUMBER	4028
FROM	[redacted]
DATE	15/02/1999
SUBJECT	PROF FARRY'S REPORT
NR OF PAGES (incl this page)	12

Dear Alan, Donna and Bill,

Please find herewith Prof. Parry's evaluation of the 4 papers I sent him on genotoxicity of glyphosate and Roundup. Could you study this carefully and formulate comments. We will then have to set up a conference call with Larry (who also received this fax) to decide what to do next.

Best regards,

[redacted]

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PRIFYSGOL CYMRU ABERTAWE
Ysgol y Gwyddorau Biolegol
Parc Singleton, Abertawe, SA2 8PP

UNIVERSITY OF WALES SWANSEA
School of Biological Sciences
Singleton Park, Swansea, SA2 8PP

[redacted]
Monsanto Europe
Parc Scientifique Fleming
Rue Laid Burniat 5
B-1348 Louvain-La-Neuve
Belgium

11 February 1999

Dear [redacted]

You will find enclosed my evaluation of the four papers you provided concerning the potential genotoxicity of glyphosate and Roundup. Although each of the papers have weaknesses, I have avoided a report which attempts to focus upon these weaknesses. Rather, I have attempted to "pull out" the data which provide an aid to the understanding of the potential mechanisms of glyphosate genotoxicity and indicated how you might clarify these mechanisms. It has been my experience with Regulatory Agencies that a positive attitude to published data is a more productive approach than just criticising individual studies.

I assume that you will already have in house data for some of the suggested experiments. In my view the *in vitro* micronucleus work suggested would be the most productive way of clarifying the question of mechanisms. I would be happy to provide you with further suggestions as to detailed protocols for such studies. They would make a rather nice Ph.D project for a graduate student if you could find the funding.

I have enclosed my invoice for the evaluation.

Yours sincerely

Professor James M. Parry

Tel [redacted] Fax [redacted]

Curriculum Vitae

James M. Parry,

B.Sc. Botany (London), Ph.D. Genetics (Liverpool), D.Sc. (Liverpool).

Date of Birth: 9.10.1940.

Professor of Genetics, School of Biological Sciences,

University of Wales Swansea,

Singleton Park, Swansea, SA2 8PP, Wales, U.K.

Chairman: Genetics and Microbiology Teaching Board

Chairman: Molecular Biology Research Group

Chairman: Centre for Molecular Genetics and Toxicology

University of Wales Swansea, Swansea, SA2 8PP

Tel: [redacted]

Fax:

e-mail: JMP@Swansea.ac.uk

Teaching Experience

General Genetics, Human Genetics, Molecular and Microbial Genetics, Basic Toxicology, Environmental and Aquatic Toxicology.

Research Interests

Mechanisms for maintaining the fidelity of the genome, role of environmental chemicals in the induction of genetic changes leading to the formation of birth defects and cancer. Mechanisms of action of chemicals leading to the disturbances in chromosome segregation and to chromosome aneuploidy. Mechanisms of formation of DNA lesions and base sequence changes *in* vitro and *in* vivo. Genetic effect of environmental chemicals upon aquatic species.

Research Laboratory is staffed by four senior research assistants, twelve graduate students and three technicians.

The Laboratory currently coordinates the European Union Research Project on the "Mechanisms of Chemically induced aneuploidy" and collaborates in the European Union Projects on "Neurotoxicity of Mercury Compounds" and "State of the art methods for detecting chemical carcinogens". The Laboratory also receives research support from the Medical Research Council, Health and Safety Executive, Ministry of Agriculture Food and Fisheries and a variety of Pharmaceutical and Chemical Companies. Author of over 200 scientific papers and articles.

Public Activities

President:	UK Environmental Mutagen Society 1974-1977
Vice-President:	European Environmental Mutagen Society 1993-1995.
President:	European Environmental Mutagen Society 1995-1997.
Editor:	the Scientific Journal "Mutagenesis"
Member:	Editorial Board "Mutation Research"
Member:	Advisory Board, Small Area Statistics Unit, St. Mary's Hospital London.
Member:	Advisory Board, Department of Health Toxicology Unit, Hammersmith Hospital, London.
Chairman:	Department of Health Advisory Committee on the Mutagenicity of Chemicals.
Member:	Department of Health Advisory Committee of the Carcinogeniety of Chemicals.
Member:	1994-1997 Working Party of Committee on Medical Aspects of Food on "Cancer and the Diet".
Member:	Medical and Toxicology Panel of UK Scientific Committee on Pesticides.
Member:	Ad-hoc Consultancy Group to Commission of European Communities Committee on "Plant Protection Products" (Pesticides).

These public duties particularly relate to my interests and expertise in the evaluation of the hazards and risks of environmental chemicals upon the human population and upon environmental species.

Evaluation of potential genotoxicity of Glyphosate and Round up Mixtures

Professor J. M. Parry, Centre for Molecular Genetics and Toxicology, School of Biological Sciences, University of Wales Swansea, Swansea SA2 8PP.

Individual Evaluation of Publications

Rank *et al* (1993)

Test Methods Used

Salmonella Assay TA98 and TA100

Roundup mixture tested - positive minus S9 in TA98, positive plus S9 in TA100.

Mouse Micronucleus Bone Marrow Assay - spontaneous frequency 0.3% i.e. 3 per 1000.

Roundup mixture - no effect up to 200mg/kg - only sampled at 48 hrs.

Glyphosate isopropylamine salt - no effect up to 200mg/kg, only 1 dose point gave reduction in PCE/NCE ratio - for other concentrations there was no evidence that compounds reached bone marrow.

Allium cepa Root Cytogenetics

Roundup mixture - positive response greater than 720µg/litre - characterised as spindle disturbance.

Glyphosate isopropylamine salt - no effect.

Conclusion

In vitro evidence of genotoxic effect for Roundup mixture, inadequate *in vivo* studies.

Bolognesi *et al* (1997)

Test Methods Used

Mouse Micronucleus Bone Marrow Assay - spontaneous frequency 0.075% i.e. 0.75 per 1000.

Roundup Mixture - positive response at 450mg/kg (multiple dosing).

Glyphosate - positive response at 300mg/kg (multiple dosing).

Reduction in PCE/NCE ratio - clear evidence that compounds reached the bone marrow.

Sister Chromatid Exchange in Human Lymphocytes *in vitro*

Roundup Mixture - positive response at 100μg/ml.

Glyphosate - positive response at 1000μg/ml.

DNA damage - alkaline elution in liver and kidney

Roundup Mixture - increase in single strand breaks in both liver and kidney at 4 hrs following 300mg/kg.

Glyphosate - increase in single strand breaks in both liver and kidney at 4 hrs following 300mg/kg.

Induction of 8-OHdG in liver and kidney as measure of oxidative damage

Roundup Mixture - increase in 8-OHdG in both liver and kidney.

Glyphosate - increase in 8-OHdG in liver only.

Note. Glyphosate induced a quantitatively greater increase in 8-OHdG in liver than Roundup mixture.

Conclusion

Positive response *in vitro* SCE for both compounds, response at 10 times lower concentration for Roundup mixture.

Both Glyphosate and Roundup mixture produced positive response in mouse bone marrow micronucleus assay.

Both Glyphosate and Roundup mixture produced increase in DNA strand breaks in mouse liver and kidney.

Glyphosphate increased 8-OHdG in mouse liver.

Roundup mixture increased 8-OHdG in mouse liver and kidney.

Peluso *et al* (1998)

Test Method Used

^{32}P post-labelling in mouse liver and kidneys.

Roundup Mixture - increase in uncharacterised DNA adducts in liver and kidney at concentrations of 400, 500 and 600mg/kg.

Glyphosate isopropylammonium salt - no increase in DNA adducts in liver and kidney at concentrations of 130 and 270mg/kg.

Note. No evidence of the sensitivity of the ^{32}P assay in the authors hands is provided in the paper.

Conclusion

Roundup Mixture produced increase in DNA adducts in mouse liver and kidney.

No increase produced by Glyphosate at concentrations calculated to roughly equate with concentrations in Roundup Mixture.

Loi *et al* (1998)

Test System Used

Induction of chromosome aberrations and SCE in bovine lymphocytes *in vitro*

Glyphosate - dose-dependent increase in chromatid aberrations 17 to 170μM solutions, dose-dependent decrease in mitotic index.

Glyphosate - increase in sister chromatid exchange 17 to 170μM solutions.

G6PD activity as measure of oxidative stress

Glyphosate - increase in G6PD activity following exposure to 17 to 170μM solutions.

Glyphosate + anti-oxidant N-acetyl-cysteine - increase in G6PD reduced in presence of anti-oxidant.

Note. Structure activity relationship between Glyphosate used and isopropylammonium salt

unclear.

Conclusion

Increase in chromatid aberrations of SCE following Glyphosate exposure.

Increase in G6PD activity following Glyphosate exposure.

Increase in G6PD reduced by presence of anti-oxidant.

Chemical preparations tested in the 4 papers

Glyphosate

Bolognesi *et al* (1997), Loi *et al* (1998)

Glyphosate isopropylammonium salt

Peluso *et al* (1998), Rank *et al* (1993)

Roundup Mixture

30.4% - Peluso *et al* (1998), Bolognesi *et al* (1997).

48% - Rank *et al* (1993)

Source of chemicals

Glyphosate -	*Soc. It. Chem.* Rome - Bolognesi *et al* (1997), Peluso *et al* (1998).
	Lab. Serv. Anal. Bologna - Loi *et al* (1998).
	Dr. Ehrenstorfer - Rank *et al* (1993).
Roundup Mixture -	Monsanto, Italy - Peluso *et al* (1998), Bolognesi *et al* (1997).
	Monsanto, USA - Rank *et al* (1993).

Comparison of results obtained in the analysis of the effects of Glyphosate and Roundup Mixture

Concordant Results

Mouse Micronucleus Assay - Positive for both.

SCE *in vitro* human lymphocytes - Both positive, Roundup more potent.

DNA strand breaks - Positive with both.

Non-Concordant Results

Allium Cytogenetics - Positive only with Roundup Mixture.

8-OHdG - Roundup positive in kidney, non-significant increase in liver.
Glyphosate positive only in liver.

^{32}P-postlabelling - Roundup positive in liver and kidney.
Glyphosate negative.

Conclusions

Roundup mixture induced frameshift mutations in *Salmonella typhimurium* TA98 in the absence of S9 mix. Roundup mixture induce base substitution mutations in *Salmonella typhimurium* TA100 in the presence of S9 mix.

These data appear to be in marked contrast with other published studies (Shirasu *et al* 1982, Wildeman and Nazar 1982, Li and Long 1988.

***In vitro* Cytogenetics**

a) Glyphosate induces a dose-dependent increase in chromatid aberrations *in vitro* in bovine lymphocytes over a concentration range of 17 to 170μM solution.

b) Sister chromatid exchanges induced in human lymphocytes by both Glyphosate and Roundup mixture. Roundup mixture produced a positive result at lower concentrations.

c) In Allium root tips positive result produced by Roundup mixture, no response with Glyphosate. Predominant aberrations were indicative of spindle damage.

d) Measurements of the activity of G6PD suggests that Glyphosate increases activity indicating oxidative stress. This modification of G6PD activity was reduced in the presence of the anti-oxidant N-acetyl-cysteine.

***In vivo* Studies**

Both Glyphosate and Roundup mixture produced a positive result in the mouse bone marrow micronucleus assay (Bolognesi *et al* 1997). The positive results were in contrast with the negative results of Rank *et al* (1993). The positive study had a clear demonstration of bone marrow toxicity and involved multiple dosing (2 doses) with the test agents in contrast to a single dosing used by Rank *et al* (1993).

The data of Bolognesi *et al* (1997) indicate that Glyphosate is a probable *in vivo* genotoxin. However, the study of Bolognesi *et al* (1997) involved only 3 or 4 animals at each sampling time and dose point and cannot be considered to be of OECD guideline standard. The frequency of micronuclei in the control culture in the Bolognesi *et al* (1997) study was substantially lower than that of the Rank *et al* (1993) study.

Both Glyphosate and Roundup induced significant increases in DNA strand breaks in mouse liver and kidney. Roundup mixture increased 8-OHdG in mouse liver and kidney. Glyphosate increased 8-OHdG in mouse liver. These data indicate that Glyphosate produces oxidative damage *in vivo* which leads to single strand breaks and 8-OHdG lesions in exposed tissues. The unique positive result in mouse kidney with Roundup mixture suggests a synergistic effect of some component of the mixture.

The ^{32}P postlabelling study of Peluso *et al* (1998) indicates that Roundup is capable of inducing DNA adducts (uncharacterised) in mouse liver and kidney. Glyphosate alone,

at equivalent concentrations to that in Roundup, failed to increase adducts. These data provide some evidence to support the concept that any *in vivo* activity of Glyphosphate may be potentiated by other components of the Roundup mixture.

The overall data provided by the four publications provide evidence to support a model that Glyphosate is capable of producing genotoxicity both *in vivo* and *in vitro* by a mechanism based upon the production of oxidative damage. If confirmed, such a mechanism of genetic damage would be expected to be produced at high concentrations of the herbicide and would be relevant only when the anti-oxidant protective mechanisms of the cell are overwhelmed. Thus, I would conclude that if the mechanism of action can be proved to be based upon oxidative damage then hazard and risk assessment could be based upon a non-linear model with a threshold of activity at low doses.

Questions raised by the studies

1) Role of components of mixture which leads to high levels of activity of Roundup?

2) Is the genotoxic activity observed due to oxidative damage?

3) Can the genotoxic activity be reduced by anti-oxidants?

Recommendations for further work to clarify the potential genotoxic activity of Glyphosate

Bacteria

I recommend a repeat of Salmonella studies particularly with Roundup mixtures. I would be surprised if these data are not already available in-house.

Cytogenetics

I recommend an *in vitro* micronucleus study preferably in human lymphocytes. If combined with analyses of the micronuclei for the presence and absence of centromeric DNA this study would indicate whether Glyphosate induces predominantly chromosome structural

or numerical damage.

The *in vitro* micronucleus assay would allow both:-

a) The assessment of the potential influence of anti-oxidants upon the genotoxic potential of Glyphosate - Note the measurement of the effect of anti-oxidant as a genetic endpoint is a critical deficiency in the Loi *et al* (1998) study.

b) Assessment of the individual components of the Roundup Mixture to determine whether there is any component(s) which act synergistically to increase the potential genotoxicity of Glyphosate. Such studies could be designed to investigate a panel of mixtures leaving out one component of the mix for each individual experiment.

***In vivo* studies**

In view of the limitations of the Bolgnesi *et al* (1977) study i.e.

limited number of animals

single dose of compound

low spontaneous micronucleus frequency

it would be worth repeating the study to a more comprehensive design.

To repeat both the DNA strand breaks and adduct work would require very large comprehensive studies to determine the nature of the adducts and the potential role of oxidative damage in their induction. I would recommend that the *in vitro* studies should take priority as they would provide valuable information relevant to the design of any *in vivo* adduct studies.

Message

From: [redacted]
Sent: 4/19/1999 8:49:08 AM
To: LARRY D KIER; WILLIAM F HEYDENS; [redacted] DONNA R FARMER
CC: STEPHEN J WRATTEN; [redacted]
Subject: Re: Meeting Minutes 2/25

Donna,

Thanks for this, it accurately reflects the situation.

Please take note of the following update:

I received from prof. Parry the signed secrecy agreement.

As a response I sent him a letter of authorisation and all relevant reports and publications re mutagenicity of glyphosate, its formulations and the surfactants for which we have mutagenicity testing data.
The list was based on the foulder that was composed for Gabriele and the German monograph on Glyphosate:

Glyphosate formulations
Roundup:
- Ames test, Monsanto report ML-91-440
- Mouse micronucleus test, Monsanto report ML-91-434/437
- Comet test on Rana tadpoles, Clements et al., Environmental and Molecular Mutagenesis, 29, 277(1997)
- Drosophila SLRL, Kale et al., Environmental and Molecular Mutagenesis, 25, 148(1995)
- SCE, Vigfusson and Vyse, Mutation Research, 79, 53(1980)

Direct:
- Ames test, Monsanto report ML-91-442
- Mouse micronucleus test, Monsanto report ML-91-436/439

Rodeo:
- Ames test, Monsanto report ML-91-441
- Mouse micronucleus test, Monsanto report ML-91-435/438

Glifos:
- Ames test, BioAgri report G1.1-050/96
- Mouse micronucleus test, BioAgri report G1.2-060/96

Active ingredient (glyphosate):
- Ames test, rec-assay, HGPRT test, UDS test, in-vivo cytogenetics, Li and Long, Fundamental and Applied Toxicology, 10, 537(1988)
- In vitro cytogenetics in human lymphocytes, NOTOX report 141918
- Ames test, Jensen, Scantox report 12323 (1991)
- Mouse lymphoma test, Jensen, Scantox report 12325 (1991)
- Mouse micronucleus test, Jensen, Scantox report 12324 (1991)
- Mouse dominant lethal test, Monsanto report IR-79-014

Surfactants:
Polyethoxylated tallowamine (MON 0818):
- Ames test, Monsanto report ML-89-461
- Mouse micronucleus test, Monsanto report ML-89-463

C8-C10 alkyl sulphate IPA salt (MON 8080):
- Ames test, Monsanto report ML-80-294

Dodigen 4022:
- Ames test, Hoechst report 92.0336
- In-vitro cytogenetics, Hoechst report 92.0337

Tween 20:
- Mouse lymphoma test, Abstract P46, Environmental and Molecular Mutagenesis, 3(3), 320(1981)

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Tween 80:
- Mouse micronucleus test, Jenssen and Ramel, Mutation Research, 75,191(1980)

Via separate mail I sent him the composition of all the formulations tested and data on the chemistry of the surfactants (not too detailed).

So, in principle he will start his review this week.

Once the review is ready it will be a good idea to have Larry visit Jim Parry for an overall discussion.

Regards, [redacted]

_____ Reply Separator _____

Subject: Meeting Minutes 2/25
Author: DONNA R FARMER [redacted]5
Date: 4/17/99 7:25 AM

Please find the meeting minutes and actions from our 2/25 meeting below.

We need to discuss where we are on each of these topics as well as well as finalize a letter of comment to the German Addendum. Steve has provided some valuable comments in a recent message, I will draft a letter and provide for discussion.

Bill - what is the drop dead date you need these comments?

Cam where are we in getting this meeting set up?

Donna

1) Update on the German Addendum

Steve Wratten joined us for this discussion. We understand that the Germans current position on the effects observed in the various studies with the formulatons as described in the open literature do not indicate a mutagenic response but rather a cytotoxic response associated with the surfactant(s). Glyphosate, it's salts, the G3 and G4 formulations (with the Dodigen surfactant) and Rodeo are free and clear.

For those formulations/surfactants that can be tested up to the limit levels per OECD guidelines and produce no toxicity such as the Dodigen (the major surfactant in MON 52276) they would be viewed favorably.

Roundup (with MON 0818), Roundup Ultra, the etheramine-based formulations and other formulations either do not meet this standard or the possiblity that they will is low.

It will be up to each country to decide which formulations it does and doesn't want and they could use this for that purpose.

It was felt that this position should not be a regulatory endpoint, it is not defensible and that once the German Addendum is made public comments and a response should be prepared for the ECCO Meetings preferably before 17th May (Mammalian Tox Meeting). Note that the Conclusion meetings are not until the 18th October - Donna will coordinate this response when a copy of the German Addendum is received.

2) Testing program - what do we test? formulations..surfactants? When is data needed? Discussion is dependant upon info from agenda item # 1

No further mutagenicity testing is needed for MON 52276.

Steps have been taken to acquire the cocoamine surfactant used in MON 35012/Roundup 2000 sold in Denmark for testing in the microames and micromicronucleus assays. In addition based on the concern for cytotoxicity it was recommended to also to run this surfactant thru the NRU assay (this assay addresses cytotoxicity and has a good correlation with the oral LD50). - Donna will coordinate and monitor these tests

Management supports the investigation of MON 35050 toxicity to the liver and kidneys to address the findings in the Peluso study. Therfore it was recommended to move forward with a study... evaluating liver and kidney histology, serum enzymes as well as glutathionine levels following high-dose, i.p. exposures of the test material. - [redacted] will draft and circulate a protocol

Donna will followup with [redacted] to get the details/and clarification behind his statement below (in green) as to what is expected, on what materials and by when. "We will need to demonstrate clearly negative Mutagenic (and cytogenic?) results for all the formulations we sell in Europe. These will certainly be required by end 2000 but public pressure may require us to do them earlier."

3) "Detergent-like molecule" testing program? Is this still something we need to do? When do we start? Discussion is dependent info from agenda item #1

In light of the position taken by the German government this investigation maybe even more important than before and could possibly be conducted by
Dr. Parry?
Dr. Williams?
Donna will arrange for further meetings to discuss/design this program

4) Global experts

Review Dr. Parry's analyis - what is our next step?
Dr. Parry concluded on his evaluation of the four articles that glyphosate is capable of producing genotoxicity both in vivo and in vitro by a mechanism based upon the production of oxidative damage.

The data that Dr. Parry evaluated is limited and is not consistant with other better conducted studies. In order to move Dr. Parry from his position we will need to provide him with the additional information as well as asking him to critically evalute the quality of all the data including the open literature studies.

As a followup [redacted] will contact Dr. Parry, discuss with him the existance of additional data and ask him to evaluate the full package. [redacted] will also explore his interest (if we can turn his opinion around) in being a spokesperson for us for these type of issues.

Larry as well as others will be available to discuss the data with Parry as needed by e-mail, phone or in person or all the above.

Dr. Williams - discuss the outcome of the Cantox meeting

The panel concluded that glyphosate and Roundup were not mutagenic. That in the evaluation of these types of studies criteria should be set... up front in the evaluation process as to what makes an acceptable study and what does not - this is to be included in the manuscript as well as a weight of evidence approach.

5) Lioi followup

An analysis of what was tested in the Lioi studies was deemed important. Therefore it was recommended that Monsanto EU or Italy contact Lioi and try to get a sample of what they used in their study

as well as getting a sample from the company that Lioi did. Donna will contact [redacted] to ask him to make the requests.

Message

From: [redacted]
Sent: 9/6/1999 8:23:05 AM
To: WRATTEN, STEPHEN J [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=119523]; FARMER, DONNA R [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]
CC: KIER, LARRY D [NCP/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=33322]; HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]; [redacted]
Subject: RE: Comments on Parry write-up

Steve,

Yes it doesn't show as a report in its definitive form. I don't think that it was Parry's intention to write up a ready-to-use document for regulatory and other defense, this report only reflects his opinion on three things which were asked and these were the quality of the data, the evaluation of the mutagenicity and its significance for man and recommendations to complete the picture. He received all reports we produced and those we obtained from competing companies and all scientific papers.

We can now determine for ourselves how such a report should look like and give him directions for a rewrite. The best way to do this is first collect all our comments and arrange a visit what actually the action is that we decided during our last meeting. See further my comments in the text below in italic. I'll send you all my comments on Parry's paper very soon.

Regards, [redacted]

-----Original Message-----
From: WRATTEN, STEPHEN J [FND/1000]
Sent: Wednesday, September 01, 1999 12:17 AM
To: [redacted]; FARMER, DONNA R [FND/1000]
Cc: KIER, LARRY D [NCP/1000]; HEYDENS, WILLIAM F [FND/1000]; [redacted]
Subject: Comments on Parry write-up

[redacted] and Donna

I was somewhat disappointed in the Parry report, not particularly from his conclusions but just the way they're presented. The style and rather casual lack of completeness and preciseness would make it hard to circulate this around to anyone as supporting information. Has he ever worked with industry before on this sort of project?--*I know that he is regularly consulted by BAA and Dow--*

I will mail the marked-up paper back to you, but some other general comments need to be made:

1. It is odd that the one study by BioAgri is discussed right on the first page in rather extensive detail but none of the others are. I understand that he didn't like this one, but it is still strange to read this way.--*he decided to only expand on the studies for which he had comments, this can be taken care of in write up of definitive report--*

2. The whole report could benefit from a couple of introductory paragraphs about what he was asked to do and what he received as far as reports. Did he have all the Monsanto reports as well as the literature articles? Was he asked to compare these, evaluate the methods, explain the differences, identify any faults, or what?--*Yes all these things were asked, but Parry was under time pressure and produced a paper which expressed his opinion, he did not get detailed instructions on how to produce a report, that is normally at the discretion of the expert, but all this can be put in a better form.-- To be honest I expected to receive a better structured report myself--*

3. Some where the report needs to identify the full citations of each report evaluated and give the full Literature references for the public documents. Also the test material should be clearly identified, ideally by both MON number and brand name if needed, but at least to say which are glyphosate and which are formulations - this is done, sort of, but not as clearly as I'd like. Separate tables would be good.--*Yes, this should be done. parry receive from me all the details on composition and signed off a secrecy agreement-- We may have to help him to write all this up in a proper way--*



4. He has an odd way of starting all conclusions with a negative - ie., points 2, 3, and 4 on page 3. Couldn't the sentence structure be modified to be less awkward? When he says "no data were provided..." time and again, it makes it sound as though he was suspicious that there were data but he didn't get them. I know this is not the intent, but it could be cleaned up.*--Yes--*

5. Table 1 seems to state repeatedly that "there was no evidence of xxx mutagenicity". It would be more powerful if it said "there was convincing evidence that glyphosate does not act as a xxx mutagen". "no evidence of" is a very weak way of stating a conclusion.*--We can bring this up in a meeting with him--*

6. He says very little about the literature reports. So little that one almost forgets about them. Can he not provide some critique about their quality and methodology as compared to the Monsanto reports? Are they included in or excluded from the statement in the first paragraph sentence "these studies were performed to a high standard and to OECD recommended guidelines"? In the section entitled "Assessment of the published..." on p. 2, I am hard-pressed to find any assessment. It is almost merely a listing of what everyone already knew from casually reading the abstract.*--Yes we will have to discuss this with him at a meeting--*

7. In his conclusions (p. 2), do the "studies evaluated" (line 2) include the literature reports or not? IN other words, is he saying that none of the studies (Monsanto plus literature) had evidence of glyphsoate genotoxic potential, or is he limiting this conclusion to the Monsanto studies?*--Will have to be discussed with him--*

8. Of course we know there were no data of the type listed in points 2, 3, and 4 on p. 3. We didn't need him to tell us that. The key point is whether the conclusions of Bolognesi, and Rank can be discounted on the basis of the strength and number of studies at hand, or whether their experiments need to be repeated independently to credibly refute the findings. Of course we knew that the latter would be the most convincing approach, but we need him to make any arguments that can be made on the data we have.

Overall, I guess we have his recommendation of studies that could be used to strengthen the database on p. 4. , but that is about it. I do not see that he has stuck his neck out on anything at all controversial, and therefore, there is little value in the write-up as written that could be useful. Hope it didn't cost much. Perhaps this is too harsh, and I don't know what your proposal to him was, but I guess I would expect more than this of a Professor.*--Please don't be too negative, it is clear that he will need some help to produce the definitive report without twisting his arms, don't forget that his opinion is well respected and I am sure he didn't have the time to write it all down as should have been the case, therefore the need to meet with him. I wrote him a note that we are reviewing his paper and that Larry will contact him soon for a meeting in person--*

Steve

Steve Wratten
[redacted] (voice)
(fax)

Evaluation of the potential genotoxicity of Glyphosate,

Glyphosate mixtures and component surfactants

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Introduction

The available data concerning the potential genotoxic activity of glyphosate, glyphosate mixtures and surfactants have been evaluated and the results of the evaluation are presented in Tables 1 to 14. Each of the tables reviews the data for the three groups of chemicals grouped according to the type of test system used to assess potential genotoxicity, the effect produce and reference to the appropriate data set.

Table 1. Glyphosate, Bacterial assays.
Table 2. Glyphosate mixtures, Bacterial assays.
Table 3. Glyphosate, chromosome studies *in vitro*.
Table 4. Glyphosate mixtures, chromosome studies *in vitro*.
Table 5. Glyphosate, point mutation studies *in vitro*.
Table 6. Glyphosate, bone marrow studies *in vivo*.
Table 7. Glyphosate mixtures, bone marrow studies *in vivo*.
Table 8. Glyphosate, Miscellaneous non-inherited endpoints.
Table 9. Glyphosate mixtures, Miscellaneous non-inherited endpoints.
Table 10. Glyphosate, Dominant lethal study.
Table 11. Glyphosate mixtures, sex-linked recessive lethal study.
Table 12. Surfactants, Bacterial assays.
Table 13. Surfactants, Chromosome studies *in vitro*.
Table 14. Surfactants, bone marrow studies *in vivo*.

Plaintiff Exhibit
0220

Conclusions

Evaluation of the genotoxicity of Glyphosate

I. Bacterial mutagenicity (Table 1)

Two comprehensive studies (Scantox 10.9.91-A, Li and Long 1988) provide no evidence of mutagenic activity for glyphosate in *Salmonella typhimurium*.

One study of differential DNA repair in the *Bacillus subtilis* rec assay gave negative results.

I conclude that there was no evidence that glyphosate is genotoxic in bacteria.

II. *In vitro* cytogenetic assays (Table 3)

(a) Chromosomal aberrations

Two studies in human and bovine lymphocytes report positive results over dose ranges up to 170μM following exposure for 72 hrs in the absence of S9 mix (Lioi *et al* 1998a, 1998b).

One negative study in human lymphocytes over a dose range of up to 562μg/ml in both the presence and absence of S9 mix and at sampling times of up to 48 hrs (Notox 141918).

Note: the Lioi *et al* studies present a combined data set of experiments from 3 separate donors.

One negative study in *Allium cepa* root tips has been reported.

(b) Sister chromatid exchange

Two studies report positive results in human and bovine lymphocytes over dose ranges of up to 170μM following exposure for 72 hrs in the absence of S9 mix (Lioi *et al* 1998a, 1998b).

Evaluation. There is published evidence that glyphosate shows clastogenic activity following 72 hrs exposure of both bovine and human lymphocytes (Lioi *et al* 1998a, 1998b).

In my view there is a need to repeat the studies of Lioi *et al* to a comprehensive protocol to clarify the potential clastogenic activity of glyphosate.

III. Point mutation in cultured mammalian cells (Table 5)

Negative results are reported in both the Tk assay using mouse lymphoma cells (up to 5000μg/ml) and the HGPRT assay using Chinese hamster cells (up to 22500 μg/ml) in both the presence and absence of S9 mix (Scantox 10.9.91-B, Li and Long 1988). There is no evidence that glyphosate is a point mutagen in cultured mammalian cells.

IV. In vivo chromosome studies in rodents. (Table 6)

a) Rat bone marrow cytogenetics assay

There is one negative study reported in the bone marrow of rats exposed to 1000mg/kg bw (Li and Long 1988),

b) Mouse bone marrow micronucleus assay.

There are two negative studies at concentrations of up to 5000mg/kg bw available for evaluation (Rank *et al* 1993, Scantox 12.9.91) However, in neither study is there substantive evidence of bone marrow toxicity.

There is one positive study at 300mg/kg with multiple dosing, sampled at 24hrs (Bolognesi *et al* 1997). However, this study only involved the use of 4 animals per dose point however bone marrow toxicity was observed.

Evaluation. There are conflicitng results concerning the bone marrow activity of glyphosate which can only be resolved by repeating the Bolognesi *et al* (1997) study.

V Dominant Lethal Study (Table 10)

There is one negative dominant lethal assay involving exposure of male mice of concentration up to 200mg/kg bw (RD 300, SRRS L1147)

Evaluation. There is no evidence that glyphosate is capable of inducing dominant lethal mutations in mouse male germ cells.

VI Miscellaneous Endpoints (Table 8)

a) **G6PD activity**

Two studies demonstrate increases in G6PD activity (as a marker of a pro-oxidant state) in human and bovine lymphocytes at concentrations of up to 170μM (Lioi *et al* 1998a, 1998b). G6 PD activity was reduced in presence of an antioxidant.

Note : no genetic endpoint was measured in these studies.

b) **Induction of 8-OHdG**

One study demonstrates the production of 8-OHdG (as a marker of oxidative damage) in the liver of mice exposed to glyphosate (Bolognesi *et al* 1997)

c) **Induction of DNA damage measured by alkaline elution**

One study demonstrates the production of single strand breaks in liver and kidney of mice following exposure to 300mg/kg bw of glyphosate (Bolognesi *et al* 1997).

d) **Induction of DNA adducts measured by ^{32}P post - labelling**

One study reports no increase in adducts in the liver and kidneys of mice following exposure to 130 and 270mg/kg of glyphosate (Peluso *et al* 1998)

e) **Hepatocyte DNA repair assay**

One limited study (low concentrations used) reported negative results for its ability of glyphosate to induce repairable DNA assay using rat hepatocytes (Li and Long 1988).

Evaluation. These studies provide some evidence that glyphosate may be capable of inducing oxidative damage under both *in vitro* and *in vivo* conditions

Evaluation of the genotoxicity of Glyphosate mixtures

Bacterial mutagenicity (Table 2)

1) The limited published study (Rank *et al* 1993) showed single dose point increases in mutagenicity of a Glyphosate mixtures in *Salmonella* strains TA98 and TA100.

Four comprehensive studies with glyphosate mixtures of concentration of 31% to 72% (MSL – 11731, MSL – 11729, MSL – 11730, BioAgri G.1.1.050/96) provide no evidence of mutagenic activity in *Salmonella typhimurium.*

Evaluation. In view of the extensive negative data in studies performed to comprehensive protocols I conclude that Glyphosate mixtures are not mutagenic to *Salmonella typhimurium..*

11) **In vitro cytogenetics (Table 4)**

a) Chromosomal aberrations

There are no available studies involving the analysis of the induction of chromosome aberrations in cultured mammalian cells.

There is one published study in *Allium cepa* root tips reporting positive results (described as being indicative of spindle disturbances) at concentrations greater then 720 µg/ml (Rank *et al* 1993).

b) Sister chromatid exchange

There are two studies reporting positive results in human lymphocytes at concentrations from 100µg/ml to 2500µg/ml (Bolognesi *et al* 1997, Vigfusson and Vysa 1980).

Evaluation. The *in vitro* cytogenetic data for glyphosate mixtures are inadequate for evaluation.

IV **_In vivo_ mouse bone marrow micronucleus assay (Table 7)**

There are 5 studies in mouse bone marrow which report negative results for micronucleus induction for various mixtures of glyphosate at concentrations of up to 3400mg/kg bw (Rank *et al* 1993, BioAgri C.1.2-60/96, MSL – 11771, MSL7173, MSL – 1172). However, most of the studies provide only limited evidence of bone marrow toxicity.

There is one positive study of a Roundup mixtures at 450mg/kg bw with multiple dosing and sampled at 24 hrs (Bolognesi *et al* 1997). Bone marrow toxicity was reported in this study but only 3 animals were used per dose point.

Evaluation. Conflicting results concerning the bone marrow activity of glyphosate mixtures can only be resolved by repeating the Bolognisi *et al* (1997) study.

V **Drosophila sex linked recessive lethal mutation assays (Table 11)**

One study provides limited evidence that following larval feeding both Roundup and Pondmaster mixtures produced some positive results in spermatocyte broods (Kale *et al* 1995)

Evaluation. Some limited evidence that Glyphosate mixtures are capable of inducing sex linked recessive mutations in the male germ cells of *Drosophila melanogaster*.

VI **Miscellaneous Endpoints (Table9)**

(a) **Induction of 8-OHdG**

One study demonstrates the production of 8-OHdG (as a marker of oxidative damage) in the liver and kidneys of mice exposed to Roundup mixture (Bolognesi *et al* 1997).

(b) **Induction of DNA damage measured by alkaline elution**

One study demonstrates the production of single strand breaks in the liver and kidney of mice exposed to 300mg/kg bw of Roundup mixture (Bolognesi *et al* 1997)

c) **Induction of DNA adducts measured by ^{32}P post labelling**

One study reports an increase in adducts in the liver and kidneys of mice following exposure to 400, 500 and 600mg/kg bw of Roundup Mixtures (Bolognesi *et al* 1997)

d) **COMET assay**

One study demonstrates the induction of chromosome damage as measures in the COMET assay following exposure of tadpoles to Roundup at concentrations above 27mg/litre (Clements *et al* 1997)

Evaluation. These studies provide some evidence that Roundup mixture produces DNA lesions *in vivo,* probably due to the production of oxidative damage.

Evaluation of the genotoxicity of Surfactants

1) **Bacterial Mutagenicity (Table 12)**

Three comprehensive studies failed to demonstrate any mutagenic activity for the surfactants in bacterial assays (MSL – 10625, MSL – 1538, Hoecht 92.0487).

11) ***In vitro* chromosome aberration assay (Table 13)**

One study failed to demonstrate any significant increase in chromosome aberrations after exposure to Dodigen 4022 at concentrations of up to 6000μg/ml (Hoecht 92.1025).

However, a number of non-significant changes in various parameters were reported. This study should be repeated.

III) **Mouse bone marrow micronucleus assay (Table 14)**

One limited experiment (ML-89-463) produced negative results in mouse bone marrow with MON 0818 at 100mg/kg bw.

Evaluation. The only adequate studies with the surfactants are those involving bacterial mutagenicity assays. There was no evidence that the various surfactants are bacterial mutagens.

Overall Conclusions

1) It is clear from the data provided that with the exception of one limited study (Rank *et al* 1993) there is an extensive range of studies which demonstrate that glyphosate and glyphosate are **not** genotoxic in bacteria.

2) There is published *in vitro* evidence that glyphosate is clastogenic and capable of inducing sister chromatid exchange in both human and bovine lymphocytes (Lioi *et al* 1998a, 1998b).

3) *In vitro* cytogenetic data on glyphosate mixtures are inadequate for evaluation.

4) There are two studies (Scantox 10.9.91, Li and Long 1988) which demonstrate that glyphosate is not a point mutagen in cultured mammalian cells.

5) This is a published study indicating that glyphosate was not clastogenic in rat bone marrow (Li and Long 1988). There are two studies which indicate that glyphosate was not capable of inducing micronuclei in mouse bone marrow (Rank *et al* 1993, Scantox 12.9.99). However, in neither study was there substantive evidence of bone marrow toxicity.

   There is one published study which suggests that glyphosate may be capable of inducing micronuclei in mouse bone marrow when delivered by multiple dosing (Bolognesi *et al* 1997).

6) Five studies report negative results for micronucleus induction in the bone marrow of mice following exposure to glyphosate mixtures. However, these studies provide only limited evidence of bone marrow toxicity. None of the studies were performed to a protocol equivalent to that of Bolognesi *et al* (1997) which gave positive results with glyphosate.

7) There is one dominant lethal study which failed to demonstrate any capacity to induce genotoxicity in mouse male germ cells (RD300, SRRS L1147). However, it should be noted that this is a relatively insensitive methodology.

8) No dominant lethal assay results are available for glyphosate mixtures.

9) No sex-linked recessive lethal assay in *Drosophila* results are available for glyphosate.

10) Following larval feeding, Roundup and Pondmaster mixtures containing glyphosate produced some positive results in spermatocyte broods (Kale *et al* 1995).

11) Glyphosate induced G6PD activity in both bovine and human lymphocytes (Lioi *et al* 1998a, 1998b) and the production of 8-OHdG in mouse liver (Bolognesi *et al* 1997). Both observations indicate that glyphosate may be capable of inducing a pro-oxidant state leading to the formation of the oxidative damage lesion 8-OHdG.

12) A Roundup mixture containing glyphosate was shown to produce 8-OHdG in both the liver and kidneys of mice (Bolognesi *et al* 1997). These observations indicate the Roundup mixture is capable of inducing oxidative damage *in vivo*.

13) Glyphosate failed to induce repairable DNA damage in a limited *in vitro* study in rat hepatocytes (Li and Long 1988).

14) Glyphosate induced single strand breaks *in vivo* in the liver and kidneys of mice (Bolognesi *et al* 1997).

15) Roundup mixture produced single strand breaks *in vivo* in the liver and kidneys of mice (Bolognesi *et al* 1997).

16) Glyphosate mixture but not Glyphosate produced an increase in uncharacterised DNA adducts *in vivo* in the liver and kidneys of mice (Peluso *et al* 1998).

The overall genotoxicity profiles of glyphosate and glyphosate mixtures are illustrated in Figures 1 and 2 respectively.

17) None of the surfactants demonstrated any mutagenic activity in bacteria.

18) There are no adequate data to evaluate the *in vitro* clastogenic activity of surfactants.

19) One limited bone marrow micronucleus assay failed to detect any micronucleus inducing activity with the surfactant MON0818.

Specific evaluation of the genotoxicity of glyphosate

On the basis of the study of Lioi *et al* (1998a and 1998b) I conclude that glyphosate is a potential clastogenic *in vitro*. The study of Bolognesi *et al* (1997) indicates that this clastogenic activity **may** be reproduced *in vivo* in somatic cells. However, the dominant lethal assay (of limited sensitivity) indicates that this genotoxic activity is not reproduced in germ cells. The work of Bolognesi *et al* (1997) and Lioi *et al* (1998a and 1998b) suggests that the genotoxicity observed may be derived from the generation of oxidative damage in the presence of glyphosate.

Specific evaluation of genotoxicity of glyphosate mixtures

In view of the absence of adequate data no evaluation of the clastogenic potential *in vitro* of glyphosate mixtures is possible. In the absence of a micronucleus study to the protocol of that used by Bolognesi *et al* (1997) no adequate assessment of the potential activity of glyphosate mixtures in bone marrow is possible. The available studies do not provide any evidence of genotoxicity in rodent bone marrow. There is some evidence from *Drosophila* to suggest that glyphosate mixtures may have some germ cell activity.

The studies of Bolognesi *et al* (1997) suggests that glyphosate mixtures may be capable of inducing oxidative damage *in vivo*.

Specific evaluation of surfactants

None of the surfactants were capable of inducing mutations in bacteria. No adequate data available to evaluate the *in vitro* or *in vivo* clastogenicity of the surfactants.

Publications utilized in the assessment of the genotoxic activity of glyphosate and glyphosate formulations.

Lioi *et al* (1998a). Genotoxicity and oxidative stress induced by pesticide exposure in bovine lymphocyte cultures *in vitro*. *Mutation Research* **403**, 13-20.

Lioi *et al* (1998b). Cytogenetic damage and the induction of pro-oxidant state in human lymphocytes exposed *in vitro* to glyphosate, vinclazolin, atrazine and DPX-E9636. *Environ. Molec. Mutagenesis* **32**, 39-46.

Rank *et al* (1993). Genotoxicity testing of the herbicide Roundup and its active ingredient glyphosate isopropylamine using the mouse bone marrow micronucleus test, *Salmonella* mutagenicity test and *Allium* anaphase-telophase test. *Mutation Research* **300**, 29-30.

Bolognesi *et al* (1997). Genotoxic activity of glyphosate and its technical formulation Roundup. *J. Agric. Food Chem.* **45**, 1957-1962.

Kale *et al* (1995). Mutagenicity testing of nine herbicides and pesticides currently used in agriculture. *Environ. Molec. Mutagenesis* **25**, 148-153.

Vigfusson and Vyse (1980). The effect of the pesticides, Dexon, Captan and Roundup on sister chromatid exchange in human lymphocytes *in vitro*. *Mutation Research* **79**, 53-57.

Clements *et al* (1997). Genotoxicity of select herbicides in *Ranacates beiana* tadpoles using the alkaline single-cell gel DNA electrophoresis (COMET) assay. *Environ. Molec. Mutagenesis* **29**, 277-288.

Peluso *et al* (1998). ^{32}P-postlabelling detection of DNA adducts in mice treated with the herbicide Roundup. *Environ. Mol. Mutagenesis* **31**, 55-59.

