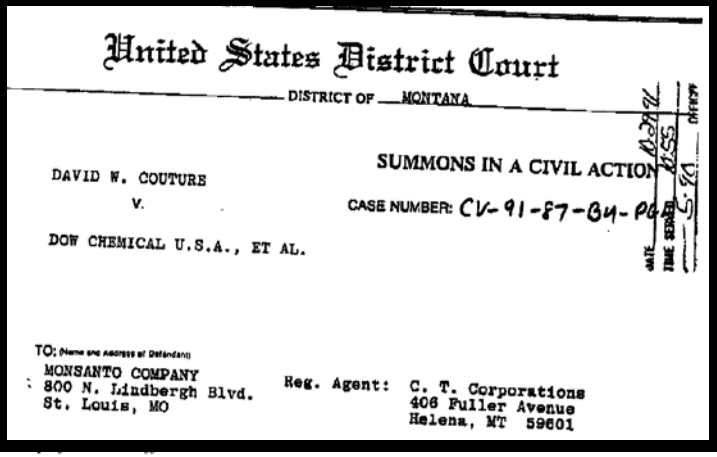
Overview of this case:

Overview of this case:

Overview of this case:

Overview of this case:

Not the first lawsuit:



United States District Court

DISTRICT OF MONTANA

DAVID W. COUTURE

v.

DOW CHEMICAL U.S.A., ET AL.

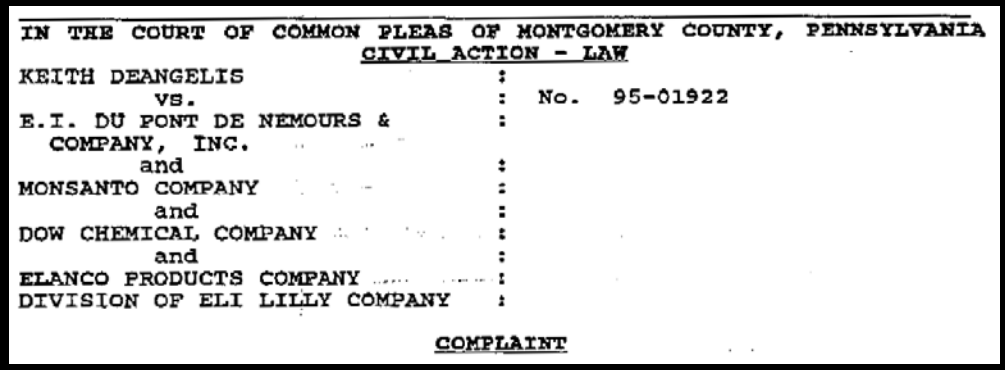
SUMMONS IN A CIVIL ACTION

CASE NUMBER: CV-91-87-BU-PGH

TO: (Name and address of Defendant)

MONSANTO COMPANY
800 N. Lindbergh Blvd.
St. Louis, MO

Reg. Agent: C. T. Corporation
406 Fuller Avenue
Helena, MT 59601



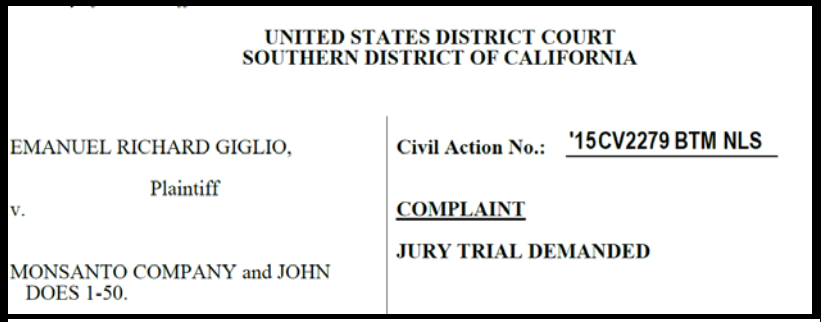
IN THE COURT OF COMMON PLEAS OF MONTGOMERY COUNTY, PENNSYLVANIA

CIVIL ACTION - LAW

KEITH DEANGELIS
vs.
E.I. DU PONT DE NEMOURS & COMPANY, INC.
and
MONSANTO COMPANY
and
DOW CHEMICAL COMPANY
and
ELANCO PRODUCTS COMPANY
DIVISION OF ELI LILLY COMPANY

No. 95-01922

COMPLAINT



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

EMANUEL RICHARD GIGLIO,

Plaintiff

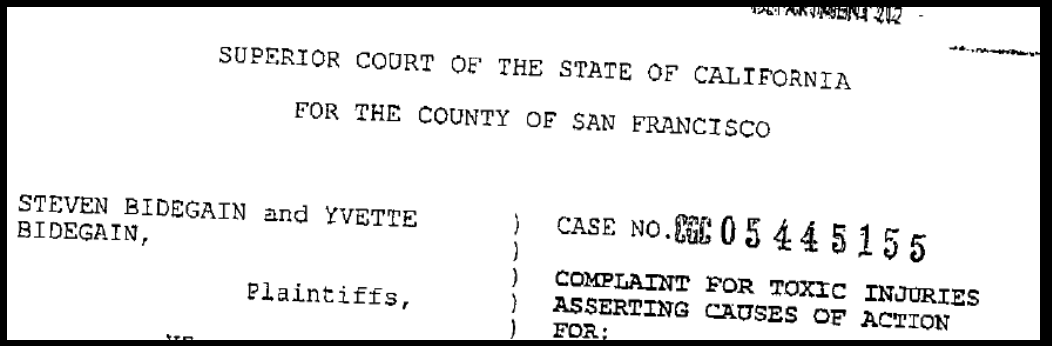
v.

MONSANTO COMPANY and JOHN DOES 1-50.

Civil Action No.: '15CV2279 BTM NLS

COMPLAINT

JURY TRIAL DEMANDED



SUPERIOR COURT OF THE STATE OF CALIFORNIA

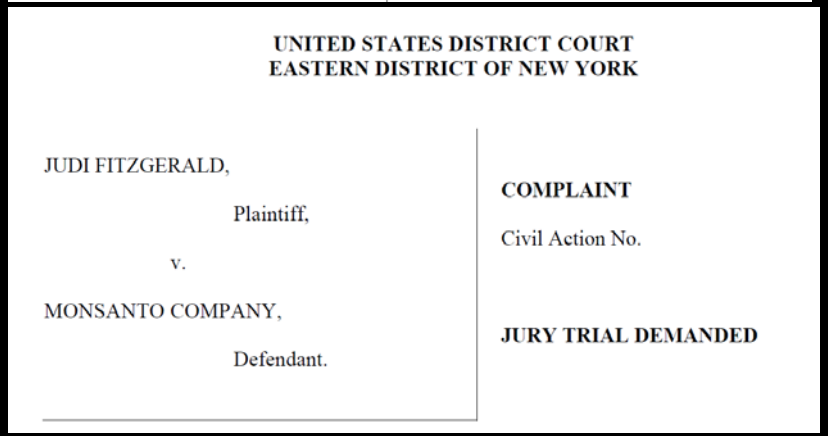
FOR THE COUNTY OF SAN FRANCISCO

STEVEN BIDEGAIN and YVETTE BIDEGAIN,

Plaintiffs,

CASE NO. CGC 05 445155

COMPLAINT FOR TOXIC INJURIES ASSERTING CAUSES OF ACTION FOR:



UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JUDI FITZGERALD,

Plaintiff,

v.

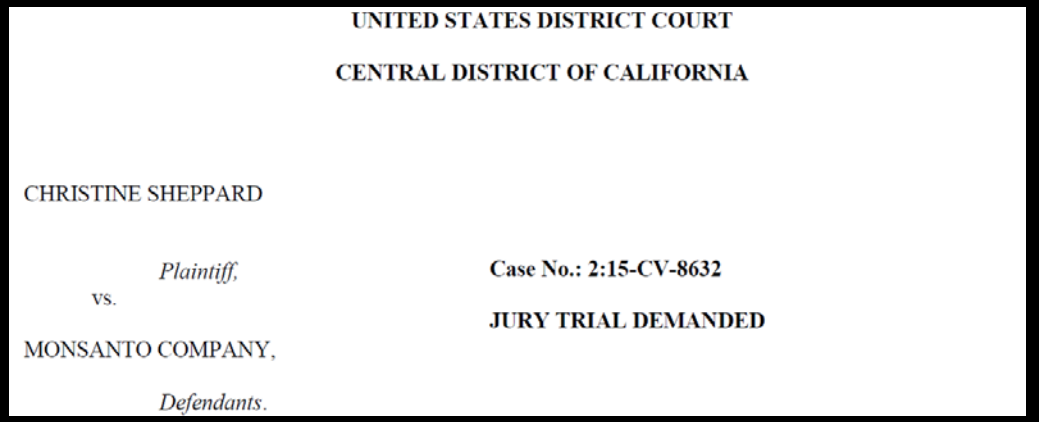
MONSANTO COMPANY,

Defendant.