Li and Long (1988). An evaluation of the genotoxic potential of glyphosate. *Fundamental and Applied Toxicology* **10**, 537-546.

Reports utilized in the assessment of the genotoxic activity of glyphosate and glyphosate formulations

1. BioAgri G.1.2-60, Micronucleus study with Glifos.
2. BioAgri G.1.1-050/96, Ames/Salmonella assay of Glifos.
3. Hoecht 92.0487, Bacterial mutagenicity assay of Dodigen 4022.
4. Hoechst 92.1024, Chromosome aberration assay of Dodigen 4022 in V79 cells.
5. ML-89-463, Mouse micronucleus assay of MON 0818
6. MSL-1538, Ames/Salmonella assay of MON 8080
7. MSL-10625, Ames/Salmonella assay with surfactant MON 0818.
8. MSL-11729, Ames/Salmonella assay with Roundup MON 2139.
9. MSL-11730, Ames/Salmonella assay of Rodeo.
10. MSL-11731, Ames/Salmonella assay of Direct of MON 14445.
11. MSL-11771, Mouse micronucleus test with Roundup.
12. MSL-11772, Mouse micronucleus study of Rodeo.
13. Notox 141918, Chromosome aberration study of Glyfosaat *in vitro* in human lymphocytes.
14. MSL-11773, Mouse micronucleus study of Direct.
15. RD 300 SRRSL1147, Dominant Lethal Study of glyphosate in mice.
16. Scantox, 12.9.91 Micronucleus test with glyphosate.
17. Scantox, 10.9.91-B, *In vitro* mammalian cell gene mutation test.

Figure 1

Profile of genotoxicity of Glyphosate

Bacteria	- ve
↓	
In vitro cytogenetics	+ ve
↓	
In vitro point mutation in mammalian cells	- ve
↓	
In vivo clastogenicity	2 – ve 1 + ve
↓	
Male germ cell dominant lethal	- ve
↓	
Drosophila sex-linked recessive lethal	?
↓	
Induction of oxidative damage *in vivo*	+ ve
↓	
Induction of single strand breaks *in vivo*	+ ve
↓	
Induction of DNA adducts *in vivo*	- ve

Figure 2

Profile of Genotoxicity of Glyphosate Mixtures

Bacterial Mutagenicity	- ve
↓	
In vitro cytogenetics	?
↓	
In vitro point mutation in mammalian cells	?
↓	
In vivo clastogenicity	- ve
↓	
Male germ cell dominant lethal	?
↓	
Drosophila sex-linked lethal	limited positive
↓	
Induction of oxidative damage *in vivo*	+ ve
↓	
Induction of single strand breaks *in vivo*	+ ve
↓	
Induction of DNA adducts *in vivo*	+ ve

Table 1

Glyphosate

Endpoint	Effect	Cell type	Reference
Glyphosate (206-Jak-25-1) Point Mutation Induction in Ames test	Negative 310 to 2500µg/plate + S9 mix 160 to 2500µg/plate – S9 mix	Salmonella TA 98 TA 100 TA 1535 TA 1537	Scantox 10.9.91-A
Glyphosate Differential sensitivity rec assay	Negative 20 to 2000µg/test disc	*Bacillus subtilis*	Li and Long (1988)
Point mutation induction in Ames test	Negative 10 to 5000µg/plate + and – S9	**Salmonella** TA 98 TA 100 TA 1535 TA 1537 TA 1538 *E. coli* WP2 hcr	Li and Long (1988)

Table 2

Glyphosate Mixtures

Endpoint	Effect	Cell type	Reference
Roundup Point Mutation Induction in Ames Test	Positive minus S9 mix at 360µg/plate	TA 98	Rank *et al* 1993
	Positive in presence of S9 mix at 720µg/plate **Note:** Single point increases No evidence of dose response	TA 100	Rank *et al* 1993
Direct Mixture (72%)			
Point mutation induction in Ames test	Negative 15 to 1500µg/plate + S9 5 to 500µg/plate –S9	TA 98 TA 100 TA 1535 TA 1537	MSL-11731
Roundup (31%) Point mutation induction in Ames test	Negative 15 to 1500µg/plate + S9 5 to 500µg/plate – S9	TA 98 TA 100 TA 1535 TA 1537	MSL-11729
Roundup Mixtures			
Rodeo (40%) Point Mutation in Ames test	Negative 50 to 5000µg/plate + and – S9 mix	TA 98 TA 100 TA 1535 TA 1537	MSL-11730
Glifos (41%) Point Mutation in Ames test	Negative 1 to 5000µg/plate + and – S9 mix	TA 97a TA 98 TA 100 TA 1535	BioAgri G.1.1-050/96

Table 3

Glyphosate

Endpoint	Effect	Cell type	Reference
Glyphosate-N-(phosphonomethyl) glycine Chromosome aberrations	Positive 5 to 51μM 72 hrs exposure in absence of S9 mix	Human lymphocytes	Lioi *et al* 1998(a)
Sister chromosome exchange	Positive 5 to 51μM 72 hrs exposure in absence of S9 mix	Human lymphocytes	Lioi *et al* 1998(a)
Chromosome aberrations	Positive 17 to 170μM 72 hrs exposure in absence of S9 mix	Bovine lymphocytes	Lioi *et al* 1998(b)
Sister chromosome exchange	Positive 17 to 170μM 72 hrs exposure in absence of S9 mix	Bovine lymphocytes	Lioi *et al* 1998(b)
Note: Lioi *et al* studies indicate data derived from 3 donors combined.			
Glyfosaat Chromosome aberrations	Negative 33 to 237μg/ml –S9 14hrs 56 to 333μg/ml –S9 48hrs 33 to 562μg/ml +S9 24hrs 100 to 562μg/ml +S9 48 hrs	Human lymphocytes	Notox 141918
Note: Reduction in mitotic index in absence of +S9 mix and at 24 hrs in presence of S9 mix.			
Glyphosate isopropylamine salt Cytogenetic changes	Negative	*Allium cepa* root tips	Rank *et al* (1993)

Table 4

Glyphosate Mixture

Endpoint	Effect	Cell type	Reference
Roundup Sister chromatid exchange	Positive at 100μg/ml 72 hrs exposures	Human lymphocytes	Bolognesi *et al* (1997)
Cytogenetic changes	Positive response at concentrations greater than 720μg/litre Characterised as spindle disturbance	*Allium cepa* root tip	Rank *et al* (1993)
Sister chromatid exchange	Small positive increase at 250 and 2500μg/ml	Human lymphocytes	Vigfusson and Vyse (1980)

Table 5

Glyphosate

Endpoint	Effect	Cell type	Reference
Glyphosate (206-Jak-25-1) Tk mutation induction in mammalian cells	Negative 0.65, 1.3, 2.5, 5.0mg/ml –S9 mix 0.52, 1.0, 2.1, 4.2mg/ml +S9 mix	Mouse lymphoma L5178Y	Scantox 10.9.91-B
Glyphosate HGPRT Mutation induction in mammalian cells	Negative 5 to 22.5mg/ml + and – S9 mix	Chinese hamster	Li and Long (1988)

Table 6

Glyphosate

Endpoint	Effect	Cell type	Reference
Glyphosate isopropylamine salt Micronucleus induction	Negative up to 200mg/kg by i.p. injection Note: only 1 dose point gave reduction in PCE/NCE ratio	Mouse bone marrow	Rank *et al* (1993)
Glyphosate (analar grade) Micronucleus induction	Positive response at 300mg/kg at 24hrs Multiple dosing i.p. injection 4 animals analysed Reduction in PCE/NCE ratio	Mouse bone marrow	Bolognesi *et al* (1997)
Glyphosate (206-Jak-25-1) Micronucleus induction	Negative 5000mg/kg at 24, 48, 72hrs No evidence of bone marrow toxicity	Mouse bone marrow	Scantox 12.9.91
Glyphosate Chromosomal aberrations	Negative 1gm/kg sampled at 6, 12, 24hrs	Rat bone marrow	Li and Long (1988)

Table 7

Glyphosate Mixtures

Endpoint	Effect	Cell type	Reference
Roundup (41%) Micronucleus induction	Negative up to 200mg/kg only sampled at 48hrs	Mouse bone marrow	Rank *et al* (1993)
Roundup Micronucleus induction	Positive response at 450mg/kg Multiple dose 3 animals sampled reduction in PCE/NCE ratio	Mouse bone marrow	Bolognesi *et al* (1997)
Glifos (41%) Micronucleus induction	Negative 68, 137, 206mg/kg i.p. delivered 2 x at 24hr intervals Note: Inadequate study	Mouse bone marrow	BioAgri G.1.2-60/96
Roundup 31% Micronucleus induction	Negative 140, 280, 555mg/kg i.p. injection sampled at 24, 48, 72hrs Note: Limited evidence of bone marrow toxicity One male 268 showed increase in micronuclei	Mouse bone marrow	MSL-11771
Direct (72%) Micronucleus induction	Negative 91, 183, 365mg/kg by i.p. sampled at 24, 48, 72hrs Note: Limited evidence of bone marrow toxicity one female 186 183mg/kg at 48hrs showed an increase	Mouse bone marrow	MSL-11773
Rodeo (40%) Micronucleus induction	Negative 850, 1700, 3400mg/kg by i.p. sampled at 24, 48, 72hrs	Mouse bone marrow	MSL-11772

Table 8

Miscellaneous Endpoints

Glyphosate, N- (phosphonomethyl)glycine

Endpoint	Effect	Cell type	Reference
G6PD activity	Increase in activities 5 to 51μM	Human lymphocytes	Lioi *et al* 1998(a)

Note, increase in G6PD activity reduced by presence of antioxidant N-acetyl cysteine, but not eliminated.

G6PD activity	Increase in activity 17 to 170μM	Bovine Lymphocytes	Lioi *et al* 1998(b)

Note, increase in G6PD activity reduced by presence of antioxidant N-acetyl cysteine, but not eliminated

Glyphosate (Analar Grade)

Induction of 8-OHdG	Increase in 8–OHdG in liver	Mice *In vivo*	Bolognesi *et al* (1997)
Induction of DNA damage measured by alkaline elution	Increase in single-strand breaks in liver and kidney at 4 hrs following 300mg/kg	Mice *In vivo*	Bolognesi *et al* (1997)

Glyphosate isopropylammonium salt.

Induction of DNA adducts measured by ^{32}P post-labelling	Negative no increase in adducts in liver and kidney at 130 and 270mg/kg	Mice *In vivo*	Peluso *et al* (1998)

Table 8 continued

Glyphosate

Hepatocyte DNA repair assay	Negative 12.5ng to 125µg/ml	Rat Hepatocytes	Li and Long (1988)

Note Very low concentrations used, study adds very little value to the analysis of the potential genotoxicity of Glyphosate.

Table 9

Miscellaneous Endpoints

Glyphosate Mixtures

Endpoint	Effect	Cell type	Reference
Roundup (41%) Mon 35050			
Induction of 8-0HdG	Increase in 8–0HdG in Liver and Kidney	Mice *In vivo*	Bolognesi *et al* (1997)
Induction of DNA damage measured by alkaline elution	increase in single-strand breaks in Liver and Kidney at 4hrs following 300mg/kg	Mice *In vivo*	Bolognesi *et al* (1997)
Induction of DNA adducts measured by ^{32}Ppost-labelling Note. Adducts were not characterised	increase in adducts in liver and kidney at 400, 500 and 600mg/kg	Mice *In vivo*	Peluso *et al* (1998)
Roundup			
COMET assay	Positive results observed at concentrations above 27mg/ litre	Tadpoles of *Rana catosbeiana*	Clements *et al* 1997

Table 10

Glyphosate

Endpoint	Effect	Cell type	Reference
Dominant Lethal Study	Negative Small reduction in viable foetuses in week 1 at 800mg/kg, week 3 at 2000mg/kg Increase in late reabsorptions at week 8 at 200mg/kg	Mouse male gametes exposed Effect measured in embryos	RD300 SRRS L1147

Table 11

Glyphosate Mixtures

Endpoint	Effect	Cell type	Reference
Roundup Sex linked recessive lethal mutations	Positive result in Spermatocyte broods At 1μg/ml.	*Drosophila melanogaster* Larval exposure	Kale *et al* (1995)
Pondmaster Sex linked recessive lethal mutations	Positive result in spermatocyte broods at 0.1μg/ml	*Drosophila melanogaster* larval exposure	Kale *et al* (1995)

Table 12

Surfactant

Endpoint	Effect	Cell type	Reference
Surfactant MON 0818			
Point Mutation induction in Ames test	Negatives 1 to 100µg/plate +S9 0.3 to 30µg/plate –S9	**Salmonella** TA 98 TA 100 TA 1535 TA 1537	MSL – 10625
Surfactant MON 8080			
Point Mutation induction in Ames test	Negatives 0.003 t0 3µl /plates + ad – S9 mix	**Salmonella** TA 98 TA 100 TA1535 TA 1537	MSL – 1538
Surfactant Dodigan 4022			
Point Mutation Induction in Ames test	Negatives 4 to 10,000 µg/plats in both presence and absence at S9 Mix	**Salmonella** TA 98 TA 100 TA 1535 TA 1537 TA 1538 *E. coli* WP2uvrA	Hoecht 92.0487

Table 13

Surfactant Dodigen 4022

Endpoint	Effect	Cell type	Reference
In vitro chromosome aberrations	Complex set of results – None significant Concentration range 600 to 6000µg/ml sampled at 7, 18 and 28hrs **Mitotic index minus S9** decreased at 7hrs increased at 18hrs decreased at 28hrs **Mitotic index plus S9** decreased at 7hrs increased at 18hrs no change at 28hrs **Polyploidy minus S9** decreased at 7hrs decreased at 18hrs increased at 28hrs **Polyploidy plus S9** decreased at 7hrs decreased at 18hrs increased at 28hrs **Aberrations minus S9** increased at 7hrs no change at 18hrs increased at 28hrs **Aberrations plus S9** increased at 7hrs no change at 18hrs increased at 28hrs	Chinese hamster V79	Hoecht 92.1024

Note: Experiments are difficult to interpret and should have been repeated.

Table 14

Surfactant MON 0818

Endpoint	Effect	Cell type	Reference
Micronucleus induction Note – limited experiment	Negatives 100mg/kg by I.p. sampled at 24 and 48 hrs No evidence of animal or bone marrow toxiety	Mouse Bone marrow	ML-89-463

in vitro ✓ cocoamine → tallow
alkyl sulfate ⟩ — ED
quat.
etheramine

Key Issues concerning the potential genotoxicity of glyphosate, glyphosate formulations and surfactants; recommendations for future work.

James M. Parry

Centre for Molecular Genetics and Toxicology
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Swansea SA2 8PP, UK

Key Questions

1. Is glyphosate an *in vitro* clastogen? Can the positive studies of Lioi *et al* (1998a, 1998b) be reproduced?
2. Is glyphosate an *in vivo* clastogen? Can the positive studies of Bolognesi *et al* (1997) be reproduced?
3. If glyphosate is an *in vitro* and *in vivo* clastogen, what is its mechanism of action and does the mechanism lead to other types of genotoxic activity *in vivo* such as point mutation induction?
4. Does glyphosate produce oxidative damage?
5. Can we explain the reported genotoxic effects of glyphosate on the basis of the induction of oxidative damage?
6. If glyphosate is an *in vivo* genotoxin is its mechanism of action thresholded? Under what conditions of exposure are the antioxidant defences of the cell overwhelmed?
7. Are there differences in the genotoxic activities of glyphosate and glyphosate formulations?
8. Do any of the surfactants contribute to the reported genotoxicity of glyphosate formulations?

Deficiencies in the Data Set

1. No adequate *in vitro* clastogenicity data available for glyphosate formulations.

2. No bone marrow micronucleus study of glyphosate available using multiple dosing and adequate animal numbers.

3. No studies available demonstrating the effects of anti-oxidants upon the induction of genotoxic endpoints by glyphosate.

4. No adequate *in vitro* or *in vivo* clastogenicity data for surfactants used in glyphosate formulations.

Actions Recommended

a) Provide comprehensive *in vitro* cytogenetic data on glyphosate formulations.

b) On the assumption that the reported *in vitro* positive clastogenic data for glyphosate is due to oxidative damage determine the influence of antioxidants. Evaluate the clastogenic activity of glyphosate in the presence and absence of a variety of antioxidant activities. Such a study should also incorporate glyphosate formulations to clarify the validity of reports of differences in activity. I recommend that both a) and b) should be undertaken using the *in vitro* micronucleus assay in human lymphocytes. The *in vitro* micronucleus assay would provide a more cost-effective method for evaluating a large number of experimental variables. Same as screen chrom ab

c) Evaluate the induction of oxidative damage *in vivo* and determine the influence of the antioxidant status of the animals. Determine the exposure concentrations of glyphosate which overwhelm the antioxidant status of tissues.

d) Perform an *in vivo* bone marrow micronucleus assay with multiple dosing with adequate numbers of animals to determine whether the work of Bolognesi *et al* (1997) can be reproduced.

e) I am making no recommendation to repeat any of the sister chromatid exchange studies. Chromosomal aberration data will always take priority over SCE data so I

see no point in repeating SCE studies as they involve an endpoint which is poorly defined and doesn't lead to genetic changes.

f) In view of the increasing appreciation of the value of the COMET assay as marker of tissue-specific damage I recommend the consideration of its use in any *in vivo* studies performed. The COMET assay would provide the ability to determine whether damage is produced in a wide range of tissues following glyphosate exposure. Such studies would also indicate whether the COMET positive results for glyphosate formulations in tadpoles (Clements *et al* 1997) are reproduced in mammals. In view of the data on oxidative damage (Bolognesi *et al* 1997) I would recommend COMET assays in the liver and kidney of mice if the oxidative data are confirmed as indicated under c).

g) I do not recommend any transgenic point mutation assay at this time. There is no available evidence that glyphosate is a point mutagen and the relatively low sensitivity of the transgenic assay means that negative results would have little value in the assessment of the hazard and risk of glyphosate exposures.

h) I do not recommend any studies of DNA adduct induction at this time. Such a study would only be of value if the adducts formed were characterised which would require major efforts. If the adducts reported by Peluso *et al* (1998) are the result of oxidative damage they are likely to be of the same type as those produced in the absence of glyphosate exposure by background oxidative damage.

i) Provide comprehensive *in vitro* data on the surfactants.

My overall view is that if the reported genotoxicity of glyphosate and glyphosate formulations can be shown to be due to the production of oxidative damage then a case could be made that any genetic damage would be thresholded. Such genetic damage would only be biologically relevant under conditions of compromised antioxidant status. If such an

oxidative damage mechanism is proved then it may be necessary to consider the possibility of susceptible groups within the human population.

If the genotoxic activity of glyphosate and its formulations is confirmed it would be advisable to determine whether there are exposed individuals and groups within the human population. If such individuals can be identified then the extent of exposure should be determined and their lymphocytes analysed for the presence of chromosome aberrations. In such populations micronucleus studies would probably only be of value in aspleenic individuals.

Comments on Parry Evaluation of
Glyphosate and Glyphosate Formulation Potential Genotoxicity.
Larry Kier
September 18, 1999

There is no summary evaluation in the initial section and no overall conclusions are presented on the genotoxicity of glyphosate or glyphosate formulations.

Although the summary says most studies (i.e. unpublished reports) were conducted according to OECD guidelines, this is clearly not the case for several published studies cited but this is not mentioned in the evaluation.

The depth of analysis of the studies is rather superficial. The analysis of the unpublished reports appears to be much more thorough than analysis of the published reports.

Ames tests--There are numerous published and unpublished negative Ames studies with glyphosate that contradict the reported positive findings of Rank et al. The evaluation doesn't go into any depth on the quality of the Rank et al. data in comparison with the other reports. (e.g., reproducibility or testing at equivalent doses).

Micronucleus--There is no analysis of the possible significance of differences in protocol between Bolognesi et al. and the other negative studies. In particular, what are the implications of multiple dosing (actually 2 doses) compared with a single dose. How many instances of clear positive/negative differences exist for these two protocols?

There is no conclusion about what the data say about glyphosate. The published studies are presented as some evidence of genotoxicity and the reports are presented as giving no evidence.

There is mixing of glyphosate and formulations in the analysis.

What's the significance of one animal showing an increase in micronuclei noted for micronucleus studies of Roundup and Direct? Apparently the conclusion is that these studies are negative, but if that is the case why mention single animal results. Are these considered significant?

There appears to be no evaluation of the significance of different endpoints--e.g. comet in tadpoles, oxidative damage, in vivo vs. in vitro. etc. These are all apparently considered as equivalent in this evaluation.

It's not clear how these data and reports lead to a concern about stability of glyphosate formulations.

WRATTEN, STEPHEN J [FND/1000]

To: [redacted] FARMER, DONNA R [FND/1000]
Cc: KIER, LARRY D [NCP/1000]; HEYDENS, WILLIAM F [FND/1000]; [redacted]

Subject: Comments on Parry write-up

[redacted] and Donna

I was somewhat disappointed in the Parry report, not particularly from his conclusions but just the way they're presented. The style and rather casual lack of completeness and preciseness would make it hard to circulate this around to anyone as supporting information. Has he ever worked with industry before on this sort of project?

I will mail the marked-up paper back to you, but some other general comments need to be made:

1. It is odd that the one study by BioAgri is discussed right on the first page in rather extensive detail but none of the others are. I understand that he didn't like this one, but it is still strange to read this way.

2. The whole report could benefit from a couple of introductory paragraphs about what he was asked to do and what he received as far as reports. Did he have all the Monsanto reports as well as the literature articles? Was he asked to compare these, evaluate the methods, explain the differences, identify any faults, or what?

3. Some where the report needs to identify the full citations of each report evaluated and give the full Literature references for the public documents. Also the test material should be clearly identified, ideally by both MON number and brand name if needed, but at least to say which are glyphosate and which are formulations - this is done, sort of, but not as clearly as I'd like. Separate tables would be good.

4. He has an odd way of starting all conclusions with a negative - ie., points 2, 3, and 4 on page 3. Couldn't the sentence structure be modified to be less awkward? When he says "no data were provided..." time and again, it makes it sound as though he was suspicious that there were data but he didn't get them. I know this is not the intent, but it could be cleaned up.

5. Table 1 seems to state repeatedly that "there was no evidence of xxx mutagenicity". It would be more powerful if it said "there was convincing evidence that glyphosate does not act as a xxx mutagen". "no evidence of" is a very weak way of stating a conclusion.

6. He says very little about the literature reports. So little that one almost forgets about them. Can he not provide some critique about their quality and methodology as compared to the Monsanto reports? Are they included in or excluded from the statement in the first paragraph sentence "these studies were performed to a high standard and to OECD recommended guidelines"? In the section entitled "Assessment of the published..." on p. 2, I am hard-pressed to find any assessment. It is almost merely a listing of what everyone already knew from casually reading the abstract.

7. In his conclusions (p. 2), do the "studies evaluated" (line 2) include the literature reports or not? IN other words, is he saying that none of the studies (Monsanto plus literature) had evidence of glyphsoate genotoxic potential, or is he limiting this conclusion to the Monsanto studies?

8. Of course we know there were no data of the type listed in points 2, 3, and 4 on p. 3. We didn't need him to tell us that. The key point is whether the conclusions of Bolognesi, and Rank can be discounted on the basis of the strength and number of studies at hand, or whether their experiments need to be repeated independently to credibly refute the findings. Of course we knew that the latter would be the most convincing approach, but we need him to make any arguments that can be made on the data we have.

Overall, I guess we have his recommendation of studies that could be used to strengthen the database on p. 4. , but that is about it. I do not see that he has stuck his neck out on anything at all controversial, and therefore, there is little value in the write-up as written that could be useful. Hope it didn't cost much. Perhaps this is too harsh, and I don't know what your proposal to him was, but I guess I would expect more than this of a Professor.

Steve

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[redacted]
Monsanto Europe
Parc Scientific Fleming
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18 August 1999

Dear [redacted]

You find enclosed my evaluation of the package of studies provided by yourself, which studied the genotoxicity of glyphosate, its various formulations and surfactants. I apologise for the time taken for the evaluation, but as I explained previously, I had a sudden urgent request from UK government to evaluate the genotoxicity of growth promoting hormones used in beef production.

Please let me know if there are any parts of my evaluation and recommendations, which you would like, clarified.

Yours Sincerely

JM

Professor James M. Parry

P.S. as a personal point - I don't really understand why you use contract labs, your "in house" studies are usually better and easier to follow

Tel [redacted] Fax [redacted]

25/08/1999 13:54 [redacted] MONSANTO TOXICOLOGY PAGE 11

MONGLY01314270

An analysis of potential genotoxicity of glyphosate and its various formulations

Professor James M. Parry, Centre for Molecular Genetics and Toxicology, School of Biological Sciences, University of Wales Swansea, Swansea SA2 8PP.

Evaluation

The various studies provided have been individually evaluated and these evaluations are summarised in Table 1. In general, these studies were performed to a high standard and to OECD recommended guidelines. Table 1 has been separated into glyphosate itself, glyphosate formulations and some component surfactants and assessments for each study provided.

I have major reservations concerning one of the studies, which are discussed below:-

why is this one study singled out at the front?

General Comments of BioAgri G.1.2-60/96

Dull sentence? — Rather confusing report-relating doses used to fraction of LD50, which is reported to be 250mg/kg b.w. My assumption from the report is that the top doses of 206mg/kg are 75% of the LD50. This is in marked contrast to the top dose of 555mg/kg used in study MSL-1171.

In general this is a poor study, for example; the measurement of the PCE/total erythrocyte ratio is normally determined by counting 500 or 1000 erythrocytes which are classified during counting into PCE or NCE, in this study they count erythrocytes until they reach 1000 of **either** NCE **or** PCE. This results in major differences between individual animals, for example in the control males one animal has a ratio of 0.31 whereas another has a ratio of 0.66, with such variation it would be difficult to demonstrate a significant change in bone marrow toxicity. The positive control chemical cyclophosphamide only gave a positive result in one animal of each sex; thus we cannot be assured that ~~the method was being correctly applied~~. In addition,

the authors.

in counting procedure

this method of measurement can distinguish a positive sample accurately.

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there was a very high level of bone marrow toxicity in one female exposed to cyclophosphamide.

Assessment of the published studies of glyphosate and its formulations

The published information on glyphosate and its formulations provide some evidence for genotoxic activity i.e. some evidence of:

a) Ames test positive results (Rank *et al* 1993)

b) Induction of sister chromatid exchange in cultured human lymphocytes (Bolognesi *et al* 1997).

b) Induction of sister chromatid exchanges and chromosome aberrations in cultured bovine lymphocytes (Lioi *et al* 1998).

c) Positive response in mouse bone marrow micronucleus assay (Bolognesi *et al* 1997).

d) Evidence for the induction of oxidative damage in rodent liver and kidney (Bolognesi *et al* 1997).

could we distinguish which are gly and which are formulations?

Conclusions of the studies provided

The overall results of the studies are combined together in Table 2. This table illustrates that ~~in~~ none of the studies evaluated ~~was there~~ contained convincing evidence that glyphosate had genotoxic potential. However, there are a number of deficiencies in the studies provided:-

1) A complete data package as generally recognised by international regulatory agencies i.e.

   a) Bacterial mutagenicity assay.

   b) *In vitro* cytogenetics assay.

   c) *In vitro* point mutation assay.

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d) Rodent bone marrow micronucleus assay

was only provided for glyphosate itself.

2) For none of the formulations of glyphosate was any *in vitro* cytogenetic or mouse lymphoma point mutation date provided.

3) No *in vivo* rodent bone marrow study was provided which is completely comparable to the published study of Bolognesi *et al* (1997).

4) No data was supplied which addresses the question of the potential oxygen radical damaging activity of glyphosate.

word order is odd.

The range of bacterial mutagenicity studies provided were all performed to a high standard and are consistently negative. Thus, they do not provide any support for the observations of Rank *et al* (1993) that glyphosate is a bacterial mutagen.

None of the rodent bone marrow micronucleus studies provide evidence that glyphosate is a potential rodent bone marrow genotoxin. However, I should emphasise that there is no study directly comparable to the positive study of Bolognesi *et al* (1997).

There was no evidence from the studies provided that glyphosate was clastogenic and/or mutagenic in cultured mammalian cells. However, equivalent data is not available for glyphosate formulations.

There was no evidence in any of the studies evaluated that the various surfactants used in glyphosate formulations were potential genotoxins.

Remaining unresolved problems concerning the genotoxicity of glyphosate

The main question to be addressed is: When studied using methodologies, which measure a recognised genetic endpoint, are glyphosate containing products genotoxic? The areas lacking in clarity are:-

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1) *In vitro* chromosome damaging activity. There are some published positives and the studies evaluated here are not comprehensive for various formulations.

2) There is a limited published bone marrow positive study (Bolognesi *et al* 1997). However, no equivalent study was available for evaluation.

3) Some published evidence is available that glyphosate is capable of inducing oxidative damage. No studies were provided which address this potential activity. No information is provided to indicate whether formulation influences this activity.

4) The confusing picture of the activity of the various formulations of glyphosate reported in the literature suggests that there may be differences in the way samples are stored. The studies on the various surfactants do not clarify the matter of the reported activity of formulations.

Recommendations for further work

To clarify the remaining problems I recommend the following additional studies:-

1) A definitive *in vivo* bone marrow micronucleus study with multiple dosing to repeat the basic protocol used in the Bolognesi *et al* (1997) study.

2) A comprehensive *in vitro* cytogenetics study. I would recommend an *in vitro* micronucleus study in which all the formulations of glyphosate could be evaluated and the potential effects of antioxidants determined.

3) In view of the differences in the responses of the various formulations reported in the published papers it would be of value to evaluate the stability of the formulations and its influence on genotoxic activity.

19-8-99.

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Include full study info please citation

Table 1a

Review of Genotoxicity Data on Glyphosate Formulations and Surfactants

MSL-11731
Salmonella mutagenicity assay of **Direct** (72% Glyphosate)

TA98, TA100, TA1535, TA1537
15 to 1500μg/plate in presence of S9 mix
5 to 500μg/plate in absence of S9 mix

Some toxicity observed above ...

There was no evidence that **Direct** was a bacterial mutagen.

MSL-11729
Salmonella mutagenicity assay of **Roundup** (31% Glyphosate)

TA98, TA100, TA1535, TA1537
15 to 1500μg/plate in presence of S9 mix
5 to 500μg/plate in absence of S9 mix

Some toxicity observed above ...

There was no evidence that **Roundup** was a bacterial mutagen.

Scantox 10.9.91
Salmonella Mutagenicity assay of **Glyphosate** (206-Jak-25-1)

TA98, TA100, TA1535, TA1537
310, 630, 1300, 2500μg/plate in presence of S9 mix
160, 310, 630, 1300, 2500μg/plate in absence of S9 mix

Toxicity observed above..

There was no evidence that **Glyphosate** was a **Salmonella** mutagen.

MSL-11730
Salmonella Mutagenicity assay of **Rodeo** (40% **Glyphosate**)

TA98, TA100, TA1535, TA1537
50 to 5000μg/plate in presence and absence of S9 mix

No toxicity observed

There was no evidence that **Rodeo** was a **Salmonella** mutagen.

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Table 1b

BioAgri Report G.1.1-050/96
Salmonella Mutagenicity assay of **GLIFOS**

TA97a, TA98, TA100, TA1535
1 to 5000μg/plate in presence and absence of S9 mix

In all cases **Glifos** reduced the number of bacterial colonies counted

There was no evidence that **Glifos** was a **Salmonella** mutagen.

Scantox Report 10.9.91
In vitro Mammalian cell mutation assay in mouse lymphoma L5178Y cells **Glyphosate** (206 Jak-25-1)

0.63, 1.3, 2.5, 5mg/ml without metabolic activation
0.52, 1.0, 2.1, 4.2mg/ml with S9 mix

No evidence that **Glyphosate** produced any increase in mutation in either the presence or absence of S9 mix.

Notox Project 141918
In vitro chromosome aberrations in cultured human lymphocytes, **Glyfosaat**

33, 56, 100, 133, 178, 237μg/ml without S9 mix, 14 hrs fixation
56, 100, 133, 178, 237, 333μg/ml without S9 mix, 48 hrs fixation
33, 56, 100, 133, 178, 237, 333, 562μg/ml with S9 mix, 24 hrs fixation
100, 133, 178, 237, 333, 562μg/ml with S9 mix, 48 hrs fixation
not all doses were scored

Reduction in mitotic index in absence of S9 mix and at 24 hrs fixation in presence of S9 mix

No evidence of any increase in chromosome aberrations in the study.

Scantox Report 12.9.91
Mouse micronucleus **Glyphosate** (206-Jak-25-1)

Oral exposure 5000mg/kg bw sampled at 24, 48 and 72 hrs

Evidence for overall toxicity not clear from report
No evidence of bone marrow toxicity
No evidence that Glyphosate produced an increase in micronuclei in bone marrow.

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Table 1c

BioAgri Report G.1.2-60/96
Mouse micronucleus **GLIFOS** (41% **Glyphosate**)

68, 137 and 206mg/kg by i.p. injection delivered twice .... at 24 hr intervals - said to relate to 75, 50 and 25% of LD50 for mice

No evidence of bone marrow toxicity
No evidence that **GLIFOS** produced an increase in micronuclei in bone marrow.
Inadequate study see text.

MSL-1171
Mouse Micronucleus **Roundup** Formulation (31% **Glyphosate**)

140, 280, 555mg/kg - sampled at 24, 48, 72 hrs single i.p. injection

Evidence of toxicity in high dose group
No evidence of increase in micronucleated erythrocytes
However limited evidence of bone marrow toxicity at doses...
No evidence of increases in micronuclei in overall data
One animal Male 268 showed increase in micronuclei

MSL-11773
Mouse Micronucleus **Direct** Formulation (72% **Glyphosate**)

91, 183 and 365mg/kg sampled at 24, 48, 72 hrs single i.p. injection

Evidence of toxicity in high dose group
This experiment used the same control and positive controls as MSL-11771
No evidence of bone marrow toxicity
No evidence of increases in micronuclei in overall data
One animal female 186 183mg/kg at 48 hrs showed an increase

MSL-11772
Mouse Micronucleus **Rodeo** Formulation (40% **Glyphosate**)

850, 1700, 3400mg/kg sampled at 24, 48, 72 hrs single i.p. injection

Toxicity observed. Some evidence of bone marrow toxicity at what levels
No evidence of increases in micronuclei

This experiment used the same control and positive controls as 11771 and 11773.

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Table 1d

RD300 SRRSL 1147
Mouse dominant lethal study, **Glyphosate**

200, 800, 2000mg/kg bw by gavage

Large comprehensive study involving mating for up to 8 weeks
Clear response from positive control

Small reduction in viable foetuses in week 1 at 800mg/kg, week 3 at 2000mg/kg and an increase in late reabsorptions at 200mg/kg at week 8

I conclude that glyphosate was not a dominant lethal inducing chemical under the experimental conditions used.

MSL-10625
Salmonella Assay of **Mon 0818** Surfactant

TA98, TA100, TA1535, TA1537 in presence and absence of S9 mix. 1 to 100μg/plate in presence of S9
0.3 to 30μg/plate in absence of S9 mix

No evidence that **MON 0818** is mutagenic in Salmonella.

MSL-1538
Salmonella Assay of **MON 8080** Surfactant

TA98, TA100, TA1535, TA37 in presence and absence of S9 mix
0.003 to 3μl/plate in absence of S9 mix and presence of S9 mix

No evidence that MON 8080 is mutagenic in **Salmonella**.

Hoecht 92.0487
Salmonella and **Escherichia coli** assay of **Dodigan 4022** Surfactant

TA98, TA100, TA1535, TA1537, TA1538 and *E. coli* WP2 uvrA
4 to 10,000μg/plate in both presence and absence of S9 mix

No evidence that **Dodigen 4022** is mutagenic in the bacterial test strains used.

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Table 1e

Hoechst 92.1024
In vitro chromosome aberrations in Chinese hamster V79 cells **Dodigen 4022** surfactant

Without metabolic activation	6000μg/ml for 7 hrs 6000, 3000, 600μg/ml for 18 hrs 6000μg/ml for 28 hrs
With S9 mix	6000μg/ml for 7 hrs 6000, 3000, 600μg/ml for 18 hrs 6000μg/ml for 28 hrs

This is a rather confusing dataset

Mitotic index	decreased at 7 hrs	)	
	increased at 18 hrs	)	in absence of S9 mix
	decreased at 28 hrs	)	
	decreased at 7 hrs	)	
	increased at 18 hrs	)	in presence of S9 mix
	no change at 28 hrs	)	
Polyploidy	decreased at 7 hrs	)	
	decreased at 18 hrs	)	in absence of S9 mix
	decreased at 28 hrs	)	
	decreased at 7 hrs	)	
	decreased at 18 hrs	)	in presence of S9 mix
	increased at 28 hrs	)	
Aberrations	increased at 7 hrs	)	
	no change at 18 hrs	)	in absence of S9 mix
	increased at 28 hrs	)	
	increased at 7 hrs	)	
	no change at 18 hrs	)	in presence of S9 mix
	increased at 28 hrs	)	

None of increases significant

Overall experiments are difficult to interpret and should have been repeated.

Table 1f

KHL 89182/ML-89-46
Mouse Micronucleus Test, **MON 0818** surfactant

100mg/kg sampled at 24 and 48 hrs by i.p. injection

No evidence of animal toxicity, no bone marrow toxicity
No evidence of increases in micronuclei

Limited experiment doesn't really tell us very much.

Evaluation of Publications

1) Li & Long (1988). Glyphosate tested in bacterial mutagenicity rec-assay, Chinese hamster gene mutation assay, hepatocyte DNA repair assay, and *in vivo* cytogenetic assay.
- negative results reported for all assays.

2) Vigfusson and Vyse (1980). Roundup evaluated for its ability to induce sister chromatid exchange in cultured human lymphocytes.
Small increase reported at 250μg/ml.

3) Kale *et al* (1995). Roundup and Pondmaster evaluated in *Drosophila* sex linked recessive lethal.
Positive result observed in spermatocyte broods at concentration of 1μgm/ml of **Roundup** and 0.1μg/ml of **Pondmaster**.

4) Clements *et al* (1997). Roundup evaluated in the COMET assay in tadpoles of *Rana catesbeiana*.
Positive results observed at concentrations above 27mg/litre.

MONGLY01314280

Table 2a

Overview Genotoxicity of Glyphosate

Preparation	Test System	Result
Glyphosate (206-Jak-25-1)	**Salmonella** Assay up to 2500μg/plate	-
	In vitro mouse lymphoma mutation assay up to 5mg/ml	- vc
	Mouse micronucleus oral dosing 5000mg/kg bw	- ve
Glyphosate (Techical)	Dominant lethal 200, 800, 2000mg/kg bw by gavage	- ve
Glyphosaat (assumed to be glyphosate)	*In vitro* cytogenetics up to 562μg/ml	- ve

Table 2b

Formulations

Preparation	Test System	Result
Rodeo (40% Glyphosate)	**Salmonella** Assay up to 5000μg/plate	- ve
	Mouse micronucleus 850, 1700, 3400mg/kg bw i.p. injection	- ve
GLIFOS (41%Glyphosate)	**Salmonella** assay up to 5000μg/plate very toxic	ve
	Mouse micronucleus 68, 127, 206mg/kg bw 2 x i.p. injections	- ve Inadequate study
Roundup (31% Glyphosate)	**Salmonella** assay up to 1500mg/plate	- ve
	Mouse micronucleus 140, 280, 555mg/kg bw i.p. route	- ve
Direct (72% Glyphosate)	**Salmonella** assay up to 1500μg/plate	- ve
	Mouse micronucleus 91, 183, 365mg/kg bw i.p. route	ve

25/08/1999 13:54 MONSANTO TOXICOLOGY PAGE 23

Table 2c

Surfactants

Preparation	Test System	Result
Dodigen 4022 Surfactant	Bacterial Mutagenicity Assay up to 10,000μg/plate	- ve
	In vitro cytogenetics up to 6000μg/ml	Poor study difficult to evaluate
Mon 0818 Surfactant	**Salmonella** Mutagenicity Assay up to 100μg/plate	ve
	Mouse Micronucleus 100mg/kg bw i.p.	- ve
Mon 8080 Surfactant	**Salmonella** Mutagenicity Assay up to 3μl per plate	- ve

Message

From: FARMER, DONNA R [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]
Sent: 4/27/2000 7:24:19 PM
To: KIER, LARRY D [NCP/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=33322]
Subject: RE: micro-MN results

Thanks for the guidance. Hope all is well!

Donna

-----Original Message-----
From: KIER, LARRY D [NCP/1000]
Sent: Thursday, April 27, 2000 2:19 PM
To: FARMER, DONNA R [FND/1000]
Subject: RE: micro-MN results

Donna,

I would ask them to design and conduct experiments that will be reasonably definitive. I expect this would involve both replication and dose level selection tailored to the existing data. At this point we are interested in defining (or divining) the answer and are not limited to just a rapid screen protocol.

Larry

-----Original Message-----
From: FARMER, DONNA R [FND/1000]
Sent: Thursday, April 27, 2000 2:00 PM
To: KIER, LARRY D [NCP/1000]; HEYDENS, WILLIAM F [AG/1000]
Cc: [redacted]
Subject: RE: micro-MN results

Should I go ahead and ask Todd to repeat the studies? Or should we do a different assay? I agree we do not send samples to Dr. Parry until we get this sorted out.

Donna

-----Original Message-----
From: KIER, LARRY D [NCP/1000]
Sent: Thursday, April 27, 2000 8:45 AM
To: HEYDENS, WILLIAM F [AG/1000]
Cc: FARMER, DONNA R [FND/1000]; [redacted]
Subject: RE: micro-MN results

Sorry it's taking me a while to look at this data but there seem to be plenty of nutrition things happening these days.

On the in situ micronucleus findings--I haven't looked at a large amount of data from this assay so my impressions are more from a general standpoint for this type of assay.

I would agree that the C12 alkyl sulfate results are equivocal w/o S9 but I would like to see a replicate experiment. The highest MN numbers are for the highest dose levels tested in the 2/14 experiment. The results with S9 are more questionable as there was no real dose response in the 2/14 experiment and no response at all in the 11/2 experiment. There doesn't seem to be any obvious toxicity associated with these responses.

The tallowamine is only "equivocal" w S9 in the 2/14 experiment and this doesn't have a very convincing dose response. There is no response in the 11/2 experiment but some evidence for toxicity and cycle delay here. Again a repeat would help to assess this result better.



I personally wouldn't send these to Parry unless and until we have repeated the "equivocal" experimental conditions. Actually, there's no reason we can't run good experiments with statistics.

Larry

-----Original Message-----
From: HEYDENS, WILLIAM F [AG/1000]
Sent: Wednesday, April 26, 2000 7:16 AM
To: KIER, LARRY D [NCP/1000]
Cc: FARMER, DONNA R [FND/1000]; [redacted]
Subject: FW: micro-MN results

Larry,

A position of treatment-related for tallowamine and C12 seems quite weak to me. The worst set of data is the C-12 w/o S9.
What's your view of the data ?

Bill

-----Original Message-----
From: FARMER, DONNA R [FND/1000]
Sent: Tuesday, April 25, 2000 8:41 AM
To: KIER, LARRY D [NCP/1000]; HEYDENS, WILLIAM F [AG/1000]; [redacted]
Subject: micro-MN results

Please see attached excel sheet.