COMPLAINT

Civil Action No.

JURY TRIAL DEMANDED



UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

CHRISTINE SHEPPARD

Plaintiff,

vs.

MONSANTO COMPANY,

Defendants.

Case No.: 2:15-CV-8632

JURY TRIAL DEMANDED

How the trial works:

1. Opening statements
2. Plaintiff's case
3. Monsanto's case
4. Rebuttal (possible)
5. Closing arguments
6. Deliberations

Current & Former Employees





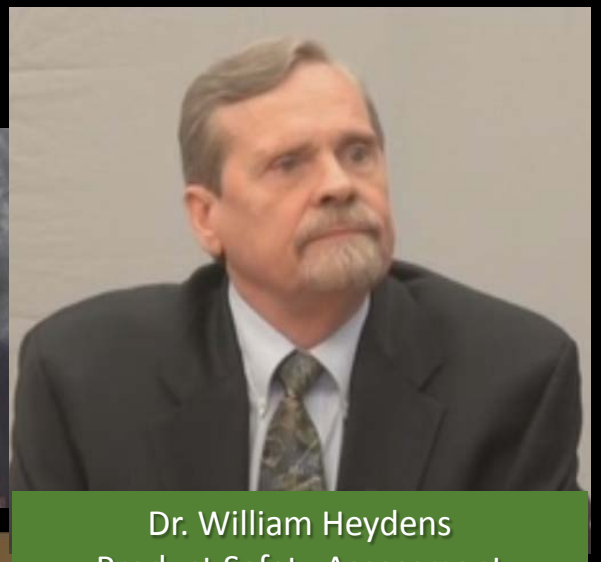





Current & Former Employees

Dr. Donna Farmer
Product Protection Lead

Dr. Daniel Goldstein
Medical Sciences and Outreach



Dr. William Heydens
Product Safety Assessment Strategy Lead

Current & Former Employees










Current & Former Employees

Dr. Mark Martens
Toxicology Director
(former)

Dr. David Saltmiras
Toxicology Manager

Dr. John Acquavella
Epidemiologist (former)

Current & Former Employees










Current & Former Employees

Daniel Jenkins
Manager for Regulatory Affairs

David Heering
Strategy, Compliance, Operations Lead

Current & Former Employees










Current & Former Employees

Steve Gould
National Accounts Manager
(includes California)

Dr. Kirk Azevedo
Sales Representative (former)

Opening Statement Roadmap:

1. What is Roundup?
2. Can Roundup cause cancer?
3. Did Roundup cause Mr. Johnson's cancer?
4. What are Mr. Johnson's damages?
5. Should Monsanto be punished for its conduct?

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1. What is Roundup?

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ACTIVE INGREDIENT:
*Glyphosate, N-(phosphonomethyl)glycine,
in the form of its potassium salt..... 48.7%
OTHER INGREDIENTS:..... 51.3%
100.0%

ACTIVE INGREDIENT:
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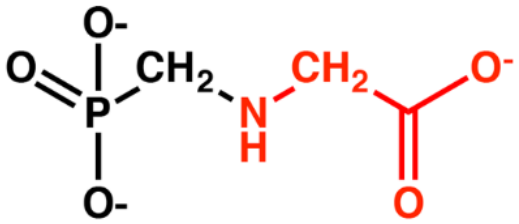
in the form of its isopropylamine salt..... 41.0%
OTHER INGREDIENTS (including surfactant): 59.0%
100.0%

1. What is Roundup?

Glyphosate

glyphosate



1. What is Roundup?

Surfactant

ACTIVE INGREDIENT:

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OTHER INGREDIENTS (including surfactant): 59.0%

100.0%

POlyEthoxylated tallow Amine

1. What is Roundup?

Surfactant

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OTHER INGREDIENTS (including surfactant): 59.0%

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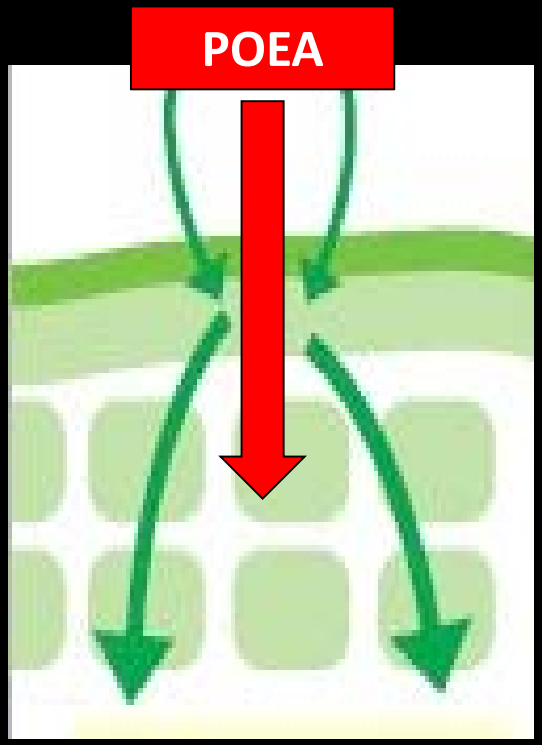
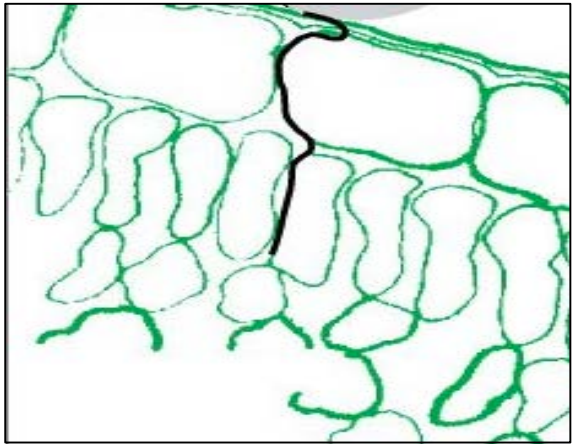
POEA

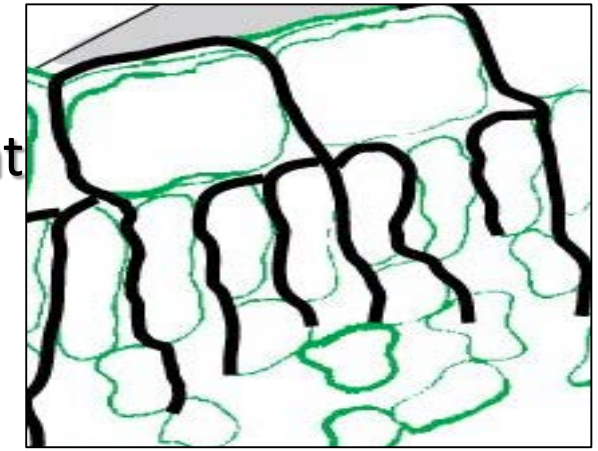
1. What is Roundup?



Without Surfactant

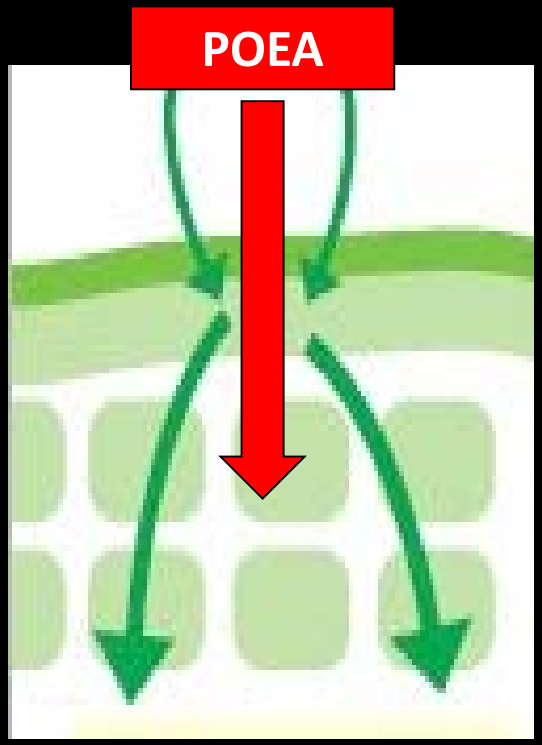


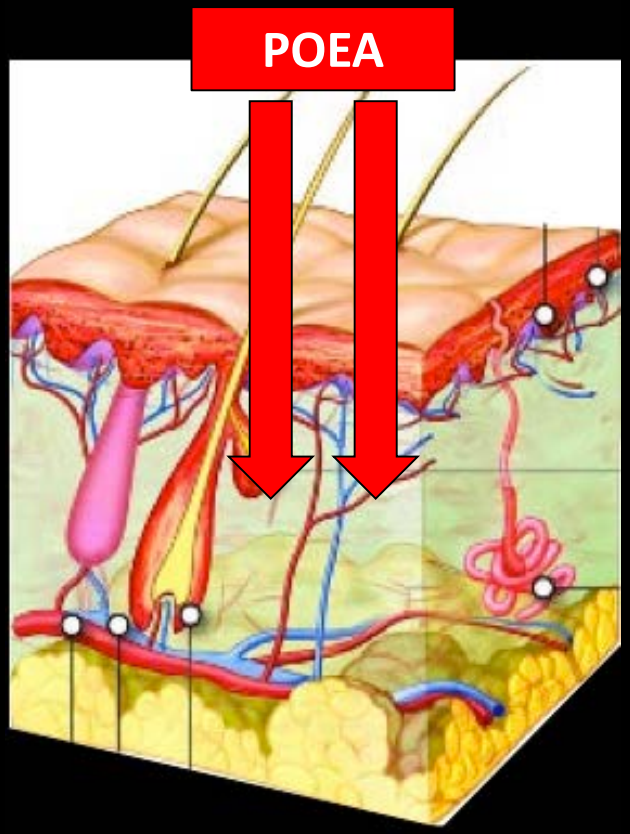
With Surfactant



1. What is Roundup?

Penetrates the surface of a leaf, but also human skin





1. What is Roundup?

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?

Plaintiff Exhibit
0366

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2. Can Roundup cause cancer?

Three Pillars of Cancer Science

1. Animal Carcinogenicity Studies
2. Mechanistic Data
3. Epidemiology

Plaintiff's Experts

Christopher Portier, PhD.

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

- Ph.D. in Biostatistics, University of North Carolina School of Public Health (1981). Thesis addressed the best way to design a two-year rodent study to assess the ability of a chemical to cause cancer.
- Former Associate Director of the National Toxicology Program (NTP)
- Former Associate Director of National Institutes of Health
- Former Director of the National Center for Environmental Health (NCEH) at the Centers for Disease Control and Prevention (CDC)
- Former Director of the Agency for Toxic Substances and Disease Registry (ATSDR)

Plaintiff's Experts

Alfred Neugut, M.D., PhD.

- Professor of Cancer Research and Professor of Medicine and Epidemiology at Columbia University
- Director of Junior Faculty Development for the Department of Epidemiology at Columbia University
- Medical oncologist with a Ph.D. in Pathology (1977) and M.P.H. in Epidemiology (1983) from the University of Columbia
- Published over 500 peer reviewed chapters and papers and received over $50 million in funding from the National Cancer Institute, American Cancer Society, and Department of Defense

2. Can Roundup cause cancer?

Three Pillars of Cancer Science

1. Animal Carcinogenicity Studies
2. Mechanistic Data
3. Epidemiology

2. Can Roundup cause cancer?

Three Pillars of Cancer Science

1. Animal Carcinogenicity Studies
2. Mechanistic Data
3. Epidemiology

2. Can Roundup cause cancer?

1. Animal Carcinogenicity Studies

Glyphosate only

Long term – typically, 2 years

Control	Low Dose	Mid Dose	High Dose

- Significant increases in tumors
- Replication
- Dose response
- Cross-species
- Rare tumors

2. Can Roundup cause cancer?

    1. Animal Carcinogenicity Studies

Admission No. 7

Monsanto admits that it did not conduct any further long-term carcinogenicity animal studies after 1991.

- Significant increases in tumors
- Replication
- Dose response
- Cross-species
- Rare tumors

2. Can Roundup cause cancer?

1. Animal Carcinogenicity Studies

Mice Studies – Tumor Chart

Knezevich & Hogan (1983)	Atkinson (1993)	Sugimoto (1997)	Wood (2009)	Kumar (2001)
Kidney carcinomas or adenomas	Malignant lymphoma	Kidney carcinomas or adenomas	Malignant lymphoma	Kidney carcinomas or adenomas
Spleen composite lymphosarcoma	Hemangiosarcoma	Malignant lymphoma	Mul. malignant tumors or neoplasms	Malignant lymphoma
		Hemangiosarcoma	Lung adenocarcinoma	Hemangioma
		Hemangioma		
		Mul. malignant tumors or neoplasms		
		Harderian gland adenoma		

2. Can Roundup cause cancer?

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Mice Studies – Tumor Chart

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2. Can Roundup cause cancer?

1. Animal Carcinogenicity Studies

George Study (2010)

- Applied to skin 3x week
- 40% of mice exposed to glyphosate had tumors in skin
- 0% of control group had tumors in skin

Evidence that glyphosate is a tumor promoter

2. Can Roundup cause cancer?

1. Animal Carcinogenicity Studies

Glyphosate only

Long term – typically, 2 years

Control	Low Dose	Mid Dose	High Dose

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Rat Studies – Tumor Chart

Lankas (1981)	Stout & Ruecker (1990)	Atkinson (1993)	Enemoto (1997)	Suresh (1996)	Brammer (2001)	Wood (2009)
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Thyroid C-Cell carcinomas or adenomas	Pancreatic islet cell tumors	Skin kera-toacanthoma	Skin kera-toacanthoma			Mammary gland carcinomas or adenomas
Pancreatic islet cell tumors	Hepatocellular carcinomas or adenomas		Basal cell tumors			Pituitary adenomas
	Adrenal cortical carcinomas					
	Skin kera-toacanthoma					

2. Can Roundup cause cancer?

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2. Can Roundup cause cancer?

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2. Can Roundup cause cancer?

Three Pillars of Cancer Science

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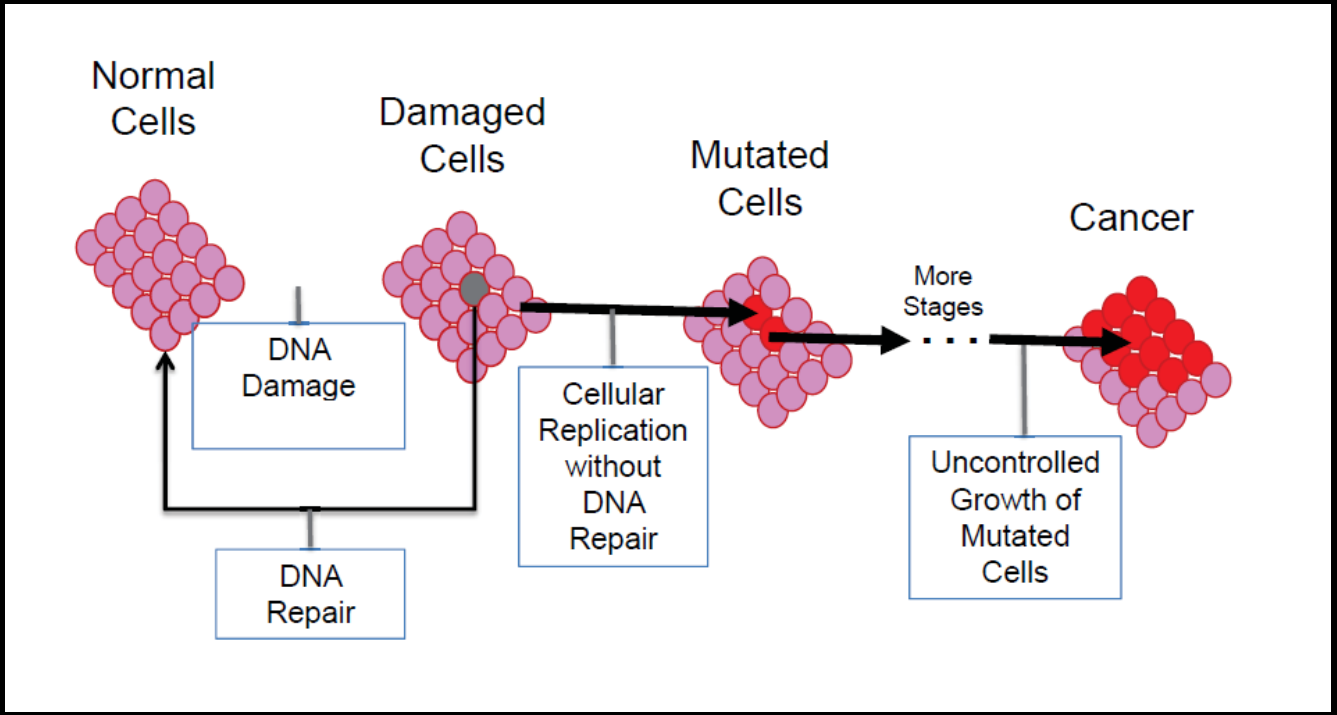
2. Can Roundup cause cancer?