Donna
-----Original Message-----
From: BUNCH, RODERICK T. [PHR/1825]
Sent: Tuesday, April 18, 2000 10:57 AM
To: FARMER, DONNA R [FND/1000]
Subject: RE: A couple of things!

Donna,
Attached is an excel data file that Cindy prepared.

You will notice that while scoring for clastogenic/aneugenic potential by looking for binucleated cells with micronuclei (Mn-Bi's), we also score uninucleated cells (uni's), binucleated cells (Bi's), and multinucleated cells (>2's). IF cells divide during the treatment period, they will be Bi's, if they divide more than once they will be >2's. If they don't divide they will be uni's. The cytochalasin B inhibits real cell division, so I really mean nuclear division. If the drug inhibits growth or is cytotoxic, you will see an increase in uni's and/or a decrease in >2's. The Bi's is always 200 as that is the goal for scoring.

Please note that the control range for Mn-Bi's is 0-4 per 200 Bi's for this data set. Our threshold for positive response is 8. The effects of the C12 and the tallow compound seem test article related, but clearly not a robust clastogenic response.

I talked to a couple other companies recently an P&G said they have, on rare occasion, had micronuclei positive surfactants. We can talk more about this later.

As an aside, we are developing a kinetochore staining assay to differentiate between clastogens and aneugens, either of which could induce micronuclei. This may not be helpful when only an equivocal response is observed, but we could discuss this further if you wish.

Let me know if you have any questions.
Todd

<< File: surfdatasum.xls >>

-----Original Message-----
From: FARMER, DONNA R [FND/1000]
Sent: Friday, April 14, 2000 7:07 AM
To: BUNCH, RODERICK T. [PHR/1825]
Cc: HEYDENS, WILLIAM F [AG/1000]
Subject: FW: A couple of things!

Todd,

Regarding the uMN results are there data tables we can take a look at? Any other thoughts on this since we last spoke?

Thanks,

Donna

-----Original Message-----
From: HEYDENS, WILLIAM F [AG/1000]
Sent: Thursday, April 13, 2000 5:57 PM
To: FARMER, DONNA R [FND/1000]; KIER, LARRY D [NCP/1000]; [redacted]
Subject: RE: A couple of things!

Donna,

1) I do have copies of the clin chem. tables for the "pre-UDS" liver tox. study. I remember you showing the numbers to me and not being real impressed by them. I don't feel strongly about doing histo given the data.

2) Do you have data tables for the micro-MN results ? It would be nice to see what kind of numbers/results we are really looking at here.

Bill

-----Original Message-----
From: FARMER, DONNA R [FND/1000]
Sent: Thursday, April 13, 2000 10:19 AM
To: KIER, LARRY D [NCP/1000]; [redacted] HEYDENS, WILLIAM F [AG/1000]
Subject: A couple of things!

1) Have all of you had a chance to look at the clin chem tables from SRI on the toxicity studies with glyphosate and MON 52276.

I asked them to give us their interpretation of the results and this is what they said:

Donna,

I would interpret the data to indicate a modest effect on the liver at 3 and 12
hours, which could be due to an increase in protein synthesis. While there are
statistically significant changes all the parameters do fall within normal
historical ranges so the changes are probably of limited biological relevance
and not an indication of a toxic effect.

Chris

When discussing whether we do histopath or not - Chris said he talked to the pathologist and their opinion is- since these fell within normal historical ranges and were not statistically significant by 48 hrs - we would not see anything.

Question???? Do we want to do histopath? If so do we do all dose leves? or just control and high-dose?

2) Below I have included a number of messages on the micromicronucleus studies. What is your opinion of the results? Where do we stand with sending these to Dr. Parry.

Thanks,

Donna

****

See messages below - according to Todd Bunch there was a decrease in cells with multiple nuclei for the tallowamine and alkyl sulfate assays. It was below their threshold for a positive response but was biostatistically different from concurrent and historical controls, that is why they called it equivocal but test-related. It appears that the changes induced in this study are changes in cell cycle kinetics and that those can be changed by toxicity as well and we certainly have toxicity in these assays.

-----Original Message-----
From: FARMER, DONNA R [FND/1000]
Sent: Thursday, March 16, 2000 9:23 AM
To: BUNCH, RODERICK T. [PHR/1825]
Subject: RE: uMN results for surfactants

Todd,

As a followup-up to my voice message. My concern is that in the first assay the results for the tallowamine and alkyl sulfate appeared to be negative, in the second they are considered equivocal but test-related and with the cocoamine we did not re-run it and it stayed a negative.

We have negative ames and negative mouse in vivo micronucleus with a tallowamine surfactant. Are these truely mutagenic responses or because of the cytotoxicity properties are we looking at secondary effects such DNA damage thru cell death.

I would appreciate your review of the data and opinion of what we are looking at here.

Thanks,

Donna

****

Todd,

As I have not heard from you regarding these assays I will try to call you tomorrow.

Donna

-----Original Message-----
From: FARMER, DONNA R [FND/1000]
Sent: Thursday, March 09, 2000 3:05 PM
To: BUNCH, RODERICK T. [PHR/1825]
Cc: MCADAMS, JAMES G [PHR/1000]; GROSS, CINDY JO [PHR/1000]; ASBURY, KAREN J [PHR/1735]
Subject: RE: uMN results for surfactants

-----Original Message-----
From: GROSS, CINDY JO [PHR/1000]

Sent: Wednesday, March 08, 2000 4:03 PM
To: FARMER, DONNA R [FND/1000]
Cc: BUNCH, RODERICK T. [PHR/1825]; MCADAMS, JAMES G [PHR/1000]
Subject: uMN results for surfactants

Todd,

Below I have cut and pasted 3 summaries regarding surfactants we requested be run in the in situ micronucleus assay. The first paragraph is a paragraph from Karen regarding a cocoamine surfactant, the second is from the first run of 4 other surfactants and the last is the repeat assays with those 4 surfactants.

I would like to discuss these in detail with you (or who ever is the appropriate person (s)). In addition if possible I would like to see the "raw" data tables in order to better understand concentration ranges and the results.

Please give me a call and let's talk about how we proceed.

Thanks,

Donna [redacted]

(1) In Situ Micronucleus
Cocoamine surfactant was tested in the in situ micronucleus assay from 7-21-99 at concentrations ranging from 7.81-500 mg/ml (24 mM - 1.5 mM) without and with metabolic activation. Countable concentrations were scored for three dosage levels without and with metabolic activation. Countable concentrations were at all levels. No evidence of micronucleus induction was observed with the compound under both metabolic activation scenarios. The negative and positive controls without and with metabolic activation demonstrated that this system was capable of detecting direct-acting and metabolism-dependent chemical clastogens in all experiments. Therefore, this compound did not induce micronuclei in CHO-WBL cells under the conditions of this assay system.

(2) Jim ran the benzalkonium chloride, tallow amine, C12 alkyl sulfate, and MON59117 in the in situ micronucleus assay on 1/10 at concentrations of 3.9, 7.8, 15.6, 31.25, 62.5, 125, 250, and 500 ug/ml with metabolic activation. Countable concentrations were scored for five dosage levels for benzalkonium chloride (500, 125, 15.6, 7.8, and 3.9 ug/ml); no evidence of micronucleus induction was observed with the compound at these doses. Unfortunately, with the tallow amine, cytotoxicity was observed for all doses tested except 7.8 and 3.9 ug/ml; similarly, with the C12 alkyl sulfate and MON59117 cytotoxicity was observed for the top four doses (500 through 62.5 ug/ml). While the lower doses which were scored appear negative, we know that cytotoxicity in this assay can affect the sensitivity of the test; thus, we would like to repeat this assay. Due to illness and Jim's knee surgery follow-up treatment, it will likely be the first or second week of February before he can repeat.

(3) Jim ran the surfactants, benzalkonium chloride, tallow amine, C12 alkyl sulfate, and MON59117, in the in situ micronucleus assay on 2/14/00 at the following concentrations with and without metabolic activation: benzalkonium chloride at 5000, 2000, 1000, and 500 ug/ml; tallow amine, C12 alkyl sulfate, and MON59117 at 62.5, 15.6, 3.9, 0.98, 0.24, and 0.06 ug/ml.

The benzalkonium chloride was insoluble at the top two doses (5000 & 2000 ug/ml) while there was no evidence of micronucleus induction at 1000 or 500 ug/ml. MON59117 also gave no evidence of micronuclei induction, although it was judged toxic at 62.5 ug/ml.

Both the tallow amine and the C12 alkyl sulfate produced an equivocal response for micronuclei induction. While the tallow amine was considered toxic at 62.5 and 15.6 ug/ml, the C12 alkyl sulfate didn't exhibit toxicity at any of the test doses. While both of these compounds produced a marginal response which didn't meet the test criteria for a robust positive, they did elicit an effect which was judged to be an equivocal, but test article-related effect.The negative and positve controls without and with metabolic activation demonstrated that this system was capable of detecting direct-acting and metabolism-dependent clastogens.

Todd Bunch [redacted] will be happy to discuss these results with you.
thanks for your patience,
Cindy

The Genetic Toxicology Discovery Screen Battery General Information:

Micro-Ames assay: This assay was designed to detect mutations within DNA, changes which can affect a single base pair within a gene. Typically, two different Salmonella typhimurium strains are used within the micro-Ames assay: strain TA98, which detects frameshift mutations, and strain TA100, which detects base-pair substitution mutations. Although being a scaled down version of the full Ames assay, a similar number of bacteria are exposed to the compound. Typically the highest dose tested in the micro-Ames assay is 250 μg/well versus 5,000 μg/plate used for the full Ames assay. While these differences in maximum doses are not significant when differences in surface area are considered, other factors may influence the effects observed in this screen.

In situ micronucleus Assay: The in situ micronucleus assay detects clastogenicity (or chromosomal aberrations) and inducers of non-disjunction. Both anomalies are detected by the presence of micronuclei, distinct membrane-bound nuclear material that separated from the nucleus during the cell division process. The assay is conducted by exposing Chinese hamster ovary cells in situ to compound concentrations generally up to 1,000 μg/ml. Micronuclei are scored manually using light microscopy. This assay is relatively new and a statistically based method for data analysis, incorporating both historical and concurrent control data, is currently being developed to create rigorous decision criteria (i.e., determining whether a compound produced a positive or negative response).

Advantages: These miniaturized assays are thought to be good predictors of their regulatory GLP counterparts, the Ames assay and the in vitro chromosomal aberration assay, but are shorter, higher throughput assays. Within a week, clastogenic and mutagenic information on at least 10 compounds can be obtained. They require very small amounts of compound. Assuming good compound solubility, both assays can be run with a minimum of 6 mg of compound. Both assays include metabolic activation conditions, which are important since only the metabolites of many compounds are mutagenic and/or clastogenic.

Disadvantages: Both of these assays have limited dosing schemes as well as limited historical reference information from which to compare results. The counterpart of the micro-Ames includes additional strains thereby increasing the probability of detecting weak mutagens. One counterpart of the in situ micronucleus assay is an in vivo assay; factors such as absorption, metabolism, distribution and excretion, which may affect the response, cannot be adequately predicted in the screening assay. All these caveats need to be considered when evaluating the results obtained from these screening assays.

Conclusions: The genetox screens provide valuable information to support the rank ordering of compounds. Equivocal or weakly positive results require repeat

testing, while a positive result in either assay suggests the need for further testing using additional standard GLP assays, particularly if the compound is promising. Most importantly however, by screening compounds in the above assays, the likelihood that a development compound will have genetox findings after more expensive animal studies are run will be significantly reduced.

Message

From: HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
Sent: 9/16/1999 6:18:36 PM
To: [redacted]'KIER, LARRY D [NCP/1000]' [/O=MONSANTO/OU=GLB-STL/CN=LEGACY ADDRESSES/CN=33322]; 'FARMER, DONNA R [FND/1000]' [/O=MONSANTO/OU=GLB-STL/CN=LEGACY ADDRESSES/CN=180070]
CC: 'HEYDENS, WILLIAM F [FND/1000]' [/O=MONSANTO/OU=GLB-STL/CN=LEGACY ADDRESSES/CN=230737]
Subject: RE: Parry report

[redacted]All,

I have read the report and agree with the comments - there are various things that can be done to improve the report.

However, let's step back and look at what we are really trying to achieve here. We want to find/develop someone who is comfortable with the genetox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genetox. issues arise. My read is that Parry is not currently such a person, and it would take quite some time and $$$/studies to get him there. We simply aren't going to do the studies Parry suggests. [redacted]do you think Parry can become a strong advocate without doing this work Parry? If not, we should ***seriously*** start looking for one or more other individuals to work with. Even if we think we can eventually bring Parry around closer to where we need him, we should be currently looking for a second/back-up genetox. supporter. We have not made much progress and are currently very vulnerable in this area. We have time to fix that, but only if we make this a high priority now.

Bill

-----Original Message-----
From: [redacted]
Sent: Thursday, September 16, 1999 2:02 AM
To: KIER, LARRY D [NCP/1000]; FARMER, DONNA R [FND/1000]
Cc: HEYDENS, WILLIAM F [FND/1000]
Subject: Parry report
Importance: High

Larry and Donna,

I would like to get some feedback to Jim Parry on his report. I sent you my comments but didn't get a reaction. Can I get your opinions and then have a discussion on the action to take?

Regards, [redacted]

Plaintiff Exhibit
0268

Glyphosate Stewardship, Epidemiology, and the Farm Family Exposure Study

Team Members:

John Acquavella
Marian Bleeke
Donna Farmer
Daniel Goldstein
[redacted]

draft for June 11, 2002

Plaintiff Exhibit
0282

Introduction

Glyphosate has very favorable toxicologic properties. It is not carcinogenic, mutagenic or neurotoxic and it is not a reproductive or developmental toxin *(1-3)*. Consumers have confidence in glyphosate formulations based on their efficacy and history of safe use. Other herbicidal active ingredients, like 2,4-D, have favorable toxicology profiles, but have negative public perceptions. We have been working to maintain glyphosate's favorable reputation through a strategy that anticipates challenges and puts appropriate initiatives in place. One of those initiatives is a unique research program called the Farm Family Exposure Study (FFES). Key FFES findings will be discussed as part of our overall glyphosate strategy.

Macro issues

The general public is selectively risk averse, especially about (perceived) risks to children's health. Individuals will assume known risks (e.g. cigarettes), yet object to infinitesimal (potential) risks from pesticide residues on foods or foreign DNA in genetically modified (GM) crops. Anti-pesticide activists orient their allegations accordingly. Glyphosate is a prime target of anti-pesticide and anti-GM activists due to its widespread use and key role with glyphosate tolerant crops.

Allegations based on results from epidemiologic studies have begun to affect our freedom to operate.[a] In Canada, enabled by a recent Supreme Court ruling, localities have cited epidemiologic findings to ban "non-essential use" of pesticides, usurping federal regulations that are based on toxicologic data. There are now six published studies that arguably associate glyphosate and other pesticides with lymphopoietic cancers *(4-6)* or adverse reproductive outcomes *(7-9)*. Independent reviewers judge these studies to be poor quality. Nonetheless, these studies have caused controversy for glyphosate and for Roundup Ready regulatory submissions in Brazil and other world areas.[b]

Epidemiologic research on pesticides is a burgeoning field for academic and government researchers. The most prominent ongoing study is the U.S. government's Agricultural Health Study (AHS). The AHS involves numerous PhD level scientists from the National Cancer Institute, the National Institute for Environmental Health Sciences, and the Environmental Protection Agency and external expenditures approaching $50 million. This study includes 75% of licensed pesticide applicators and their

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[a] Epidemiologists study people to identify factors that may cause or prevent disease. Agricultural researchers often have to rely on sketchy information about exposure and potential confounding factors.

[b] A Google internet search found 1,410 web pages touting a 1999 study that arguably linked glyphosate and non-Hodgkin's lymphoma.

MONGLY00888455

families in North Carolina and Iowa. The purpose of the AHS is to look for associations between farmers' reported use of pesticides and adverse health outcomes for them and their families (e.g. cancer, birth defects, child development, etc.). Numerous other studies are ongoing in the U.S., Canada, and Europe. Experience has shown that these studies will associate widely used pesticides with a number of diseases. The stage is set, therefore, for more allegations about human effects associated with glyphosate and other pesticides.

Strategy

Glyphosate stewardship consists of four elements: 1) publish relevant toxicologic, ecotoxicologic, and epidemiologic information about glyphosate in the peer reviewed literature *(3, 10-13)*; 2) review the literature regularly for glyphosate findings and respond when appropriate *(e.g. 14)*; 3) establish a network of prestigious scientists in key world areas and provide them the latest information about glyphosate; and 4) assess data gaps and fund appropriate research.

Data Gaps

The FFES was developed to fill two data gaps. First, there is a lack of information about applicator pesticide exposure under "real world" conditions. Epidemiologic studies assume that reported use of a pesticide is equivalent to a potentially hazardous exposure(s). Second, there is little empirical exposure information for farm children although children's health is a driving force in environmental regulation and a focus of epidemiologic research. Gladden et al. drew attention to farm spouses and children in a 1998 article *(15)*:

> *"Farming is unlike most other occupations in that the workplace is often the same as the worker's home. Thus families of farmers have unusual opportunities for indirect exposure to occupational hazards"*

The Natural Resources Defense Council made alarming allegations about risks to farm children in a report later that year *(16)*:

> *"There is an increasingly compelling body of scientific evidence indicating that farm children face particularly significant health risks." … Farm children are like canaries in the coal mine. … the record shows that U.S. EPA has failed to adequately consider the extensive evidence that children are exposed to significant amounts of pesticides …"*

By the time these reports appeared, we had organized an industry task force to assess the feasibility of the FFES. The

task force approach enabled us to leverage costs[c] and technical expertise across a number of companies. In 1999, we completed a one-year pilot study that demonstrated feasibility and the FFES was initiated in 2000.

The purpose of the FFES is to characterize pesticide exposures for farm families by urinary biomonitoring before, during, and after a pesticide application. The study was coordinated by researchers at the University of Minnesota (UM), approved by the UM Institutional Review Board, and benefited from the advice of a distinguished panel of academic and government experts. FFES participants were randomly selected from licensed pesticide applicators in Minnesota and South Carolina. Families were eligible if there was a farmer, spouse, and at least one child between the ages of 4 and 17 living on the farm, if they owned or leased at least 10 acres of cropland, if they planned to apply at least one of the target pesticides (2,4-D, glyphosate, or chlorpyrifos) within one mile of their residence, if they were willing to collect all their urine for five consecutive days (the day before, the day of, and the three days after a pesticide application), and if they were willing to fill out pre-application and post-application questionnaires.

One hundred and six farm families participated in the study. Field staff observed pesticide applications and documented information relevant for exposure assessment. Recruitment began in 2000 and all fieldwork was completed by July 2001.

FFES Glyphosate Results

Forty-two participating farmers applied glyphosate in 2000.[d] Less than half (45%) of these farmers had detectable urinary glyphosate (> 1 part per billion (ppb) in urine) on the day of application, declining to 24% three days later. Urinary values were concentrated below or near the limit of detection (Figure 1) and the geometric mean on the day of application was 2 ppb. The highest observed value was 182 ppb - a level, if experienced daily for a lifetime, that would be 100 to 1000-fold below the U.S. reference dose.

Two of 42 farm spouses (5%) showed detectable values on the day of application - both at the limit of detection (Figure 2). There were no detectable values thereafter. Of 69 participating children, 5 (7%) had detectable values on the day of application, which declined to 3% three days after application. The highest value for children was 20 ppb. All of the children with

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[c] The FFES cost $2 million. Monsanto's share was $275,000. $150,000 was returned to Monsanto as reimbursement for glyphosate analyses.
[d] Five FFES farmers applied glyphosate in 2001. Results for these families are pending.

detectable values were involved in the pesticide mixing and application or were present in the pesticide mixing area.

Preliminary results for the other FFES chemicals (2,4-D and chlorpyrifos) show many more detectable values for all family members than were seen for glyphosate. For farmers, geometric mean values were much higher for the other chemicals than for glyphosate, though values for all chemicals were well within regulatory standards. Geometric mean values for spouses and children were slightly higher for the other FFES chemicals, though the differences were trivial. Data on 2,4-D and chlorpyrifos are still being processed and will be presented later this year at scientific meetings. Nonetheless, it is clear that glyphosate has a favorable exposure profile compared to these other FFES chemicals.

Implications

Results from the FFES show that reported use of glyphosate is not a reliable predictor of appreciable absorbed dose for applicators and that worst-case exposures are orders of magnitude below regulatory limits. Detectable urinary levels were found to be rare for spouses and children. Detectable levels for children were associated with helping or being present for pesticide mixing or application.

The FFES has become a key element in our scientific network briefings and in our responses to allegations about glyphosate. We're working actively to disseminate the results for glyphosate. FFES presentations have already occurred at 7 public meetings - including the last 3 AHS advisory panel meetings - and 10 peer-reviewed publications are planned. Longer term, we expect publication and presentation of these results to influence agricultural epidemiology positively. We are coordinating an international symposium later this year in Oxford, UK - convened by Sir Richard Doll - on pesticides and cancer. This affords an international scientific platform for the FFES data and for glyphosate toxicology data. The proceedings of this symposium will be published in the Scandinavian Journal of Work, Environment, and Health as a special supplement, making the FFES findings broadly available in a high profile publication.

The FFES provides "real world" information about how our pesticides are being used in the U.S. Subsequent analyses are planned to support predictive exposure models. Inspection of the FFES field reports for glyphosate show that children's exposure in the study, though trivial, probably could have been prevented by rudimentary precautions (e.g. wearing gloves when helping their fathers, taking care to avoid incidental contact with containers). Likewise, farmers' failure to wear gloves while mixing and loading was a common finding for those who showed detectable glyphosate values. We are currently looking to

MONGLY00888458

leverage the FFES data into a stewardship opportunity, perhaps in collaboration with EPA and agricultural organizations.

The FFES data are also being analyzed to assist with European re-registration. EU regulations call for thorough evaluation of operator exposure, usually based on very conservative predictive models. Some potential uses may be restricted unless relevant data can be presented. The FFES data provides a basis to challenge conservative predictions and may be useful to the workgroups that are currently developing/modifying the new (uniform) European predictive model (EUROPOEM).

Challenges

Monsanto's analytic chemistry expertise was essential to the FFES. However, our current method is outdated. It requires relatively large volumes of urine (100 ml, versus 5 ml for the 2,4-D and chlorpyrifos methods) and produces less precise results than methods for other FFES chemicals. Given the likelihood that human health allegations will continue to surface for glyphosate, it seems advisable to invest in modernizing the analytic method to increase analytic flexibility and precision.

MONGLY00888459

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Appendix – Abbreviations

2,4-D – 2,4-dichlorophenoxy acetic acid

AHS – Agricultural Health Study

FFES – Farm Family Exposure Study

GM – genetically modified

ppb – parts per billion

MONGLY00888462

[EMBED Excel.Chart.8 \s]

[EMBED Excel.Chart.8 \s]

[DATE \@ "MM/dd/yyyy"],[[PAGE \@ "h:mm AM/PM"]

Message

From: GOULD, STEVEN D [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=116457]
Sent: 9/10/2015 10:41:00 PM
To: HARDY, JOHN O [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=53364]
Subject: Fwd: [redacted]

I liked this analogy from Greg

Steve Gould

Begin forwarded message:

From: Greg Fernald [redacted]@wilburellis.com>
Date: September 10, 2015 at 3:19:21 PM PDT
To: "GOULD, STEVEN D [AG/1000]" [redacted]@monsanto.com>
Subject: RE: [redacted]

We are being overrun by liberals and morons...sort of like a zombie movie, so we just have to start taking them out one at a time, starting with the elections next year.

Greg Fernald
Professional Markets

Wilbur-Ellis Company
1427 Abbott Street
Salinas, CA 93901
Cell: (408) [redacted]
Fax: (650) [redacted]
[redacted]@wilburellis.com

-----Original Message-----
From: GOULD, STEVEN D [AG/1000] [mailto:[redacted]@monsanto.com]
Sent: Thursday, September 10, 2015 1:08 PM
To: Greg Fernald
Subject: RE: [redacted]

He sent to me too. It's hard to understand how against all science and law the can do this.

Steve Gould

Steven D. Gould
Monsanto IT&O
Account Manager
951-894-[redacted] office
951-704-[redacted] mobile
monsantoITO.com

-----Original Message-----
From: Greg Fernald [mailto[redacted]@wilburellis.com]

Plaintiff Exhibit
0290

MONGLY07120036

Message

From: [redacted]
Sent: 3/10/2015 7:06:44 PM
To: FARMER, DONNA R [AG/1000] [redacted]
CC: HEYDENS, WILLIAM F [AG/1000] [redacted]
Subject: RE: Glyphosate Overview.

Donna and Bill

You will have received my earlier blackberry email with the final evaluation. The initial recommendation of the experimental cancer sub-group was inadequate/limited. This morning they brought forward a revised document recommending 'limited'. On questioning from the mechanisms sub-group as to why they were circumspect on certain studies, they came back with a final recommendation of 'sufficient'. This was voted in with no votes against.

[redacted]

From: [redacted]
Sent: Monday, March 09, 2015 6:25 PM
To: FARMER, DONNA R [AG/1000]
Cc: HEYDENS, WILLIAM F [AG/1000]
Subject: RE: Glyphosate Overview.

They have said that there are enough positive findings in the US, Canadian and Swedish case-control studies to warrant a limited evaluation. I would have given much more weight to the negative AHS study. Other votes haven't been taken but the experimental animals group have recommended limited. This would give 2B. But the mechanistic group are saying that they can support a higher evaluation which would give 2A. We shall see tomorrow.

[redacted]

From: FARMER, DONNA R [AG/1000] [redacted]
Sent: Monday, March 09, 2015 6:1[redacted] PM
To: [redacted]
Cc: HEYDENS, WILLIAM F [AG/1000]
Subject: RE: Glyphosate Overview.

[redacted]

What is the basis for a 2A? The Swedish studies?

Donna

-----Original Message-----
From: [redacted]
Sent: Monday, March 09, 2015 1:05 PM
To: FARMER, DONNA R [AG/1000]
Cc: HEYDENS, WILLIAM F [AG/1000]
Subject: RE: Glyphosate Overview.

Donna and Bill

We are at the end of day. TCVP has been classifies as 2B, parathion as 2B and malathion as 2A (limited for human data for both NHL and prostate cancer).

Human data for glyphosate classified today as limited for NHL (on unanimous vote) and final classification tomorrow is likely to be 2A.The Working Group seemed to believe in those early Swedish case-control studies even though the NHL hypothesis gets no support from the AHS.

[redacted]

From: [redacted]
Sent: Friday, March 06, 2015 7:05 PM
To: FARMER, DONNA R [AG/1000]
[redacted]

Plaintiff Exhibit
0288

Subject: RE: Glyphosate Overview.

Donna and Bill

We are at the end of day 4. A lot of bad news which will not be consistent with what you know about glyphosate and a small amount of good news. I will start with the bad news. The sub groups have now made their preliminary proposals to the whole group, and prepared revised documents of their summaries of the data. These recommendations are to be discussed by the whole group (glyphosate on Monday) and things can move up or down.

Current proposals

Glyphosate
humans: limited for NHL (based on case-control studies not AHS)
animals: limited or inadequate
mechanisms: strong data that agent is genotoxic, can induce oxidative stress and can induce chronic inflammation

Diazinon
humans: limited for NHL, leukaemia, lung
animals: limited
mechanisms: strong data that agent is genotoxic, can induce oxidative stress, and can induce chronic inflammation

Malathion (on track for 2A)

humans: limited for NHL, prostate
animals: sufficient
mechanisms: strong data that agent is genotoxic, can induce oxidative stress, can induce inflammation, can modulate receptor-mediated effects, and can alter cell proliferation/death or nutrient supply.

TCVP

humans: inadequate
animals: sufficient
mechanisms: (unclear to me)

Parathion

humans: inadequate
animals: sufficient
mechanisms: moderate data that agent can alter cell proliferation/death or nutrient supply

The good news is that glyphosate almost got 'limited in humans' for multiple myeloma as well, on the basis of the case-control studies, but when the Chair put up a summary summary table of the epi findings he only had RRs of 1.1 and 2.6 from the De Roos 2005 study. I intervened to say that there was another report from the AHS. He looked at me rather blankly and I said Sorahan 2015. He reluctantly agreed to add RRs of 1.1 and 1.2 from my report. This led to some questions from the other experts, as to how this all came about (they clearly had not read my paper). Aaron then said 'it is inadequate' and everyone silently agreed. The Chair announced to the whole group later in the afternoon,there is no evidence in the AHS for multiple myeloma. It was clear to me that me being was helpful to the panel.

[redacted]

From: [redacted]
Sent: Thursday, March 05, 2015 6:01 PM
To: FARMER, DONNA R [AG/1000]
Cc: william.f.heydens@monsanto.com
Subject: RE: Glyphosate Overview.

Donna and Bill

We are at the end of day 3. The epi panel went through the first draft of the epi document this morning. [redacted] led the discussion and it was clear from his comments and comments from Aaron Blair that they accept the main conclusions of my multiple myeloma paper. They have written it up as if De Roos had already agreed to this in his reply to your 2005 letter and that I merely confirmed what he had already said. This isn't quite the case, as we know, but the important thing is that Aaron is not arguing that the AHS paper is positive for multiple myeloma. I proposed that the Landgren et al 2009 paper on

MGUS also be included. Aaron was keen for this which again argues against a positive multiple myeloma classification.

At the end of this session they concluded that there was no suggestion of an NHL problem in the AHS, but that they had four positive case-control studies. The errors in the meta analysis that Elizabeth identified have been corrected for Hardell (2002) and Eriksson (2008). Aaron said he thought the evidence was inadequate, no-one responded and the conversation moved on. Andrea t'Mannetje thought there was limited evidence for multiple myeloma in the case-control studies, again the conversation moved on without conclusion They will be coming back to their proposed evaluations tomorrow.

The afternoon moved on to summaries for TCVP, parathion and diazinon. The proposed evaluations are inadequate for TCVP, inadequate for parathion and limited for diazinon (NHL and lung cancer).

Important day tomorrow.

[redacted]

From: [redacted]
Sent: Wednesday, March 04, 2015 5:36 PM
To: FARMER, DONNA R [AG/1000]
Cc: william.f.heydens@monsanto.com
Subject: RE: Glyphosate Overview.

Donna and Bill

We are at the end of day 2. Some good news and some bad news. The good news. [redacted] from the IARC meta-analysis came in to the epi subgroup to discuss what parts of their review could go into the monographs. This gave me a suitable opportunity to mention the problems that Elizabeth Delzell had identified about selection of RRs for glyphosate. She took it away and came back to me to say that errors had been made for Hardell (2002) and Eriksson (2008), and she is going to re-run her programs tomorrow. The revised findings will go in the monograph as "The Working Group carried out its own calculations..."

The bad news is they started to discuss their evaluation of malathion. There were three case-control studies for NHL giving a significant excess risk when you added them up. The AHS on the other hand had no excess risk (RR=0.9) and the dose-response was as 'flat as a pancake', to quote one of the experts. It was also bigger than the three case-control studies put together. But it seems they are going to recommend 'limited for NHL and malathion'. There was a 'signal' apparently. On this basis anything can be classified as limited. My prediction (it may be pointless to predict) is that as many of the five chemicals as possible are going to be classified as limited human evidence for NHL.

I was wrong about the glyphosate epi section. It was drafted by [redacted] from Italy. Glyphosate for discussion tomorrow.

[redacted]

From: [redacted]
Sent: Tuesday, March 03, 2015 5:54 PM
To: FARMER, DONNA R [AG/1000]
Cc: william.f.heydens@monsanto.com
Subject: RE: Glyphosate Overview.

Donna and Bill

Thanks for the document. We are at the end of day 1. Aaron Blair is the chair of the whole thing. The epi subgroup comprises Aaron, John McLaughin (Canada), [redacted] (France), [redacted] (Italy and chair of epi sub-group), and Andrea t'Mannetje (New Zealand). The epi sub-group has now been through the drafts on TCVP (written by Aaron), parathion (written by John M) and malathion (written by [redacted]). There was much discussion on what sort of things should be in tables and what should be in the text. The discussion on the individual studies lacked insight I thought and the experts seemed to have little to add to what had been drafted. In fact most of the experts didn't seem to have studied the papers for the chemicals they didn't have to write about. The sub-group did not take a straw poll of how they would vote, but TCVP is on the way to being inadequate, and parathion will be inadequate or limited.

Drafts of glyphosate have been circulated. All the draft says about [redacted] paper is that "The re-analysis conducted by Sorahan (2015) confirmed that the excess risk was present only in the subset with missing information". Poor science, to put it mildly. I suspect the glyphosate epi section was written by Andrea M but this hasn't been announced yet.

Glyphosate (all sections) is due for discussion on Thursday morning, but the epi section may well be reviewed tomorrow afternoon. Bizarely, the Schinasi and Leon review has not been written about in any of the five chemicals under review, but that will change.

Tom Sorahan

From: FARMER, DONNA R [AG/1000] [donna.r.farmer@monsanto.com]
Sent: Tuesday, March 03, 2015 3:05 PM
To: [redacted]@de.adama.com'
Subject: Glyphosate Overview.

Please find attached a brief summary of glyphosate.

I have included information on ADME (absorption, distribution, metabolism and excretion), the toxicological profile, human exposure and epidemiology.

Again please don't hesitate to contact me if you need any additional information.

I hope your travels went well.

How is the first day of the meeting going? Have you seen any of the drafts yet on glyphosate?

Regards,

Donna

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Message

From: ROSS, JIM [redacted]@HORIZONONLINE.COM]
Sent: 9/9/2015 3:51:18 PM
To: GOULD, STEVEN D [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=116457]
Subject: RE: CA and Glyphosate

OK to the extent we can assist in communicating a rational message to the industry let me know. We would of course rely on Monsanto as the subject matter experts and follow your guidance on the communication.

Jim Ross
President
Horizon Distributors, Inc.
www.horizononline.com

From: GOULD, STEVEN D [AG/1000] [[redacted]@monsanto.com]
Sent: Wednesday, September 9, 2015 11:45 AM
To: ROSS, JIM
Subject: RE: CA and Glyphosate

We are all over it! More resources than I have seen in my career!
I will update when I get legal approval probably today I will send out an update.

Steve Gould

Steven D. Gould
Monsanto IT&O
Account Manager
[redacted] office
[redacted] mobile
monsantoITO.com

From: ROSS, JIM [mailto:[redacted]@HORIZONONLINE.COM]
Sent: Wednesday, September 09, 2015 8:22 AM
To: GOULD, STEVEN D [AG/1000]
Subject: CA and Glyphosate

Steve:

Presume that you and your folks are aware of this. [redacted].

http://ecowatch.com/2015/09/08/[redacted]

Let me know how we can help.

Thanks

JR

Jim Ross
President
Horizon Distributors, Inc.

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0289
Case No.
CGC-16-550128

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Sent: Thursday, September 10, 2015 12:40 PM
To: GOULD, STEVEN D [AG/1000]
Subject: FW: [redacted]

Got this from Parks yesterday. They are so full of crap.

Greg Fernald
Professional Markets

Wilbur-Ellis Company
1427 Abbott Street
Salinas, CA 93901
Cell: (408) [redacted]
Fax: (650) [redacted]
[redacted]@wilburellis.com

-----Original Message-----
From: Mike Parks
Sent: Wednesday, September 09, 2015 11:50 AM
To: Greg Fernald
Subject: FW: [redacted]

FYI

Mike Parks
Wilbur-Ellis Company
160 Grant Ave.
Healdsburg, CA 95448
C (707) [redacted] /F (707) [redacted]
[redacted]@wilburellis.com
www.wilburellis.com

-----Original Message-----
From: Frank [[redacted]@gglandscape.com]
Sent: Tuesday, September 08, 2015 12:27 PM
Subject: [redacted]

http://www.eastbayexpress.com/SevenDays/archives/2015/09/05/[redacted]-label-monsantos-roundup-carcinogenic

lovely

--
Frank Patane
Golden Gate Landscape Mgt. Inc./Lic # 760731
2425 Cleveland Ave, Suite 230
Santa Rosa, CA 95403
707[redacted]

707 [redacted] Fax
email: [redacted]@gglandscape.com

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cost on CA Municipalities Markets

By Steve Gould

Volumes:

I would estimate a gradual 2-3 year loss of up to 200 K REGS of all tiers of Roundup IT&O Glyphosate.

High Tier 65K

Mid Tier 75 K

Low Tier 60K

The volume will come from customers like CALTRANS. Caltrans Volume is a mix of high and mid tier and we stand to loss 5-10K depending on internal decisions

School districts are another big risk with the healthy schools act and increased attention. They frequently use PROMAX and PRO Concentrate today.

Airports, arenas, stadiums, municipal buildings any public facility especially if it goes out to bid could be affected

Cities, Counties, reservoirs, wildlife management areas and other similar locations could also be affected.

We will not really know the costs until we see how the agencies react and how many of them must address this.

This volume is based on discussing with distributor representatives, Monsanto sales volume estimates and knowledge of the market.

Customers that I am aware have already stopped using Glyphosate since the IARC ruling:

Irvine Unified School District and several bay area cities and school districts.

Plaintiff Exhibit
0291
Case No:
CGC-16-550128

Glyphosate: IARC

INTRODUCTION

The International Agency for Research on Cancer (IARC), part of the World Health Organization, coordinates and conducts both epidemiological and laboratory research into the causes of human cancer. It also evaluates the carcinogenic potential of individual substances based only on publicly available information. While glyphosate has been a low priority for evaluation by IARC for more than two decades, it was nominated for review in ~~mid-~~April,2014.

After learning of the ~~nomination~~ selection of glyphosate for review in September, the regulatory team's initial focus was publishing safety studies that were not yet in the public domain. All research had to be published or accepted for publication by Feb. 3, 2015 to be considered in the IARC review. Regulatory Affairs has shared these recent publications with IARC and is continuing to share directly with panelists and observers.

IARC has a history of questionable and politically charged rulings on the carcinogenic properties of products such as cell phones, coffee and caffeine. We should assume and prepare for the outcome of a 2B rating (*possible* human carcinogen); a 2A rating (*probable* human carcinogen) is possible but less likely.

It is possible that IARC's decision will impact future regulatory decision making. Regulatory is not aware of a situation where a regulatory body took a different position than IARC. Competent authorities for regulating pesticides and assessing chemical hazard typically evaluate a broader range of studies and make their own decisions. They also use the most broadly accepted hazard classification system, the Globally Harmonized System, which differs significantly from that used by IARC. Thus IARC classifications can readily differ from those of ~~other~~ regulatory bodies. This could further delay the U.S. EPA review.

The IARC meeting where glyphosate will be reviewed and the decision will be made will occur March 3-10, 2015. IARC will post its decision soon after on its website ({ HYPERLINK "http://www.iarc.fr/" }). We are already seeing activists increase allegations against the Roundup brand (ilo glyphosate) and link those allegations directly to GM crops. We anticipate this will increase with the IARC decision. CLI seems to be willing to develop high-level communications around the IARC process to prepare for the publication of the IARC decision. To date, CLA and ECPA have not been engaged; we will need industry support specific to the glyphosate rating.

International Agency for Research on Cancer
World Health Organization

"The International Agency for Research on Cancer (IARC) is the specialized cancer agency of the World Health Organization"

Comment [wh1]: No – contact with panelists ('Members')is not allowed

Comment [wh2]: And key regulators

Formatted: Complex Script Font: +Body (Calibri), 10 pt, Highlight

Comment [wh3]: No GHS doesn't play into this. I would say "more broadly accepted 'Weight-of-Evidence' approach to evaluate carcinogenic potential, which…"

Comment [k4]: and EU? Canada? Japan?

Comment [drf5]: We asked CLA to nominate an observer to the meeting, while they were supportive there was push back by some of the member companies that this action would supporting a "single ai" we tried to make the case that this is about defending pesticides but that argument didn't work with those companies

TEAM

Jen Listello	**Reg Affairs – US**	**LEAD**
Kelly Clauss	Issues Preparedness and Engagement	
Linda Dudenhoeffer	Stakeholder Outreach	
[redacted]	Regulatory Affairs – Global	
Bill Heydens	Regulatory Product Safety Assessment / Strategy	
Dan Jenkins	U.S. Agency Regulatory Affairs	
Kim Link	Issues Preparedness and Engagement	
Kim Magin	Industry Affairs	
John Vicini	Regulatory Policy / Scientific Affairs	

Plaintiff Exhibit 0292
MONGLY02913526

Glyphosate: IARC

KEY DELIVERABLES

Due Date	Who/What	Objective	MON Owner	Status
Pre-Decision/Posting				
Feb 3, 2015	Deadline for data submission	Update public record with most current and complete data	Bill Heydens	Complete
	Monsanto.com/glyphosate	Update to include gly not carcinogen	Bill Reeves Kyel Richard	
Week of Feb. 23-27	**Planning and Preparation**			
	Engage Henry Miller	Inoculate / establish public perspective on IARC and reviews	Eric Sachs	
	Blog post to reiterating gly not carcinogen/tweets	Establish SM content and amplify scientific studies	Aimee Hood Kim Link Heather McClurg	
	Outreach to EPA / IARC participants	Ensure awareness of scientific studies	Dan Jenkins	
Prior to March 3	Contact journals to inquire about press releases for 6 new publications	Amplification of scientific studies	David Saltmiras	
	Inform/ Engage Industry Associations	Lead voice in "who is IARC" plus 2B outrage	Kim Link Kelly Clauss [redacted] Kim Magin	Ongoing
	Engage CLI and regional industry associations in communications	Communicate the perspective of the IARC process	Kelly Clauss [redacted]	Ongoing
	Address new allegations	Neutralize impact	Kim Link Charla Lord	Ongoing
	Outreach to / collaboration with DAS (2,4D scheduled for IARC review in June 2015)	Maximize efforts / coordinated industry response	Bill Heydens Donna Farmer	Ongoing
	Global Reg Affairs (Canada, US, EU, LAS, Brazil, Asia Pacific, India)	Inform ongoing activities for regulator outreach	[redacted]	Ongoing
Week of March 2-6	**Implement Inoculation Plan / Continue Preparations**			
	Engage with experts to plan for publications and other activities in case IARC classification is unfavourable	Respond to the classification and defend at global regulatory	Bill Heydens, Donna Farmer John Acquavella	

Comment [drf6]: [HYPERLINK "http://www.monsanto.com/glyphosate/documents/no-evidence-of-carcinogenicity.pdf"], [HYPERLINK "http://www.monsanto.com/glyphosate/pages/is-glyphosate-safe.aspx"] we already have statements and a backgrounder out there that says just that – is this something different?