2. Mechanistic Data

Mechanistic Data:

Refers to the way in which a substance can cause cancer.



2. Can Roundup cause cancer?

2. Mechanistic Data

Genotoxicity:

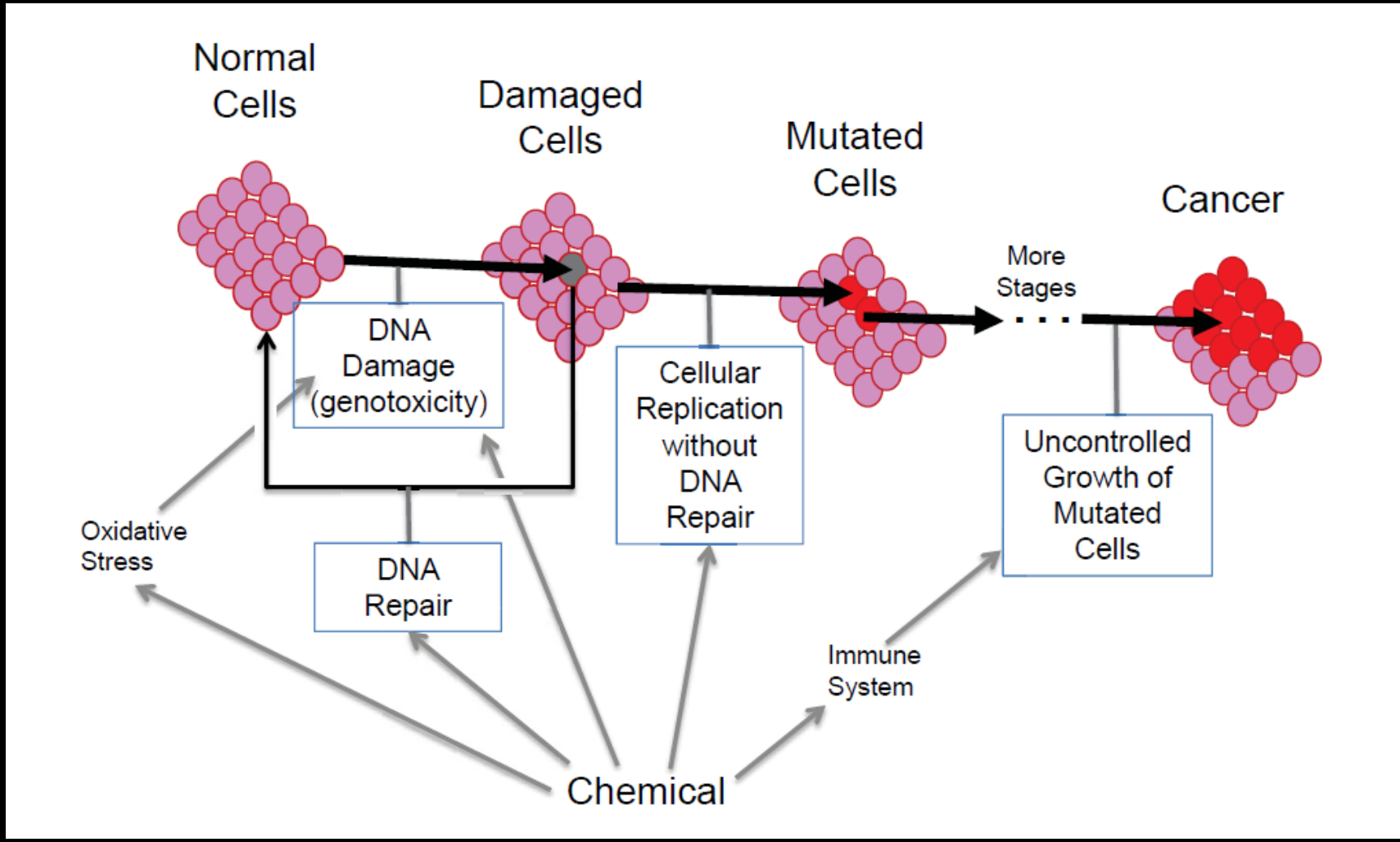
The property of chemical agents that damage the genetic information within a cell that can cause mutations.

Oxidative Stress:

An imbalance between the production of free oxygen particles and the ability of the body to counteract their harmful effects with antioxidants.

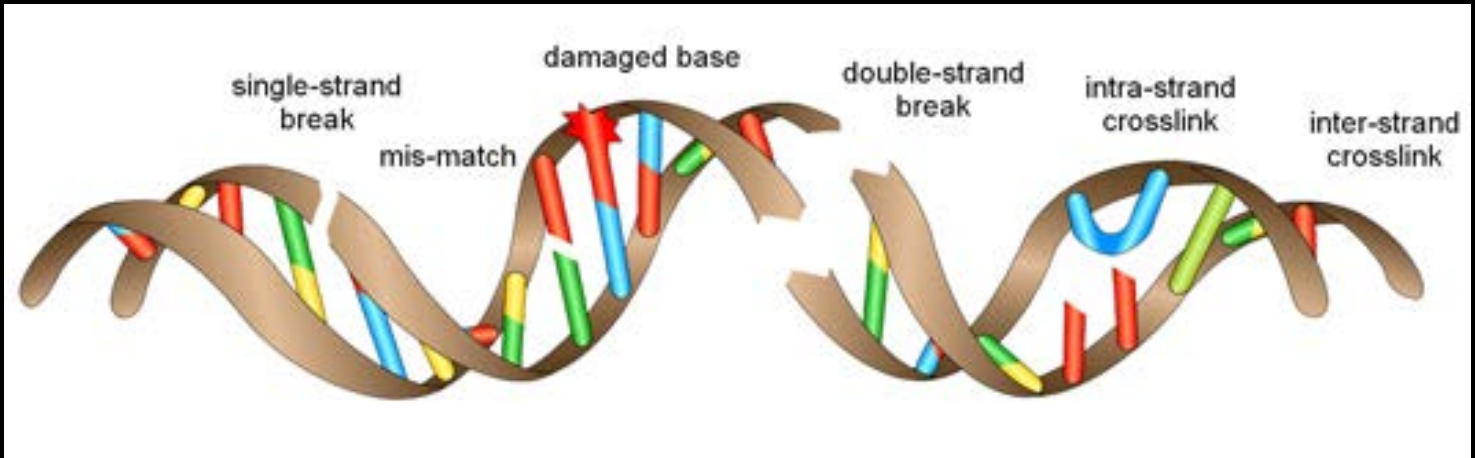
2. Can Roundup cause cancer?

2. Mechanistic Data



2. Can Roundup cause cancer?

2. Mechanistic Data



Different methods of testing DNA damage
Over 100 different studies

- Both Roundup & glyphosate
- In humans (*vivo* & *vitro*)
- Non-human mammals (*vivo* & *vitro*)
- Non-mammals (*vivo* & *vitro*)

In vivo:
In a living organism.

In vitro:
In glass, as in a test tube.

2. Can Roundup cause cancer?

2. Mechanistic Data

In the 1990's four published genotoxicity studies Rank, Bolognesi, Lioi, & Peluso prompted Monsanto to hire an independent genotox expert

Jan 1992

Rank study shows that Roundup exposure, as opposed to glyphosate alone, causes elevated increases of DNA damage.

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

J. Rank, A.-G. Jensen, B. Skov, L.H. Pedersen and K. Jensen

Jan 1992

Rank study shows that Roundup exposure, as opposed to glyphosate alone, causes elevated increases of DNA damage.

Genotoxic Activity of Glyphosate and Its Technical Formulation Roundup

Table 2. Summary of Results on the Genotoxicity of Glyphosate

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

J. Rank, A.-G. Jensen, B. Skov, L.H. Pedersen and K. Jensen

Plaintiff Exhibit 0852

Mar 1997

Plaintiff Exhibit 0686

Bolognesi study shows that Roundup formulation causes genetic damage in human cells.

Genotoxic Activity of Glyphosate and Its Technical Formulation Roundup

Claudia Bolognesi,* Stefania Bonatti, Paolo Degan, Elena Gallerani, Marco Peluso, Roberta Rabboni, Paola Roggieri, and Angelo Abbondandolo

Centro Nazionale per lo Studio dei Tumori di Origine Ambientale, Istituto Nazionale per la Ricerca sul Cancro, Largo Rosanna Benzi 10, 16132 Genova, Italy

Glyphosate (*N*-phosphonomethylglycine) is an effective herbicide acting on the synthesis of aromatic amino acids in plants. The genotoxic potential of this herbicide has been studied: the results available in the open literature reveal a weak activity of the technical formulation. In this study, the formulated commercial product, Roundup, and its active agent, glyphosate, were tested in the same battery of assays for the induction of DNA damage and chromosomal effects *in vivo* and *in vitro*. Swiss CD1 mice were treated intraperitoneally with test substances, and the DNA damage was evaluated by alkaline elution technique and 8-hydroxydeoxyguanosine (8-OHdG) quantification in liver and kidney. The chromosomal damage of the two pesticide preparations was also evaluated *in vivo* in bone marrow of mice as micronuclei frequency and *in vitro* in human lymphocyte culture as SCE frequency. A DNA-damaging activity as DNA single-strand breaks and 8-OHdG and a significant increase in chromosomal alterations were observed with both substances *in vivo* and *in vitro*. A weak increment of the genotoxic activity was evident using the technical formulation.

Keywords: *Pesticides; In vivo genotoxicity; In vitro genotoxicity; SCE; micronucleus test; alkaline elution; DNA oxidative damage*

INTRODUCTION

Roundup, an extremely effective nonselective postemergence herbicide, is a combination of an active ingredient, the isopropylamine salt of glyphosate, and a surface-active agent that enhances the spreading of

1985), but Roundup has been identified as a cau
irritation phenomenon or contact dermatitis, repo
in occupationally exposed agricultural workers (
1986).

The formulated commercial product, Roundup, s

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Claudia Bolognesi,* Stefania Bonatti, Paolo Degan, Elena Gallerani, Marco Peluso, Roberta Rabboni, Paola Roggieri, and Angelo Abbondandolo

Centro Nazionale per lo Studio dei Tumori di Origine Ambientale, Istituto Nazionale per la Ricerca sul Cancro, Largo Rosanna Benzi 10, 16132 Genova, Italy

Glyphosate (*N*-phosphonomethylglycine) is an effective herbicide acting on the synthesis of aromatic amino acids in plants. The genotoxic potential of this herbicide has been studied: the results available in the open literature reveal a weak activity of the technical formulation. In this study, the formulated commercial product, Roundup, and its active agent, glyphosate, were tested in the same battery of assays for the induction of DNA damage and chromosomal effects *in vivo* and *in vitro*. Swiss CD1 mice were treated intraperitoneally with test substances, and the DNA damage was evaluated by alkaline elution technique and 8-hydroxydeoxyguanosine (8-OHdG) quantification in liver and kidney. The chromosomal damage of the two pesticide preparations was also evaluated *in vivo* in bone marrow of mice as micronuclei frequency and *in vitro* in human lymphocyte culture as SCE frequency. A DNA-damaging activity as DNA single-strand breaks and 8-OHdG and a significant increase in chromosomal alterations were observed with both substances *in vivo* and *in vitro*. A weak increment of the genotoxic activity was evident using the technical formulation.

Keywords: *Pesticides; In vivo genotoxicity; In vitro genotoxicity; SCE; micronucleus test; alkaline elution; DNA oxidative damage*

INTRODUCTION

Roundup, an extremely effective nonselective postemergence herbicide, is a combination of an active ingredient, the isopropylamine salt of glyphosate, and a surface-active agent that enhances the spreading of

1985), but Roundup has been identified as a cau
irritation phenomenon or contact dermatitis, repo
in occupationally exposed agricultural workers (
1986).

The formulated commercial product, Roundup, s

Jan 1992

Rank study shows that Roundup exposure, as opposed to glyphosate alone, causes elevated increases of DNA damage.

Genotoxic Activity of Glyphosate and Its Technical Formulation Roundup

Claudia Bolognesi,* Stefania Bonatti, Paolo Degan, Elena Gallerani, Marco Peluso, Roberta Rabboni, Paola Ruggieri, and Angelo Abbondandolo

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Table 2. Summary of Results on the Genotoxicity of Glyphosate

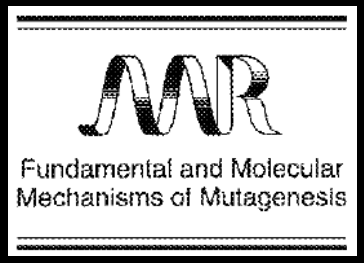
Mar 1997

Bolognesi study shows that Roundup formulation causes genetic damage in human cells.

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

J. Rank, A.-G. Jensen, B. Skov, L.H. Pedersen and K. Jensen

Jul
1998



Lioi study shows that glyphosate induces cell stress in animal cells.

Dec 1998

Plaintiff Exhibit 0842

Peluso study shows that Roundup exposure induces “dose dependent” DNA damage in mice.

Jul 1998

MR Fundamental and Molecular Mechanisms of Mutagenesis

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Dec 1998

Monsanto’s Reaction:
Need to hire an expert to refute these studies, so Monsanto reaches out to Dr. James Parry.

Plaintiff Exhibit 0215

not heard yet).

AM of:

Reply Separator

Subject: Actions from12/17 Meeting on Mutagenicity
Author: [redacted]
Date: 12/27/98 1:31 PM

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 [redacted] will be included in discussion to outline issue/needs etc.

For North America - [redacted] will be here in early February as part of the CANTOX project. [redacted] as graciously agreed to join in those discussions.

****

2) Unfortunately our time rain out but [redacted] and [redacted] stayed a little while longer and dicussed the [redacted] 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 [redacted] paper. Therefore we do some things quickly!

- The results of the human lymphocyte test by [redacted] do not agree with

Dec 1998

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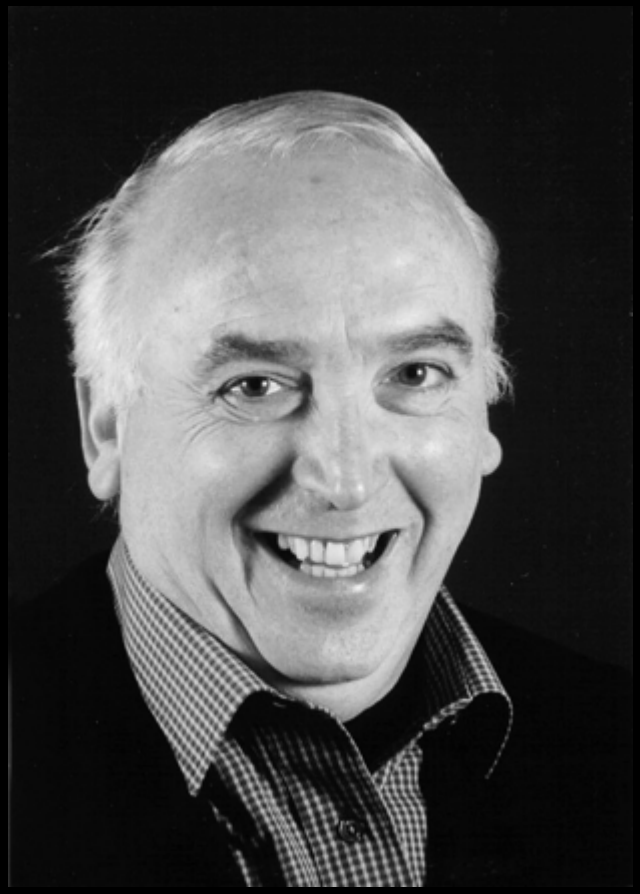
Dr. James Parry



1940 - 2010

Swansea University
Prifysgol Abertawe

- Author of two influential textbooks “Comparative Genetic Toxicology” and “Principles and Methods of Genetic Toxicology”
- Published over 300 papers on toxicology
- Founder of Journal “Mutagenesis” and the “European Journal of Molecular Genetics and Toxicology”
- President of the European Environmental Mutagen Society

Dr. James Parry

Monsanto Unsure About Dr. Parry

Plaintiff Exhibit
0263

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

6). External global network of genotox experts:

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Dr. James Parry

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

Dec 1998

Plaintiff Exhibit 0842

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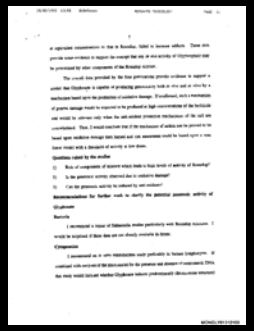
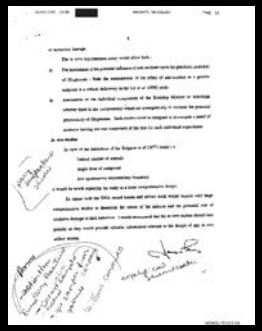
Feb 1999

Dr. Parry submits his first internal report, concluding glyphosate is genotoxic.