Glyphosate: IARC

		authorities		
	Share SM messages (Twitter, Facebook)	Amplify positive gly content	Kim Link Heather McClurg	
	Prepare key Monsanto spokespeople	Ensure strong, consistent MON messaging	FH Kelly Clauss	
	Communicate to employees via ET email and Connection article	Raise awareness and inoculate employees	Jaclyn Pollnow	
Post-Decision/Posting				
Week of March 9-13	**Implementation of Crisis Plan, as necessary**			
March 10	Outreach to key stakeholders (utilize discussion guide)	Neutralize impact of decision / gain active support	Linda Dudenhoeffer	
March 10	Outreach to grower groups (utilize discussion guide, provide key talking points)	Neutralize impact of decision / gain active support	Kim Magin IA colleagues	
	Outreach to regional regulators	Neutralize impact of decision / gain active support	Dan Jenkins Regional RA	
@ Posting	Publish / amplify blog post on the meaning of the IARC ruling	Ensure MON POV / neutralize SM	Kim Link Charla Lord Heather McClurg	
@ Posting	Add IARC statement to web	Ensure MON POV / neutralize SM	Kyel Richard	
@ Posting	Publish Connection article for employees	Ensure MON POV	Jaclyn Pollnow	
@ Posting	Outreach to ag media	Ensure MON POV in coverage	John Combest	

See Attachment A: Communications Plan

RESOURCES

EXTERNAL (Glyphosate is not carcinogenic)

- @EPA concluded in 2013 that "glyphosate does not pose a cancer risk to humans" [HYPERLINK "http://www.regulations.gov/" \l "!documentDetail;D=EPA-HQ-OPP-2012-0132-0009"]
- @EPA groups glyphosate in the lowest category E, indicating glyphosate does not pose a cancer risk to humans http://www.epa.gov/oppsrrd1/reregistration/REDs/factsheets/0178fact.pdf
- FAQ #7 Does glyphosate cause cancer? [HYPERLINK "http://www.monsanto.com/glyphosate/pages/glyphosate-frequently-asked-questions.aspx" \l "seven"]
- Backgrounder Glyphosate: No evidence of carcinogenicity [HYPERLINK "http://www.monsanto.com/glyphosate/Documents/no-evidence-of-carcinogenicity.pdf"]
- Discover.com [HYPERLINK "http://discover.monsanto.com/conversation/question/are-you-ready-to-be-held-accountable-for-the-many-diseases-which-are-caused-by-your-poison-such-as-leaky-gut-syndrome-and-cancer"]

Comment [k7]: Ensure Mink link is fixed

Glyphosate: IARC

- GMOAnswers, Does glyphosate cause cancer? [HYPERLINK "http://gmoanswers.com/ask/does-glyphosate-cause-cancer"]
- GMOAnswers, Breast cancer from glyphosate? [HYPERLINK "http://gmoanswers.com/ask/how-can-you-say-they-are-safe-when-recent-studies-not-conducted-monsanto-show-direct-link-breast"]
- Science Direct, Epidemiologic studies of glyphosate and non-cancer health outcomes: [HYPERLINK "http://www.sciencedirect.com/science/article/pii/S0273230011001516"]
- Regul Toxicol Pharmacol. Epidemiologic studies of glyphosate and cancer: a review
  - http://www.ncbi.nlm.nih.gov/pubmed/22683395

INTERNAL

- xxx

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Comment [drf8]: If this is about cancer why is the Mink non-cancer health out comes here and not the cancer review?

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Draft Feb 23, 2015

ATTACHMENT A: PREPAREDNESS AND ENGAGEMENT PLAN
FOR IARC CARCINOGEN RATING OF GLYPHOSATE
Last Updated: February 17, 2015

OBJECTIVES FOR PREPAREDNESS & ENGAGEMENT

- Protect the reputation and FTO of Roundup by communicating the safety of glyphosate
- Amplify science-based information to prevent unfounded claims from becoming popular opinion
- Provide cover for regulatory agencies to continue making re-registration decisions based on science

AUDIENCES

- IARC Panelists and Observers
- Regulators
- Stakeholders
- Farmer Customers

STRATEGIES/TACTICS

PRE-IARC

1. **Amplification of Scientific Studies**
   - Support the development of three new papers on glyphosate focused on epidemiology and toxicology
   - Work with RPSA and Strategic Communications to amplify existing studies and new papers
     - Authors work directly with scientific journals to issue alerts and news releases on new bodies of work
     - RPSA posts blog from first-person viewpoint of Monsanto's David Saltmiras, co-author of one of the glyphosate cancer papers
     - Share resources and content with Monsanto key regions to amplify the message globally

2. **Inform / Inoculate / Engage Industry Partners**
   - Develop a "toolkit" containing key information and resources
     - Identify any message shortcomings and address through updates to monsanto.com/glyphosate and through US and EU blog posts
   - Work with RPSA, Stakeholder Outreach Team, Industry Affairs, Government Affairs, US Business, Global CE and Regulatory teams, etc. to engage industry partners
     - Tier 1: Crop Life International / European Crop Protection Association / GMO Answers / BIO – identify committees that are best to engage
     - Tier 2: Academics (AgBioChatter), Biofortified, Sense About Science, Genetic Literacy Project, Academics Review
     - Tier 3: Alert food companies via Stakeholder Engagement team (IFIC, GMA, CFI) for "inoculation strategy" to provide early education on glyphosate residue levels, describe science-based studies versus agenda-driven hypotheses
     - Tier 4: Inoculate key grower associations

3. **Address New Allegations**
   - Respond quickly and publically to new pseudoscience cancer studies
   - Identify / request third-party experts to blog, op/ed, tweet and/or link, repost, retweet, etc.

POST-IARC

4. **Orchestrate Outcry with IARC Decision ~ March 10, 2015**
   - Industry conducts robust media / social media outreach on process and outcome
     - [Sense About Science?] leads industry response and provides platform for IARC observers and industry spokesperson
     - CLI and other associations issue press releases

MONGLY02913530

- Joint Glyphosate Taskforce publishes press release, letter signed by leaders of each manufacturer in North America and Europe
- Push opinion leader letter to key daily newspaper on day of IARC ruling with assistance of Potomac Group

- Monsanto responds with strong reactive statement
  - Distribute video and audio responses to IARC decision
  - Address media inquiries with company glyphosate spokesperson
  - Utilize Monsanto channels (web, FB, Twitter, blog, etc) to provide Monsanto POV
  - Corporate Engagement team packages industry and Monsanto responses, then distributes via email to ~20 most influential ag media outlets across print, radio and TV

5. **Engage Regulatory Agencies**
   - Grower associations / growers write regulators with an appeal that they remain focused on the science, not the politically charged decision by IARC

Message

From: HEYDENS, WILLIAM F [AG/1000] [redacted@monsanto.com]
Sent: 10/15/2014 9:08:37 PM
To: [redacted@monsanto.com]
CC: [redacted@monsanto.com]; FARMER, DONNA R [AG/1000] [redacted@monsanto.com]; SALTMIRAS, DAVID A [AG/1000] [redacted@monsanto.com]; KOCH, MICHAEL S [AG/1000] [redacted@monsanto.com]
Subject: IARC Evaluation of Glyphosate

[redacted]

It is my recollection that you notified the EU-GTF of this IARC evaluation, but I am not aware that there has been any talk of approaching the GTF about providing funding to fight this because it is not considered in the remit of achieving Annex I renewal. If so, is this really the case? I thought the EU evaluation could go well into the summer of 2015, and wouldn't an adverse IARC evaluation have the real potential to impact the results of the Annex I renewal?

I really started thinking about this after our phone call yesterday with the outside epidemiology experts that Donna lined up. The bottom line of the call was that there really is no meaningful publication that we can complete prior to the February submission to positively impact the epidemiology discussion outcome in March. One has to consider that this situational timing did not happen by chance and that more than just pure bad luck is working against glyphosate.

And while we have vulnerability in the area of epidemiology, we also have potential vulnerabilities in the other areas that IARC will consider, namely, exposure, genetox, and mode of action (David has the animal onco studies under control). If there is a force working against glyphosate, there is ample fodder to string together to help the cause even though it is not scientifically justified in its purest form. Putting all this in the proper perspective will be quite resource intensive, so can't we consider approaching the GTF? Recall that the PAG already agreed to fund the onco publication 2+ years ago for this exact reason.

Thanks.

Bill

Plaintiff Exhibit
0294

Message

From: FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]
Sent: 9/21/2009 5:12:07 PM
To: COMBEST, JOHN C [AG/1000] [redacted]@Monsanto.com]
Subject: RE: Roundup article in Fremantle Herald

I didn't find anything on the Australian site either ...however take this question 5. It is not Roundup that is taken up it is glyphosate. It stops the synthesis of 3 amino acids (they are used to make proteins) and this "process" is also found in microbes and fungi.

5. How does Roundup work?
Roundup is taken up through the leaves and moves in the sap flow throughout the plant. It stops the production of proteins so that the plant starves. This process is found only in plants; Roundup has extremely low toxicity to humans and wildlife.

Or this - you cannot say that Roundup does not cause cancer..we have not done carcinogenicity studies with "Roundup".

2. Will Roundup harm my family or me?
Based on the results of short term and long term testing, it can be concluded that Roundup poses no danger to human health when used according to label directions. In long term exposure studies of animals, Roundup did not cause cancer, birth defects or adverse reproductive changes at dose levels far in excess of likely exposure.

I will follow up with the Monsanto folks who interface with Scotts...they are aware that Scotts does these things.

Donna

-----Original Message-----
From: COMBEST, JOHN C [AG/1000]
Sent: Monday, September 21, 2009 11:07 AM
To: FARMER, DONNA R [AG/1000]
Subject: RE: Roundup article in Fremantle Herald

I did not find any reference on their main (US) page to "biodegradable."

-----Original Message-----
From: FARMER, DONNA R [AG/1000]
Sent: Monday, September 21, 2009 11:06 AM
To: COMBEST, JOHN C [AG/1000]
Subject: RE: Roundup article in Fremantle Herald

Did you find the link?
This is to their Q&A and I can tell you they have a number of things that a not acceptable.
http://www.scottsaustralia.com.au/FAQs/Roundup

-----Original Message-----
From: COMBEST, JOHN C [AG/1000]
Sent: Monday, September 21, 2009 8:11 AM
To: PERSON, JANICE L [AG/1030]; FARMER, DONNA R [AG/1000]; HELSCHER, THOMAS M [AG/1000]
Subject: FW: Roundup article in Fremantle Herald

Janice and Donna,

Here's the Australian thread, to the latest message.

John

----- Original Message -----
From: LEADER, MICHAEL [AG/5020]
To: ANDERSON, NEIL J [AG/5020]; MCNAUGHTON, HONI JANINE [AG/5020]; MCGREGOR, JOHN [AG/5020]; HELSCHER, THOMAS M [AG/1000]

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0305

Cc: MCLEAN, KERYN [AG/5020]; TAYLOR, IAN N [AG/5020]; ARMSTRONG, JANICE M [AG/5340]; COMBEST, JOHN C [AG/1000]
Sent: Mon Sep 21 00:08:56 2009
Subject: RE: Roundup article in Fremantle Herald

Thanks Neil. Honi has already have pointed out the flaws in the studies, but there can't be any harm in doing so again. Studies on the safety of Roundup is a good approach, but I believe there are also some on glyphosate's benefits for the environment (even if the surfactant is not biodegradable). It's a shame the Scott's guy is blaming us too!!

Cheers

Michael

Michael Leader

Corporate and Regulatory Affairs Lead, Australia/New Zealand

Level 12, 600 St Kilda Road; Melbourne VIC 3004

Email: [redacted]@monsanto.com

Ph: +61 [redacted] | Mob: +61 4[redacted] | Fax: +61 [redacted]

<http://www.monsanto.com.au/>

From: ANDERSON, NEIL J [AG/5020]
Sent: Monday, September 21, 2009 12:39 PM
To: MCNAUGHTON, HONI JANINE [AG/5020]; MCGREGOR, JOHN [AG/5020]; HELSCHER, THOMAS M [AG/1000]
Cc: LEADER, MICHAEL [AG/5020]; MCLEAN, KERYN [AG/5020]; TAYLOR, IAN N [AG/5020]; ARMSTRONG, JANICE M [AG/5340]; COMBEST, JOHN C [AG/1000]
Subject: RE: Roundup article in Fremantle Herald

Hi Honi

The reporter has printed the correct information that "Glyphosate is biodegradable but the surfactant is not". However, then she goes into a sensationalism mode quoting "studies" that suggest Roundup is not safe, which is probably derived from her interview of the Fremantle activist. I feel the response to FH needs to reiterate that her statement on biodegradability is correct, reiterate that Roundup is safe (and provide references), and if there are flaws in any of the studies quoted, point out these flaws.

Neil Anderson
QA & Formulations Lead, Asia Pacific
Monsanto Australia Ltd
Mobile phone: International [redacted]; Australia [redacted]

From: MCNAUGHTON, HONI JANINE [AG/5020]
Sent: Monday, September 21, 2009 10:56 AM
To: MCGREGOR, JOHN [AG/5020]; ANDERSON, NEIL J [AG/5020]; HELSCHER, THOMAS M [AG/1000]
Cc: LEADER, MICHAEL [AG/5020]; MCLEAN, KERYN [AG/5020]; TAYLOR, IAN N [AG/5020]; ARMSTRONG, JANICE M [AG/5340]; COMBEST, JOHN C [AG/1000]
Subject: Roundup article in Fremantle Herald
Importance: High

Hi John and Neil

The article in question has appeared in the Fremantle Herald as expected.

We need to think about our response. Possible suggestions:

- Letter from Scott's to the FH reiterating the correct information

- Letter from Monsanto to FH reiterating the safety of Roundup, etc

We may also need to compose a letter to all of Scott's Roundup customers (in WA) dismissing the allegations in the article. FH has a circulation of 20,000. However, the FTO concern is here in WA during this critical time.

- Keryn: You may want to contact DAFWA and other stakeholders as well as growers to explain what we plan to do.

- Ian: GSWG letter reiterating the safety of glyphosate from Steve Powles

Any actions and responses will need to be cleared with the US.

We will need to have a phone call about this including Scotts.

Please let me know your thoughts. I think you'll agree we need to jump on this.

Honi

Honi McNaughton
Public Affairs Manager

Monsanto Australia
PO Box 6051
St Kilda Central
Vic 3008
Office: (03) [redacted]
Fax: (03) [redacted]
Mobile: [redacted]
<http://www.monsanto.com.au/>

Monsanto Twitter: http://www.twitter.com/monsantoco <http://www.twitter.com/monsantoco>

Monsanto's Blog: Monsanto According to Monsanto <http://www.monsantoblog.com/>

Monsanto For the Record: http://www.monsanto.com/monsanto_today/for_the_record/default.asp
<http://www.monsanto.com/monsanto_today/for_the_record/default.asp>

Message

From: ACQUAVELLA, JOHN F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=145465]
Sent: 5/12/2000 8:28:30 PM
To: CARRATO, J [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=49246]; COWELL, JOHN [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=146747]; DINICOLA, NATALIE [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=293515]; FARMER, DONNA [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]; FISHER, LORI [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=31258]; GOLDSTEIN, DANIEL [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=527246]; HEYDENS, WILLIAM [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]; HOOGHEEM, THOMAS [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=131872]; KRONENBERG, JOEL [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=501517]; WRATTEN, STEPHEN [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=119523]
Subject: NHL abstract
Attachments: mcduffee glyphosate nhl abstract.doc

Importance: High

All:

The Canadian NHL/glyphosate abstract we discussed last week is on the Internet, so I think it is fair game to distribute (see attached). I'm planning to attend the presentation of this paper to talk to the author. I note that one of her co-authors (JR McLaughlin) is an epidemiologist I recently recruited to serve on American College of Epidemiology Admissions Committee, which I chair. I think we might want to include him, or perhaps even the first author (after I check her out), in the scientific outreach meeting we were thinking about for Canadian scientists.

I can't stress enough that we should not take this abstract at face value. Many times abstracts are based on preliminary analyses that often don't hold up when the author has time to do more detailed analyses. Nonetheless, Donna, Lori, and I will begin working on this in case things don't change and the paper gets media attention. As you can tell from the abstract, the quality of the data is not great and the authors looked at lots of pesticides. I'm going to bring this abstract to the attention of some of our scientific outreach experts so that they are ready if needed.

John



mcduffee
glyphosate nhl a...

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John Acquavella, PhD
Senior Fellow, Epidemiology
Monsanto Company/C2SE
[redacted]
St. Louis, MO 63167
314[redacted]
314[redacted] (fax)

Monsanto[PRIVATE]

FROM (NAME,LOCATION,PHONE): John F. Acquavella, PhD (C2SE) (4-8813)

DATE: August 24, 2000

SUBJECT: ISEE meeting - epidemiology studies re glyphosate

TO: D. Farmer
J. Cowell
W. Heydens
T. Carrato
D. Goldstein
L. Fisher (Lori, please pass along to Janice Armstrong)
T. Hoogheem
S. Wratten
J. Hjelle

FYI, herein I report on two related papers from the International Society for Environmental Epidemiology (ISEE) meeting this week in Buffalo, New York. Both papers have results for glyphosate (one for non-Hodgkin's lymphoma (NHL) and one for Hodgkin's disease (HD)) that are of interest to us and our scientific outreach activities.

1. *"Non-Hodgkin's lymphoma and the pesticide hypothesis: dose response"* by Helen McDuffee, Pahwa Punam and colleagues at the Center for Agricultural Medicine at the University of Saskatchewan

We discussed this abstract at our ag epidemiology strategy meeting earlier this year. I learned a bit more about this paper from the author's presentation and from discussions with the author, but I don't yet have enough information to critique this study.

This is a case control study of 517 NHL cases and 1,506 controls funded by Health Canada - the latest in a long line of agricultural epidemiologic studies funded by Health Canada. Epidemiologists from Health Canada have previously published papers where they concluded that pesticides (in the generic sense) are related to various cancers. This latest study addresses individual pesticides in relation to NHL, Hodgkin's disease, and soft tissue sarcoma. [Of historical note, these same cancers were the subject of NCI's Kansas/2,4-D study and, indeed, at least one of Health Canada's epidemiologists have been on the Ag Health Study Advisory Panel since the inception of the Ag Health Study.]

Dr. McDuffee and colleagues identified NHL cases from the various Canadian provincial cancer centers and controls were selected from the general population in proportion to the provincial distribution of the cases. Study subjects were interviewed by mail and phone to ascertain lifetime occupational history and pesticide use. Reported use of a number of pesticides was significantly related to increased

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Case No.
CGC-16-550128

risk of NHL including mecoprop, malathion, DDT, carbaryl, aldrin, and lindane. When the authors controlled for personal factors including antecedent cancer, family history of cancer, personal history of measles, and allergy desensitization treatments, the only pesticide that was significantly related to NHL was mecoprop (a.k.a. MCPP 2-(4-chloro-2-methylphenoxy) propanoic acid).

Additional analyses found significant relationships for more than 2 days use/year for glyphosate (odds ratio 2.1, 95% CI 1.2-3.7) and mecaprop (odds ratio 2.1, 95% CI 1.2-3.6). The full range of confounding factors was not considered in these analyses, but one presumes that again only mecoprop would remain associated with NHL in a multivariate analysis.

Since the organizers of the ISEE meeting asked me to chair the pesticide session which included this paper, I had the opportunity to spend some time with the author. She struck me as a reasonable person. I was expecting a [redacted] but Dr. McDuffee is [redacted]. She doesn't seem to have any preconceived notions about glyphosate. She agreed to share her paper with me when it is ready for submission for publication. She also agreed to come and present her work to an industry audience (ACPA, us, etc.). I gave her a copy of the Cantox glyphosate review and told her of our ongoing Farm Family Exposure Study (FFES). She was extremely interested in the FFES and asked to be kept informed of the results from this program. We obviously need to establish a relationship with Dr. McDuffee because her research program will be generating findings for the next few years. The FFES would seem to provide a basis for an equitable sharing of information with her.

It remains to be seen how glyphosate is treated in the eventual publication from this study and whether anyone picks up selectively on the (presumably) confounded glyphosate finding that was included in the meeting abstract. Obviously, we need to be as prepared as we can, given limited information. I mention some specific follow-up plans below.

2. *"Non-Hodgkin's lymphoma, Hodgkin's disease and pesticide exposure: regional differences"* by Pahwa Punam, Helen McDuffee and colleagues at the Center for Agricultural Medicine at the University of Saskatchewan

This study, presented as a poster at the meeting, has the same NHL cases and controls as the previous study and HD cases and controls from across Canada. The point of the analysis was to look for regional differences in the relationships between pesticides and NHL/HD. Most pesticides showed variable findings by province. Of interest to us, the authors reported a significant glyphosate/HD result in British Columbia, but not elsewhere in Canada (see table). [note - As is typical with epidemiologists, only the British Columbia finding was included in the meeting abstract.]

Province	odds ratio	conf. Interval
Ontario	0.5	0.2-1.9
Quebec	1.0	0.2-5.0
Prairies	1.6	0.9-2.6
British Columbia	4.0	1.4-11.3

I spoke with the author and asked her:

- why is there so much variability across provinces for the various pesticides? Wouldn't one expect consistent results if a specific pesticide was carcinogenic?

She didn't have a ready answer. She speculated that the variation might be explained by heavier use or the tendency to use higher exposure application equipment in specific provinces. I pointed out that agricultural glyphosate application would probably not vary that much across the provinces and that the same might be said for most other pesticides. [note - This is one of the problems in agricultural epidemiology: epidemiologists try to explain obviously disparate findings so as to make a causal relationship (rather than systematic error) seem the most plausible explanation.]

The author does not plan to publish this version of her analysis. She plans to go back and do multivariable analyses to see whether the findings for specific pesticides are confounded by findings for other pesticides or the personal factors that Dr. McDuffee considered (e.g. antecedent cancer, allergy desensitization, etc.). She agreed to send me a copy of her poster and to share a manuscript when it is available. I gave her a copy of the Cantox glyphosate review.

This paper is at a much earlier stage than the previous paper. I'm not sure what the results will be once the author has time to do all the analyses she is considering. So, at present, it's probably best to keep in touch with the author, through her senior colleague Dr. McDuffee. In the interim, if we get any inquires, we can point out that the variation in the findings is inconsistent with a causal relationship with glyphosate.

Follow-up plans

I think our best approach is to develop a collegial relationship with Dr. McDuffee. We can share our findings from the FFES, when available, and ask her to share her findings, when available. Also, I suggest we include Dr. McDuffee in our plans to develop a scientific outreach network in Canada. We've been planning to have a scientific outreach meeting in Canada, so this study provides a good reason to expedite our plans for Canada. This could be important strategically in light of Health Canada's continued investment in agricultural epidemiology and the ongoing networking between Health Canada and the NCI. Dr. McDuffee

would benefit by learning about glyphosate toxicology and exposure assessment.

Donna and I will make plans immediately to arrange a scientific outreach meeting in Canada. I expect that such a meeting could be arranged in October or November. We plan to include several prominent epidemiologists from Canada, along with Len Ritter and Keith Solomon from the University of Guelph. Len is a toxicologist and Keith in an exposure assessor; both know glyphosate well. In addition to our usual scientific outreach agenda, we would ask Dr. McDuffee to present her NHL and HD findings. This would allow her to consider her findings in light of the available glyphosate toxicology/exposure information and to get feedback from the Canadian experts.

Please let me know if you have comments, questions, or other follow-up suggestions.

Message

From: FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]
Sent: 11/29/2001 2:07:23 PM
To: ACQUAVELLA, JOHN F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=145465]
CC: GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=527246]; ARMSTRONG, JANICE M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=597137]; HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
Subject: RE: the McDuffee article appears - glyphosate not mentioned in the abstract

John,

I know we don't know yet what is says in the "small print" - but the fact that glyphosate is no longer mentioned in the abstract is a huge step forward - it removes it from being picked up by abstract searches!

Donna

-----Original Message-----
From: ACQUAVELLA, JOHN F [AG/1000]
Sent: Thursday, November 29, 2001 7:54 AM
To: FARMER, DONNA R [AG/1000]
Cc: GOLDSTEIN, DANIEL A [AG/1000]; ARMSTRONG, JANICE M [AG/1000]; HEYDENS, WILLIAM F [AG/1000]
Subject: the McDuffee article appears - glyphosate not mentioned in the abstract
Importance: High

The McDuffee article appeared in the November issue of the journal Cancer Epidemiology, Biomarkers, and Prevention (see abstract below). Unlike the abstract presented at the International Society for Environmental Epidemiology meeting August 1999, Glyphosate is no longer mentioned as a risk factor in the abstract. I'll have to get the article and see what it says in "the small print."

John

Non-Hodgkin's lymphoma and specific pesticide exposures in men: Cross-
Canada study of pesticides and health
HH McDuffie, P Pahwa, JR McLaughlin, JJ Spinelli, S Fincham, JA Dosman, D Robson, LF Skinnider, NW Choi
Article
1155-1163
Abstract: Our objective in the study was to investigate the putative associations of specific pesticides with non-Hodgkin's Lymphoma [NHL; International Classification of Diseases, version 9 (ICD-9) 200, 202]. We conducted a Canadian multicenter

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population-
based incident, case (n = 517)-control (n = 1506) study among men in
a diversity of occupations using an initial postal questionnaire
followed by a telephone interview for those reporting pesticide
exposure of 10 h/year or more, and a 15% random sample of the
remainder. Adjusted odds ratios (ORs) were computed using conditional
logistic regression stratified by the matching variables of age and
province of residence, and subsequently adjusted for statistically
significant medical variables (history of measles, mumps, cancer,
allergy desensitization treatment, and a positive history of cancer
in first-degree relatives). We found that among major chemical
classes of herbicides, the risk of NHL was statistically
significantly increased by exposure to phenoxyherbicides [OR, 1.38;
95% confidence interval (CI), 1.06-1.81] and to dicamba (OR, 1.88;
95% Cl, 1.32-2.68). Exposure to carbamate (OR, 1.92; 95% CI, 1.22-
3.04) and to organophosphorus insecticides (OR, 1.73; 95% Cl, 1.27-
2.36), amide fungicides, and the fumigant carbon tetrachloride (OR,
2.42; 95% Cl, 1.19-5.14) statistically significantly increased risk.
Among individual compounds, in multivariate analyses, the risk of NHL
was statistically significantly increased by exposure to the
herbicides 2,4-dichlorophenoxyacetic acid (2,4-D; OR, 1.32; 95% CL
1.01-1.73), mecoprop (OR, 2.33; 95% CI, 1.58-3.44), and dicamba (OR,
1.68; 95% CI, 1.00-2.81); to the insecticides malathion (OR, 1.83;
95% Cl, 1.31-2.55), 1,1,1-trichloro-2,2-bis (4-

chlorophenyl) ethane
(DDT), carbaryl (OR, 2.11; 95% CI, 1.21-3.69), aldrin, and lindane;
and to the fungicides captan and sulfur compounds. In additional
multivariate models, which included exposure to other major chemical
classes or individual pesticides, personal antecedent cancer, a
history of cancer among first-degree relatives, and exposure to
mixtures containing dicamba (OR, 1.96; 95% CL 1.40-2.75) or to
mecoprop (OR, 2.22; 95% CL 1.49-3.29) and to aldrin (OR, 3.42; 95%
Cl, 1.18-9.95) were significant independent predictors of an
increased risk for NHL, whereas a personal history of measles and of
allergy desensitization treatments lowered the risk. We concluded
that NHL was associated with specific pesticides after adjustment for
other independent predictors.

John Acquavella, PhD
Senior Fellow, Epidemiology
Monsanto Company/A2NE
St. Louis, MO 63167
phone: [redacted]
cell phone: [redacted]
fax: [redacted]
e-mail: j[redacted]

Message

From: FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]
Sent: 12/6/2001 6:46:24 PM
To: ACQUAVELLA, JOHN F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=145465]; HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
CC: ARMSTRONG, JANICE M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=597137]
Subject: RE: McDuffee paper

John,

Darn. But at least it is out of the abstract and not a huge discussion in the text. Regarding the Journal it is published in - how is it viewed? Is it a premier journal or a lower rung journal?

Yes - please get a third party review.

Donna

-----Original Message-----
From: ACQUAVELLA, JOHN F [AG/1000]
Sent: Thursday, December 06, 2001 7:57 AM
To: HEYDENS, WILLIAM F [AG/1000]
Cc: FARMER, DONNA R [AG/1000]; ARMSTRONG, JANICE M [AG/1000]
Subject: RE: McDuffee paper

Right. It's a good result, but not everything we wanted. The (invalid) result could be cited as a second glyphosate/NHL "finding." However, it will not be picked up by most of the usual suspects because it's not mentioned in the abstract.

John

John Acquavella, PhD
Senior Fellow, Epidemiology
Monsanto Company/A2NE
St. Louis, MO 63167
phone: 314-[redacted]
cell phone: 314-[redacted]
fax: 314-[redacted]
e-mail [redacted]@monsanto.com

-----Original Message-----
From: HEYDENS, WILLIAM F [AG/1000]
Sent: Thursday, December 06, 2001 7:51 AM
To: ACQUAVELLA, JOHN F [AG/1000]; FARMER, DONNA R [AG/1000]; ARMSTRONG, JANICE M [AG/1000]
Cc: GOLDSTEIN, DANIEL A [AG/1000]
Subject: RE: McDuffee paper

John,

So if I understand the situation correctly, even though reference to glyphosate wasn't removed entirely, there was a substantial reduction in emphasis, including, *but not limited to,* removal from the Abstract ?

Bill

-----Original Message-----



From: ACQUAVELLA, JOHN F [AG/1000]
Sent: Wednesday, December 05, 2001 1:30 PM
To: FARMER, DONNA R [AG/1000]; ARMSTRONG, JANICE M [AG/1000]; HEYDENS, WILLIAM F [AG/1000]
Cc: GOLDSTEIN, DANIEL A [AG/1000]
Subject: McDuffee paper

I received the McDuffee paper today and have scanned it briefly. There are findings for glyphosate in only two tables. In table 2, for ever having used glyphosate, the odds ratio is 1.2 (95% CI 0.8 to 1.7) [not significant]. In table 8, for glyphosate use less than 2 days the odds ratio is 1.0 (95% CI 0.6 to 1.6) [exactly null], but for use 2 days or more the odds ratio is 2.1 (95% CI 1.2 to 3.7) [significant]. This finding is one of numerous significant pesticide associations in the paper. Glyphosate is only mentioned once in the text (p 1160 2nd paragraph). The authors are talking about herbicides and mention "... glyphosate, which was not significant for exposure [*meaning in table 2*] but for which we demonstrated a dose-response relationship. Glyphosate is not mentioned again in the paper.

Well, it goes without saying that the findings in table 8 do not demonstrate a dose response relationship for glyphosate. But the authors said it, so it's out there for people who read the entire paper. Folks like Hardell might seize on the results to say they confirm his findings.

I'll write a review of this paper over the next week or so that can be made available to the Monsanto community. I think we should have at least one external review. If you agree, I'll ask Elizabeth Delzell to review this paper for us.

I'll circulate the article to everyone for your reading enjoyment.

John

John Acquavella, PhD
Senior Fellow, Epidemiology
Monsanto Company/[redacted]
St. Louis, MO 63167

phone: 314-[redacted]
cell phone: 314-[redacted]
fax: 314-[redacted]
e-mail: [redacted]@monsanto.com

From: [redacted]
Sent: 02 September 2003 21:29
To: [redacted]
Cc: [redacted]
Subject: RE: Article re: NHL and glyphosate, alachlor

Thanks to [redacted] for bringing the De Roos et al. paper to our attention (see below). I have a few quick thoughts abou it. More information will follow.

This is a paper from investigators at the National Cancer Institute (NCI). For those of you who don't know the history of the NCI's agricultural epidemiology research, the present paper is a reanalysis of data from the Kansas, Nebraska, and Minnesota/Iowa studies from the mid-1980s. It surprises me greatly that they would spend such effort on this old and limited dataset, when they are collecting and analyzing data from the Agricultural Health Study. A fair amount of the data in these old studies came from next-of-kin respondents and is of questionable accuracy. Others have shown that next-of-kin of cancer cases tend to over-report pesticide use. Accordingly, they should have done some analyses segregating out the next-of-kin information, but they didn't.

What's new in this paper is that the investigators use a form of regression analysis that weights prior information (like in a Bayesian analysis) to influence measures of association. The lead author specialized in this type of analysis for her PhD dissertation and she did a postdoc at NCI. Relatively few people have much experience with this analysis, but it is said to be more conservative when doing multiple comparisons (viz. yields fewer false positives).

It is interesting that this analysis did not find an association between NHL and 2,4-D. The Kansas and Nebraska studies are always cited as evidence that 2,4-D does cause NHL. Unfortunately, the authors get into a bit of a convoluted argument in order to avoid saying that their most recent analyses seems to refute much of what they have said previously about 2,4-D.

It is clear that alachlor is near the top of the investigator's list of pesticides that might cause NHL, even though alachlor seemed not to be related to NHL in this analysis (see Table 3). As you know, the NCI Ag Health Study team has a soon to be published paper that shows a weak relationship between reported use of alachlor and lymphopoietic cancers.

Strangely, glyphosate looks to be one of the pesticides most associated with NHL in this analysis (see Table 3). At the time these NHL cases were diagnosed (1979-83), glyphosate was very early in its commercial history. Not only doesn't the association between glyphosate and NHL make sense given glyphosate's toxicology profile, but it doesn't make sense on a timing of exposure basis - one expects a fairly long period between exposure and related cancers for other than extremely potent carcinogens. I did note that De Roos et al. misclassified glyphosate in Table 1 as to its carcinogenic probability (they had it as 0.3, same as alachlor, when it should have been 0.1). Had it been classified correctly, the odds ratio in the last column of Table 3 would have been lower (perhaps much lower).

The authors spent an entire paragraph in the discussion on glyphosate, specifically mentioning the Hardell and McDuffie studies:

> Glyphosate, commercially sold as Roundup, is a commonly used herbicide in the United States, both on crops and non-cropland areas.[30] An association of glyphosate with NHL was observed in another case-control study, but the estimate was based on only four exposed cases.[31] A recent study across large region of Canada found an increased risk of NHL associated with glyphosate use that increased by the number days used per year.[8] These few suggestive findings provide some impetus for further investigation into the potential health effects of glyphosate, even though one review concluded that the active ingredient is non-carcinogenic and non-genotoxic.[30]

I'm afraid this could add more fuel to the fire for Hardell et al.

I'm going to see one of the authors of this paper this weekend at the American College of Epidemiology meeting. I'll ask him about some of these issues.

It looks like NHL and other lymphopoietic cancers continue to be the main cancer epidemiology issues both for glyphosate and alachlor. We're assembling a panel of experts to work on this.

Regards.

[redacted]

[redacted]
Monsanto Company/A2NE
St. Louis, MO 63167
phone: [redacted]
cell phone: [redacted]
fax: [redacted]
e-mail: [redacted]

-----Original Message-----
From: [redacted]
Sent: Tuesday, September 02, 2003 12:39 PM
To: [redacted]
Cc: [redacted]
Subject: Article re: NHL and glyphosate, alachlor

Plaintiff Exhibit
0314
Case No.
CGC-16-550128

See the following recent article, in which glyphosate and alachlor are included:

AJ De Roos, SH Zahm, KP Cantor, DD Weisenburger, FF Holmes, LF Burmeister, and A Blair
Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men.
Occup Environ Med 1 Sep 2003 60(9): p. E11.

Link to abstract: MEDLINE Citation]
Full text: \\finch\ggtt-folder\public\external articles - full text\deRoos_2003.pdf

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[redacted]
Monsanto Company
Tel: [redacted]
Fax: [redacted]
Email: [redacted]

Message

From: GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=527246]
Sent: 5/18/2007 5:32:36 PM
To: SACHS, ERIC S [AG/1000] [redacted]@monsanto.com]; WALLIS, DARREN [AG/1000] [redacted]@monsanto.com]; STEVENER, SCOTT E [AG/1000] [redacted]@monsanto.com]; GLICK, HARVEY L [AG/5340] [redacted]@monsanto.com]; HEDGECOCK, F ANDY [AG/1000] [redacted]@monsanto.com]; MARSHALL, KAREN K [AG/1000] [redacted]@monsanto.com]; CARR, KATHERINE H [AG/1000] [redacted]@monsanto.com]
CC: FARMER, DONNA R [AG/1000] [redacted]@monsanto.com]
Subject: RE: FYI - Aerial spraying of herbicide 'damages DNA' - SciDev.Net

All-

Donna will be in, I believe, Monday. We have local business contacts, but have also been in contact with the US State Department and may need to coordinate communications efforts. I would note that the symptoms noted in the article are those of O-P insecticide poisoning and are not consistent with glyphosate in any event. The results do not frankly sound credible on the face of it- it is not easy to generate a 6 to 8 fold increase in genetic injury- presumably sister chromatid exchange. This may also be new publication of older data as the allegation is not new and the date of application now some 5 years ago. (These types of testing cannot generally be done on stored samples, suggesting that data themselves are older, even if not previously published.)

The publication is in a Brazilian journal and is not yet available on line as best I can tell. The journal operates in English and provides free access PDF's- but this volume is not yet posted. As a 1-page reference (unless they are just giving the first page of a multi-page article), this could not have a lot of detailed content.

Dan

-----Original Message-----
From: SACHS, ERIC S [AG/1000]
Sent: Friday, May 18, 2007 12:08 PM
To: WALLIS, DARREN [AG/1000]; STEVENER, SCOTT E [AG/1000]; GLICK, HARVEY L [AG/5340]; HEDGECOCK, F ANDY [AG/1000]; MARSHALL, KAREN K [AG/1000]
Cc: GOLDSTEIN, DANIEL A [AG/1000]; FARMER, DONNA R [AG/1000]
Subject: RE: FYI - Aerial spraying of herbicide 'damages DNA' - SciDev.Net

Darren and Andy,
Please engage Donna and Dan as this is an old issue and they have extensive experience and information on this topic.
Eric

-----Original Message-----
From: WALLIS, DARREN [AG/1000]
Sent: Friday, May 18, 2007 9:59 AM
To: STEVENER, SCOTT E [AG/1000]; GLICK, HARVEY L [AG/5340]; HEDGECOCK, F ANDY [AG/1000]; MARSHALL, KAREN K [AG/1000]; SACHS, ERIC S [AG/1000]
Subject: RE: FYI - Aerial spraying of herbicide 'damages DNA' - SciDev.Net

Can we get a copy of the study? Sounds like it will be published in Genetics and Molecular Biology. Seems like we might be able to get out in front of this one. Wondering if we might be able to also send clarifying information on glyphosate to the author of this article through our regional contact in Latin America?

-----Original Message-----
From: STEVENER, SCOTT E [AG/1000]
Sent: Friday, May 18, 2007 8:43 AM
To: WALLIS, DARREN [AG/1000]; GLICK, HARVEY L [AG/5340]; HEDGECOCK, F ANDY [AG/1000]; MARSHALL, KAREN K [AG/1000]; SACHS, ERIC S [AG/1000]

Plaintiff Exhibit
0315

Subject: FYI - Aerial spraying of herbicide 'damages DNA' - SciDev.Net

SciDev.Net
17 May 2007

Aerial spraying of herbicide 'damages DNA'
http://www.scidev.net/news/index.cfm?fuseaction=readnews&itemid=3622&language=1

By Lisbeth Fog

BOGOTA - Aerial spraying of a herbicide by the Colombian government on the border of Colombia and Ecuador has caused a high degree of DNA damage in local Ecuadorian people, according to a study.

The research will be published in the next issue of Genetics and Molecular Biology.

The scientists, from the Pontificia Catholic University in Ecuador, analysed blood samples from 24 Ecuadorians living within three kilometres of the border of the two countries. Aerial spraying of a herbicide formulation containing glyphosate — sold under the name Roundup by Monsanto — took place there between late 2000 and early 2001.

The Colombian government sprays illegal coca plantations — used to make cocaine — as part of its 'war on drugs'.

According to the paper, the application rate of the herbicide (litres per hectare) was 20 times the maximum recommended rate for the formulated product.

Half the individuals in the group received spraying directly over their houses, and the blood samples were taken within two months of the spraying taking place.

For comparison, blood samples were taken from 21 Ecuadorian individuals living 80 kilometres away from the border, where aerial spraying of the herbicide formulation did not take place.

In addition to expected symptoms — including vomiting and diarrhoea, blurred vision, and difficulty in breathing — the researchers found a significantly higher degree of DNA damage — 600 to 800 per cent higher — in the people living near the border compared with those 80 kilometres away.

The researchers ruled out tobacco, alcohol, non-prescription drugs and asbestos as causing the DNA damage. None of the individuals used or had been exposed to other herbicides or pesticides when the samples were taken.

DNA damage may activate genes associated to the development of cancer, lead researcher Cesar Paz y Miño told SciDev.Net, and may also lead to miscarriage or malformations in embryos.

Both Colombia and Ecuador have formed national scientific and technical commissions to study the effects of aerially spraying this herbicide formulation, with the Ecuadorian commission concluding it does affect humans and the Colombian commission refuting this claim (see Pesticides used in Colombian war on drugs 'not harmful').

President of the Colombian commission, Alberto Gómez Mejía, told SciDev.Net that it is difficult to establish the real cause of the effects of agrochemicals in humans.

Reference: *Genetics and Molecular Biology* 30, 456 (2007)

Scott E. Stevener
Information & Research Manager
Commercial Acceptance
Monsanto Company

Message

From: HEDGECOCK, F ANDY [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=170931]
Sent: 8/4/2008 3:53:19 PM
To: HEDGECOCK, F ANDY [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=170931]; FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]; GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=527246]; CADY, ROGER A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=555464]; MITCHELL, BRADLEY C [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=BCMITC1]
CC: SACHS, ERIC S [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=171736]; KASPER, GARRETT D [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=GDKASP]
Subject: RE: AGENDA/AWARENESS FILE - IMT, August 4th @ 11:30 - A2215N (DIAL IN 694-6840, code: 127069)
Attachments: New Hardell paper; miRNA paper Nature; FW: FW: Chicago Tribune: Raising a Global Stink; RE: Issues management - Argentina; Current Science Paper-July2008.pdf; FW: GMO Risk Assessment Around the World
Importance: High

All,

The awareness files are attached. See you at 11:30.

- Yield brochure – Standing Partnership
- New Hardell paper
- miRNA paper Nature
- Chicago Tribune: Raising a Global Stink
- Issues management – Argentina
- Current Science / Commentary - *Peer review contestations in the era of transgenic crops* - S. Shantharam et al.
- Food Science and Technology - *GMO Risk Assessment around the World: Some Examples* - Claudia Paoletti et al.

Thanks,

Andy

Plaintiff Exhibit
0316

From: HEDGECOCK, F ANDY [AG/1000]
Sent: Monday, July 28, 2008 9:49 AM
To: HEDGECOCK, F ANDY [AG/1000]; FARMER, DONNA R [AG/1000]; GOLDSTEIN, DANIEL A [AG/1000]; CADY,

ROGER A [AG/1000]; MITCHELL, BRADLEY C [AG/1000]; KASPER, GARRETT D [AG/1000]
Cc: SACHS, ERIC S [AG/1000]
Subject: RE: AGENDA/AWARENESS FILE - IMT, July 21st @ 11:30 - A2215N (DIAL IN 694-6840, code: 127069)
Importance: High

All,

Here are the week's awareness files. See you at 11:30 today.

Thanks,

Andy

- Judy Carmen op-ed
- New Hardell paper (see email from Donna)
- response to POISON PROFITS
    - Additional doc for Public Health...
- CropLife Canada – Pesticide Benefits (RE: Help?)

Message

From: GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=527246]
Sent: 2/26/2015 8:08:31 PM
To: VICINI, JOHN L [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=56908]; REYNOLDS, TRACEY L [AG/1000] [/O=MONSANTO/OU=Na-1000-01/cn=recipients/cn=133378]
CC: SACHS, ERIC S [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=171736]
Subject: ACSH

While I would love to have more friends and more choices, we don't have a lot of supporters and can't afford to lose the few we have....

I am well aware of the challenges with ACSH and know Eric has valid concerns- so I can assure you I am not all starry-eyed about ACSH- they have PLENTY of warts- but:

You WILL NOT GET A BETTER VALUE FOR YOUR DOLLAR than ACSH:

They are working with us to respond if needed to IARC- Gil has asked for information feed.