[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

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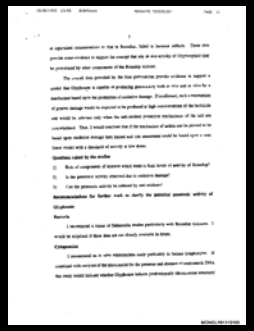

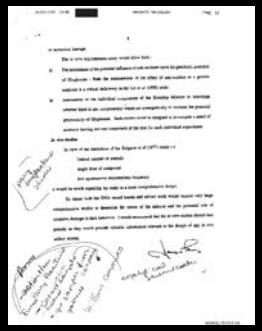

at equivalent concentrations to that in Roundup, failed to increase adducts. These data provide some evidence to support the concept that any *in vivo* activity of Glyphosphate may be potentiated by other components of the Roundup mixture.

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

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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

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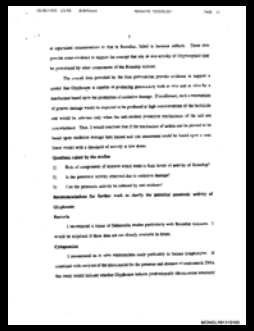

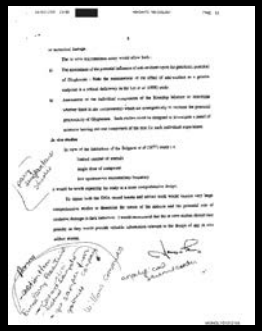

or numerical damage.

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 Dolgnesi *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

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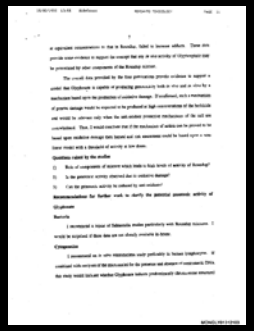

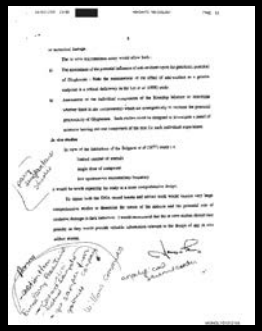

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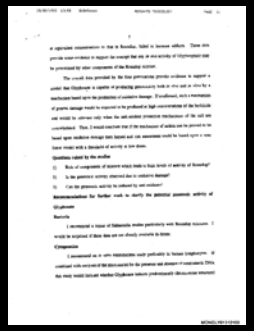

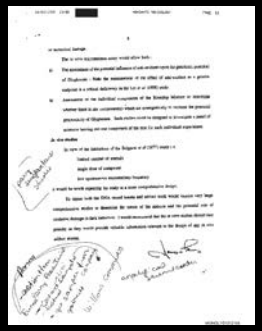

Apr 1999

Monsanto Reaction:

Monsanto decides to give Dr. Parry more data with the hope of turning him around.

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 Mark will contact Dr. Parry, discuss with him the existance of additional data and ask him to evaluate the full package. Mark 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

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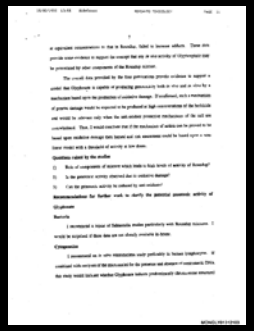

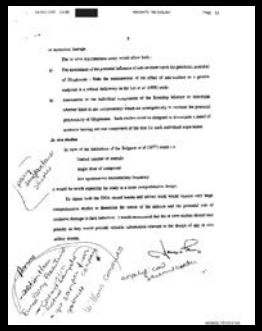

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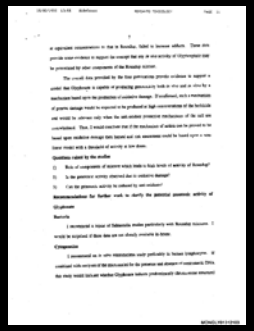
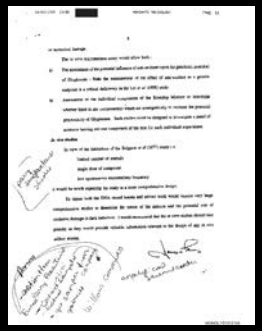




Aug 1999

Dr. Parry submits second comprehensive report.

Aug 1999

Dr. Parry submits second comprehensive report.

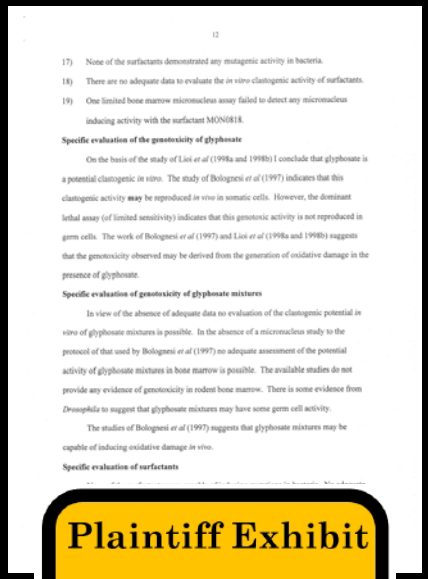
Clastogen:

A clastogen is an agent that can induce mutation by disrupting or damaging chromosomes.

Aug 1999

Dr. Parry submits second comprehensive report.

Dr. Parry concludes glyphosate is clastogenic.



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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

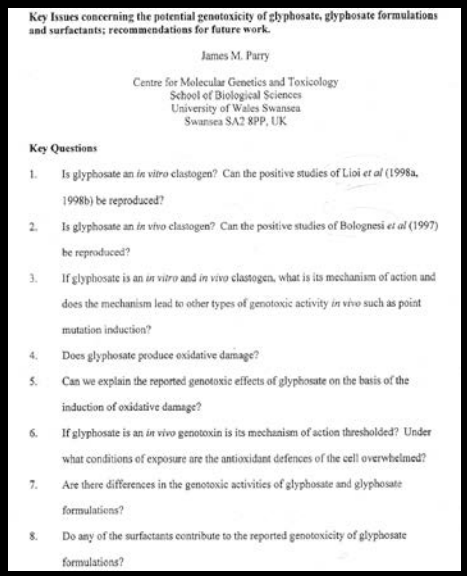
On the basis of the study of Lioi *et al* (1998a and 1998b) I conclude that glyphosate is a potential clastogenic *in vitro*. The study of Bolognesi *et al* (1997) indicates that this clastogenic activity **may** be reproduced *in vivo* in somatic cells. However, the dominant lethal assay (of limited 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



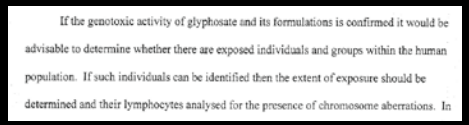
Key Issues concerning the potential genotoxicity of glyphosate, glyphosate formulations and surfactants; recommendations for future work.

James M. Parry

Centre for Molecular Genetics and Toxicology
School of Biological Sciences
University of Wales Swansea
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?



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

inducing activity with the surfactant MON0818.