Today: http://acsh.org/2015/02/gmo-labeling-laws-will-harm-good/

They host TWO BOOKS and a Pamphlet that are EXTREMELY USEFUL:

http://acsh.org/2014/03/whats-story-genetically-modified-food/

http://acsh.org/2014/03/food-guide-modern-agricultural-biotechnology/

http://acsh.org/2014/03/food-feeding-world-modern-agricultural-biotechnology-2/

AND the recent pesticide review:

http://www.amazon.com/Pesticides-Health-Myths-vs-Realities/dp/061548512X

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0321
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http://www.amazon.com/Pesticides-Perspective-William-Kucewicz/dp/0615485162/ref=sr_1_2?s=books&ie=UTF8&qid=1323363102&sr=1-2

FIFTY THREE Recent examples of posting in 2014/15..... NOT complete:

http://acsh.org/2015/02/scientifically-unsound-discussion-gmos-watch-fox-news-sunday-housecall/

http://acsh.org/2015/02/new-gmo-labeling-bill-introduced-amidst-approval-gm-apple/

http://acsh.org/2015/02/many-consumers-want-gmo-labeling-dont-really-know-much-gmo-foods-ingredients/

http://acsh.org/2015/02/health-news-gmo-labeling-long-lasting-gm-apples-added-vitamins-foods/

http://acsh.org/2015/02/health-news-gmo-labeling-epa-attacked-secret-science-skinny-bariatric-surgery/

http://acsh.org/2015/02/health-news-gmo-knowledge-deadly-flu-season-news-anticholinergics/

http://acsh.org/2015/02/gmo-labeling-laws-will-harm-good/

http://acsh.org/2015/02/food-babe-food-poisoning-harmful/

http://acsh.org/2015/01/science-endocrine-disrupter-debate-explains-absence-science/

http://acsh.org/2015/01/really-killing-bees-may-surprised/

http://acsh.org/2015/01/publics-scientists-views-diverge-widely-important-issues/

http://acsh.org/2015/01/new-variety-gmo-potato-introduced-jr-simplot/

http://acsh.org/2015/01/henry-miller-wall-st-journal-epausda-strangled-biopharming-cradle/

http://acsh.org/2015/01/cspi-dead-gm-labeling-good/

http://acsh.org/2014/12/top-10-scares-2014/

http://acsh.org/2014/12/label-label-gmos-question-considered-federal-lawmakers/

http://acsh.org/2014/12/gmo-debate/

http://acsh.org/2014/12/dr-henry-miller-calls-american-farmers-wake/

http://acsh.org/2014/12/acshs-top-stories-2014-part-2/

http://acsh.org/2014/11/recent-eu-vote-may-allow-ge-crops-nations/

http://acsh.org/2014/11/meta-analysis-shows-gm-crops-reduce-pesticide-use-37-percent/

http://acsh.org/2014/11/labeling-gmos-benefits-one-except-organic-foods-industry/

http://acsh.org/2014/11/health-news-gmo-spud-laundry-pods-dangers-chemical-mix-ups/

http://acsh.org/2014/11/acsh-comment-pesticide-residues-wash-examiner/

http://acsh.org/2014/10/la-city-council-pushes-symbolic-gmo-ban/

http://acsh.org/2014/10/indian-government-sees-light-gmo-crops/

http://acsh.org/2014/07/greenpeace-gets-small-taste-medicine/

http://acsh.org/2014/07/gmo-labeling-considered-oregon/

http://acsh.org/2014/07/fewer-pesticides-antioxidants-organic-crops/

http://acsh.org/2014/07/fewer-bees-just-bee-s/

http://acsh.org/2014/07/debunked-five-chemical-misconceptions/

http://acsh.org/2014/07/buzz-bee-pocalyse-honey-trap/

http://acsh.org/2014/06/uc-davis-group-links-pesticides-autism-without-measuring-pesticides/

http://acsh.org/2014/06/dr-miller-nails-take-genetic-engineering/

http://acsh.org/2014/06/bee-s-anti-pesticide-activists/

http://acsh.org/2014/05/survey-agrees-fda-need-label-food-biotech-engineered-ingredients/

http://acsh.org/2014/05/organic-pesticide-free-claims-debunked/

http://acsh.org/2014/05/monsantos-gm-soy-approved-efsa/

http://acsh.org/2014/05/gmo-labeling-issue-wont-go-away/

http://acsh.org/2014/04/something-fishy-junk-science-public-policy/

http://acsh.org/2014/04/president-obama-signs-norman-borlaugs-biotech-crusade-feed-hungry/

http://acsh.org/2014/04/organic-food-reduce-cancer-risk-science-2-0-says/

http://acsh.org/2014/04/beliefs-organic-mommy-mafia-trial/

http://acsh.org/2014/03/thought-piece-imagines-gmo-free-world-hunger-game/

http://acsh.org/2014/03/just-think-science-cant-get-junkier-comes-along/

http://acsh.org/2014/02/go-another-california-gmo-labeling-bill-introduced/

http://acsh.org/2014/02/common-sense-agricultural-pesticides-genuine-expert/

http://acsh.org/2014/02/bee-bee-behind-bee-colony-collapse-one/

http://acsh.org/2014/01/latest-buzz-bee-colony-collapse-disorder-virus-pesticide-problem/

http://acsh.org/2014/01/junk-science-rules-eu-says-parliamentarian/

http://acsh.org/2014/01/experts-food-biotechnology-gmo-containing-food-tell-like/

http://acsh.org/2014/01/big-island-small-minds-gmo-ban-hawaii-flouts-science-sense/

http://acsh.org/2013/12/ways-really-reduce-cancer-risk/

From: VICINI, JOHN L [AG/1000]
Sent: Thursday, February 26, 2015 1:12 PM
To: GOLDSTEIN, DANIEL A [AG/1000]; REYNOLDS, TRACEY L [AG/1000]
Subject: RE: Glyphosate- IARC assessment

Tracey – I know that ACSH is a pain to work with but we should not go in one year and out the next – repeat as necessary. I'm not sure I can best judge how impactful they are. Maybe the Fusion Center can tell what volume their website gets?

From: GOLDSTEIN, DANIEL A [AG/1000]
Sent: Thursday, February 26, 2015 9:33 AM
To: REYNOLDS, TRACEY L [AG/1000]; VICINI, JOHN L [AG/1000]
Subject: FW: Glyphosate- IARC assessment

ACSH outreach....

Per my discussion w John- we had some money set aside for IARC and should go ahead and make a contribution. I had hoped to start a multicompany project with them this year but that clearly will not happen and they need continued support. They had DOZENS of pro- GMO and glyphosate postings last year.

(I can compile them- I keep most in a folder- if anyone doubts their utility)

Dan

From: Gilbert Ross [mailto:[redacted]@acsh.org]
Sent: Wednesday, February 25, 2015 6:40 PM
To: GOLDSTEIN, DANIEL A [AG/1000]
Cc: CHERYL MARTIN
Subject: Re: Glyphosate- IARC assessment

Dear Dan,

Thanks for your prompt reply to our request for Monsanto's continued, *and much needed,* support in 2015.

Responding to your email below: Yes, the glyphosate/IARC issue was something we recently discussed in a meeting here at ACSH, so it is on our radar. (We are involved in a full-court press re: IARC, regarding ag-chemicals, DINP [phthalate] and diesel exhaust).

As you know, ACSH is proactive in many areas of mutual interest, so we'd welcome any additional information you are willing to share with us that would help bring us further up-to-speed on the topic, particularly if ACSH's commentary is needed to critique an adverse outcome. This situation, however, further illustrates why Monsanto's ongoing support of ACSH is critical, for both Monsanto and ACSH. It ensures that we have the resources needed to advance ongoing and emerging educational initiatives and programs in a more dynamic way.

Interestingly, I did just a quick google news search of Monsanto (see below) and it confirms why on many fronts a science-based organization like ACSH, which consistently debunks the junk-science attacks of activists, is needed. Let's find a way to secure Monsanto's renewed and continued funding of ACSH's ongoing work to provide a rational voice of scientific reason to the public. Your renewed commitment (prior to the close of our fiscal year budget on 6/30/2015) is critical.

Thanks again. I look forward to receiving all the information on glyphosate — and I look forward to hearing from you regarding Monsanto's 2015 commitment to ACSH.

Best

Gil and Cheryl

1.

Hold **Monsanto** Responsible for Killing Monarch Butterflies

<images.jpeg>

Care2.com

Care2.com - 4 days ago

Monsanto makes Roundup and benefits handsomely from global sales, but Roundup also destroys

milkweeds, a plant critical to the survival of ...

Online petition to save monarch butterfly from GMOs, **Monsanto** Digital Journal
Monsanto Herbicide Wiping Out Monarch Butterflies MINA
Dispatches from Skip Gorman's Audioblog: Monarch, milkweed and ...Ridgecrest Daily Independent

2.

3.

We Won! **Monsanto** Ad has been Pulled from O Magazine

<images.jpeg>

Food Integrity Now - 5 days ago

Food Integrity Now

Monsanto states that "we partner with farmers:" **Monsanto** requires farmers who use their seeds to sign an agreement that they will not save ...

4.

5.

Monsanto: Firing On All Cylinders. But Driving Toward A Cliff? (MON)

<images.jpeg>

Seeking Alpha (registration) - 1 day ago

Center for Research on Globalization

Monsanto (NYSE:MON) appears be doing well financially. Net Sales: $15.9 Billion, up 6.7% year over year. Gross Profit: $8.6 Billion, up 13.4% ...

Monsanto Glyphosate Roundup Herbicide Triggers Autism in ... Center for Research on Globalization
This Hated Company Is Poised For An 80% Gain Nasdaq

6.

7.

Monsanto readies for Muscatine expansion, add jobs

Muscatine Journal - 2 days ago

ST. LOUIS — **Monsanto** is expanding its Muscatine, Iowa plant. This project will expand the formulations and packaging capacity at the plant to ...

8.

9.

Monsanto needs to consider human health, too

<images.jpeg>

DesMoinesRegister.com - 2 days ago

DesMoinesRegister.com

In the Feb. 15 Des Moines Register article "**Monsanto** nears its largest biotech trait launch," Michael Firko, the Animal and Plant Health ...

10.

11.

Be Part of the Conversation...About Food Sustainability

Shape Magazine - 1 day ago

0 shared this. Printer-friendly version. 0 shared this. Printer-friendly version. 0. Printer-friendly version. By Advertisement by **Monsanto** ...

12.

13.

Monsanto Shareholder Meeting Gets Heated

<images.jpeg>

Napa Valley Register

Wall Street Journal (blog) - Jan 30, 2015

Monsanto Co. has long been a lightning rod for debate, but at its annual shareholder meeting Friday, the biotech-seed company was tagged ...

Monsanto shareholders seek ability to nominate board membersSTLtoday.com
Napa's Harrington wins vote at **Monsanto** Napa Valley Register
Moms and Doctors Have a Message for **Monsanto**: 'You're Making ... eNews Park Forest
Seeking Alpha (registration)

14.

15.

Monsanto makes highly hybridized seeds available to home ...

<images.jpeg>

Sacramento Business Journal

Sacramento Business Journal - Feb 17, 2015

Monsanto's Seminis Home Garden has introduced new vegetable varieties for home growers, developed to be disease-resistant and easy to ...

16.

17.

Monsanto Inches Closer To Biggest Biotech Launch In Company's ...

<images.jpeg>

St. Louis Public Radio

St. Louis Public Radio - Feb 6, 2015

To counter a “super weed” epidemic plaguing farmers, agribusiness giant**Monsanto** is steadily moving forward on the introduction of its next ...

18.

19.

What **Monsanto** Doesn't Want You To See

Environmental Working Group - Jan 28, 2015

When consumers across Europe started campaigning for GMO labeling in the early 1990s, **Monsanto** released a series

of advertisements in ...

From: "GOLDSTEIN, DANIEL A [AG/1000]" <[redacted]@monsanto.com>

To: Gilbert Ross <[redacted]@acsh.org>

Cc: "VICINI, JOHN L [AG/1000]" <[redacted]@monsanto.com>

Subject: Glyphosate- IARC assessment

Date: February 24, 2015 at 1:14:23 PM EST

Gil-

I wanted to give you and ACSH a head's up on a issue for early March. As always, I fully understand that ACSH will decide both whether to respond and how to respond- I just want to make sure that you have the full array of information on the topic at your disposal either ahead of time or, if you prefer, on your request when/if needed.

ISSUE- In the context of the re-registration of glyphosate in the EU and the US, IARC has decided to take up glyphosate. The circumstances are quite odd. Sticking to established factual information, we know that glyphosate was on the intermediate tier for future assessment (a list that IARC rarely gets to as the first tier is not empty), that glyphosate was inexplicably combined with three selected organophosphate insecticides for collective consideration, and that the public announcement of the meeting to evaluate glyphosate was made only in late 2014- about 4 months prior to the meeting, and AFTER the deadline for nomination of participants in the panel had passed.

This event was presaged by an IARC review of pesticides and lymphoma (Shinasi et al) which combined B-cell lymphoma types and concluded on meta-analysis that there was an association of ever/never used glyphosate with the occurrence of B cell lymphoma.

Much of the strength of this association comes from the Ag Health study paper on multiple myeloma and glyphosate (DeRoos)- which has a fundamental problem. While the study reports an increased risk in the exposed population, a review of the entire data set indicates no such association. The association only becomes apparent when cases are dropped out of the control group as a result of missing personal habits history (smoking, etc).

While the latter procedure was consistent with the stated method, the authors do not report the actual raw numbers, and thus it is not readily apparent in the DeRoos publication that the association hinges entirely on the fact that multiple cases were dropped from the control group and non from the exposed group as a result of missing data.

We do not, of course, know what the outcome of the deliberations will be. If glyphosate is classified as a possible or probably human carcinogen, this will obviously have a large impact on a molecule the EPA and the EU (German BfR) have recently concluded (preliminary EPA assessment and BfR rapporteur report for the EU) is not a carcinogen. In the event of an adverse outcome, you may perhaps decide that some commentary is warranted.

If so, I would like to provide you the full set of materials. As noted, I am happy to do so now or can provide as needed as it is all compiled in a single resource folder. We will also be preparing a number of epidemiology and clinical experts on the topic who might participate in a conversation with ACSH.

My thanks- Dan

Daniel A. Goldstein, M.D.

Senior Science Fellow

Lead, Medical Sciences and Outreach

Monsanto, Mail Zone C3ND

800 N. Lindbergh Blvd.

St. Louis, MO 63167

Office: 314-[redacted]

Cell: 314-[redacted]

[redacted]@monsanto.com

Gilbert Ross M.D.
Medical and Executive Director, Acting President
The American Council on Science and Health
1995 Broadway NYC NY 10023
[redacted]@acsh.org
212-[redacted]
fax 212-[redacted]
cell 516-[redacted]
Website | Facebook | Twitter



Message

From: SCHRADER, SHAWN [AG/1630] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=538369]
Sent: 1/22/2015 3:57:39 PM
To: EDWARDS, JEAN A [AG/1630] [/O=MONSANTO/OU=NA-1630-01/cn=Recipients/cn=152055]; WILTS, MIKE E [AG/1630] [/O=MONSANTO/OU=NA-1630-01/cn=Recipients/cn=16109]; JOHNSON, GLENN M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=161205]; SEIFERT-HIGGINS, SIMONE [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=546720]; DE WILDE, ANNEMIEKE [AG/1000] [/O=MONSANTO/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ADEWI]; GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=527246]
CC: SCHNEIDER, TIMOTHY L [AG/1630] [/O=MONSANTO/OU=NA-1630-01/cn=Recipients/cn=133403]; TRASER-SCHMALZ, SHERI E [AG/1630] [/O=MONSANTO/OU=NA-1630-01/cn=Recipients/cn=117539]
Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Thanks Jean and Mike for follow up and closure. Thanks to the team for the support.

From: DE WILDE, ANNEMIEKE [AG/1000]
Sent: Thursday, January 22, 2015 8:39 AM
To: EDWARDS, JEAN A [AG/1630]; GOLDSTEIN, DANIEL A [AG/1000]
Cc: WILTS, MIKE E [AG/1630]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; JOHNSON, GLENN M [AG/1000]; SEIFERT-HIGGINS, SIMONE [AG/1000]
Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Jean,

Thank you for bringing closure to this employee report!

Annemieke

"Better health is better performance in all you do" – What are you doing for your health today?

Annemieke De Wilde, MD, MPH, FACOEM

Office: 314-[redacted] **Mobile**: 314[redacted]

E-mail: [redacted]@monsanto.com

Location: LS1029 **Mailstop**: LS1A

Plaintiff Exhibit
0326

From: EDWARDS, JEAN A [AG/1630]
Sent: Thursday, January 22, 2015 6:44 AM
To: EDWARDS, JEAN A [AG/1630]; GOLDSTEIN, DANIEL A [AG/1000]; DE WILDE, ANNEMIEKE [AG/1000]
Cc: WILTS, MIKE E [AG/1630]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; JOHNSON, GLENN M [AG/1000]; SEIFERT-HIGGINS, SIMONE [AG/1000]
Subject: RE: 2014 Annual Adverse Effects Reporting Notification

To All,

I spoke with the retired employee yesterday and explained that his report has been reviewed by

by the Monsanto medical director and epidemiologist (I explained what that was), then sent to the adverse effects team.

I told him that we had gathered his work history and chemicals he would have been exposed to here. These were reviewed and

they have not determined an association between his medical condition and the chemicals

he would have worked with here at the plant.

He did not seem to have any further questions or concerns, but I asked him to contact me if he had any questions

or concerns in the future or would like to speak with anyone else.

Thanks to all for your assistance in addressing this matter,

Jean

From: EDWARDS, JEAN A [AG/1630]
Sent: Tuesday, January 20, 2015 2:41 PM
To: GOLDSTEIN, DANIEL A [AG/1000]; DE WILDE, ANNEMIEKE [AG/1000]
Cc: WILTS, MIKE E [AG/1630]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; JOHNSON, GLENN M [AG/1000]; SEIFERT-HIGGINS, SIMONE [AG/1000]
Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Dan,

Thank you for your response and for your assistance with this. I spoke to Annemieke and I will be following up with

the individual by phone to let him know that his report has been reviewed.

I would like Mike Wilts to sit in on the conversation and he is out of the plant today, so we'll try to

make the call tomorrow. I'll let you know how the call is received and if any remaining questions or concerns.

Jean

From: GOLDSTEIN, DANIEL A [AG/1000]
Sent: Tuesday, January 20, 2015 12:19 PM
To: DE WILDE, ANNEMIEKE [AG/1000]; EDWARDS, JEAN A [AG/1630]
Cc: WILTS, MIKE E [AG/1630]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; JOHNSON, GLENN M [AG/1000]; SEIFERT-HIGGINS, SIMONE [AG/1000]
Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Annemieke and Jean-

- I agree with the Adverse Effects Committee that there is no FIFRA(6)a2 report needed for glyphosate or other active ingredients at this time.
- With no clear allegation or specific association, I do not believe there is a TSCA 8(e) reporting issue either.

QUESTIONS:

- Is there any OSHA reporting requited for this illness? I do NOT believe that there is a need to report, but I am not generally involved in the OSHA reporting and it has been a very long time since I have been involved. I just want to make sure the issue has been considered.

- Finally- I assume that there is a desire to follow up with the individual who made the original inquiry. I am happy to participate in any communications. Do you have any sense of whether you want this to be in written form, personal communication via phone (or both) and who else should be in the conversation? Obviously Occ

Med and Site safety (and possibly HR) may want to be involved or at least be aware and may wish to be a part of any verbal communication.

Please let me know how the plant/ESH/Occ-Med wants to move forward on communications. Happy to help any way necessary.

Dan

From: DE WILDE, ANNEMIEKE [AG/1000]
Sent: Wednesday, December 10, 2014 7:49 PM
To: GOLDSTEIN, DANIEL A [AG/1000]
Cc: WILTS, MIKE E [AG/1630]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; JOHNSON, GLENN M [AG/1000]; VICINI, JOHN L [AG/1000]; FARMER, DONNA R [AG/1000]; EDWARDS, JEAN A [AG/1630]
Subject: Re: 2014 Annual Adverse Effects Reporting Notification

Mike,

Once you and Glen have had a chance to review the exposure data, let's reconvene to discuss communicating back to Adverse Effect committee and to [redacted] (talking points for Jean Edwards).

What is your thoughts on getting back to [redacted] via Jean?

If you agree, what are your comments on proposed talking points:

- your concern has been forwarded to the adverse effect committee, - - - literature does not show any significant workplace exposures

- we are checking on your exposure history

- we will review all data to see if your personal HC leukemia experience can possibly add to the scientific knowledge base.

I have included Jean in CC.

Happy to discuss by phone too

Annemieke De Wilde - Sent from my iPhone

On Dec 10, 2014, at 14:37, "GOLDSTEIN, DANIEL A [AG/1000]" <[redacted]@monsanto.com> wrote:

Please see attached Medline search for hairy cell leukemia. This is a small body of literature and there do not appear to be any well established links between occupational exposures and hairy cell leukemia.

Previously reported chemical specific associations (which have not been borne out by further studies) include the triazine herbicides as reviewed by Sathiakumar et al (this was a Monsanto funded study if I recall correctly), glyphosate (discussed below), and some very weak allegations around solvents and benzene.

The glyphosate allegations by Hardell are very weak, and in a much larger study (the Ag Health Study from the US National Cancer Institute- the largest study of its type) this association was not found.

There are some broad associations with pesticide categories, including herbicides and organophosphate insecticides.

At this point, it would be worth looking for an exposure history for various pesticide active ingredients, as this would likely include glyphosate, triazine, and possibly 2,4-D depending on his role and on the production at Muscatine (we sell a glyphosate/2,4-D product- but not sure where it is formulated). The organic solvent connection appears very weak, but it would be worth assessing potential ongoing benzene exposure as this has been a topic of discussion in the literature. I am not aware of routine benzene exposure at Muscatine- bat cannot say I have ever looked into the matter specifically.

I am not suggesting that finding any of these esposures would indicate a causal relationship- only that we need to follow up with the patient at some point and that we need to understand exposures to have an intelligent conversation around the reported associations.

Dan

From: WILTS, MIKE E [AG/1630]
Sent: Friday, December 05, 2014 9:07 AM
To: ADVERSE, EFFECTS [AG/1000]
Cc: SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; GOLDSTEIN, DANIEL A [AG/1000]; JOHNSON, GLENN M [AG/1000]; DE WILDE, ANNEMIEKE [AG/1000]
Subject: FW: 2014 Annual Adverse Effects Reporting Notification

Adverse effect committee,

I am forwarding you this email chain regarding a comment received by our plant nurse in Muscatine. Dr. Goldstein, Glenn Johnson and Dr De Wilde recommend that I send this to you for review. They are currently reviewing additional information for Hairy Cell Leukemia.

If you have any questions please feel free to contact me

Michael E. Wilts, ASP

Industrial Hygienist

Monsanto Muscatine

Phone: 563[redacted]

Cell : 563-[redacted]

Fax : 563-[redacted]

[redacted]@monsanto.com

From: GOLDSTEIN, DANIEL A [AG/1000]
Sent: Thursday, December 04, 2014 8:42 AM
To: JOHNSON, GLENN M [AG/1000]; DE WILDE, ANNEMIEKE [AG/1000]; FARMER, DONNA R [AG/1000]
Cc: WILTS, MIKE E [AG/1630]; SHELTON, PAUL E [AG/1000]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; EDWARDS, JEAN A [AG/1630]
Subject: RE: 2014 Annual Adverse Effects Reporting Notification

This goes back to the allegation/publication by Hardell et al, specifically related to glyphosate exposure and Hairy Cell leukemia. This has not held up to further examination, but obviously the work exposure history is key.

I should be able to look at this. My long string of travels is over, and other than a trip on Dec 9/10 this month is pretty sedate.

Dan

From: JOHNSON, GLENN M [AG/1000]
Sent: Wednesday, December 03, 2014 4:38 PM
To: GOLDSTEIN, DANIEL A [AG/1000]; DE WILDE, ANNEMIEKE [AG/1000]
Cc: WILTS, MIKE E [AG/1630]; SHELTON, PAUL E [AG/1000]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; EDWARDS, JEAN A [AG/1630]
Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Mike,

I agree with sending to the committee for review as Dan said below.

Most of the sources I looked at (Mayo Clinic, NCI, Medline Plus, Leukemia and Lymphoma Society, Hairy Cell Leukemia Foundation, Leukemia and Lymphoma Research (UK) and Lymphoma Association (UK)) echoed what Jean had found. Most said the cause or risk factors of hairy cell leukemia are not known.

The Hairy Cell Leukemia Association (US) linked to the U.S. Department of Veterans Affairs' Agent Orange information.

Getting the work history sounds like a good idea, but before you spend a lot of time trying to figure out his exposure profile I think it would be helpful to get some more specific guidance on what chemical(s) we should be targeting, if any. Dan and Annemieke, I don't know if you have time to look at this when you return or if some of the toxicologists would be able to give some specific guidance.

Best regards,

Glenn M. Johnson, CIH, ROH
Phone: 314-[redacted]
Fax: 314-[redacted]
Cell: 314[redacted]
[redacted]@monsanto.com

From: GOLDSTEIN, DANIEL A [AG/1000]
Sent: Wednesday, December 03, 2014 1:11 PM
To: DE WILDE, ANNEMIEKE [AG/1000]
Cc: WILTS, MIKE E [AG/1630]; SHELTON, PAUL E [AG/1000]; JOHNSON, GLENN M [AG/1000]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; EDWARDS, JEAN A [AG/1630]
Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Agree- could be TSCA 8e if not active or formulated pesticide- do send on to reporting committee and we will follow up.

Dan

From: DE WILDE, ANNEMIEKE [AG/1000]
Sent: Wednesday, December 03, 2014 1:09 PM
To: GOLDSTEIN, DANIEL A [AG/1000]
Cc: WILTS, MIKE E [AG/1630]; SHELTON, PAUL E [AG/1000]; JOHNSON, GLENN M [AG/1000]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; EDWARDS, JEAN A [AG/1630]
Subject: Re: 2014 Annual Adverse Effects Reporting Notification

I agree that this is not an allegation. In previous lives, the companies kept this on file. If similar "stories surface" the combination of stories may make it an allegation subject to TSCA 8(c).

My advice is to report it to the adverse events team as an FYI, not as a formal allegation report. They will know what to do with it.

Annemieke

Annemieke De Wilde - Sent from my iPhone

On Dec 3, 2014, at 12:52, "GOLDSTEIN, DANIEL A [AG/1000]" <[redacted]@monsanto.com> wrote:

This is not reportable in my opinion because he did not make an allegation of relatedness but rather asks a question.

I am not suggesting we ignore the issue or fail to respond to the employee- just saying that as currently worded this would not trigger 6(a)2 report. On the road today- will follow up with further information. Dan

Sent from my iPhone

On Dec 3, 2014, at 10:53 AM, "WILTS, MIKE E [AG/1630]" <[redacted]@monsanto.com> wrote:

Dan, Paul, Glenn and Annemieke,

I was requested to look into this by Muscatine's plant manager. This comes from a retiree that is working currently as a contractor for Monsanto. He saw the adverse effects notice and sent this to Jean Edwards our plant nurse. She has done some research (since I was on vacation) and found that this type of cancer is related to age and gender vs. chemical exposure. I have gone to HR to see if they can pull up employment records and will look at exposure records for the areas that he worked in during those periods of time. I am forwarding this to you to find out your opinions. Thank you in advance.

Best regards,

Michael E. Wilts, ASP

Industrial Hygienist

Monsanto Muscatine

Phone: 563-[redacted]

Cell : 563-[redacted]

Fax : 563-[redacted]

[redacted]@monsanto.com

From: EDWARDS, JEAN A [AG/1630]
Sent: Wednesday, December 03, 2014 9:34 AM
To: WILTS, MIKE E [AG/1630]
Subject: FW: 2014 Annual Adverse Effects Reporting Notification

From: [redacted] [AG-Contractor/1000]
Sent: Monday, November 24, 2014 7:54 AM
To: EDWARDS, JEAN A [AG/1630]
Subject: FW: 2014 Annual Adverse Effects Reporting Notification

Jean,

I have been diagnosed with Hairy Cells Leukemia. You may or may not remember that I had irregular blood counts before I retired. I don't know if this diagnosis

Is related to working around all of the chemicals that I may have been exposed to at Muscatine.

I don't know if it has anything to do with the message below so I am sending you this as information only.

Regards,

[redacted]

From: ADVERSE, EFFECTS [AG/1000]
Sent: Friday, November 21, 2014 3:24 PM
Subject: 2014 Annual Adverse Effects Reporting Notification

To Monsanto Employees:

NOTICE: Pursuant to Monsanto Company's obligations under several laws, all Monsanto employees are receiving this email regarding the procedure for notifying the appropriate internal personnel about potential adverse effects of our commercial and research products. As described in this notification, it is your responsibility as an employee to report any such effect if you become aware of it. Thank you for your attention to this important matter.

This annual notification is for all Monsanto employees who could come into possession of either: (a) information regarding alleged or actual "adverse effects" from conventional, biological, or biotechnology-based pesticide products currently or previously registered by Monsanto Company; or (b) information which suggests a conclusion of "substantial risk of injury to health or the environment" relating to non-pesticide "chemical substances," which includes most chemicals and even certain recombinant microorganisms. For pesticide products, the information may be related to the active ingredient (chemical or protein) itself, or any component of the product including inerts, safeners, metabolites, contaminants and degradation products.

The United States Environmental Protection Agency (U.S. EPA) and other international regulatory agencies require the reporting of this information under certain circumstances. If you become aware of information which suggests a conclusion of "adverse effect" or "substantial risk," you must immediately forward that information to the Adverse Effects Reporting Committee as instructed below. The information may originate inside or outside of the United States.

The types of information which may be reportable include, but are not limited to, the following:

(a) Results from scientific studies

(b) Allegations of injury to human or animal health

(c) Environmental contamination

(d) Allegations of damage from off-target movement (e.g. drift, run-off)

For more information, Adverse Effects Reporting CBTs can be taken through Monsanto University.

IMPORTANCE:

Monsanto has reporting obligations under provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or Toxic Substances Control Act (TSCA). Under these laws, Monsanto may be considered to be in possession of adverse effect information when the information becomes known to any employee or agent of Monsanto, and timelines for Monsanto to report to the relevant agency can be short. Failure of an employee to report the required information to the Adverse Effect Reporting Committee in a prompt fashion can result in civil and/or criminal penalties against Monsanto or the employee and cancellation or suspension of a product.

REPORTING:

It is not your responsibility to determine if the information you possess is reportable to the U.S. EPA or other agencies. It is, however, your responsibility to notify the Adverse Effects Reporting Committee if you believe the information *might be* reportable under the provisions of the laws mentioned above. When received, the information will be reviewed and, if appropriate, an official report will be submitted by the Adverse Effects Reporting Committee to the relevant agencies according to the reporting guidelines. We encourage you also to discuss the information with your supervisor.

If you have questions regarding information you possess, please contact the Adverse Effects Reporting Committee through one of the following:

- Simone Seifert-Higgins
- By phone: (314) [redacted]
- By Outlook address: ADVERSE, EFFECTS [AG/1000]
- By: e-mail address: effects.adverse@monsanto.com

Subject: Notificacion annual sobre el reporte de consecuencias adversas 2014

Para los empleados de Monsanto:

AVISO: De acuerdo con las obligaciones de Monsanto Company conforme a varias leyes, todos los empleados de Monsanto están recibiendo este correo electrónico en relación con el procedimiento para notificar al personal interno adecuado sobre las posibles consecuencias adversas de nuestros productos comerciales y en investigación. Como se describe en esta notificación, como empleado tú eres responsable de reportar cualquiera de estas consecuencias, si llegas a darte cuenta de ellas. Gracias por tu atención a este importante asunto.

Esta notificación anual es para todos los empleados de Monsanto que puedan entrar en posesión de: (a) información sobre "consecuencias adversas" presuntas o reales de productos pesticidas convencionales, biopesticidas, o pesticidas basados en biotecnología, registrados anterior o actualmente por Monsanto Company; o (b) información que sugiera una conclusión de "riesgo considerable de lesión a la salud o al medio ambiente", en relación con "sustancias químicas" no pesticidas, que incluye a la mayoría de los productos químicos e incluso algunos microorganismos recombinantes. Para los productos pesticidas, la información puede relacionarse con el ingrediente activo (sustancia química o proteína) por sí solo, o cualquier componente del producto incluyendo inertes, protectores, metabolitos, contaminantes y productos de degradación.

La Agencia de Protección Ambiental de Estados Unidos (U.S. EPA, por sus siglas en inglés) y otros organismos reguladores internacionales requieren que se reporte esta información bajo determinadas circunstancias. Si llegas a darte cuenta de información que sugiera una conclusión de "consecuencia adversa" o "riesgo considerable", debes remitir tal información de inmediato al Comité de Reporte de Consecuencias Adversas, tal como se explica a continuación. La información puede originarse dentro o fuera de los Estados Unidos.

Los tipos de información que pueden ser reportables incluyen, entre otros, los siguientes:

a) Resultados de estudios científicos

b) Reclamos de daños a la salud de seres humanos o animales

c) Contaminación ambiental

d) Reclamos por daños como resultado de la movimiento fuera del objetivo de aplicación (ej. deriva o escorrentía)

Para obtener más información puedes tomar Capacitación Basada en Computadora (Computer Based Training o CBT) sobre reporte de consecuencias adversas a través de la Universidad Monsanto.

IMPORTANCIA:

Monsanto tiene obligaciones de reportar sobre consecuencias adversas conforme a las disposiciones del Acta Federal relativa a los insecticidas, fungicidas y raticidas (FIFRA, por sus siglas en Inglés) o el Acta sobre control de sustancias tóxicas (TSCA, por sus siglas en Inglés). De acuerdo a estas leyes se puede considerar que Monsanto está en posesión de información sobre consecuencias adversas cuando cualquier empleado o agente de Monsanto tiene conocimiento de la información, y los plazos para que Monsanto lo reporte al organismo pertinente pueden ser breves. La omisión por parte de un empleado de reportar con prontitud la información requerida al Comité de Reporte de Consecuencias Adversas, podrá acarrear sanciones civiles y/o penales contra Monsanto o el empleado, y la cancelación o suspensión de un producto.

NOTIFICAR:

No es tu responsabilidad determinar si la información que posees es reportable a la U.S. EPA o a otros organismos. No obstante, es tu responsabilidad notificar al Comité de Reporte de Consecuencias Adversas si crees que la información *puede ser* reportable conforme a las disposiciones de las leyes mencionadas más arriba. Una vez que se reciba, la información se analizará, y si corresponde, el Comité de Reporte de Consecuencias Adversas presentará un informe oficial a las agencias pertinentes, de acuerdo con las pautas para reportar. Te animamos también a platicar sobre esta información con tu supervisor.

Si tienes preguntas sobre la información que posees, ponte en contacto con el Comité de Reporte de Consecuencias Adversas a través de alguno de los siguientes medios:

- Simone Seifert-Higgins
- Por teléfono: (314) [redacted]
- Por la dirección de Outlook: ADVERSE, EFFECTS [AG/1000]
- Por: dirección de correo electrónico: effects.adverse@monsanto.com

<hairy cell leukaemia.docx>

Message

From: GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=527246]
Sent: 11/11/2014 8:19:51 PM
To: BIEHL, PATRICIA M [AG-Contractor/1045] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=208718]
Subject: RE: Ranger Pro Exposure

I will call him. The story is not making any sense to me at all.

Dan

From: BIEHL, PATRICIA M [AG-Contractor/1045]
Sent: Tuesday, November 11, 2014 2:12 PM
To: GOLDSTEIN, DANIEL A [AG/1000]
Subject: Ranger Pro Exposure

Spoke with Dewayne Johnson @ [redacted] and this is his story.

He told me he works for a school district in CA and about 9 months ago had a hose break on a large tank sprayer. This resulted in him becoming soaked to the skin on his face, neck and head with Ranger Pro. He said he was wearing a white exposure suit and it even went inside that. A few months after this incident he noticed a rash on his knee then on his face and later on the side of his head. He said he changed his laundry detergent, dryer sheets and used all creams available to him but nothing seemed to help. His entire body is covered in this now and doctors are saying it is skin cancer.

He is just trying to find out if it could all be related to such a large exposure to Ranger Pro since he stated his skin was always perfect until this happened. He is looking for answers.

Thanks in advance for your assistance.

Patricia Biehl
Product Support Specialist
314-[redacted]
800-768-6387
[redacted]@monsanto.com

Plaintiff Exhibit
0332

Human Exposure / Adverse Effect Incidents
Involving Monsanto Agricultural Products

Reporting Categories: H-A, H-B, H-C
Reporting Period: March 1, 2015 – March 31, 2015

Substance:	Ranger Pro Herbicide from Monsanto
Serial Number:	32283189
Date:	03/27/2015
Medical Outcome:	Major Effect H-B
EPA Reg. No.	524-517
Active Ingredients:	Glyphosate 41%
State:	California
History and Notes:	Caller states he has been using Ranger Pro as part of his job for 2 to 3 years. He has recently been diagnosed with cutaneous T cell lymphoma. He has concerns about continuing to use Roundup as part of his job and questions if Roundup could be a source of his cancer. As the call progressed, caller said that doctors are unsure as to how to treat his condition and they are not even sure if it is cancer. Caller states that he works with Ranger Pro using a 50 gallon tank and also using a backpack sprayer. He dilutes 10 ounces of the Roundup per gallon (3.0%) for the 50 gallon tank and 4 ounces of Roundup per gallon (1.25%) when using the backpack sprayer. He recalls having been exposed to Roundup twice in the past 2 to 3 years, both from the backpack leaking/malfunctioning. In one case, he was wearing personal protective equipment (PPE) but it soaked through the PPE and his clothing. Recently, he has had a swollen foot and the MD's cannot figure out what is going on. The caller's level of fear is rising over his continued use of Ranger Pro. He states he continues to get unexplained rashes and nodules over his body. MRPC discussed the product toxicity. The symptoms are not an expected response from the product. Advised MRPC is available, if the treating MD has any questions.



Message

From: KOCH, MICHAEL S [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=MSKOCH]
Sent: 5/11/2015 10:47:35 PM
To: HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=230737]; FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=180070]; HODGE-BELL, KIMBERLY C [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=KCHODG]; SALTMIRAS, DAVID A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=DASALT]
Subject: RE: Post-IARC Activities to Support Glyphosate

Bill,

I agree with everything you written and have a couple of suggested additions, please see green text below.

Thanks,

Mike

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Monday, May 11, 2015 5:36 PM
To: KOCH, MICHAEL S [AG/1000]; FARMER, DONNA R [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]; SALTMIRAS, DAVID A [AG/1000]
Subject: RE: Post-IARC Activities to Support Glyphosate

All,

Here is what I think I heard (and 1 question) in our meeting today – please send any corrections/additions

Conduct & publish Meta-analysis

- We will recommend proceeding with this

Publish updated AHS study data

- We will recommend proceeding with this
- David will check at HARC meeting next week if there is interest in CLA requesting data for all chemistries

Genetox/MOA

- Set-up 1 hr meeting with Gary Williams & Larry Kier to better understand what could be done (who had this action item?) I think this was Donna's action item.

Publication on Animal Data Cited by IARC

- It was noted that this is only other idea that could be done prior to IARC Monograph publication
- Manuscript to be initiated by MON as ghost writers
- It was noted this would be more powerful if authored by non-Monsanto scientists (e.g., [redacted] Kier, Williams, [redacted] and maybe Keith Solomon)
- Decide within 1-2 weeks if we will recommend going forward with this

Other Action Item

- Donna to talk with Elizabeth about value in sending letter to editor on Meta-analysis



- Check with Richard on status of Elizabeth's dietary exposure manuscript – Bill send email to Richard

Thanks,

Bill

-----Original Appointment-----
From: KOCH, MICHAEL S [AG/1000]
Sent: Friday, May 08, 2015 11:07 AM
To: KOCH, MICHAEL S [AG/1000]; HEYDENS, WILLIAM F [AG/1000]; FARMER, DONNA R [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]; SALTMIRAS, DAVID A [AG/1000]
Subject: Post-IARC Activities to Support Glyphosate
When: Monday, May 11, 2015 1:00 PM-2:00 PM (UTC-06:00) Central Time (US & Canada).
Where: Grow Room in D Building

A couple of you will need to leave at 1:50 to make a 2:00 pm meeting in C on Monday. This will be a weekly meeting; they were to be re-occurring but because everyone's calendar is almost full, I will probably have to make them separate days and times each week.

Chris on behalf of Mike Koch

Message

From: HEYDENS, WILLIAM F [AG/1000] [/o=Monsanto/ou=NA-1000-01/cn=Recipients/cn=230737]
on behalf of HEYDENS, WILLIAM F [AG/1000]
Sent: 3/17/2015 6:51:32 PM
To: MONKEN, JOSH [AG/1000] [/O=Monsanto/OU=NA-1000-01/cn=Recipients/cn=JMONKEN]
Subject: RE: CE Collaboration Project

Josh,

I was reminded of 5 more issues we faced in the early glyphosate days (mid-late 1980s):

- Low level presence of formaldehyde (carcinogen by inhalation) in Roundup
- Low level presence of NNG (N-nitroso-glyphosate) in Roundup – many N-Nitroso compounds are carcinogenic
- Many tox studies for glyphosate had been done at a lab ([redacted]
- EPA seriously questioned if glyphosate produced tumors in the chronic mouse study – glyphosate was put in Category D for carcinogenicity for several years – our detractors falsely spread the word that EPA considered glyphosate to have carcinogenic potential
- It was falsely said that glyphosate is an organophoshate (OP) molecule, and OPs produce neurotoxicity, thus glyphosate is a neurotoxin

Bill
William F. Heydens
Product Safety Assessment Strategy Lead
Phone: [redacted]

-----Original Appointment-----
From: MONKEN, JOSH [AG/1000]
Sent: Friday, March 13, 2015 11:29 AM
To: MONKEN, JOSH [AG/1000]; HEYDENS, WILLIAM F [AG/1000]
Subject: CE Collaboration Project
When: Tuesday, March 17, 2015 12:30 PM-1:00 PM (UTC-06:00) Central Time (US & Canada).
Where: Bill's Office

Bill,

I'm working with Corporate Engagement on a timeline project around historical sentiment against Monsanto. I talked earlier this week with Donna about glyphosate, Caroline Cox, NCAP, and some other history stuff, and would like to pick your brain a bit as well if you have a little time. Thanks!

Josh

Plaintiff Exhibit
0357

Message

From: SALTMIRAS, DAVID A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=DASALT]
Sent: 2/19/2015 11:35:16 PM
To: HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=230737]
Subject: Re: IARC Planning

... And it is an IARC category 1

Sent from my iPhone

On Feb 19, 2015, at 5:31 PM, "HEYDENS, WILLIAM F [AG/1000]" <[redacted]@monsanto.com> wrote:
David,

Thanks for the update/feedback from Roger. If he ultimately doesn't want to run it in CRT, I'm sure we can find some journal to take it.

Btw, I looked at the butadiene paper – it was 108 pages long!! I don't think we need (or want) to do anything that big. Butadiene had lots of stuff going on that glyphosate doesn't.

Bill

From: SALTMIRAS, DAVID A [AG/1000]
Sent: Thursday, February 19, 2015 4:01 PM
To: HEYDENS, WILLIAM F [AG/1000]; FARMER, DONNA R [AG/1000]
Cc: KOCH, MICHAEL S [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]
Subject: RE: IARC Planning

Bill et al.,

I had an extended chat with Roger this afternoon, as is the custom. He said that Critical Reviews has already dedicated some significant space to the glyphosate topic, especially the pending issue #3 with both the carc paper & Kier paper. However, to the contrary, he did say he'd consider something along the lines of the 1, 3 – butadiene issue... I think we would have to prepare a very compelling story.

David Saltmiras, Ph.D., D.A.B.T.
Science Fellow
Novel Chemistry and Microbials Product Lead
Toxicology and Nutrition Center
Monsanto
ph [redacted]

> **From:** HEYDENS, WILLIAM F [AG/1000]
> **Sent:** Thursday, February 19, 2015 7:53 AM
> **To:** FARMER, DONNA R [AG/1000]
> **Cc:** KOCH, MICHAEL S [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]
> **Subject:** RE: IARC Planning



Donna,

Per our phone call with John the other day, the next two most important things that we need to do are the Meta-analysis publication and the Ag Health Study Follow-up publication, assuming we can get our hands on the data in a reasonable timeframe. I feel confident that we will have organizational support for doing these projects, so I think we need to start setting them up now.

For the meta-analysis, please contact Elizabeth, let her know we would like her/Ellen to do this, and get a cost estimate from her.

For the AHS data, I heard 2 action items during our call: first - get with the lawyers to initiate the FOI process; second - contact [redacted] and get him lined up to do the analysis when we get the data; also, get a cost estimate from him.

For the overall plausibility paper that we discussed with John (where he gave the butadiene example), I'm still having a little trouble wrapping my mind around that. If we went full-bore, involving experts from all the major areas (Epi, Tox, Genetox, MOA, Exposure - not sure who we'd get), we could be pushing $250K or maybe even more. A less expensive/more palatable approach might be to involve experts only for the areas of contention, epidemiology and possibly MOA (depending on what comes out of the IARC meeting), and we ghost-write the Exposure Tox & Genetox sections. An option would be to add [redacted] and Kier or [redacted] to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000.

One thing we could do now on this is to contact Roger McClellan at CRC and see if they would be amenable to putting this publication in *Crit. Rev. Toxicol.* John said he knew that Roger had done such a publication in the past. David, since you have worked with Roger on the other papers, would you be willing to contact him to judge his willingness to publish such a paper?

Any other thoughts welcomed.

Bill

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Tuesday, February 17, 2015 4:53 PM
To: KOCH, MICHAEL S [AG/1000]; FARMER, DONNA R [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; [redacted] LISTELLO, JENNIFER J [AG/1000]
Cc: HEYDENS, WILLIAM F [AG/1000]
Subject: IARC Planning

All,

Attached is an updated spreadsheet for our IARC preparations.

Please let me know if you have any additions/corrections. Ongoing Activities are indicated by light blue fill color.

We did not have our IARC Planning meeting Monday due to the site being closed. However, Donna and I had a phone conference with John Acquavella today, and this resulted in several additions which are on page 4 of the attached Work Plan document.

Please let me know if you have other ideas or comments.

Thanks.

Bill

Message

From: HEYDENS, WILLIAM F [AG/1000] [/o=Monsanto/ou=NA-1000-01/cn=Recipients/cn=230737]
on behalf of HEYDENS, WILLIAM F [AG/1000]
Sent: 1/6/2016 10:46:07 PM
To: 'Ashley Roberts Intertek' [[redacted]@intertek.com]
Subject: RE: Glyphosate Expert Panel Manuscripts

Great – I will call you tomorrow AM – thanks!

From: Ashley Roberts Intertek [mailto:[redacted]@intertek.com]
Sent: Wednesday, January 06, 2016 4:22 PM
To: HEYDENS, WILLIAM F [AG/1000]
Subject: RE: Glyphosate Expert Panel Manuscripts

Hi Bill,

I am free tomorrow morning so give me a call anytime.

I am just going through the summary so hope to have this to you by COB on Friday. We can discuss the other aspects/questions tomorrow.

Best Wishes

Ashley

Ashley Roberts, Ph.D.
Senior Vice President
Food & Nutrition Group
Intertek Scientific & Regulatory Consultancy
Tel: +1 [redacted]
Fax: +1 [redacted]
E-mail: [redacted]@intertek.com



2233 Argentia Road, Suite 201
Mississauga, Ontario Canada L5N 2X7

From: HEYDENS, WILLIAM F [AG/1000] [mailto:[redacted]@monsanto.com]
Sent: January-06-16 5:08 PM
To: Ashley Roberts Intertek
Subject: Glyphosate Expert Panel Manuscripts

Hi Ashley,

Thanks for the updates on the Animal Bioassay and Summary chapters – I am not surprised at the challenges with the Summary chapter!

I wanted to update you on what I/we have been doing on our end.

Back in mid-December, I forwarded the final Epidemiology & Genotoxicity manuscripts from John & Larry to our resident expert report/manuscript preparation person here at Monsanto to put them in the format (including references) specified by *Critical Reviews in Toxicology*. The re-formatting was done and a number of questions came up (mostly on references), which I have sent back to Larry & John to resolve (John says he will be done tomorrow – no surprise).

During re-formatting of Epi & Genetox sections, the question came up about needing an Abstract for each chapter (currently none have Abstracts written). That makes sense for a single stand-alone publication, but I don't know if *CRT* will require an Abstract for each chapter when they publish a multi-chapter stand-alone Supplement? Or could we get by with 1 overall Abstract that goes with either the Introduction chapter or the Summary chapter? Do you have thoughts on that? Should we ask Roger McClellan?

I had already written a draft Introduction chapter back in October/November, but I want to go back and re-read it to see if it could benefit from any 're-freshing' based on things that have transpired over the last 10-12 weeks. I will do that in the next few days. Then I was thinking I would run it by you for your comments/edits. And then comes the question of who should be the ultimate author – you or Gary? I was thinking you for the Introduction chapter and Gary for the Summary chapter, but I am totally open to your suggestions.

That leaves the Exposure chapter from Keith – I am not totally sure where that stands – I vaguely recall that he was still going to make a few changes? I think you and I should talk about how that chapter gets completed, as it is not exactly what I was expecting. Do you have any time Thursday AM? I have a meeting 7:30-8:00 AM and 9:00-10:00 my time, but I could call you before/between/after those meetings. Alternatively, bright & early Friday morning? Let me know what works.

Thanks much,

Bill

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Message

From: FARMER, DONNA R [AG/1000] [/o=Monsanto/ou=NA-1000-01/cn=Recipients/cn=180070]
on behalf of FARMER, DONNA R [AG/1000]
Sent: 8/7/2015 6:52:42 PM
To: 'Ashley Roberts Intertek' [[redacted]s@intertek.com]
Subject: RE: Keith
Attachments: Document List.docx

Ashley attached is a list of document I will be sending you for the Animal Bioassay Expert Group.

If they need other references, publications please let me know.

Donna

From: Ashley Roberts Intertek [[redacted]@intertek.com]
Sent: Thursday, August 06, 2015 10:15 AM
To: FARMER, DONNA R [AG/1000]
Subject: RE: Keith
Importance: High

Thanks Donna,

Please could you let me know in a sentence what we will be providing to the Animal Bioassay Expert group. I just need this information to finalise an email to [redacted] regarding the Charge to this group. I would like to send this to him ASAP as I have a couple of messages with him I need to deal with. I can also let him know that this background information will be provided to him for circulation either tomorrow or next week.

Look forward to receiving your reply.

Best Wishes

Plaintiff Exhibit
0366

Ashley

Ashley Roberts, Ph.D.
Senior Vice President
Food & Nutrition Group
Intertek Scientific & Regulatory Consultancy
Tel: [redacted]
Fax:
E-mail: [redacted]@intertek.com

2233 Argentia Road, Suite 201
Mississauga, Ontario Canada L5N 2X7

From: FARMER, DONNA R [AG/1000] [redacted]@monsanto.com]
Sent: August-06-15 11:05 AM
To: HEYDENS, WILLIAM F [AG/1000]; Ashley Roberts Intertek
Subject: RE: Keith

If you look at the williams et al. there was an assessment of exposure of the POEA and I think the BfR did one as well. I will check.

Marian and I are meeting either today or tomorrow to talk about exposure and I will follow up with her.

Also Ashley I am pulling together the background info for the animal section and will sent that to you later today or tomorrow.

After I meet with Marian I will pull the exposure info together and get that off early next week.

I will be sending the documents to you via Intralinks Courier because of the large size of some of them.

> **From:** HEYDENS, WILLIAM F [AG/1000]
> **Sent:** Thursday, August 06, 2015 9:55 AM
> **To:** 'Ashley Roberts Intertek'; FARMER, DONNA R [AG/1000]
> **Subject:** RE: Keith

Ashley,
I think the short answer is no. The focus of this is what is the carcinogenic potential of glyphosate.

That said, the surfactant in the formulation will come up in the tumor promotion skin study because we think it played a role there.

-----Original Message-----
From: Ashley Roberts Intertek [redacted@intertek.com]
Sent: Thursday, August 06, 2015 09:47 AM Central Standard Time
To: FARMER, DONNA R [AG/1000]; HEYDENS, WILLIAM F [AG/1000]
Subject: Keith

Hi Donna/Bill,

Just received a question from Keith in response to my email message on the exposure piece this morning.

He has asked if we need to give any consideration to exposures of formulants in the commercial product, at least in applicators? I was under the impression these were inert but reading a response this morning in the Ecologist makes it sound like it is the combination that is toxic!!!

What do you think?

Thanks

Ashley

Ashley Roberts, Ph.D.
Senior Vice President
Food & Nutrition Group
Intertek Scientific & Regulatory Consultancy
Tel: [redacted]
Fax: [redacted]
E-mail: [redacted]@intertek.com

2233 Argentia Road, Suite 201
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Message

From: Ashley Roberts Intertek [redacted]@intertek.com]
Sent: 1/21/2016 4:00:44 PM
To: HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=230737]
Subject: FW: Genotoxicity Panel Final Manuscript
Attachments: Formatted Expert Panel Genotoxicity Paper V 6. 5 with final changes 1-21-16.doc

Hi Bill,

Please find attached the genetox report for your review.

I did receive back [redacted]'s comments on the animal bioassay report so just need to make sure everything is now covered along with the references abstract etc.

Best Wishes

Ashley

Ashley Roberts, Ph.D.
Senior Vice President
Food & Nutrition Group
Intertek Scientific & Regulatory Consultancy
Tel: +1 905-[redacted]
Fax: +1 905[redacted]
E-mail[redacted]@intertek.com

[redacted]

From: David Brusick [mailto:[redacted]com]
Sent: January-21-16 10:50 AM
To: Ashley Roberts Intertek
Cc: ldkier@q.com; [redacted] mjaardema@[redacted]@nymc.edu
Subject: Genotoxicity Panel Final Manuscript

Plaintiff Exhibit
0369
MONGLY01041641

Ashley

Attached is the final version of the Genetic Toxicology paper. It has been reviewed and approved by the panel members.

This version contains an Executive Summary, that may be unique to our report. It seems to fit nicely in the paper, but can be omitted if

the Journal editors feel it is inappropriate.

Please feel free to contact me if you have any questions or suggestions.

David Brusick

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Message

From: HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
Sent: 12/8/2010 10:17:48 PM
To: SALTMIRAS, DAVID A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=DASALT]
Subject: FW: Updated glyphosate activities presentation for Friday's CPTLT meeting
Attachments: Glyphosate Toxicology Activities #2.pptx

David,

I took a quick look and have a few comments in deck in red font. Let me know if you have any questions.

Also, add page numbers and "Monsanto Company Confidential" to slide deck.

Bill

From: SALTMIRAS, DAVID A [AG/1000]
Sent: Wednesday, December 08, 2010 11:17 AM
To: HEYDENS, WILLIAM F [AG/1000]
Subject: Updated glyphosate activities presentation for Friday's CPTLT meeting

Bill,

Updated and attached for your comment.

Thanks,

David Saltmiras, Ph.D., D.A.B.T.
Toxicology Manager
Regulatory Product Safety Center
Monsanto
ph [redacted]

Plaintiff Exhibit
0373

Glyphosate Toxicology Activities Supporting Registration Reviews

David Saltmiras, PhD, DABT

CPTLT December 10, 2010

Overview

- Pending glyphosate regulatory reviews
- Expert engagement
- Testing – voluntary and mandatory
- Publications– positioning ourselves with strong science against emotive research and politically pressured regulatory reviews
- Political Science

Glyphosate Registration/ADI Reviews

- EU Annex I Renewal
  - May 2012 dossier submission
- US EPA / Canada PMRA Registration Review
  - DCIs issued
- Japan ADI review
  - ~~on hold~~ Ongoing
  - MON data ADI = 0.75 mg/kg/day; Syngenta's = 1 mg/kg/day
- Brazil – formulation registrations & ADI review.....
- Regulators are increasingly more concerned with allegations arising in peer reviewed literature
- More balanced peer reviewed publications are needed to place poor science in context

EU Expert Panel

- EU Expert Panel established in mid 1990's to provide guidance from recognized experts in toxicology, pathology and epidemiology
- Recommended voluntary glyphosate testing strategies and scientific publications to support glyphosate regulatory reviews/ approvals and freedom to operate
- Funding to maintain a similar South American network of experts was withdrawn earlier this decade

EU Expert Panel Recommendation 1
Affirmed MON Study Proposal

- Evaluation of rat salivary gland hypertrophy
  - Arguably a driver in EU endpoint selection , ADI 0.3 mg/kg/day
  - Driver in JMPR (2004) endpoint selection , ADI 1.0 mg/kg/day
- JMPR (2004) determined salivary gland hypertrophy "of unknown toxicological significance"
  - Hypothesis of local oral irritation due to an organic acid in diets causes an adaptive response in rodents
- 8-week rat study
  - Dietary citric acid (low pH), sodium citrate (high pH) and gavage citric acid (bypassing oral cavity) Vs diet and gavage controls

Salivary Gland Study Results

- Statistically significant increase in parotid salivary gland weight in the low pH diet group
- Cytoplasmic alteration in the parotid salivary glands was most severe in the low pH diet group
- Considered an adaptive response rather than an adverse effect
- Future publication planned
- Opens opportunity to argue for increased glyphosate ADI in the European Union Again

EU Expert Panel Recommendation 2

- Context of two *In vitro* publications by the Seralini group
  - Gasnier et al. (2009), *Glyphosate-based herbicides are toxic and endocrine disruptors in human cell lines*
  - Benachour et al. (2009), *Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells*
- Professor , Uni. of Birmingham, UK
- Comparison of R400 and R400 formulation blank cytotoxicity to that of widely used generic detergents
  - Sodium dodecyl sulphate (SDS) – anionic detergent
  - Benzalkonium chloride (BC) – cationic detergent
  - Biosoft N-25 – non-ionic detergent

In Vitro Cytotoxicity Findings

- R400 and R400 blank have very similar toxicity profiles
  - Seralini assertion of "enhanced" glyphosate toxicity from surfactants is debunked; no synergistic effects
- Seralini R400 cytotoxicity data are repeatable
- Cell lines tested perform fairly similarly – suggests a non specific effect
- Rank order of cytotoxic potency
  - BC (cationic) > Biosoft (non-ionic)> SDS (anionic) ~ R400 = R400 blank
- Evidence that serum is protective as expected
  - Seralini stressed the *in vitro* systems with absence of serum
- Future publication(s) planned

THIS SLIDE HAS NOTHING TO DO

WITH REST OF DECK Testing – mandatory

- Immunotoxicity – US EPA Data Call In
  - In life complete and no issues
  - Immunoassay results due next week
- – US EPA Program
  - Test Orders: 11 "Screening" assays @ $1,000,000
  - OSRI Review: likely EPA rejection by end 2010
    - Head of retiring this year
    - Talk of industry law suit through the Endocrine Policy Forum
  - Coordinate testing through JGTF ToxTWG

Publications

- Williams et al. (2000) an invaluable asset
  - Monsanto responses to agencies
  - Scientific Affairs rebuttals
  - Regulator reviews
- More current external expert publications are now needed to support our FTO and Registration Reviews
  - EU Annex 1 Renewal requires extensive lit. review
  - Will weight of evidence be measured by number of publications or quality of the science???

Third Party White Papers

- Often critique methodology, interpretation of data and context of findings
- Kept in "back pocket"
- Response to Romano et al. (2010) *Prepubertal exposure to commercial formulation of the herbicide glyphosate alters testosterone levels and testicular morphology*
  - Exponent: Bill Kelce, Jim Lamb and John DeSesso
- Response to Bolognesi et al. (2009) *Biomonitoring of Genotoxic Risk in Agricultural Workers from Five Colombian Regions: Association to Occupational Exposure to Glyphosate*
  - Larry Kier

Publications in the works

- Letter to the Editor of Chemical Research in Toxicology
  - Carrasco publication; Paganelli et al. (2010) *Glyphosate-Based Herbicides Produce Teratogenic Effects on Vertebrates by Impairing Retinoic Acid Signaling*
  - Currently undergoing internal Monsanto review
  - HARC Letter to Editor addressing industry data integrity
- Jack Mandel – epidemiology cancer endpoints currently in peer review
- Jack Mandel – epidemiology non-cancer endpoints
- John DeSesso – reproductive and developmental toxicity and endocrine disruption, final Monsanto review next week
- Adaptive responses of the salivary glands to an acidic diet. Eurotox presentation and manuscript for publication

Proposed Publications – funding?

- – independent review of Agricultural Health Study (epidemiology) for rebuttals to claimed associations of health effects with glyphosate exposure
- Epidemiology methods paper – to provide a concise reference for critique of poor epidemiological methods
- – *in vitro* cytotoxicity evaluations of surfactants. Eurotox presentation and manuscript for publication

Proposed Publications cont.

- Larry Kier – Glyphosate genetox overview (post-2000)
  - Note: is on the EFSA Scientific Panel on Plant Protection products and their Residues (PPR Panel)
  - The Panel works closely with the Pesticide Risk Assessment Peer Review (PRAPeR) which is responsible for the EU- peer review of active substances used in new or existing plant protection products.
  - http://www.efsa.europa.eu/en/ppr/aboutppr.htm
- – *in vitro* exposures and the relevance to human health risk assessment. Evaluating published doses Vs human serum levels
- – dietary exposure assessment for European regions

Political Science

- Unfortunately, we are facing regulatory reviews with increased focus on
  - Claims in the peer reviewed literature, irrespective of the quality of the science
  - Stakeholder input including activist researchers
  - Political pressure on outcomes – e.g. POEAs in Germany
  - Reduced pesticide use in general
- Williams et al. (2000) has served us well in toxicology over the last decade
- We need a stronger arsenal of robust scientific papers to support the safe use of our products as we face the next set of chemistry registration reviews across the globe
- With increasing business interests in South America, a local network credible expert scientists is crucial to facilitate scientifically robust and objective regulatory evaluations of our products *We have not determined exactly what we should & could do here. I would modify bullet to reflect that we need to determine an appropriate & do-able (i.e., we can get someone to pay for it course of action here*

Message

From: HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
Sent: 5/26/1999 2:09:18 PM
To: [redacted]@monsanto.com]
Subject: RE: FW: SCIENTIFIC OUTREACH COUNCIL MEETING

[redacted]

I thought you were in the loop on what Jerry was trying to accomplish with setting up this 'Scientific Outreach Plan'. It's somewhat difficult to explain over e-mail, as the Plan is forming and evolving as we go along. But basically, Jerry wants to make sure we have the people and information in place to resolve issues related to biotechnology, including Roundup. An underlying concept is that our opponents are extremely well Networked but we are not.

Western Europe is the first priority for obvious reasons, but the plan is to cover the whole world.

Elements of the network/plan include, but are not necessarily limited to:

1) Monsanto people who are responsible for dissemination and coordination of scientific information within and outside of Monsanto. They will also play a role in establishing & 'managing' relationships with outside experts. Some of these will be full-time dedicated headcount and some will be part-time (the good ol' Monsanto way of doing things - give people an extra job). Initially, Jerry talked about adding 4 full time people to Europe for this role and 1 in STL - I don't know if this has changed. It is my understanding that [redacted] will have an overall coordination role for Western Europe.

2) Outside scientific experts who are influential at driving science, regulators, public opinion, etc. We would have they people directly or indirectly/behind-the-scenes work on our behalf.

3) Presentations/publications in the scientific literature. Get our data out there so it can be referenced and used to counter-balance the negative stuff. In some cases, we may want to publish specific work in certain world areas to help out in that region. We may use our experts as authors (eg. the CanTox project in which you were fortunate enough to participate).

4) Projects/studies to generate critical, lacking data.

I would really like you to participate so you can critically evaluate if we are doing the right things. As a seasoned veteran who is on the ground in the middle of this mess, you are in the best position to provide thoughts and ideas. If you think we have Roundup reasonably covered, then fine. But we need to go through the process of making a systematic, detailed analysis and document it to adequately support such a conclusion.

As far as how we get "people to get up and shout Glyphosate is Non-toxic", I think Jerry recognizes this will be different in specific situations/locations. The key here is to determine what is best in Western Europ and then do it.

Prior to the phone conference, I'll send out what ideas and ongoing projects we have so far. Hopefully this will stimulate some thinking and make the task easier.

Thanks.

Bill

-----Original Message-----
From: [redacted]
Sent: Monday, May 24, 1999 1:15 PM
To: HEYDENS, WILLIAM F [FND/1000]
Subject: RE: FW: SCIENTIFIC OUTREACH COUNCIL MEETING

> It is difficult to understand what is the purpose without knowing the goals/remit of this group. As far as I know [redacted] and [redacted] know the key scientists, so I do not know if I add much. In fact many Eurpean scientific advisors zealously guard their independance and the only way to them is through their research work.
>
> On the tox front we have access routes to [redacted] Jim Parry.With John Jacksons and [redacted] networks we seem pretty tight on the regulatory defence front.

Plaintiff Exhibit
0378

If we want people to get up and shout Glyphosate is Non-toxic then I think we may have to divorce Monsanto from direct association with the expert or we will waste the $1000/ day these guys are charging.

[redacted]

---------- Reply Separator ----------
Subject: FW: SCIENTIFIC OUTREACH COUNCIL MEETING
Author: WILLIAM F HEYDENS at Exchange
Date: 24/05/99 16:52

All,

At the last Scientific Outreach Council Meeting (meeting minutes from Ed Debus attached), Jerry Hjelle requested that we put together a plan/strategy for Glyphosate in Western Europe. Toward that end, I would like to set up a conference call so we can begin to scope this out.

Please send your availability to my administrative assistant, Cam Verdin, for the afternoon (Europe) of the following dates so we can set something up:

May 27-28
June 1 - 4
June 7-10

Thanks.

Bill

-----Original Message-----
From: EDWARD E DEBUS
Sent: Friday, May 07, 1999 5:00 PM
To: JERRY J HJELLE; MARGARET MORRIS; ROY L FUCHS; THOMAS W FUHREMANN; GEORGE B FULLER; JAMES D ASTWOOD; MONTE A MARSHALL; RASHMI S NAIR; WILLIAM F HEYDENS; MICHAEL J MCKEE; MARIAN S BLEEKE; [redacted]; HARRIETT H BUTCHKO; [redacted]; THOMAS NICKSON
Subject: SCIENTIFIC OUTREACH COUNCIL MEETING

All, attached are detailed notes from the May 6 Global Scientific Outreach Council meeting (GSOC). Hopefully folks not able to attend will be able to get a sense of the discussion. I may not have the Council address list complete, please let me know who may be missing.

If there are still corrections/missings for the notes, please let me know. I designated leads for the various action items, for some I knew, for others I guessed to get the ball rolling, know you will let me know if you are not on the hook!! Please correct as appropriate. After further discussions with most of you, I will add target dates to the action list.

If there is a need for corrections, clarifications, please let me know. We all agreed this is crticially important to continue to build and get into action.

A summary of Action Items/leads follows:

* Job description for the SO person for GErmany/Germanic countries - [redacted]/Tom N.

* Glyphosate strategy/plan for Western Europe - [redacted]/ Bill H.

* Circulate charter of environmental issues team - Monte/Ed

* Draft Glyphosate Epidemiology white paper/assessment of HArdell work - Bill H.

* Set up next meeting of council - Ed (Look for first week of June)

* Survey IARST regarding current SO needs - George

* Implement CE/CIS program - [redacted]/Constantin

* Engage Mark Holland to connect to LRP efforts - ED

* Prepare SO plan for Indian Continent - Rashmi/George

* Talk with Searle Information specialist - MAggie

* Suggested Candidates for US information coordinator position to Maggie - all

* Propose new SO model/Counterproposal considering needs in Asia/Latin America - George/Rashmi

* Prepare list of internal experts - Ed (If one exists please send to Ed)

* Formulate draft goal document for Asia and Latin America - George

* Copy of draft animal feed manuscript to Jerry ASAP- Jim (Send final draft to Ed when completed)

* Draft goal/scope document to enhance product benefit information - Monte/Ed

* Compile a Global SO Goals document, including 1999/2000 budget information - first draft in 1 month - Ed/All

Message

From: LINK, KIMBERLY KAY [AG/1000] [redacted]@monsanto.com]
Sent: 2/12/2015 10:13:27 PM
To: FARMER, DONNA R [AG/1000] [redacted]@monsanto.com]; HEYDENS, WILLIAM F [AG/1000] [redacted]@monsanto.com]
Subject: Revised IARC reactive messaging
Attachments: Glyphosate Key Points on IARC Decision 2B (draft 2-12-15B).docx

Attached please find revised messaging for IARC. This is an ever-evolving document. Thank you for your continued input. Kelly Clauss said she gained acceptance from CropLife International to speak out for the entire industry if the decision is a 2B in March. That plus the JGTF and academics and we should be in good shape for the reactive plan.

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Glyphosate Key Points Following IARC Decision

Draft 2/12/15

This component represents the orchestrated outcry that could occur following the March 3-10 IARC monograph expert meeting. The following reactive communications efforts would be deployed if glyphosate receives an unfavorable 2B classification. A series of positive communication efforts already will have occurred leading up to the meeting. The proposed approach suggests industry associations and credible third parties lead, and Monsanto plays a secondary role to defend its Roundup brand.

2B Decision

Key Industry Points:

- We disagree with the decision made by IARC. Comprehensive assessments of the scientific evidence that spans four decades prove that glyphosate does not cause cancer.
- The 2B classification does not establish a link between glyphosate and an increase in cancer. "Possible" simply means not impossible. 2B substances can include "agents for which there is limited evidence of carcinogenicity in humans and lack of sufficient evidence of carcinogenicity in experimental animals."
    - It's important to put this 2B classification into perspective. Many common exposures are classified in Category 2B, including coffee, alcohol and pickled vegetables.
- Unlike regulatory reviews that consider all available data, IARC narrows its review to only publicly available data. [or] In contrast to the IARC process, regulatory authorities in developed countries consider all available data, published and unpublished, in a comprehensive evaluation.
- IARC based its decision on a limited data review, which included one study co-authored by two members of IARC – the same study that at least four expert epidemiologists later identified as flawed.
- Many experts, including the World Health Organization and most recently the German BfR, have determined with a high degree of science-based confidence that glyphosate does not pose an unreasonable risk to humans and is non-carcinogenic.
    - In fact a new scientific study published in 2014 by the German Federal Institute for Risk Assessment (BfR) showed no link between glyphosate exposure and cancer.
    - The U.S. EPA assigned glyphosate to pesticide category E based on its safety profile "evidence of non-carcinogenicity for humans."
- All glyphosate-based herbicides on the market meet regulatory and health authorities' high margin of safety for the public, including infants and children.
- There is no biological rationale for glyphosate presenting a chronic health risk because the herbicide targets an enzyme found in plants that does not exist in humans or animals.

European Joint Glyphosate Task Force / Public Acceptance Group

- The decision by IARC was made without the benefit of the extensive and relevant data base generated for and evaluated by the Regulatory Authorities of OECD countries.
- The regulatory authorities of OECD countries on reviewing all of the available data, published and unpublished, have consistently concluded that glyphosate does not cause cancer in either animals or humans.

Academics

- IARC has done the public a disservice by creating baseless fears with a cancer rating for glyphosate, and the confusing classification is certainly open to distortion by alarmists.
- The limited evidence on which the IARC findings are based are far from conclusive.
- Given the way IARC works, their decision was predictable and political. The suggested classification is essentially meaningless because it was made without the benefit of the extensive and relevant database and it is believed that a key piece of information was a report authored by IARC itself.
- Government regulators remain reassuring about the potential risks. For example, the U.S. EPA is currently reviewing glyphosate and is obligated to act immediately if they shared concerns of a possible cancer causing agent. Instead the EPA is continuing with its routine risk assessment.
- Glyphosate has gotten a longstanding endorsement from the World Health Organization (WHO) based on decisions grounded in science.
- The IARC paper and its panel's decision are contrary to 40 years of scientific consensus on the safety profile of glyphosate.
- [*Fact check: The rating by IARC is not the end. The WHO will conduct its own science-based assessment, and the expected outcome is a conclusion of noncancerous that echoes its previous decisions and follows broad scientific consensus.*]

American Cancer Society, European Association of Cancer Education and/or Research

- It is critical that the IARC panel's findings be interpreted with great care. The evidence, based on scientific studies spanning 40 years, does not demonstrate that glyphosate causes cancer in animals or humans.
- It's important to put this 2B classification into perspective. Many common exposures are classified in Category 2B, including coffee, alcohol and pickled vegetables.

Monsanto Company statement to supplement industry and third-party messaging

Thank you for contacting us.

Product safety is of paramount importance to Monsanto. Comprehensive toxicological studies repeated over the last 40 years have time and again demonstrated that glyphosate, the active ingredient in Roundup® branded agricultural herbicides, does not cause cancer. This IARC classification is based on a limited literature review and is contrary to four decades of previous scientific conclusions, including the 2014 German risk assessment that found no link between glyphosate exposure and cancer. (Link to Jan/Feb BfR news statement)

To learn more about glyphosate, visit Monsanto.com/glyphosate and glyphosate.eu.

In addition to the prepared media statement, Monsanto will issue the following materials to ensure the facts are presented.

- Monsanto Beyond the Rows blog title: What the IARC 2B Rating for Glyphosate Really Means
- Add new web page on Monsanto.com/glyphosate dedicated to glyphosate and cancer with links to studies, BfR opinion in English and German
- Encourage physician to talk about glyphosate and cancer for op/ed

Grower Groups

- Glyphosate is one of the most studied pesticides on the market, yet it's under political attack.
- An agency in France, IARC, classified glyphosate as a "possible carcinogenic" substance based on a limited data review.
- This is a clear case of anti-pesticide fear overtaking science-based logic.
- The rating by IARC is based on limited information that included one joint paper authored by IARC itself. However 40 years of science-based evidence indicates glyphosate does not cause cancer. This includes the 2014 German assessment on behalf of the EU that conducted a full periodic review.
- Currently regulatory agencies in several countries are reviewing the registration and approved uses of glyphosate. We encourage growers to submit comments to regulatory agencies, such as the U.S. EPA, during the public comment period and share the many benefits and economic impact of glyphosate.
- Growers are encouraged to post, share and tweet a copy of your letter to EPA to amplify your point of view and help educate the public on the importance of glyphosate to modern agriculture.

Scotts/ Major Retailers

- It is critical that the IARC panel's findings on glyphosate (a major active ingredient in Roundup® brand herbicides) be interpreted with great care. The evidence, based on scientific studies spanning 40 years, does not demonstrate that glyphosate causes cancer in humans or animals.
- IARC conducts a limited data review, which is different than the comprehensive database review that public health authorities undertake.
- It's important to put this 2B classification into perspective. Many common exposures are classified in Category 2B, including coffee, alcohol and pickled vegetables.
- Roundup remains a trusted solution within our lawn and garden product offering.

Message

From: MURPHEY, SAMUEL [AG/1000] [samuel.murphey@monsanto.com]
Sent: 5/2/2016 7:36:19 PM
To: JENKINS, DANIEL J [AG/1920] [daniel.j.jenkins@monsanto.com]
Subject: Re: Urgent review -- Draft press release

Oh god -- the ET, not EPA

Sent from my iPhone

On May 2, 2016, at 2:35 PM, "JENKINS, DANIEL J [AG/1920]" <daniel.j.jenkins@monsanto.com> wrote:

Sending to EPA?

Dan Jenkins
U.S. Agency Lead
Regulatory Affairs
Monsanto Company
1300 I St., NW
Suite 450 East
Washington, DC 20005
Office: [redacted]
Cell: [redacted]

From: MURPHEY, SAMUEL [AG/1000]
Sent: Monday, May 02, 2016 3:32 PM
To: HEYDENS, WILLIAM F [AG/1000]; JENKINS, DANIEL J [AG/1920]; LISTELLO, JENNIFER J [AG/1000]; REBMAN, JOHN [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]; STUMP, JEREMY [AG/1920]; KUSCHMIDER, SCOTT [AG/1920]; HEERING, DAVID C [AG/1000]; DUNCAN, MELISSA S [AG/1000]; REEVES, WILLIAM R [AG/1000]
Cc: WAGGONER, COLE [AG/1000]; LORD, CHARLA MARIE [AG/1000]; DIXON, CHRISTI M [AG/1000]; STUART, DANIELLE C [AG/1000]
Subject: RE: Urgent review -- Draft press release

Bill and I just chatted. He's comfortable adding this line to the release: Results from any further studies would not change the conclusion that glyphosate is not carcinogenic.

He has verified everything technically. I am sending the release to EPA for review now.

Regards,

Sam

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Monday, May 02, 2016 2:26 PM

Plaintiff Exhibit
0382

To: MURPHEY, SAMUEL [AG/1000]; JENKINS, DANIEL J [AG/1920]; LISTELLO, JENNIFER J [AG/1000]; REBMAN, JOHN [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]; STUMP, JEREMY [AG/1920]; KUSCHMIDER, SCOTT [AG/1920]; HEERING, DAVID C [AG/1000]; DUNCAN, MELISSA S [AG/1000]; REEVES, WILLIAM R [AG/1000]
Cc: WAGGONER, COLE [AG/1000]; LORD, CHARLA MARIE [AG/1000]; DIXON, CHRISTI M [AG/1000]; STUART, DANIELLE C [AG/1000]
Subject: RE: Urgent review -- Draft press release

Not quite – I don't see that they reviewed the Feinchemie/Adama mouse onco study, and they didn't review the full reports for 2 other mouse studies and 3 rat onco studies (they read the Greim et al review of those studies).

From: MURPHEY, SAMUEL [AG/1000]
Sent: Monday, May 02, 2016 2:17 PM
To: JENKINS, DANIEL J [AG/1920]; LISTELLO, JENNIFER J [AG/1000]; REBMAN, JOHN [AG/1000]; HEYDENS, WILLIAM F [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]; STUMP, JEREMY [AG/1920]; KUSCHMIDER, SCOTT [AG/1920]; HEERING, DAVID C [AG/1000]; DUNCAN, MELISSA S [AG/1000]; REEVES, WILLIAM R [AG/1000]
Cc: WAGGONER, COLE [AG/1000]; LORD, CHARLA MARIE [AG/1000]; DIXON, CHRISTI M [AG/1000]; STUART, DANIELLE C [AG/1000]
Subject: RE: Urgent review -- Draft press release

Bill H. – can we say that EPA reviewed the "totality of carcinogenicity data on glyphosate"?

From: JENKINS, DANIEL J [AG/1920]
Sent: Monday, May 02, 2016 2:15 PM
To: MURPHEY, SAMUEL [AG/1000]; LISTELLO, JENNIFER J [AG/1000]; REBMAN, JOHN [AG/1000]; HEYDENS, WILLIAM F [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]; STUMP, JEREMY [AG/1920]; KUSCHMIDER, SCOTT [AG/1920]; HEERING, DAVID C [AG/1000]; DUNCAN, MELISSA S [AG/1000]; REEVES, WILLIAM R [AG/1000]
Cc: WAGGONER, COLE [AG/1000]; LORD, CHARLA MARIE [AG/1000]; DIXON, CHRISTI M [AG/1000]; STUART, DANIELLE C [AG/1000]
Subject: RE: Urgent review -- Draft press release

Is there a statement that can be added to further head off arguments supporting a need to still do an SAP? Got it that they reviewed what IARC did and then some, but again, I think EPA would come back saying there is still more data to review (that you provided us recently as you can see in the docket) since this report was written and thus we still need to do this.

What can we say to the effect of there is no additional data to review re carcinogenicity or that any additional data that could be reviewed would not change the conclusions in the report because…

Dan Jenkins
U.S. Agency Lead
Regulatory Affairs
Monsanto Company
1300 I St., NW
Suite 450 East
Washington, DC 20005
Office: [redacted]
Cell: [redacted]

From: MURPHEY, SAMUEL [AG/1000]
Sent: Monday, May 02, 2016 2:59 PM
To: LISTELLO, JENNIFER J [AG/1000]; REBMAN, JOHN [AG/1000]; JENKINS, DANIEL J [AG/1920]; HEYDENS, WILLIAM F [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]; STUMP, JEREMY [AG/1920]; KUSCHMIDER, SCOTT [AG/1920]; HEERING, DAVID C [AG/1000]; DUNCAN, MELISSA S [AG/1000]; REEVES, WILLIAM R [AG/1000]
Cc: WAGGONER, COLE [AG/1000]; LORD, CHARLA MARIE [AG/1000]; DIXON, CHRISTI M [AG/1000]; STUART, DANIELLE C [AG/1000]
Subject: Urgent review -- Draft press release
Importance: High

Team –

Attached is a draft press release regarding the CARC report. Please review and provide comments ASAP. I apologize for the short timeframe, but it would be very helpful to have technical and legal comments by 2:30 p.m. CDT if at all possible so that we can get this to senior leadership for review.

Please call or email with any questions.

Regards,

Sam

HEYDENS, WILLIAM F [AG/1000]

From: [redacted]
Sent: Monday, February 01, 2010 2:51 AM
To: HEYDENS, WILLIAM F [AG/1000]; [redacted]
Subject: RE: KP conversation on POEA
Attachments: RE: CAER update conference call

Sensitivity: Confidential

Bill,
Yes we will defend the regulatory principles and process to defend POEAs. However, we are heavily pushed into a corner by the BVL. The ideal outcome is a quid pro quo. We get a quicker approval of Zanussi/new dry, so they achieve their need to get the politicians (or whoever it is) off their backs. And they accept a proper risk evaluation procedure (which is the direction they have gone again, having been knocked off course at Christmas) in which we choose to carry out the new tests, or not. See attachment for proposed studies received on Friday. We will also promote proportionate regulation - requiring these studies only for PEA in glyphosate products is clearly disproportionate and inconsistent.

We will meet with the head of the pesticide unit at the Commission later this month, and this will be one of the agenda items

Regards
[redacted]

Reasons for defending Tallowamines

-----Original Message-----
From: HEYDENS, WILLIAM F [AG/1000]
Sent: 30 January 2010 23:51
To: [redacted]
Subject: RE: KP conversation on POEA
Sensitivity: Confidential

#1

I cede to [redacted]'s knowledge of the situation in Germany/EU.

A couple comments. First, There is still a strong sentiment in STL that we need to continue to defend tallowamines even though we prepare to switch over because of their impending demise. Reasons to do so: "domino effect" on etheramines; defend other world areas to the best of our ability. Second. I was in Brazil all last week - they are very worried about this coming across the Atlantic to their part of the American hemisphere.

Bill

#2

-----Original Message-----
From: [redacted]
Sent: Monday, January 25, 2010 12:36 PM
To: [redacted]HEYDENS, WILLIAM F [AG/1000]
Subject: Re: KP conversation on POEA
Sensitivity: Confidential

Plaintiff Exhibit
0383

MONGLY02062439

[redacted]

Good summary. Thank you.

Re-your 2 other points;:
* clean results in new akzo studies will be inconsequential - the results of the existing studies are what we would expect, and there are all those [redacted] claims to fall back on to keep the concerns going.. Anyway, there are non-hazardous formulations so why sell a hazardous one?
* how can you ban just glyphosate products - easy, glyphosate is safe so they have to regulate based on the most toxic part of the formulation. But, yes, there are a lot of logic problems and disproportionate regulation issues here.

Regards
[redacted]

----- Original Message -----
From: [redacted]
To: [redacted] HEYDENS, WILLIAM F [AG/1000]
Sent: Mon Jan 25 18:07:38 2010
Subject: KP conversation on POEA

FYI I jotted these down when KP asked about POEA during a Data Protection conversation. I think I held the party line.

- Why are they doing it? Political with a touch of Hazard not Risk and Comparative assessment)

- how should we react? Prepare for worst case, defend the principles on tallowamine or we could lose etheramine. Get Akzo to look at any legal options.

- Will it spread - If Germany goes who else? German followers plus Scandinavia, probably not science based UK /Ireland or France.

- What is Akzo's agenda - do they have a better value added replacement? No idea

- Full speed on replacement? Yes it is the sensible option

- How quickly can it be done? It should be a new formulation but under the circumstances we can always ask for speedy review of an unrelated replacement.

My thoughts (not discussed)

What happens when Akzo comes up with clean results in their 2 ecotox studies.

How can you just ban it in Glyphosate products and not other pesticides or personal health care (is it really widely used or is that an Akzo smokescreen?)

[redacted]

[redacted]@monsanto.com

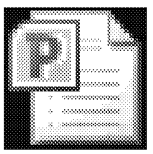
+44 [redacted]

Message

From: HEYDENS, WILLIAM F [AG/1000] [/o=Monsanto/ou=NA-1000-01/cn=Recipients/cn=230737]
on behalf of HEYDENS, WILLIAM F [AG/1000]
Sent: 5/11/2015 12:43:25 PM
To: KOCH, MICHAEL S [AG/1000] [/O=Monsanto/OU=NA-1000-01/cn=Recipients/cn=MSKOCH]; FARMER, DONNA R [AG/1000] [/o=Monsanto/ou=NA-1000-01/cn=Recipients/cn=180070]; HODGE-BELL, KIMBERLY C [AG/1000] [/O=Monsanto/OU=NA-1000-01/cn=Recipients/cn=KCHODG]; SALTMIRAS, DAVID A [AG/1000] [/O=Monsanto/OU=NA-1000-01/cn=Recipients/cn=DASALT]
Subject: RE: Post-IARC Activities to Support Glyphosate
Attachments: Post-IARC Meeting Science Proposals.pptx

All,

See attached, which reflects the results of conversations Donna & I had with various stakeholders (e.g., Law, CE, RPSA). This will be the basis of our discussion today. Thanks.



-----Original Appointment-----
From: KOCH, MICHAEL S [AG/1000]
Sent: Friday, May 08, 2015 11:07 AM
To: KOCH, MICHAEL S [AG/1000]; HEYDENS, WILLIAM F [AG/1000]; FARMER, DONNA R [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]; SALTMIRAS, DAVID A [AG/1000]
Subject: Post-IARC Activities to Support Glyphosate
When: Monday, May 11, 2015 1:00 PM-2:00 PM (UTC-06:00) Central Time (US & Canada).
Where: Grow Room in D Building

A couple of you will need to leave at 1:50 to make a 2:00 pm meeting in C on Monday. This will be a weekly meeting; they were to be re-occurring but because everyone's calendar is almost full, I will probably have to make them separate days and times each week.

Chris on behalf of Mike Koch

Plaintiff Exhibit
0391

Proposal for Post-IARC Meeting Scientific Projects

DRAFT

May 11, 2015

Why do more?