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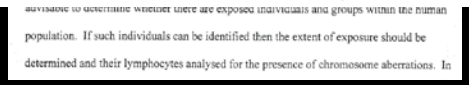
Specific evaluation of surfactants

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.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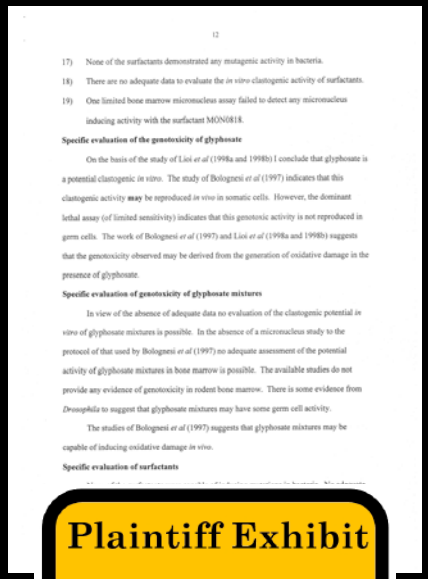

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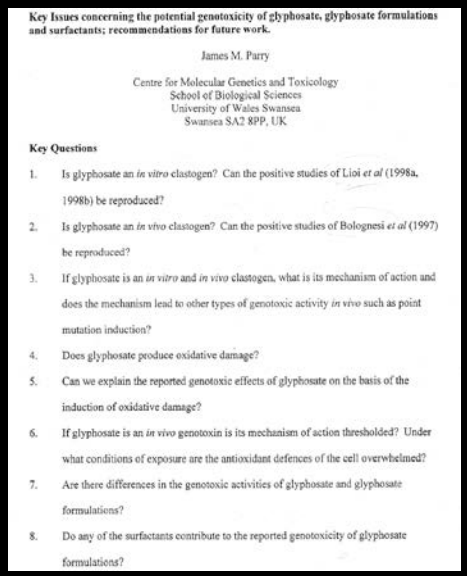

Key Issues concerning the potential genotoxicity of glyphosate, glyphosate formulations and surfactants; recommendations for future work.

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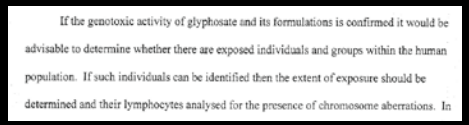

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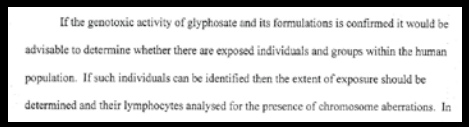
Specific evaluation of surfactants

Plaintiff Exhibit
0220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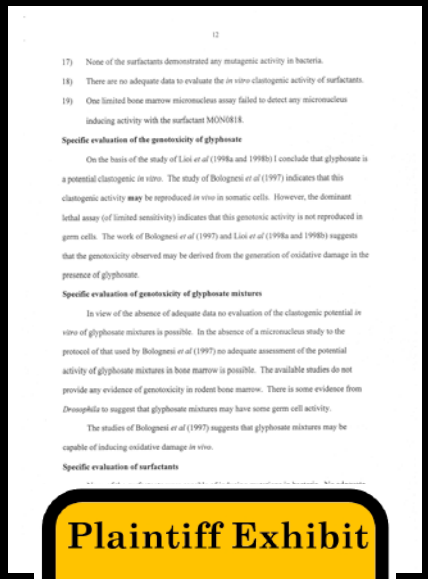

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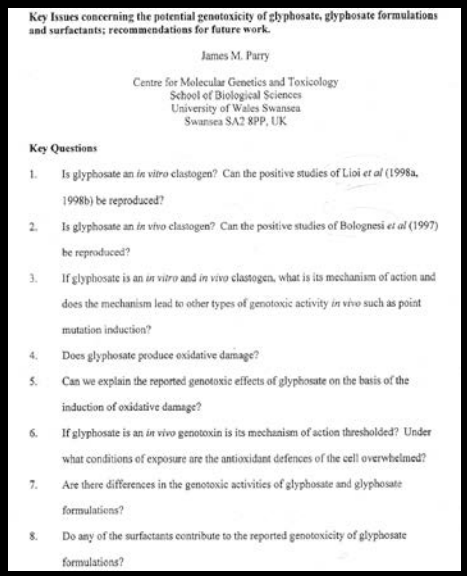

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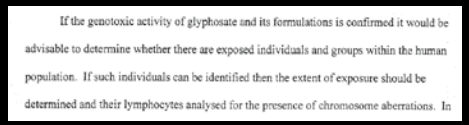

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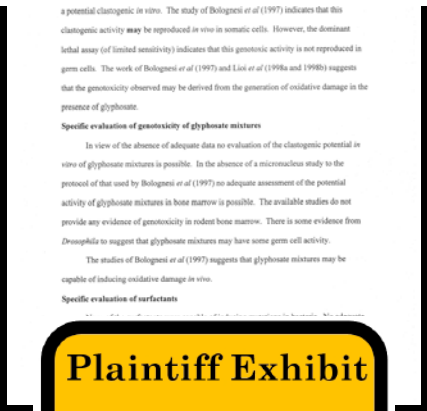

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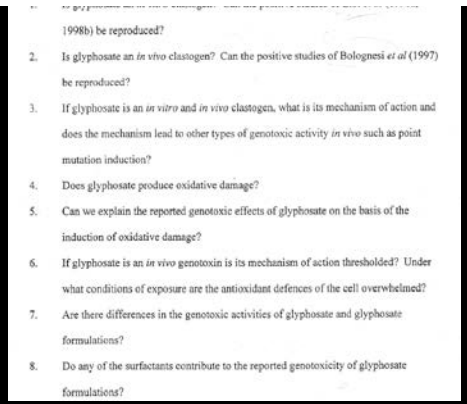

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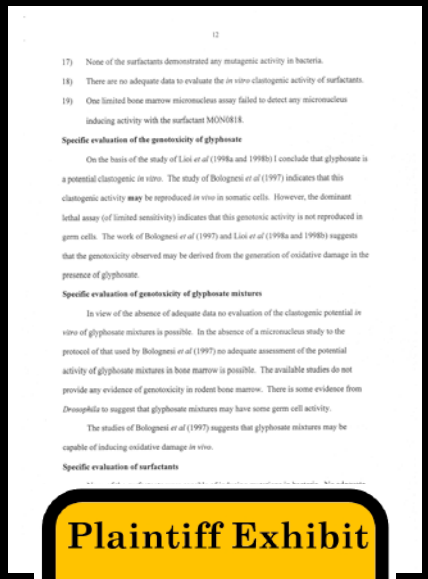

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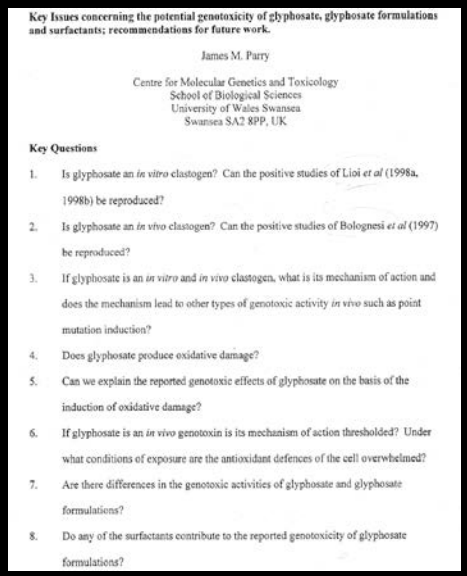

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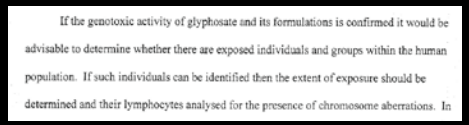

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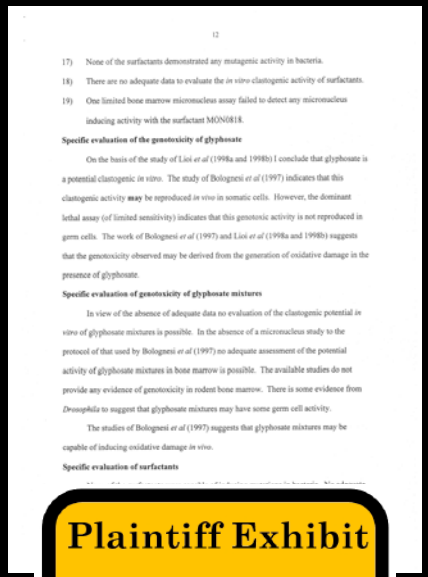