- Severe stigma attached to Group 2A Classification
- Aaron Blair continues to defend work & exaggerate number of studies w/ association while ignoring AHS
- In response to our critique, can expect IARC to beef-up monograph as much as possible
- IARC plans to pool data globally in the future
  - Blair announced at meeting that he has already put together an unofficial work group to begin the process
  - North American Pooled Project (NAPP) already underway and early results reported in 2014
  - Believe this will be used to move pesticides to Group 1
- Provide additional support ('air cover') for future regulatory reviews
  - Broad EU review recently recommended by BfR
  - Other regulatory agencies stated they will review after Monograph publishes
- ASTDR evaluation
- [redacted]
- Litigation support

Counter IARC's selective use of data and flawed analyses/conclusions on Epidmiology, Animal Bioassays, and Genotoxicity (Mode of Action); Prevent future adverse outcomes

Possibilities:

- Conduct and Publish new Meta-analysis
- Publication on Animal Data Cited by IARC* *New*
- Publish updated AHS study data
- Publish WoE/Plausibility Paper
- Genetox/MOA

New Meta-analysis

- **Project Description**
  - Conduct proper meta-analysis to support the position that glyphosate is NOT associated with NHL and multiple myeloma
  - Publish separately & can be used in overall WOE/Plausibility publication (below)
  - Could be completed/published prior to IARC Monograph
- **Risk**
  - None, since we have already done the analysis
- **Cost**
  - $32K plus any translation costs

[Timing – Donna checking w/ Exponent, but currently estimate 3-4 months to write plus 2+ months to get online publication]

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Publication on Animal Carcinogenicity Data

- **Project Description**
  - Publication on Animal Data Noted by IARC as Evidence for Carcinogenicity
  - Studies/Tumors Involved:
    - Mouse kidney tumors – subject of claims that Monsanto convinced EPA to change conclusions
    - Haemangiosarcoma in mice (Cheminova), pancreatic islet cell tumors in 2 rat studies (Monsanto) – multiple regulatory reviews conducted, including WHO/FAO
    - Publication on Initiation-promotion study with Roundup®
  - Greim & 1or 2 other external authors?
  - Could be completed/published prior to IARC Monograph
  - Could we add Japan data (TAC, Mitsui (formerly Sankyo)? Would likely increase timeline
- **Cost**
  - Majority of writing can be done by Monsanto, keeping OS$ down

AHS Collaboration

- **Project Description**
  - Submit proposal to AHS to collaborate on project to add last several 10 years of data & publish
  - Do with expert academicians – (e.g., Tom Sorahan, Tim Lash, David Coggin)
- **Risk – low**
  - We already know data is 'negative' through 2008/2009 (Freeman *et al*, 2009)
  - AHS certainly would have already published any "+"
  - Write stringent protocol ahead of time
  - 'Seasoned' rational experts would be doing the analysis not just post-docs from AHS who need to 'make a mark'
- **Downside**
  - Longer term project – won't get quick results
  - AHS Executive Committee may decline
    - Plan B -> FOI Request
- **Cost**
  - Total ~$75K; initial cost to make proposal substantially less

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Overall WOE/Plausibility Publication Possibly via Expert Panel Concept

- **Project Description**
  - Publish comprehensive evaluation of carcinogenic potential by credible scientists
- **Possible Panelists/Authors**
  - Solomon? (Exposure), Sorahan (Epidemiology), Greim? (Animal bioassay), G. Williams, Kirkland? (Genetox/MOA), Sir Colin Barry, Jerry Rice (ex-IARC head)
- **Cost**
  - $200 – 250 K, depending on:
    - Who/how many scientists we include
    - How much writing can be done by Monsanto scientists to help keep costs down
  - Alternative: 1 or 2 separate publications w/ subset of authors?

Genetox / MOA

- Counter IARC's claim of strong evidence of DNA damage/oxidative stress
- Could be important for future litigation support
- Gary Williams (NY Medical College) - Use gene expression to firm-up non-genotoxic MOA in positive *in vitro* studies with formulations
- Contact Rich Irons?

Feedback

Conduct and Publish new Meta-analysis

- ***Legal*** – value not apparent
- ***RPSA*** – 'No-Brainer'
- ***CE*** – Makes sense; have pre-release and/or present at scientific meeting before publication; RPSA needs to work on explaining to public
- ***Brussels RA*** – clear value; get out before IARC Monograph

Publish updated AHS study data

- ***Legal*** – most appealing; MON somewhat distanced & AHS involved
- ***RPSA*** – 'No Brainer'; add 2,4-D & dicamba?
- ***CE*** – Makes sense; have pre-release and/or present at scientific meeting before publication; RPSA needs to work on explaining to public
- ***Brussels RA*** – clear value; agree w/ RPSA; get out before IARCMonograph if possible (not likely)

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Feedback

Publish WoE/Plausibility Paper

- ***Legal*** – Appealing; best if use big names; better if sponsored by some group
- ***RPSA*** – How helpful to regulators? Could we do totally independent?
- ***CE*** - If done, real value in having 3rd party manage process; add a couple MDs; work with Shawna to have a couple key stakeholders (e.g., GMA) watch/hear the proceedings & take back to their communities
- ***Brussels RA*** – less clear benefit; will it really 'trump' IARC in needed circles?

Genetox/MOA

- ***Legal*** – cannot assess value
- ***RPSA*** – Need to address this; include household surfactants
- ***CE*** – no real comment
- ***Brussels RA*** – agree with RPSA; also finish Nik Hodges study

Additional Suggestions from CE

- Get someone like Jerry Rice (ex-IARC) to publish paper on IARC
  - How it was formed, how it works, hasn't evolved over time, they are archaic and not needed now
- Exposure paper that shows how exposure is really, really low!
- Form Crop Protection Advisory Group?
  - Includes nutritionist, MDs along with traditional science groups; include a NGO?
  - Internal contacts = Mike Parish/ Matt Helms, Kelly Fleming, Cvance Crow, Janice Persons
- Communication Plans
  - Need to build in right plans for all steps/actions, including plan that works for millenials; start as early as possible

Message

From: John Acquavella [redacted].com]
Sent: 11/4/2015 4:57:23 PM
To: HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=230737]
CC: FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=180070]
Subject: Re: John,Glyphosate Expert Panel Poster at 2015 SRA Annual Meeting

Hi Bill/Donna:

The time is fine for me. It is 11:30 AZ time (AZ is on mountain time in the fall/winter and Pacific time in spring/summer).

You guys know me. I can't be a part of deceptive authorship on a presentation or publication. Please note the ICJME guidelines below that everyone goes by to determine what is honest/ethical regarding authorship.

Regards,

John
928-[redacted]

The International Committee of Medical Journal Editors (ICJME) Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals, states:

<!--[if !supportLists]--> <!--[endif]-->Authorship credit should be based on (1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; (3) final approval of the version to be published and (4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Authors should meet conditions 1, 2, and 3 and 4.

<!--[if !supportLists]--> <!--[endif]-->When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above.

<!--[if !supportLists]--> <!--[endif]-->Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

<!--[if !supportLists]--> <!--[endif]-->**All persons designated as authors should qualify for authorship, and all those who qualify should be listed**.

<!--[if !supportLists]--> <!--[endif]-->Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

From: "HEYDENS, WILLIAM F [AG/1000]" <[redacted]@monsanto.com>
Date: Wednesday, November 4, 2015 at 9:25 AM
To: John Acquavella [redacted].com>

Plaintiff Exhibit
0392

Cc: "FARMER, DONNA R [AG/1000]" <[redacted]@monsanto.com>
Subject: RE: John,Glyphosate Expert Panel Poster at 2015 SRA Annual Meeting

Hi John,

Any chance that Donna & I could call you at 1:30 PM today our time?
If that doesn't work, how about 1 PM or even 12:30 PM our time?

Thanks,

Bill
From: HEYDENS, WILLIAM F [AG/1000]
Sent: Tuesday, November 03, 2015 3:34 PM
To: 'John Acquavella'
Subject: RE: John,Glyphosate Expert Panel Poster at 2015 SRA Annual Meeting

John,
We will have to pick this up tomorrow. Sorry.
Bill

-----Original Message-----
From: John Acquavella [redacted].com]
Sent: Tuesday, November 03, 2015 02:55 PM Central Standard Time
To: HEYDENS, WILLIAM F [AG/1000]
Subject: Re: John,Glyphosate Expert Panel Poster at 2015 SRA Annual Meeting
I didn't realize that Bill. Also, I don't think that will be okay with my panelists. We call that ghost writing and it is unethical.

Regards,

John

From: "HEYDENS, WILLIAM F [AG/1000]" <[redacted]@monsanto.com>
Date: Tuesday, November 3, 2015 at 1:49 PM
To: John Acquavella <[redacted].com>
Subject: RE: John,Glyphosate Expert Panel Poster at 2015 SRA Annual Meeting

John,

I thought we discussed previously that it was decided by our management that we would not be able to use you or Larry as Panelists/authors because of your prior employment at Monsanto – was that not your understanding? I'm really sorry if there is any confusion on that...

Bill

From: John Acquavella [mailto:[redacted].com]
Sent: Tuesday, November 03, 2015 2:33 PM
To: HEYDENS, WILLIAM F [AG/1000]
Subject: Re: John,Glyphosate Expert Panel Poster at 2015 SRA Annual Meeting

Bill

The plan sounds fine. I don't see my name in the author list. I should be where [redacted] is and he should be later in the alphabetical order.

Regards,

John

From: "HEYDENS, WILLIAM F [AG/1000]" <[redacted]@monsanto.com>
Date: Tuesday, November 3, 2015 at 1:09 PM
To: John Acquavella <[redacted].com>, Larry Kier <[redacted]com>
Subject: John,Glyphosate Expert Panel Poster at 2015 SRA Annual Meeting

John, Larry,

I have touched base with Ashley to discuss what the Author list should/could look like for the poster.

Our thoughts:

- Gary Williams as first author as agreed previously
- then those who lead the 4 sub-groups (in the same order as IARC: Exposure, Animal Bioassay, Epidemiology, Genetox/MOA)
  and/or contributed at a higher level in the 4 groups ([redacted])
- followed by all the other panelists in alphabetical order
- then Ashley is the final author as being the facilitator and having overall oversight responsibilities

So it would look like this:

Expert Panel Review of the Carcinogenic Potential of the Herbicide Glyphosate

Gary Williams, Keith Solomon, [redacted], [redacted], David Brusick, [redacted] Marilyn Aardema, Michele M. Burns,
Joao Lauro Viana de Camargo, David Garabrant, David J. Kirkland, Gary Marsh, Douglas Weed, and Ashley Roberts.
Intertek Scientific & Regulatory Consultancy Services, Mississauga, Ontario Canada.

See any problems from your perspectives?

Thanks,

Bill

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Plaintiff Exhibit
0401
Case No.
CGC-16-550128



22:50:40 (UTC)

[redacted]

iMessage,Outgoing,2015-01-08 03:24:48 (UTC),They know otherwise it could prevent from getting a [redacted]

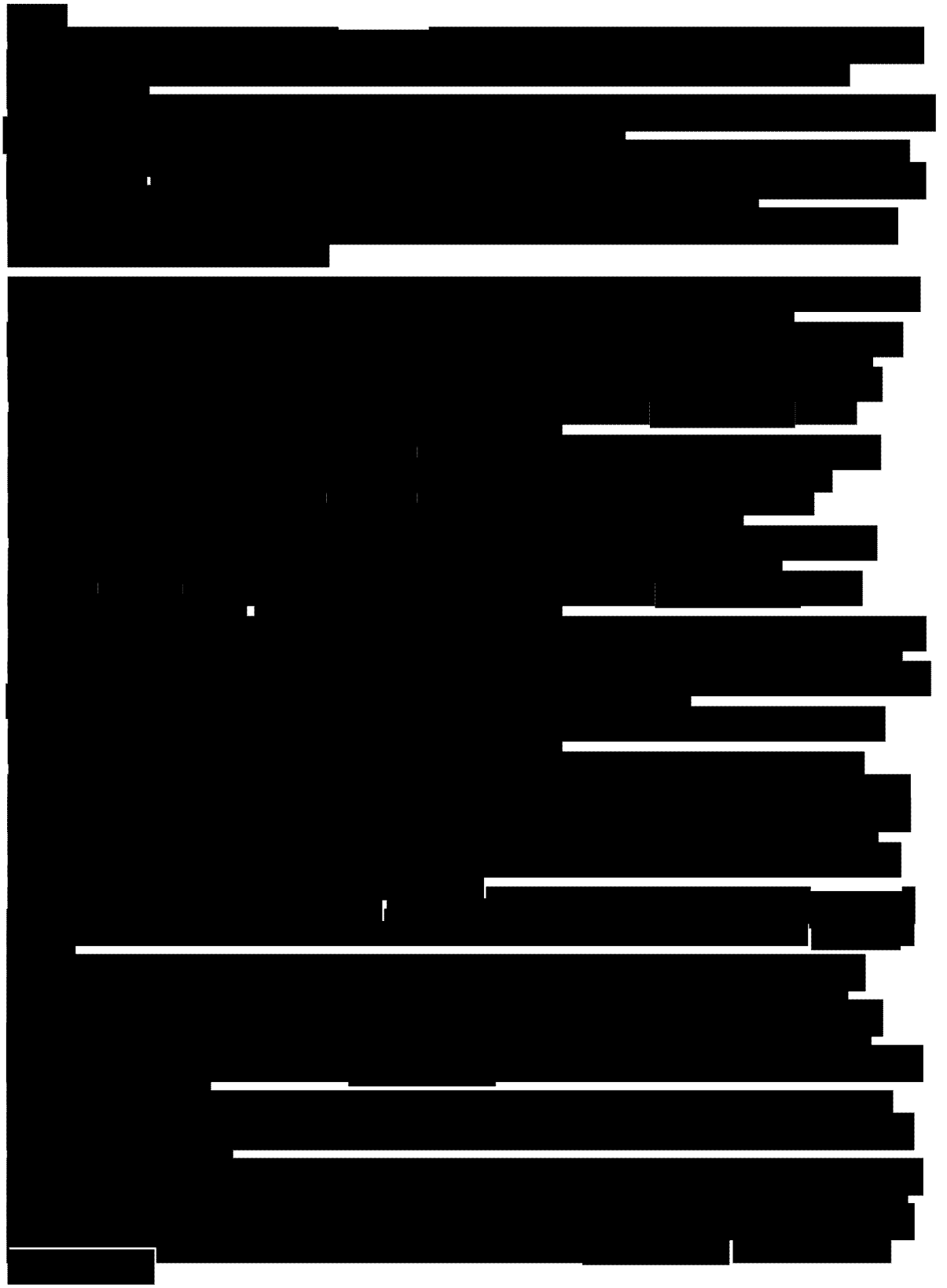
C),Just had IARC call. Have you discussed this with Bradberry (sp?),,JENNIFER LISTELLO ((314) [redacted]),JENNIFER LISTELLO ((314) [redacted]), Self,0,2015-03-14 19:32:42 (UTC),,
iMessage,Incoming,2015-03-14 19:22:30 (UTC),Is there anyone we can get to in EPA?,,JENNIFER LISTELLO ((314) [redacted]),JENNIFER LISTELLO ((314) [redacted]), Self,0,2015-03-14 19:32:42 (UTC),,
iMessage,Outgoing,2015-03-14 19:34:43 (UTC),I sent him an email. He's somewhat familiar w IARC will talk to him Monday. Re EPA: I've called them 5 times on this issue and dykes has called them to. They're not going to be proactive.,,Self,JENNIFER LISTELLO ((314) [redacted]), Self,0,,2015-03-14 19:34:43 (UTC),

[redacted]









[redacted]15-10-[redacted]UTC),[redacted]

iMessage,Outgoing,2015-11-17 19:25:15 (UTC),According to bradbury, What we need to do is get some key Democrats on the hill to start calling jim. This helps in several ways: focuses on gly and gets him to move; shoots across his bow generally that he's being watched which is needed on several fronts and finally sets the stage for possible hearings. I laid this all out yesterday w Michael before our call and he agreed ,,Self,TY VAUGHN ((314) [redacted]), Self,0,2015-11-17 19:25:15 (UTC),2015-11-17 19:25:16 [redacted])





Message

From: JENKINS, DANIEL J [AG/1920] [redacted]@monsanto.com]
Sent: 6/24/2015 1:32:17 PM
To: HEYDENS, WILLIAM F [AG/1000] [redacted]@monsanto.com]
CC: LISTELLO, JENNIFER J [AG/1000] [redacted]@monsanto.com]
Subject: RE: GA Update on US Government Outreach - WHO IARC Clarification on Glyphosate

Completely agree. Mary Manibusan told me yesterday that EPA has had several issues in the past with ATSDR coming to different conclusions. She said they tried to execute several MOUs but were unsuccessful. She describes ATSDR as being VERY conservative and IARC like in this regard as well as the fact that they are hazard based.

Makes me very nervous, but I asked Jack whether or not he was worried about ATSDR coming out with something different and he said he wasn't and I think he was being genuine.

Dan Jenkins
U.S. Agency Lead
Regulatory Affairs
Monsanto Company
1300 I St., NW
Suite 450 East
Washington, DC 20005
Office: [redacted]
Cell: [redacted]

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Wednesday, June 24, 2015 8:49 AM
To: JENKINS, DANIEL J [AG/1920]
Cc: LISTELLO, JENNIFER J [AG/1000]
Subject: RE: GA Update on US Government Outreach - WHO IARC Clarification on Glyphosate

Dan,

'Distinguishable and not duplicative'? Seriously? And I will believe the not 'making a call on cancer' part when I see it.

Anyway, at least they know they are being watched, and hopefully that keeps them from doing anything too stupid...

Thanks much for the follow-up.

Plaintiff Exhibit
0402

Bill

From: JENKINS, DANIEL J [AG/1920]
Sent: Tuesday, June 23, 2015 8:17 AM
To: DYKES, MICHAEL D [AG/1920]
Cc: VAUGHN, TY T [AG/1000]; JACOBS, ERIK [AG/1000]; REYNOLDS, TRACEY L [AG/1000]; MARTINO-CATT, SUSAN J [AG/1000]; STATER, STACEY L [AG/1000]; DUNCAN, MELISSA S [AG/1000]; SCHLICHER, MARTHA A [AG/1000]; PARRISH, MICHAEL [AG/1000]; CHRISTIANSEN, JESSICA [AG/1000]; LISTELLO, JENNIFER J [AG/1000]; MILLER, PHILIP W [AG/1000]; AGUSTIN, MELISSA [AG/1920]; GUARD, JAMES [AG/1000]; HORAK, MICHAEL J [AG/1000]; COLE, RICHARD M [AG/1000]; HEERING, DAVID C [AG/1000]; REBMAN, JOHN [AG/1000]; TRAVIS, JAMES K [AG/1920]; FARMER, DONNA R [AG/1000]; LOWRY, BRIAN R [AG/1000]; KUSCHMIDER, SCOTT [AG/1920]; MURPHY, STEPHANIE L [AG/1920]; HOLLAND, MIKE [AG/1920]; HEYDENS, WILLIAM F [AG/1000]
Subject: RE: GA Update on US Government Outreach - WHO IARC Clarification on Glyphosate

Spoke to EPA:

ATSDR Director and Branch Chief have promised Jack Housenger (Director of the US Office of Pesticide Programs) to put their report "on hold" until after EPA releases its preliminary risk assessment (PRA) for glyphosate. EPA will not have the final meeting of its internal cancer review technical group until after the IARC monographs are published, and thus will not put out the PRA until after this (guessing this would mean around mid-August).

ATSDR has cited a GAO Audit report in arguing that their process is distinguishable and not duplicative. They look at different endpoints and told EPA they don't "make a call on cancer", but I think we should continue to be cautious.

EPA will send me the name of the Branch Chief so that we can hopefully set up a meeting.

Thanks,

Dan Jenkins
U.S. Agency Lead
Regulatory Affairs
Monsanto Company
1300 I St., NW
Suite 450 East
Washington, DC 20005

Office: [redacted]

Cell: [redacted]

From: DYKES, MICHAEL D [AG/1920]
Sent: Sunday, June 21, 2015 11:44 PM
To: JENKINS, DANIEL J [AG/1920]
Cc: VAUGHN, TY T [AG/1000]; JACOBS, ERIK [AG/1000]; REYNOLDS, TRACEY L [AG/1000]; MARTINO-CATT, SUSAN J [AG/1000]; STATER, STACEY L [AG/1000]; DUNCAN, MELISSA S [AG/1000]; SCHLICHER, MARTHA A [AG/1000]; PARRISH, MICHAEL [AG/1000]; CHRISTIANSEN, JESSICA [AG/1000]; LISTELLO, JENNIFER J [AG/1000]; MILLER, PHILIP W [AG/1000]; AGUSTIN, MELISSA [AG/1920]; GUARD, JAMES [AG/1000]; HORAK, MICHAEL J [AG/1000]; COLE, RICHARD M [AG/1000]; HEERING, DAVID C [AG/1000]; REBMAN, JOHN [AG/1000]; TRAVIS, JAMES K [AG/1920]; FARMER, DONNA R [AG/1000]; LOWRY, BRIAN R [AG/1000]; KUSCHMIDER, SCOTT [AG/1920]; MURPHY, STEPHANIE L [AG/1920]; HOLLAND, MIKE [AG/1920]; HEYDENS, WILLIAM F [AG/1000]
Subject: Re: GA Update on US Government Outreach - WHO IARC Clarification on Glyphosate

The person I talked with at HHS said they had checked with ATSDR and confirmed their review of glyphosate. I explained that their review was duplicative and I was now concerned about another glyphosate review coming any day. He said he didn't know when but didn't expect anything out of ATSDR for at least two weeks and suggested that we should meet with the technical people at ATSDR to better understand their process and timing.

I assume you have already met with the ATSDR people. I suggest you follow up with them just to confirm the facts as you may already know them as that will be more accurate than the information I received from HHS

You now have all the information I received from my conversation with HHS

Michael

Sent from my iPhone

On Jun 21, 2015, at 6:15 PM, JENKINS, DANIEL J [AG/1920] <[redacted]@monsanto.com> wrote:

Michael:

Can you clarify what you're referring to regarding reports from ATSDR? They're not scheduled to put anything out for public comment until October- has this been accelerated?

Dan Jenkins

US Agency Lead

Monsanto Company

[redacted] (o)

[redacted] (c)

On Jun 19, 2015, at 4:10 PM, DYKES, MICHAEL D [AG/1920] <[redacted]@monsanto.com> wrote:

REPORT ON FOLLOW UP DISCUSSION WITH HHS ON REQUEST FOR WHO CLARIFICATION

After repeated attempts, I connected this morning with Mitch Wolfe, Deputy Assistant Secretary for Global Affairs at HHS. I connected with one of his colleagues last week as a follow-up to our June 5 meeting but there was nothing significant to report.

Mitch reports that they have been assessing the collective actions across the USG on glyphosate. They have an interagency call today to discuss our request for a clarification from the WHO to ask if the other agencies are aligned. He plans to have more information available next week. He does not expect to have a final conclusion coming out of today's meeting. I reminded him that the final monograph is expected to be released on July 15 and the urgency of our request.

I then asked for an update on ATSDR. He said that they had checked with ATSDR and they were in fact doing a glyphosate review. I explained that this confirmed what we already understood but our question was about the purpose and scope of such a duplicative review by ATSDR. I also told him that we were concerned that ATSDR may come out any day with a report. He said that he thought it would be at least 2 weeks before they issued any reports. I again stressed that we were concerned that they were even reviewing glyphosate as were the people we talked with at EPA. He suggested that we should reach out to the reviewers at ATSDR. He is sending me the most appropriate contact point at ATSDR.

We also received intelligence today that ATSDR has reached out to other companies that sell glyphosate asking questions about glyphosate. If we have not already met with the technical people at ATSDR to understand their scope of investigation and timing of their report, I suggest that we meet with ATSDR as soon as something can be scheduled. HHS confirmed today that they are preparing a report.

CONGRESSIONAL SUPPORT SOUGHT FOR HHS ACTION

While we work to secure a commitment from HHS to obtain a clarification from the WHO, we are also focusing members of congress to engage HHS leadership to support this effort.

In particular, we have briefed the senior staff of our home state senators Roy Blunt (R-MO) and Claire McCaskill (D-MO) with the goal of those senators sending a letter to Ambassador Jimmy Kolker, the Assistant Secretary of Global Health at HHS, that underscores the urgent need for a WHO clarification with a direct ask that HHS do so.

In addition to representing our headquarters, Senator Blunt is also the Chairman of the Senate Appropriations Subcommittee that has oversight of HHS. Given his familiarity with the agency, his request would likely compel HHS leadership to make a thoughtful evaluation.

In addition, we have briefed key Senate Agriculture Committee staff should we need additional input from the Senate.

Lastly, we are also capitalizing on an opportunity in the House of Representatives. Last week, HHS Secretary Sylvia Burwell testified before the House Ways & Means Committee about the Administration's view on the current health care law, an issue which has come to the forefront in advance of an anticipated ruling by the Supreme Court in late June. While the hearing was focused on health care, members of the committee have the ability to submit *Questions for the Record*, or QFR's to the Secretary on any subject after the hearing has concluded. The Secretary is compelled to respond to those questions in writing.

The value of submitting a statement and question through this process is that it forces an agency to pull in expertise from its various departments because it is a deliberative effort that becomes part of the Congressional Record.

Representative Lynn Jenkins has agreed to submit a statement to HHS Secretary Burwell this week. The QFR will underscore the domestic and international confusion that has been generated and squarely asks the Secretary to seek a much needed clarification from the WHO.

From: DYKES, MICHAEL D [AG/1920]
Sent: Friday, June 05, 2015 3:59 PM
To: VAUGHN, TY T [AG/1000]; JACOBS, ERIK [AG/1000]; REYNOLDS, TRACEY L [AG/1000]; MARTINO-CATT, SUSAN J [AG/1000]; STATER, STACEY L [AG/1000]; DUNCAN, MELISSA S [AG/1000]; SCHLICHER, MARTHA A [AG/1000]; PARRISH, MICHAEL [AG/1000]; CHRISTIANSEN, JESSICA [AG/1000]; JENKINS, DANIEL J [AG/1920]; LISTELLO, JENNIFER J [AG/1000]; MILLER, PHILIP W [AG/1000]; AGUSTIN, MELISSA [AG/1920]; GUARD, JAMES [AG/1000]; HORAK, MICHAEL J [AG/1000]; COLE, RICHARD M [AG/1000]
Cc: TRAVIS, JAMES K [AG/1920]; FARMER, DONNA R [AG/1000]; LOWRY, BRIAN R [AG/1000]; KUSCHMIDER, SCOTT [AG/1920]; MURPHY, STEPHANIE L [AG/1920]; HOLLAND, MIKE [AG/1920]
Subject: US Government Outreach - WHO IARC Clarification on Glyphosate

This message provides an update on Washington based efforts to assist Monsanto teams managing the IARC issue.

THE STRATEGY

One strategy for addressing widespread confusion in the wake of the IARC classification has been to seek clarification from the World Health Organization (WHO) which would provide the proper context of the classification for governments and regulators around the world to have greater confidence defending their science based regulatory decisions. Because IARC is part of

the WHO, the clarification would be a compelling tool for governments and stakeholders to reference.

RECENT ACTIONS

To execute against this strategy, the Washington office has conducted significant outreach within the U.S. government to secure its engagement with the WHO in an effort to obtain that clarification.

We have briefed key staff at EPA, USTR, USDA and the State Department as well as members of Congress. These officials are interested in clarifying this issue for several reasons: maintain~~ing~~ scientific integrity that promotes public confidence, protect international trade and the economy and preserve safe, valuable tools for farmers continued use.

HEALTH & HUMAN SERVICES: A KEY AGENCY BRIEFED

Yesterday, we briefed officials at Health and Human Service (HHS), the agency that will be particularly crucial because it is the primary U.S. government interlocutor with the WHO. Its support will be key to the U.S. government effort to secure a WHO clarification.

Specifically, we met with Dr. Mitchell Wolfe, the Deputy Assistant Secretary for Global Health. Donna Farmer traveled to Washington to help with the briefing. Her knowledge and background with glyphosate was instrumental in communicating information to the Secretary, who himself is a medical doctor.

We came prepared with a robust set of technical materials for the Secretary's background. In addition, we were joined by a small group of value chain stakeholders to underscore the challenges the confusion of the IARC classification and concomitant media reports have generated in a short period of time. Those groups included the American Farm Bureau Federation, the National Corn Growers Association and the U.S. Grains Council.

The HHS briefing covered the following:

- Overview of the concerns raised by IARC's classification: health concerns, undermining national and international regulatory authorities reviews, food security and impact on agricultural trade (bans and restrictions).

- We described the reviews and toxicological profile of glyphosate - multiple reviews that have been conducted by agencies around the world, whose primary responsibility is to assess the safety of pesticides, and that over 40 years those agencies have repeatedly come to the conclusions that glyphosate is not carcinogenic or genotoxic and that it does not pose a carcinogenic risk to humans.

- We discussed that the strikingly different conclusion that IARC came to was not based on new data but the way IARC reviews existing data. For example an increase in tumors in low-dose animals compared to controls with no increase in the numbers of tumors in higher doses is considered as evidence of cancer in animals – thus a "created hazard". In addition a timeline of international responses to the IARC classification over the past several months including impacts on regulatory reviews not only for glyphosate but biotech products, bans and proposed bans on uses and suspensions of imports was provided;

- Dr. Wolfe was not aware that the Agency for Toxic Substances and Disease Registry (ATSDR, an agency under HHS) is currently doing a review of glyphosate as well as 2,4-D. It was discussed that similar to IARC, this is not the primary role of this agency – the US EPA is the primary agency for review and determination of pesticide safety and that glyphosate is currently undergoing registration review by the EPA.

- A common element between IARC and ATSDR was brought to Dr. Wolfe's attention; Christopher Portier, Ph.D. Dr. Portier was Director of ATSDR and the co-chair of the IARC Advisory Group that met in April of 2014 to recommend priorities for IARC Monographs during 2015-2019. He was also an invited specialist representing the Environmental Defense Fund at IARC's meeting when glyphosate was reviewed in March 2015. Dr. Wolfe said he would follow up on what was going on with ATSDR and he was encouraged to have discussions with EPA staff, as well.

- Next, the farm groups articulated how challenges surrounding the IARC classification were negatively impacting their members and the potential for even greater challenges should a clarification not be made. They highlighted the need for tools like glyphosate and maintaining trade that is so critical to America's farm economy. The farm organizations added significant value to the discussion.

- Finally, we ended the discussion with the request for HHS assistance in securing a WHO clarification. We emphasized that we were not seeking changes to IARC, the classification or the IARC process. Dr. Wolfe commented that he felt that this was a reasonable request and

indicated that he was in Geneva when the Lancet article came out in March and that he had been expecting to hear from us. Dr. Wolfe and his staff will review the material and delve deeper on a number of the areas of discussion. We will follow up with HHS.

NEXT STEPS

In the coming week, we will follow up with all of the previously briefed U.S. agencies and seek requests to the Administration from key members of Congress outlining the need for a WHO clarification and urge that they secure it before the release of the IARC monograph on glyphosate anticipated in July.

Donna Farmer, Jim Travis , Brian Lowry & Michael Dykes

Message

From: HEYDENS, WILLIAM F [AG/1000] [/o=Monsanto/ou=NA-1000-01/cn=Recipients/cn=230737]
on behalf of HEYDENS, WILLIAM F [AG/1000]
Sent: 4/28/2015 2:52:30 PM
To: JENKINS, DANIEL J [AG/1920] [/o=Monsanto/ou=NA-1000-01/cn=Recipients/cn=813004]
CC: LISTELLO, JENNIFER J [AG/1000] [/o=Monsanto/ou=NA-1000-01/cn=Recipients/cn=533682]
Subject: RE: Glyphosate IARC Question

Dan,

Wow! - that's very encouraging. Thanks for the news update.

Regarding the sarcomas Jess mentions in Cheminova's mouse study, I'm assuming he is talking about the Haemangiosarcomas in high dose males (1000 mg/kg/day, the limit dose) and low numbers (1-3) of histiocytic sarcomas 'spattered' across all dose groups. These were discussed in the 2004 WHO/FAO JMPR documents which states: "Owing to the lack of a dose-response relationship, the lack of statistical significance and the fact that the incidences recorded in this study fell within the historical ranges for control, these changes are not considered to be caused by administration of glyphosate."

Bill

From: JENKINS, DANIEL J [AG/1920]
Sent: Tuesday, April 28, 2015 9:33 AM
To: HEYDENS, WILLIAM F [AG/1000]
Cc: LISTELLO, JENNIFER J [AG/1000]
Subject: RE: Glyphosate IARC Question

Hey- cc'ing Jen

So...Jess called me out of the blue this morning:



"We have enough to sustain our conclusions. Don't need gene tox or epi. The only thing is the cheminova study with the sarcoma in mice- we have that study now and its conclusions are irrelevant (bc at limit dose...?). I am the chair of the CARC and my folks are running this process for glyphosate in reg review. I have called a CARC meeting in June..."

Also, Jess called to ask for a contact name at ATSDR. I passed on Jesslyn's email. He told me no coordination is going on and he wanted to establish some saying "If I can kill this I should get a medal". However, don't get your hopes up, I doubt EPA and Jess can kill this; but it's good to know they are going to actually make the effort now to coordinate due to our pressing and their shared concern that ATSDR is consistent in its conclusions w EPA.

Dan Jenkins
U.S. Agency Lead

Regulatory Affairs
Monsanto Company
1300 I St., NW
Suite 450 East
Washington, DC 20005

C[redacted]

[redacted]

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Monday, April 27, 2015 1:20 PM
To: JENKINS, DANIEL J [AG/1920]
Subject: RE: Glyphosate IARC Question

That would be great, Dan.

From: JENKINS, DANIEL J [AG/1920]
Sent: Monday, April 27, 2015 11:51 AM
To: HEYDENS, WILLIAM F [AG/1000]
Subject: Re: Glyphosate IARC Question

I think you and I could get on the phone w Jess Rowland and discuss this pretty openly. He'll give us straight talk.

Dan Jenkins

US Agency Lead

Monsanto Company

202.383.2851 office

571.732.6575 cell

On Apr 27, 2015, at 8:02 AM, HEYDENS, WILLIAM F [AG/1000] [redacted]@monsanto.com> wrote:

Dan,

As you know, we are considering the value/advisability of doing more work to help us deal with the IARC fallout (see attached), and we are trying to get feedback from various stakeholders to help us decide on pulling any triggers.

The first two suggestions (New Meta-analysis & AHS Collaboration) would involve beefing-up the Epidemiology area with two new/updated analyses culminating in 2 new publications.

The 3rd possible endeavor would be an expert panel meeting and subsequent publication. This would be very expensive to do well with sufficient big names. An alternative approach would be one or two smaller expert panels two address one or two areas of most need/value (Epidemiology, Animal Bioassay data, and/or genetox/MOA).

Finally, we are considering doing some additional experiment to directly address all the positive in vitro formulation genetox studies out there – we have had only a very early/superficial talk with Gary Williams so there are no details yet.

NOW THE QUESTION - What are your thoughts on approaching EPA and having a conversation, probably a generic one, about what area they see as most problematic (e.g., human epidemiology vs. animal bioassays vs. genetox) or just ask if there is anything that would help them defend the situation?

Bill

<Post-IARC Meeting Science Proposals.pptx>

Monsanto Manuscript Clearance Form
Global Regulatory

***NOTE**: this form needs to be completed and submitted for review at least 4 weeks prior to manuscript submission and a minimum of 2 weeks prior to abstract/presentation submission*

Questions regarding completion of this form can be directed to Jeanna Graf [redacted] or Kevin Glenn [redacted]

Date: 2/29/2012

Please indicate type of publication: ☒ Manuscript ☐ Conference/meeting presentation ☐ Abstract

Has this information been publicly disclosed previously? ☐ No ☒ Yes If yes, where & when? This manuscript reviews glyphosate genotoxicity publications since the Williams et al. (2000) review

(If the information has previously been published, no need to include Patent Scientist & Patent Atty review)

Title: Review of Genotoxicity of Glyphosate and Glyphosate Based Formulations

Author(s): David Saltmiras, Larry Kier (consultant)

Author Handling Correspondence: David Saltmiras **Mail Zone:** C1NA **Phone:** [redacted]

Is this related to a Monsanto collaboration? ☐ No ☒ Yes If yes, Other

Meeting Date & Location at which Manuscript will be presented:

Journal Submitted To: Reg. Toxicol. Pharmacol.

Lead Author's Comments: (Please provide information on **purpose of presentation/publication** and any relevant patents or manuscript disclosures.) This manuscript provide a comprehensive quality check on the large number of genotoxicity publications on glyphosate since the Williams et al. (2000) glyphosate toxicology review manuscript. This work falls under the scope of the EU Glyphosate Task Force and will be a valuable resource in future product defense against claims that glyphosate is mutagenic or genotoxic.

Plaintiff Exhibit 0443

MONGLY02117800

Title: Review of Genotoxicity of Glyphosate and Glyphosate Based Formulations

Author Material Transfer Agreement Statement: (Please refer questions to a patent attorney.) I have reviewed the material transfer and data disclosure requirements of the proposed journal and have discussed any such requirements with my direct supervisor. I ensure that when I submit this manuscript, the journal either does not or will not in this instance require Monsanto to provide restricted plasmids or other materials referenced in our manuscript, or that I will obtain legal approval for any such materials prior to submission of this paper.

I have reviewed that the appropriate individuals that have contributed substantial, direct, intellectual work to this manuscript/presentation are included as authors, and other significant contributors have been appropriately acknowledged.

REQUESTOR'S SIGNATURE: _____

Reviewer: Please review, sign, and return.		
Reviewer	**Approval Signature**	**Date**
Program Lead, Tech Center John Vicini, C1NA, (W.Blackden)		3/9/2012
Center Lead * Nordine Cheikh, C3NA, (J.Graf)		
Regulatory Team Lead (Crop/Chem) Chemistry: Susan Martino-Catt C3NA (L. Billadeau)		
Crop/ChemTeam Lead Not Applicable		
Regulatory Law Not Applicable **Regulatory Law (Add'l Reviewer)** Brandon Neuschafer, E1NH (J. Wardlow)		
Regulatory Scientific Affairs Eric Sachs, C3NA, (J. Graf)		
Biotechnology Not Applicable		
Patent Scientist Not Applicable **Patent Scientist (Add'l Reviewer)** Not Applicable		
Patent Attorney Not Applicable **Patent Attorney (Add'l Reviewer)** Not Applicable		
Regulatory Regional Lead ** Not Applicable		
Additional Reviewer: Other:		

Requestor must send an email message as well as the manuscript clearance form to the administrative assistant of the selected Lead.

***Center Lead**: Please add any other Program Leads that should be included in the review process, and choose "not applicable" for any reviewers that should not be included.

**To be selected when involving samples / data from regional investigators.

MONGLY02117801

Requestor must first collate all the signed pages and then send them to Gracie Williams, BB1B (Chesterfield Valley).

Monsanto Manuscript Clearance Reviewer Guidelines Form
Global Regulatory

Reviewers: *Please complete your review of this manuscript within 7 working days (abstract/presentation) and 21 working days (publication/manuscript). If timely review is not possible, please communicate this to the lead author within 2 – 3 days of receipt of this MCF indicating a delegate within your organization that can perform the review. Also, please note, reviews are being completed* ***concurrently****, not sequentially.*

Program Lead, Tech Center (TC)
Determine if this is the first TC publication on this trait or MON # and that the publication follows past TC practices with earlier Monsanto publications. Ensure that the scientific conclusions (e.g. of compositional equivalence, natural variability) are justified by presented data. Ensure that individuals that have contributed substantial, direct, intellectual work to this manuscript are included as authors and other significant contributions are appropriately acknowledged.

Center Lead
Determine that the scientific conclusions are clearly stated and supported by the data. Review assessment of the TC Program Lead (if available). Determine if other TC representatives need to review and provide additional scientific insights and input. Ensure that individuals that have contributed substantial, direct, intellectual work to this manuscript are included as authors and other significant contributions are appropriately acknowledged.

Regulatory Team Lead (Crop/Chem)
Ensure that descriptions of MOA, product concepts, etc. are consistent with Product Core Team (PCT) standards, any prior Biotechnology communications, submission documents, etc. Ensure that the manuscript is consistent with the Regulatory and Biotechnology publication strategy.

Crop/Chem Team Lead
Ensure that descriptions of MOA, product concepts, etc. are consistent with any prior Biotechnology communications, PCT standards or submissions of trait or MON #. Ensure that the manuscript is consistent with the Regulatory and Biotechnology publication strategy. Confirm that publication contains no comparative assessments or statements between different MONs and that any reference to other MONs is accurate and consistent with prior communications.

Regulatory Law
Ensure that publication of MON # (or other invention) is legal and does not compromise Monsanto FTO.

Regulatory Scientific Affairs
Ensure that descriptions of MOA, product concepts are consistent with prior communications of trait or MON #. Ensure that the manuscript is consistent with the Regulatory and Biotechnology publication strategy. Ensure that any policy statements or implications are consistent with both Regulatory strategies and scientific outreach efforts.

Biotechnology
Ensure that descriptions of MOA, gene sequence, product concepts, etc. are consistent with any prior Biotechnology communications or publications on MON # or related biotech traits. Ensure that the manuscript is consistent with the Regulatory and Biotechnology publication strategy.

Patent Scientist
Determine that all relevant patents related to MON # are fully in place. Ensure publication does not impact right of Monsanto to make, use, or sell the claimed invention or MON #. Ensure there are no statements or assessments that could result in a loss of IP.

Patent Attorney
Determine if any patents related to MON # are fully in place. Ensure publication does not impact right of Monsanto to make, use, or sell the claimed invention or MON # or a limited period of time. Ensure there are no statements or assessments that could result in a loss of IP. Confirm assessment of patent scientists.

Regulatory Regional Lead
Ensure that the manuscript is consistent with the regional Regulatory strategy. Ensure that individuals that have contributed substantial, direct, intellectual work to this manuscript are included as authors and other significant contributions are appropriately acknowledged.

Responsibility	Program Lead, TC	TC Lead	Regulatory TL	Crop/Chem TL	Regulatory Law	Scientific Affairs	Biotech-nology	Patent Scientist	Patent Attorney	Regional Lead
Scientific conclusions are clearly stated and supported by the data	x	x								
Determine whether publication is first TC publication on this event and follows past TC publication practices	x									
Forward MCF to other TC representatives for review		x								
Description of MOA, product concept, etc. is consistent with PCT and Biotech standards			x	X		x	x			
Manuscript fits with crop team's overall strategic positioning and publication strategy			x	x		x	x			x
Confirm no comparative assessments or statements between different MONs and that reference to other MONs is accurate and consistent with prior communications				x						
Ensure that any policy statements or implications are consistent with Regulatory and scientific outreach strategies						x				x
Ensure that publication of MON # (or other invention) is legal and does not compromise Monsanto FTO or intellectual property					x			x	x	
Verify authorship and acknowledgements	x	x								x

MONGLY02117804

Message

From: [redacted]@fcs-feinchemie.com]
Sent: 7/19/2012 10:18:12 AM
To: [redacted]@gtaduran.com]; [redacted]@arystalifescience.com; [redacted]@cheminova.com]; [redacted]@dow.com; [redacted]@at.nufarm.com; [redacted]@syngenta.com; [redacted]@afrasa.es; [redacted]@agria.bg; [redacted]@Laronkarn.co.uk]; [redacted]@agrotrade.de; [redacted]@etracoms.com; [redacted]@agrichem.nl; [redacted]@barclay.ie; [redacted]@bros.pl]; [redacted]@excelcropcare.com; [redacted]@helmag.com; [redacted]@pinus-[redacted]@rotam.com; [redacted]@sabero.com]; [redacted]@sfp-rd.com; [redacted]@uk.exponent.com; [redacted]@agro.sapec.pt; [redacted]@uniphos.com; [redacted]@wynca.com
CC: [redacted]@live.co.uk]; [redacted]HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=230737]; SALTMIRAS, DAVID A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=DASALT]; [redacted]
Subject: AW: Genotox Review: your approval requested!

Dear [redacted]

FCS agrees to the additional costs as well.

Best regards,

[redacted]

Von: [redacted]@monsanto.com]
Gesendet: Mittwoch, 18. Juli 2012 19:12
An: [redacted]@arystalifescience.com; [redacted]@dow.com; [redacted]@at.nufarm.com; [redacted]@syngenta.com; [redacted]@afrasa.es; [redacted]@agria.bg; [redacted]@agrotrade.de; [redacted]@etracoms.com; [redacted]@agrichem.nl; [redacted]@barclay.ie; [redacted]@excelcropcare.com; [redacted]@helmag.com; [redacted]@pinus-tki.si; [redacted]@rotam.com; [redacted]@sfp-rd.com; [redacted]@uk.exponent.com; [redacted]@agro.sapec.pt; [redacted]@uniphos.com; [redacted]@wynca.com
Cc: [redacted]HEYDENS, WILLIAM F (AG/1000); SALTMIRAS, DAVID A (AG/1000); [redacted]
Betreff: Genotox Review: your approval requested!
Wichtigkeit: Hoch

Plaintiff Exhibit
0445

URGENT REQUEST

Dear RWG,

As part of the GTF literature review the RWG and Board agreed to ask Larry Kier (former Monsanto expert and now independent consultant) to write a genetox review paper on technical glyphosate and glyphosate based Plant Protection Products. This paper would pool data from confidential Taskforce Member studies which was the reason why David Saltmiras (MON), chair to the tox-TWG, stepped down as a co-author for this paper. In addition when trying to combine both reviews (on technical glyphosate and PPPs) the manuscript turned into such a large mess of studies reporting genetoxic effects, that the story as written stretched the limits of credibility among less sophisticated audiences. For most 'stories', the approach would have been fine. But even though we feel confident that glyphosate is not genotoxic, this became a very difficult story to tell given all the complicated 'noise' out there. So David Saltmiras, Larry Kier and Bill Heydens consulted by other Monsanto tox experts thought there was a need to re-group & redesign the approach to the manuscript.

The suggested approach was to split-up the reviews in 2 papers (one on tech glyphosate and one on PPPs). In addition it was suggested that one way to help enhance credibility is to have an additional author on the papers who is a renowned specialist in the area of genotoxicity. Larry Kier did a search for possible co-authors and came up with 5. After internal discussion and some checking by David Saltmiras with fellow TWG tox folks (see extracts from TWG-meeting minutes below), [redacted] was identified as the best candidate.

[redacted] is an independent consultant with a history at Covance Laboratories. He is an expert in 'COMET'-assays on PPPs and is member of the editorial board for 'Mutagen Research' and member of the Environmental Mutagen Society in the UK. [redacted] would most definitely add substantial expertise and credibility to this critical paper.

The initial cost estimate for this manuscript was 9k$ (approved by the board).

Adding [redacted] as a co-author to both review papers would add £14,000 (pounds Stirling) to the project, which split by 25 seems a fair investment.

Please let me know as soon as possible if we have your support to proceed with [redacted] as a co-author. We need a decision soon since [redacted] only has the month of August to work on the papers.

David, Bill, please let me know if I missed or misinterpreted something.

Best regards,

[redacted]

From: SALTMIRAS, DAVID A [AG/1000]
Sent: Wednesday, July 18, 2012 4:54 PM
To: [redacted]
Subject: RE: Genotox Review

[redacted]

Below are extracts from recent meeting minutes this month. [redacted] was discussed as a strong candidate to coauthor on July 2nd and ToxTWG endorsed him on July 16th and plans to engage him were put in motion.

- **From July 2nd**

a. Genotoxicity review manuscript.

i. Discussed approaches for literature and data reviews

ii. Consensus gained for two companion papers on active ingredient and formulated product genotoxicity data (GTF member company data and peer reviewed publications

iii. **Co-authors with Larry Kier were discussed.** [redacted] **was proposed as strong candidate for this role.** Syngenta proposed [redacted] expressing possible bias towards COMET assay data by [redacted] will inquire within the Syngenta genotox group on suitability of [redacted] to provide an objective scientific review including weight of evidence for the full data set (GTF member study reports and peer reviewed publications).

- **NOTE**: Larry had contacted [redacted] yesterday to discuss the paper and Larry contacted David Saltmiras today (Tuesday July 3rd) to debrief.

- Larry is convinced that [redacted] will provide a strong technical skill set to evaluate the breadth of data including the COMET data (weighing convenience of

COMET assays with credible data interpretability) and believes [redacted] would be an excellent choice to co-author the manuscript.

- [redacted] is available to work on this project in August/Sept and submit to the journal by the end of September.

iv. Still targeting *Critical Reviews in Toxicology*, based on the length of these papers.

- Larry has briefly discussed with the chief editor of *Critical Reviews in Toxicology* (Roger McClellen), who expressed concern that the GTF member study reports are not public (weighing in on negative genotox results) vs the publication record (weighing in on positive genotox results). This will present itself as an issue with any credible journal. To have credibility, rather than make all study reports public, the GTF may consider submitting all the genotoxicity study Tier II Summaries from the dossier (which may well fall into the public domain) as supplementary data to the journal.

- **Please email David Saltmiras regarding this approach of submitting the TIIS for genotox studies as supplementary data if your company owns genotoxicity data.**

- **From July 16th**

2. Genotoxicity review manuscript

a. David Saltmiras will circulate contact information for [redacted] for individual companies to arrange CDAs (Arysta LifeScience, Cheminova, Excel Crop Care, Feinchemie Schwebda, Helm, Nufarm, Syngenta).

b. Data for manuscript

i. General agreement was reached to provide member company study methodology and data summaries as supplementary information in support of publications on (i) active substance and (ii) formulated products.

ii. Study summaries and citations should be sanitized to exclude

- Study director names

- Data owner/company name

iii. Study summaries and citations may include

- Study/report number
- Study/report title
- Year of study/report
- Performing laboratory (not necessary, sometimes deleted/sanitized for public information like DARs)
- Test substance purity (for active substance)
- Formulation type (for formulated product)
- Note of whether GLP or non-GLP
- Test Guideline(s) followed (OECD/US EPA, JMAFF, etc.)
- Brief description of methodology
- Summarized data tables

iv. Transfer of study information between coauthors

- Larry Kier needs to email a rider/CDA amendment for each company to grant him permission to share data with [redacted]
- Larry Kier and [redacted] should sign a CDA with eachother.

David Saltmiras, Ph.D., D.A.B.T.
Toxicology Manager
Regulatory Product Safety Center
Monsanto
ph (314) [redacted]

From: [redacted]
Sent: Wednesday, July 18, 2012 9:40 AM
To: SALTMIRAS, DAVID A [AG/1000]

Cc: [redacted] HEYDENS, WILLIAM F [AG/1000]
Subject: RE: Genotox Review

Will do!!

From: SALTMIRAS, DAVID A [AG/1000]
Sent: Wednesday, July 18, 2012 3:47 PM
To:
Cc: [redacted] HEYDENS, WILLIAM F [AG/1000]
Subject: FW: Genotox Review
Importance: High

[redacted]

Will you please take this to the RWG ASAP? At this point we have an open Monsanto contract with [redacted] CDA's with individual member companies are being initiated and Larry Kier plans to get a draft manuscript to him by the end of the month (i.e. in less than 2 weeks). [redacted] is only available to work in this project in August and approval of his involvement is strongly recommended by the ToxTWG. If our time lines slip on this we will probably not have a genotoxicity review manuscript available for our submission window in January.

Is there a way to get this through the RWG in a week?

Thanks,

David Saltmiras, Ph.D., D.A.B.T.
Toxicology Manager
Regulatory Product Safety Center
Monsanto
ph (314) [redacted]

From: [redacted]
Sent: Wednesday, July 18, 2012 8:24 AM

To: HEYDENS, WILLIAM F [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; [redacted]
Cc: LEMKE, SHAWNA LIN [AG/1000]; KRONENBERG, JOEL M [AG/1000]
Subject: RE: Genotox Review

I think it has to go through the normal process- TWG to RWG to Board, with documented agreement at each stage. Once the RWG has agreed we can do the Board by email.

I think Bill H's summary could be a good basis for getting RWG alignment.

BillG

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Tuesday, July 17, 2012 5:54 PM
To: [redacted] SALTMIRAS, DAVID A [AG/1000]; [redacted]
Cc: LEMKE, SHAWNA LIN [AG/1000]; KRONENBERG, JOEL M [AG/1000]
Subject: RE: Genotox Review

[redacted]

David & I were just touching base on a couple things, and we were wondering what your thinking is on how to progress this with the Board – let us know – thanks.

Bill

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Friday, July 13, 2012 1:09 PM
To: HEYDENS, WILLIAM F [AG/1000]; [redacted] SALTMIRAS, DAVID A [AG/1000]; [redacted]
Cc: LEMKE, SHAWNA LIN [AG/1000]; KRONENBERG, JOEL M [AG/1000]
Subject: RE: Genotox Review

[redacted]

Here is my further perspective on top of David's…

As David notes, we are still essentially talking about lines 12 & 13 on the Excel spreadsheet you sent. David embarked on the Genetox publication work with Larry Kier as agreed by the Board.

But here is what transpired after that. After they got all the studies amassed into a draft manuscript, it unfortunately turned into such a large mess of studies reporting genetoxic effects, that the story as written stretched the limits of credibility among less sophisticated audiences. For most 'stories', the approach would have been fine. But even though we feel confident that glyphosate is not genotoxic, this became a very difficult story to tell given all the complicated 'noise' out there. So we (David, Larry, Bill H, Joel & Shawna) thought we needed to re-group & redesign the approach to the manuscript. As part of that re-tooling approach, it was suggested that one way to help enhance credibility is to have an additional author on the paper who is a heavy-hitter in the area of genotoxicity. Larry did a search for possible co-authors and came up with 5. After internal discussion and some checking by David with fellow TWG tox folks, we landed on [redacted] as the best candidate. That has led to the request you have before you.

So if you think there needs to be a discussion with the Board rather than trying to gain approval via e-mail, then we could take that approach, but this obviously slows down the process. Is there a Board phone conference scheduled anytime soon?

Bill

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Friday, July 13, 2012 11:20 AM
To: [redacted] SALTMIRAS, DAVID A [AG/1000]; [redacted]
Subject: RE: Genotox Review

[redacted] I have to run to a meeting, but I will give you my perspective later today when you are drinking G&Ts.

From: [redacted]
Sent: Friday, July 13, 2012 11:17 AM
To: SALTMIRAS, DAVID A [AG/1000]; [redacted] HEYDENS, WILLIAM F [AG/1000]; [redacted]
Subject: RE: Genotox Review

There is a lot of information here which the Board has not seen (to my knowledge) . The discussion of published summaries took place at the 13th Meeting (March 2012) and I attach the information which was presented and agreed (according to the Minutes). I think you will agree that the current situation needs to go to the Board for a second discussion and updated Agreement.

If [redacted]or Bill H have any additional information about the Board discussions on this subject then I will gladly change my opinion.

Bill

From: SALTMIRAS, DAVID A [AG/1000]
Sent: Friday, July 13, 2012 3:48 PM
To: [redacted] HEYDENS, WILLIAM F [AG/1000]; [redacted]
Subject: RE: Genotox Review

[redacted]

Two different projects have been merged, the first of which was well underway before the PAG was instituted. The initial project was a review manuscript of the glyphosate genotoxicity literature authored by Larry Kier and me (authorized Feb 22, 2011 for $9,000). The second (initiated by the PAG and supported by the RWG and Board, cost estimate of $13,195) was a review manuscript involving all glyphosate genotoxicity studies owned by GTF member companies on both active ingredient and formulated products, authored by Larry; the review of GTF members' proprietary study reports prohibit my coauthorhip.

This first became a very long and tedious manuscript, which would have been difficult to publish. Following on from this first draft manuscript review, discussions with Bill H., Joel, me and Larry Kier resulted in a merging of the two projects (also discussed at the ToxTWG) with a view to publish two companion manuscripts on glyphosate genotoxicity for the active ingredient (paper 1) and formulated products (paper 2). Thus Larry was

the sole author and given his geography and industry alignment, other highly credible genotoxicologists coauthors from European were sought. [redacted] was the first choice of the GTF ToxTWG.

[redacted] expertise comes at a premium. I believe Larry Kier significantly under charges for his services, but his combined cost estimate for project 1 and project 2 is $22,195. [redacted] believes his efforts will be less than 10 days at £1,400/day (equivalent to $21,780 with the current exchange rate), so we are effectively doubling the cost of the combined projects, but reaping significant value/credibility from [redacted] involvement. Given the growing number of questionable genotoxicity publications, in my mind this is worth the addition cost.

I have subsequently coordinated an open master contract between Monsanto and [redacted] (we may need his services in the future) and on the next ToxTWG call (Monday) will request all member companies get confidentiality agreements in place with him ASAP (the same CDAs as previously signed with Larry Kier, enabling him to see their study reports).

David Saltmiras, Ph.D., D.A.B.T.
Toxicology Manager
Regulatory Product Safety Center
Monsanto
ph (314)[redacted]

From: [redacted]
Sent: Friday, July 13, 2012 9:01 AM
To: [redacted] HEYDENS, WILLIAM F [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; [redacted]
Subject: Genotox Review

The project was initiated by the PAG and supported by the RWG and Board. The cost was $9k and I thought the job had been completed. The name [redacted] has never come to my attention before and I would suggest that the RWG needs to explain to the Board why , at this point, it believes that trebling the expenditure to include a second author is a justifiable expense.

I wonder if this is a true PAG project where those companies who want to see this work carried out pay for it.

I have received questions about future expenditure and I cannot see it on [redacted] list which went to the Board for approval/discussion last month.

[redacted]

From: [redacted]
Sent: Friday, July 13, 2012 2:04 PM
To: HEYDENS, WILLIAM F [AG/1000]; SALTMIRAS, DAVID A [AG/1000]
Cc: [redacted]
Subject: RE: A FedEx shipment [793774060139] was created.

Hi [redacted]

The proposal sounds very reasonable and having [redacted] co-authoring this paper can only strengthen the case. Since the board has approved the project I agree it makes sense to ask the board directly to approve the extra funding. It I don't seem to remember this (adding [redacted] being discussed at RWG level but could be wrong. If not I'll send out an update message to make sure everyone is on the same page.

Regards,

[redacted]

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Thursday, July 12, 2012 10:52 PM
To: SALTMIRAS, DAVID A [AG/1000]; [redacted]
Cc: [redacted]
Subject: RE: A FedEx shipment [793774060139] was created.

[redacted]

We (David, Joel, Kier, me) think we should proceed with pursuing [redacted] as a co-author for the glyphosate genetox publication. David also got some other toxicologist feedback from within the Tox TWG and that was favorable as well.

So how should we proceed? For expediency, since this project is already supported by the Board, could we have [redacted] go directly to the Board by sending out a note asking them to approve contracting with [redacted] for an estimated maximum amount of £14,000?

Thanks.

Bill

From: SALTMIRAS, DAVID A [AG/1000]
Sent: Thursday, July 12, 2012 11:03 AM
To: HEYDENS, WILLIAM F [AG/1000]; [redacted]
Subject: FW: A FedEx shipment [793774060139] was created.

Bill & [redacted],

We (Monsanto) have a signed master contract with [redacted] This will enable him to coauthor the genotoxicity review paper with Larry Kier, as well as engaging him on any other projects which may come up…. it may be necessary to have an EU based expert in genotoxicity on hand if issues arise during the regulatory review.

Please note [redacted] estimated cost, below, which will need GTF board approval…..he thinks likely less than 10 days work (at £1,400/day).

David Saltmiras, Ph.D., D.A.B.T.
Toxicology Manager
Regulatory Product Safety Center

Monsanto
ph (314) [redacted]

From: [redacted]@genetoxconsulting.co.uk]
Sent: Thursday, July 12, 2012 10:49 AM
To: SALTMIRAS, DAVID A [AG/1000]
Subject: RE: A FedEx shipment [793774060139] was created.

David,

Daily rate is equivalent to 8 hours, namely GBP1400 per day.

I estimate a maximum of 10 days (i.e. GBP14,000) but unless I have to delve very deeply into a lot of the reports and papers that Larry includes, it should be less than this.

Kind regards,

[redacted]

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Edmund-Rumpler-Str. 6
51149 Koeln

Geschaeftsfuehrer: [redacted]
Amtsgericht Koeln HRB 66957

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Message

From: FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]
Sent: 10/14/2008 6:31:44 PM
To: Nasser Dean [redacted]@healthyplants.org]; Scott Kohne [redacted]@bayercropscience.com]; Karen Cain [redacted]@bayercropscience.com]; GOUGH, GEORGE N [AG/1230] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=556077]; info@24d.org
CC: McAllister, Ray [redacted]@croplifeamerica.org]; MITCHELL, BRADLEY C [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=BCMITC1]
Subject: RE: Study Shows Herbicides Increase Risk of Non-Hodgkin's Lymphoma - Beyond Pesticides, October 14

Nassar,

Thank you for fowarding this. We have been aware of this paper for awhile and knew it would only be a matter of time before the activists pick it up. I have some epi experts reviewing it. As soon as I have that review we will pull together a backgrounder to use in response.

Here is their bottom line...how do we combat this?

Avoid carcinogenic herbicides in foods by supporting organic agriculture, and on lawns by using non-toxic land care strategies that rely on soil health, not toxic herbicides.

Regards,

Donna
-----Original Message-----
From: Nasser Dean [redacted]@healthyplants.org]
Sent: Tuesday, October 14, 2008 11:33 AM
To: Scott Kohne ; Karen Cain ; FARMER, DONNA R [AG/1000]; GOUGH, GEORGE N [AG/1230]; [redacted]@24d.org
Cc: McAllister, Ray
Subject: Study Shows Herbicides Increase Risk of Non-Hodgkin's Lymphoma - Beyond Pesticides, October 14

Study Shows Herbicides Increase Risk of Non-Hodgkin's Lymphoma

(Beyond Pesticides, October 14, 2008)

Exposure to glyphosate or MCPA can more than double one's risk of developing non-Hodgkin lymphoma (NHL), according to a new epidemiological study published in the October issue of the *International Journal of Cancer*. The case-control study finds a 2.02 odds ratio (OR) for exposure (two times the chance of contracting the illness) to glyphosate, a 2.81 OR for exposure to MCPA, and a 1.72 OR for exposure to herbicides. According to EPA, glyphosate is the most commonly used pesticide in the U.S. with 103 to 113 million pounds used annually. MCPA is a phenoxyacetic acid pesticide, a family of pesticides that has previously been linked to cancer and includes 2,4-D and mecoprop (MCPP).

NHL is a cancer of the immune system. There are several different types of NHL, which are differentiated by the type of immune cell that is cancerous, the characteristics of the cancerous cell, and different genetic mutations of the cancerous cells. Treatment for NHL varies depending on NHL type, patient age, and other existing medical conditions. The incidence of NHL has been increasing over the past several decades.

Plaintiff Exhibit
0513

The link between pesticides and cancer has long been a concern. While agriculture has traditionally been tied to pesticide-related illnesses, 19 of 30 commonly used lawn pesticides and 24 of 48 commonly used school pesticides are probable or possible carcinogens. The consistency of the scientific findings linking pesticide exposure to cancer raises serious questions about their allowed use.

In 2002, the same researchers published a study that shows an increased risk to NHL from exposure to certain pesticides: a 1.75 OR for herbicides, a 3.11 OR for fungicides, a 3.04 OR for glyphosate, and a 2.62 OR for MCPA. And even earlier, in 1999, another study by these researchers, published by the American Cancer Society, finds an increased risk of NHL for people exposed to common herbicides and fungicides, particularly MCPP. People exposed to glyphosate are 2.7 times more likely to develop NHL.

NHL has been linked to pesticides in other studies as well, including 2,4-D, the most commonly used nonagricultural herbicide. A 2007 case-control study published in *Environmental Health Perspectives* finds that children born to mothers living in households with pesticide use during pregnancy have over twice as much risk of getting cancer, specifically acute leukemia (AL) or NHL. A study published in a 2001 issue of *Cancer* also correlates an increased risk of NHL with exposure to household pesticides. The study examined pesticide exposure routes to children either through the mother while she was pregnant, or directly to the child. Exposed children showed a three to seven time greater likelihood of developing NHL, as compared to unexposed children. In studying different types of NHL, the researchers found that household insecticide use was correlated to a greater risk of lymphoblastic lymphoma by 12.5 times. Researchers at the Northwestern University, University of Nebraska Medical Center, and the National Cancer Institute find that agricultural exposure to insecticides, herbicides, and fumigants are associated with a 2.6 to 5.0 fold increase in the incidence of t(14;18)-positive NHL (refers to a specific genetic alteration in a type of NHL).

Avoid carcinogenic herbicides in foods by supporting organic agriculture, and on lawns by using non-toxic land care strategies that rely on soil health, not toxic herbicides.

Message

From: Janet Collins [jcollins@croplifeamerica.org]
Sent: 7/1/2016 6:12:30 PM
To: FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=180070]; GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=527246]; HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=230737]
Subject: RE: [CLA-HHRAC] RE: NTP will be evaluating Glyphosate now!

This is something that is going to need some communication at the "Hill" level. This is more of the same and there is not a thing that would be good coming out of this.

Thanks Donna. If you identify a role that you would like for CLA to play, please let me know. In the meantime, I will write a blurb to share with our SOC (Mike Parrish is vice chair of that).

Have a good holiday weekend.

From: FARMER, DONNA R [AG/1000] [mailto:donna.r.farmer@monsanto.com]
Sent: Friday, July 1, 2016 1:27 PM
To: GOLDSTEIN, DANIEL A [AG/1000] <daniel.a.goldstein@monsanto.com>; HEYDENS, WILLIAM F [AG/1000] <william.f.heydens@monsanto.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: [CLA-HHRAC] RE: NTP will be evaluating Glyphosate now!

Janet,

I was talking with Don Stomp from WIL now Charles River at the Teratology meetings this week and he told me has been selected as a new member of the NTP Board.

If you look at the NTP slide deck the proposal appears to be an extension of the IARC monograph. They appear to have "accepted" IARC's opinion that glyphosate and its formulations display 2 key characteristics of carcinogens (gentoxicity and oxidative stress) that Ivan Rusyn and Christopher Portier worked so hard to create and have been saying in public for months because this is the area they propose to do research.

Plaintiff Exhibit
0556
Case No.
CGC-16-550128

Here is a new publication on this very topic:

http://ehp.niehs.nih.gov/wp-content/uploads/124/6/ehp.1509912.alt.pdf

The authors:

Martyn T. Smith,1 Kathryn Z. Guyton, Catherine F. Gibbons, Jason M. Fritz,Christopher J. Portier, * Ivan Rusyn, David M. DeMarini,3 Jane C. Caldwell, Robert J. Kavlock, Paul F. Lambert, Stephen S. Hecht, John R. Bucher, Bernard W. Stewart, Robert A. Baan, Vincent J. Cogliano, and Kurt Straif

I point out two things from the article:

The first is they mention the glyphosate meeting:

Recently, using this same approach, the Working Groups of IARC Monograph Volume 112 and Volume 113 (in progress) concluded that strong mechanistic evidence exists for five key characteristics being involved in malathion carcinogenicity (i.e., genotoxicity, oxidative stress, inflammation, receptor-mediated effects, and cell proliferation or death), three in DDT carcinogenicity (i.e., immunosuppression, receptor-mediated effects and oxidative stress), and two each for diazinon and glyphosate (i.e., genotoxicity and oxidative stress), providing evidence to support their classification as probable human carcinogens in Group 2A (Guyton et al. 2015; Loomis et al. 2015).

The second is they mention this:

The approach described is similar in many respects to those currently being implemented by the U.S. EPA's Integrated Risk Information System Program and the U.S. National Toxicology Program.

Interesting to note that substances declared carcinogens by IARC ...NTP is finding tumors of interest...see cell phones and aloe vera:

http://ntp.niehs.nih.gov/results/areas/cellphones/index.html

The occurrences of two tumor types in male Harlan Sprague Dawley rats exposed to RFR, malignant gliomas in the brain and schwannomas of the heart, were considered of particular interest, and are the subject of this report.

http://www.niehs.nih.gov/news/newsroom/interviews/aloevera/index.cfm

Firstly, that within these NTP studies, we found there was clear carcinogenic activity of the nondecolorized whole leaf extract, in both male and female rats, based on the increase in large intestinal tumors. Now, secondly, we believe these are relevant to humans.

See a pattern here?

Donna

From: GOLDSTEIN, DANIEL A [AG/1000]
Sent: Friday, July 01, 2016 9:37 AM
To: HEYDENS, WILLIAM F [AG/1000]; FARMER, DONNA R [AG/1000]; Janet Collins
Subject: RE: [CLA-HHRAC] RE: NTP will be evaluating Glyphosate now!

Ditto.....

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Friday, July 01, 2016 9:33 AM
To: FARMER, DONNA R [AG/1000] <donna.r.farmer@monsanto.com>; Janet Collins <jcollins@croplifeamerica.org>
Cc: GOLDSTEIN, DANIEL A [AG/1000] <daniel.a.goldstein@monsanto.com>
Subject: RE: [CLA-HHRAC] RE: NTP will be evaluating Glyphosate now!

Hi Janet,

Yes we learned about this last week. What a colossal waste of taxpayers money. I don't know where our plans are right now but I expect we will really get into this after the 4th of July weekend.

Thanks.

Bill

-------- Original Message --------

Subject: RE: [CLA-HHRAC] RE: NTP will be evaluating Glyphosate now!

From: "FARMER, DONNA R [AG/1000]" <donna.r.farmer@monsanto.com>

Date: Jun 30, 2016, 3:27 PM

To: Janet Collins <jcollins@croplifeamerica.org>

Janet,

Thanks for forwarding. I had heard something about this but did not know that it was this far along.

I have included Bill Heydens on this email, he may have more information.

Regards,

Donna

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, June 30, 2016 3:01 PM
To: GOLDSTEIN, DANIEL A [AG/1000]; FARMER, DONNA R [AG/1000]
Subject: FW: [CLA-HHRAC] RE: NTP will be evaluating Glyphosate now!

Dan and Donna- are you all aware of this? Plans to execute?

From: Wolf Doug USGR [mailto:doug.wolf@syngenta.com]
Sent: Thursday, June 30, 2016 12:33 PM
To: BENTLEY, KARIN SHEETS <KARIN.S.BENTLEY-1@dupont.com>; Charles E Hastings <charles.hastings@basf.com>
Cc: Papineni, Sabitha (S) <SPapineni@dow.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: [CLA-HHRAC] RE: NTP will be evaluating Glyphosate now!

Was not a question I felt it was appropriate to ask, however the proposal is going to the board of scientific councilors so if we really want to have an impact then we should look up who is on the board and see if we can communicate with some of them.

http://ntp.niehs.nih.gov/ntp/about_ntp/bsc/current_roster_508.pdf

From: BENTLEY, KARIN SHEETS [mailto:KARIN.S.BENTLEY-1@dupont.com]
Sent: Thursday, June 30, 2016 12:28 PM
To: Wolf Doug USGR <doug.wolf@syngenta.com>; Charles E Hastings <charles.hastings@basf.com>
Cc: Papineni, Sabitha (S) <SPapineni@dow.com>; jcollins@croplifeamerica.org
Subject: RE: [CLA-HHRAC] RE: NTP will be evaluating Glyphosate now!

And do they intend to do anything about it?

From: Wolf Doug USGR [mailto:doug.wolf@syngenta.com]
Sent: Thursday, June 30, 2016 12:18 PM
To: Charles E Hastings <charles.hastings@basf.com>
Cc: BENTLEY, KARIN SHEETS <KARIN.S.BENTLEY-1@dupont.com>; Papineni, Sabitha (S) <SPapineni@dow.com>; clA-HHRAC@yahoogroups.com
Subject: Re: [CLA-HHRAC] RE: NTP will be evaluating Glyphosate now!

By the way I checked and EPA is aware of this activity by NIEHS

Sent from my iPhone

On Jun 30, 2016, at 8:32 AM, Charles E Hastings charles.hastings@basf.com [CLA-HHRAC] <CLA-HHRAC-noreply@yahoogroups.com> wrote:

I agree with Karin's idea. For one thing it's a total waste of tax dollars.

Best Regards / Mit freundlichen Grüssen,

Charles Hastings, Ph.D., DABT
Manager, Regulatory Toxicology
BASF - The Chemical Company

Phone: +1 919[redacted] Mobile: +1-973[redacted] Fax: +1 919[redacted] E-Mail: charles.hastings@basf.com
Postal Address: BASF Corporation, Research Triangle Park, 27709 Research Triangle Park, USA

150 years
BASF - We create chemistry

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From: CLA-HHRAC@yahoogroups.com [mailto:CLA-HHRAC@yahoogroups.com] **On Behalf Of** 'BENTLEY, KARIN SHEETS' Karin.S.Bentley-1@dupont.com [CLA-HHRAC]
Sent: Thursday, June 30, 2016 9:50 AM
To: Papineni, Sabitha (S) <SPapineni@dow.com>; clA-HHRAC@yahoogroups.com
Subject: [CLA-HHRAC] RE: NTP will be evaluating Glyphosate now!

Thank you Sabitha for alerting us to this review.

Janet, HHRAC:

I am wondering if consideration should be given to CLA (and any other allies such as ACC) submitting a letter to NTP (and any other government organization that can put pressure on NTP) indicating that this planned review is not good use of federal funds given the number of recent independent reviews that have been conducted, including JMPR, EFSA, and EPA.

Thoughts?

Karin

From: CLA-HHRAC@yahoogroups.com [mailto:CLA-HHRAC@yahoogroups.com] **On Behalf Of** 'Papineni, Sabitha (S)' SPapineni@dow.com [CLA-HHRAC]
Sent: Thursday, June 30, 2016 9:19 AM
To: clA-HHRAC@yahoogroups.com
Subject: [CLA-HHRAC] NTP will be evaluating Glyphosate now!

FYI in case you not aware of this already

Due to the different conclusions in the various human health assessments conducted to date and the significant public concern regarding glyphosate use and exposure, the NTP began to consider whether additional investigations into the potential toxicity of glyphosate and its formulations were warranted.

The initial focus is on genetic toxicity and cancer, particularly studies that would inform mechanisms and pathways relevant to carcinogenicity.

Below are the links of NTP scoping document and presentation discussing their strategy/plan which includes public literature review on both cancer and non-cancer endpoints followed by studies to investigate mechanisms of the toxic effects.

http://ntp.niehs.nih.gov/ntp/about_ntp/bsc/2016/june/meeting%20materials/glyphosate_508.pdf

http://ntp.niehs.nih.gov/ntp/about_ntp/bsc/2016/june/presentations/glyphosate_508.pdf

Thanks,

Sabitha Papineni, DVM, Ph.D

Senior Toxicologist

Human Health Assessment

Regulatory Sciences and Government Affairs

Dow AgroSciences

9330 Zionsville Rd

Indianapolis, IN-46268

Ph.317-[redacted]

Fax.317-[redacted]

E-mail:spapineni@dow.com

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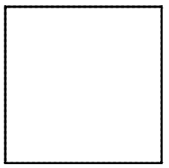
Posted by: Charles E Hastings <charles.hastings@basf.com>



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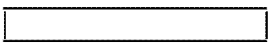

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Toxicological Assessment of Dewayne Johnson and Toxicological Risk Assessment of Glyphosate and Roundup® and Ranger PRO® Formulations

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Cancer Risk Assessment Results: Cancer Slope Factor (CSF) Basis

Cancer risk level is determined as a consequence of applying a standard set of equations as established by U.S. EPA to specific variables as shown in the equations below. This section presents cancer risk level calculations using the cancer slope factor (CSF) for glyphosate exposures to herbicide applicators and the general population as well as dietary exposure cancer risk to the U.S. general population

Cancer Risk for Herbicide Applicators and the General Population

The cancer risks introduced from dietary glyphosate within the general U.S. population as well as to exposed farmers and applicators is calculated based on determined glyphosate exposure doses and the frequency and duration of exposure to the carcinogen (glyphosate). This is then spread across the lifetime of the individual. The calculation uses the cancer slope factor and is determined by the following equation:

$$Cancer\ Risk = \frac{Exposure\ dose\ X\ risk\ factor\ (cancer(oral)\ slope\ factor) X\ years\ of\ exposure}{70\ years\ (lifetime)}$$

Cancer Risk to the U.S. General Population via Dietary Exposure

Glyphosate exposures occur through dietary consumption of glyphosate residue on food and in drinking water. As reported in Solomon, (2016),[266] the U.S. EPA Dietary Exposure Evaluation Model (DEEM) estimates the average exposure of the general population to glyphosate as 0.088 mg/kg bw/day from an estimate that ranged from 0.058 – 0.23 mg/kg bw/day.

Consequently, the upper range of the dietary exposure cancer risk level is determined as:

$$Cancer\ Risk = \frac{\left[0.23\frac{mg}{kg}per\ day\ X\ 0.00169\left(\frac{mg}{kg}per\ day\right)^{-1}\ X\ 70\ years\right]}{70\ years\ (lifetime)} = 3.9\ X\ 10^{-4}$$

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[266] Solomon, K., "Glyphosate in the general population and in applicators: a critical review of studies on exposures," 2016, Critical Reviews in Toxicology, Vol.46: sup 1, 21 -27, DOI: 10.1080/10408444.2016.1214678

Table 26 displays the range of cancer risk levels from typical dietary exposure.

Table 26

Cancer Risk Levels Based on the U.S. EPA DEEM Estimated Dietary and Drinking Water Exposure to Glyphosate

(US DEEM exposures from Solomon, 2016)

Exposure	Dietary Residue and Drinking Water Dose	Cancer Risk Level
Low	0.058 mg/kg bw/day	9.8×10^{-5}
Average	0.088 mg/kg bw/day	1.5×10^{-4}
High	0.23 mg/kg bw/day	3.9×10^{-4}

Acceptable risk levels have been generally recognized and applied in public health for decades. Levels exceeding the *de minimus* level are generally considered unsafe. In this context, the above levels of cancer risk to the general public are clearly unacceptable as the generally accepted *de minimus* benchmark level for cancer risk is 1×10^{-6} (one in one million). [267]

However, slightly higher levels of cancer risk are often used in public health and are based upon prudent regulatory judgement. Factors for consideration include the impacted population size, reasonable availability of technology to reduce risk, beneficial aspects of the ruling, etc. For example, chlorination of public water is extremely beneficial to reduce morbidity and mortality, but chlorination carries a low level risk of cancer due to the formation of trihalomethane contaminants in the water.

Thus, a *de minimus* benchmark increase to 1×10^{-5} (one in one hundred thousand) is occasionally applied in such a regulatory context, but the cancer risk levels shown in Table 26 far exceed this "enhanced" risk level as well.

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[267] Payne-Sturges, DC, "Personal exposure meets risk assessment: A comparison of measured and modeled exposures and risks in an urban community," 2004, Environmental Health Perspectives, Vol. 112(5), pg. 589-598.

Additionally, a study by Caldwell, et al., discusses the history and use of the *de minimus* benchmark $1x10^{-6}$ risk level for hazardous air pollutants (HAPs).[268] The Caldwell study, with two of the three authors affiliated with the U.S. EPA, states that "*much of the needed information and science policy judgments were previously compiled for U.S.EPA's proposed rulemaking under section 112(g) of the CAA and were supplemented by information from several other data sources…known, probable, or possible human carcinogens representing the upper-bound of a one in a million excess probability of contracting cancer over a lifetime of exposure. This benchmark was based on provisions of CAA sections 112(f) and 112 (c)(9) that allow source categories to be exempted from regulation and residual risk to be negligible when posing less than a one in a million ($1x10^{-6}$ risk level) lifetime risk to the most exposed individual.*"

Cancer Risk to Glyphosate Applicators

Also at risk are farmers and commercial applicators of glyphosate who are part of the agricultural industry and use glyphosate for weed management and in seeding and/or harvesting crops.

"The Agricultural Health Study" (AHS) is an ongoing cohort study which includes 89,000 farmers and their spouses from Iowa and North Carolina. The study is funded by the National Cancer Institute and the National Institute of Environmental Health Sciences and is partnered with the U.S. EPA and NIOSH.[269] In 1993, the AHS initial study[270] had a cohort of 20,235 private farmer and commercial applicators with 70.6 and 47.5 percent respectively reported to have applied herbicides. Their reported frequency of pesticide application is shown in Table 27.

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[268] Caldwell, JC, "Application of health information to hazardous air pollutants modeled in EPA's cumulative exposure project," 1998, Toxicology and Industrial Health, Vol. 14(3), pg. 429-454.

[269] Alavanja, M., et al., "The Agricultural Health Study," 1996, Environmental Health Perspectives, Vol. 104 (4), pg. 362 – 369. Retrieved from: https://aghealth.nih.gov/

[270] Id.

Table 27

Demographic Characteristics of "The Agricultural Health Study"[271] Cohort
(Total applicators n = 20,235)

Days per year personally mixed or applied pesticide	Percentage of applicators in each category of days per year	Years personally mixed/applied pesticide	Percentage of applicators in each year of application category
<5	13.5	<1	3.3
5 – 9	17.2	2 – 5	12.8
10 – 19	22.7	6 – 10	14.9
20 – 39	17.7	11 – 20	27.9
40 – 59	5.8	21 – 30	17.0
60 – 150	5.5	>30	9.1
>150	1.3	Unknown	15.0
Unknown	16.4		
Median days	**23.3**	**Median Years**	**15.4**

The days of pesticide application as well as the years of use can be used to determine the lifetime years of exposure as:

$$\left(\frac{23.3 \text{ application days}}{365 \text{ days}}\right) x \ 15.4 \text{ years} = 0.983 \ years$$

Consequently, the risk of cancer, given the exposure levels to glyphosate amongst applicators, is calculated using the equation:

$$\text{Cancer Risk for Applicators} = [\text{applicator risk}] + [\text{dietary risk}]$$

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[271] Id.

Derivation of Dermal Toxicity Values

The oral cancer slope factor of 0.00169 mg/kg/day was determined from dietary doses of glyphosate and requires an adjustment for absorption through the gastrointestinal tract. The oral slope factor can be converted to an absorbed slope factor, which can be applied to the dermal absorbed dose to calculate a cancer risk. The absorbed slope factor can be derived using methods provided in the Risk Assessment for Superfund: Volume 1, Human Health Evaluation Manual, Part A (EPA/540/1-89/002). The absorbed slope factor can be calculated as:

$$\frac{\text{Oral Slope Factor}}{\text{GI Absorption Factor}} = \text{Slope Factor}_{\text{absorbed}}$$

The default Gastro Intestinal (GI) absorption factor, which is being applied in the absence of a determined GI absorption factor for glyphosate in humans is 50%[272] - the default for semi-volatile organic compounds per EPA Region 4's Supplemental Guidance to RAGS:

$$\frac{0.00169}{0.5} = 0.00338\ i.e., 3.38\ X\ 10^{-3}\ \text{Slope Factor}_{\text{absorbed}}$$

Region 4 Bulletins Human Health Risk Assessment from November 1995.

For the highest exposure level reported among hand-held outdoor hydraulic nozzle applicators (see Tables 29 and 31), the cancer risk equation is:

[272] RAIS, "Toxicity Values" The Risk Assessment Information System. Retrieved from: https://rais.ornl.gov/tutorials/toxvals.html

Cancer Risk for Applicators = [applicator risk] + [dietary risk]

$$Cancer\ Risk = \frac{\left[4.635\frac{mg}{kg}per\ day\ X\ 0.00338\left(\frac{mg}{kg}per\ day\right)^{-1}\ X\ 0.983 years\right]+\left[0.23\frac{mg}{kg}per\ day\ X\ 0.00169\left(\frac{mg}{kg}per\ day\right)^{-1}\ X\ 70\ years\right]}{70\ years\ (lifetime)}$$

$$\frac{0.0154+0.0272}{70} = \frac{0.0426}{70} = 6.1\ X\ 10^{-4}$$

The resulting cancer risk level of **6.1 x 10^{-4}** is based on a mid-point dermal absorption rate of 10%[273] as shown in Tables 28 and 29.

The glyphosate exposure levels for applicators under various conditions were provided from Monsanto-derived exposure models and a realistic adjustment for glyphosate dermal absorption of 3%, 5% or 10% as shown in Tables 30 and 31.

It is important to note that exposure calculations should normally include the amount inhaled during herbicide spraying activity; however, the inhalation dose of 3.24 mg/day was excluded as the Inhalation Unit Risk (IUR) has not been established via inhalation chamber studies. *As a consequence, the risk values shown have been underestimated.*

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[273] 10% Absorption was demonstrated in an unpublished Monsanto TNO study which is consistent with Wester et al. 1991, which revealed absorption range in primates of 4.4% - 22.6% with a midpoint value of 13.5%.

NO Study: Johan van Burgsteden, "In vitro percutaneous absorption study with [14C]-glyphosphate using viable rat skin membranes," June 14, 2002, Unaudited draft report V4478 (Tab 24).

Wester, R. et al. 1991. "Glyphosate skin binding, absorption, residual tissue distribution and skin decontamination". *Fundamental and Applied Toxicology* 16,725-732.

Tables 28 and 29 list the dose levels associated with each exposure scenario:

Table 28
Estimation of Spray Operator Exposure (Rotary Disc Atomizers)

Hand-held Outdoor Rotary Disc Atomizers	Dermal Exposure (Dose, mg/day)	Percentage Dermal Absorption (%)	Dermal Absorption (mg/day)	Exposure Level for a 60 Kg Operator, (mg/kg/day)
No gloves	1782	3	53.460	0.891
No gloves	1782	5	89.100	1.485
No gloves	1782	10	178.200	2.97
Gloves during mixing/loading	1766.1	3	52.983	0.883
Gloves during mixing/loading	1766.1	5	88.305	1.472
Gloves during mixing/loading	1766.1	10	176.610	2.944
Gloves at all times	1183.41	3	35.502	0.592
Gloves at all times	1183.41	5	59.171	0.986
Gloves at all times	1183.41	10	118.341	1.972
Boots, gloves, coveralls	357.21	3	10.716	0.179
Boots, gloves, coveralls	357.21	5	17.861	0.298
Boots, gloves, coveralls	357.21	10	35.721	0.595

Table 29
Estimation of Spray Operator Exposure (Hydraulic Nozzles)

Hand-held Outdoor Hydraulic Nozzles	Dermal Exposure (Dose, mg/day)	Percent Dermal Absorption (%)	Dermal Absorption (mg/day)	Exposure Level for a 60 Kg Operator, (mg/kg/day)
No gloves	2781	3	83.430	1.391
No gloves	2781	5	139.050	2.318
No gloves	2781	10	278.100	4.635
Gloves during mixing/loading	2755	3	82.650	1.378
Gloves during mixing/loading	2755	5	137.750	2.296
Gloves during mixing/loading	2755	10	275.500	4.592
Gloves at all times	1337.85	3	40.136	0.669
Gloves at all times	1337.85	5	66.893	1.115
Gloves at all times	1337.85	10	133.785	2.23
Boots, gloves, coveralls	507.6	3	15.228	0.254
Boots, gloves, coveralls	507.6	5	25.380	0.423
Boots, gloves, coveralls	507.6	10	50.760	0.846