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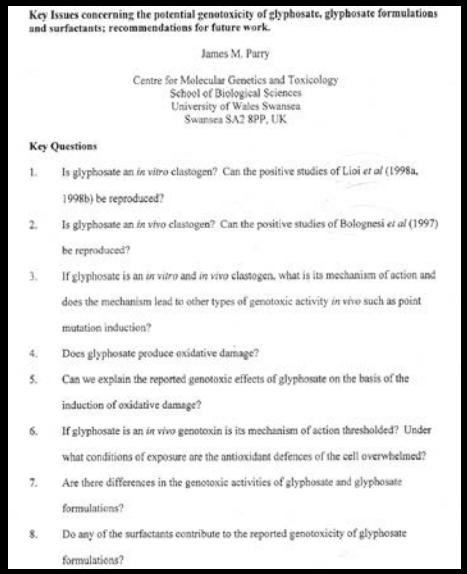
Specific evaluation of surfactants

Plaintiff Exhibit 0220



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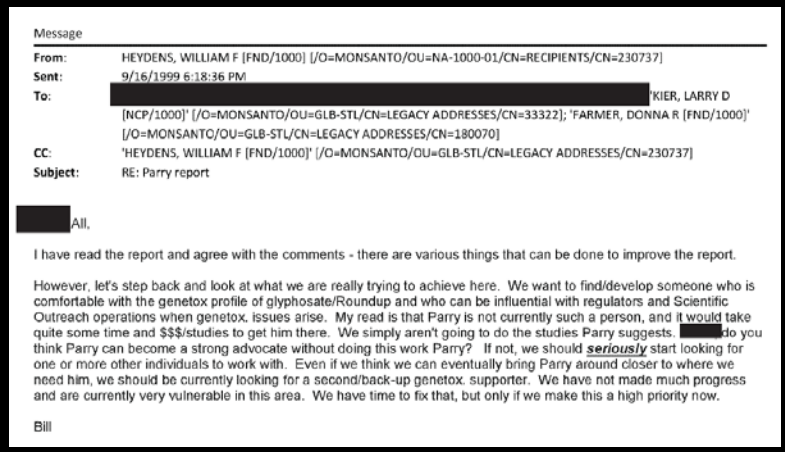

Message

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

Plaintiff Exhibit 0221

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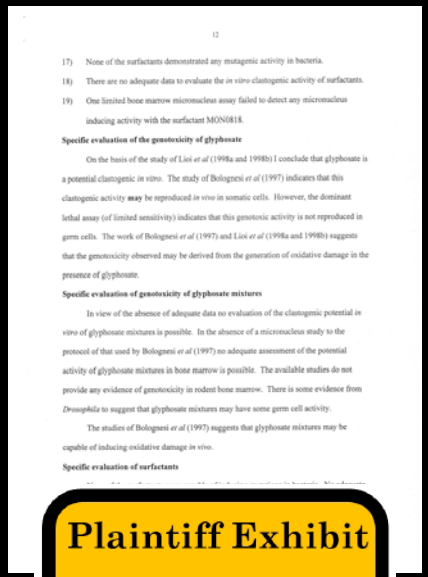

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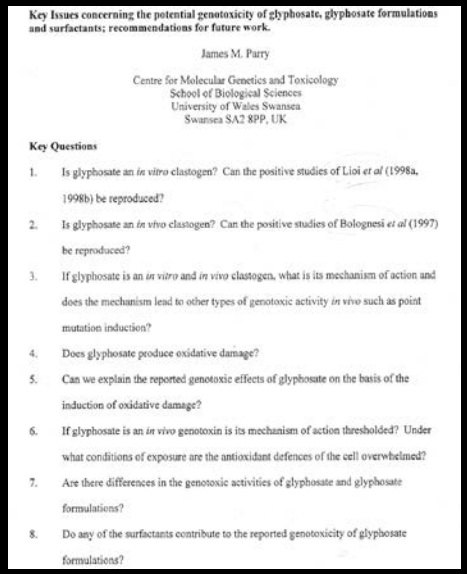
The studies of Bolognesi *et al* (1997) suggests that glyphosate mixtures may be capable of inducing oxidative damage *in vivo*.

Specific evaluation of surfactants

Plaintiff Exhibit 0220



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
School of Biological Sciences
University of Wales Swansea
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?
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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?
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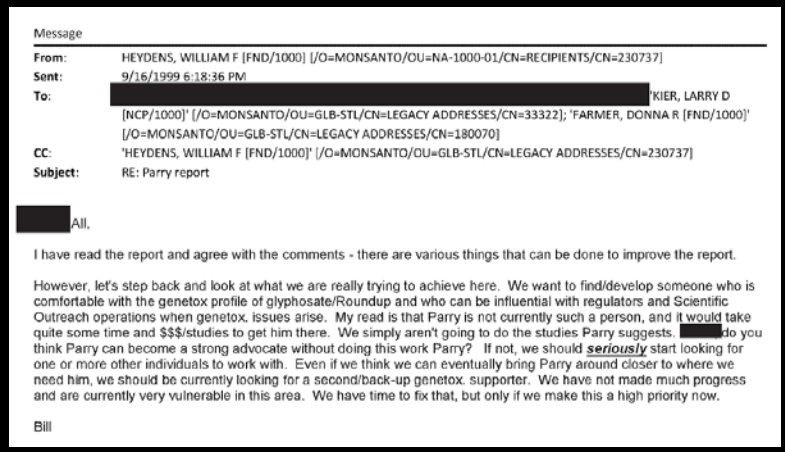
If the genotoxic activity of glyphosate and its formulations is confirmed it would be advisable to determine whether there are exposed individuals and groups within the human population. If such individuals can be identified then the extent of exposure should be determined and their lymphocytes analysed for the presence of chromosome aberrations. In



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]
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Bill

Plaintiff Exhibit 0221

Aug 1999

Dr. Parry submits second comprehensive report.

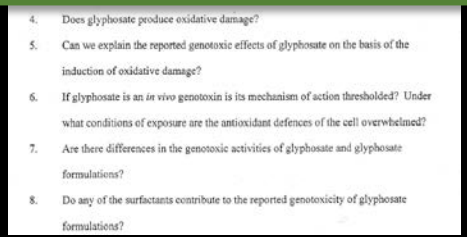
Sept 1999

Monsanto Reaction:
"We simply are not going to do the studies Parry suggests."

Admission No. 26

Monsanto admits that it has no record of submitting Dr. Parry's Reports to the EPA.

Plaintiff Exhibit
0220



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Bill

Plaintiff Exhibit
0221

Aug 1999

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Dr. Parry concludes glyphosate is clastogenic.

Sept 1999

Monsanto Reaction:
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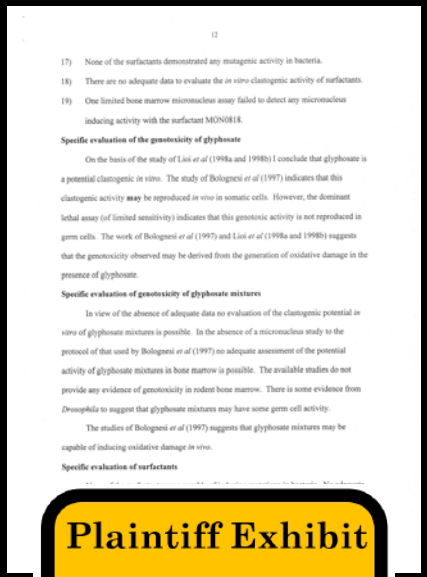

17) None of the surfactants demonstrated any mutagenic activity in bacteria.

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Specific evaluation of surfactants

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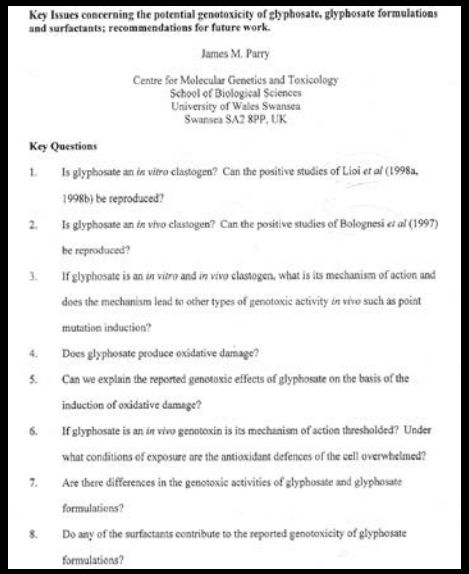

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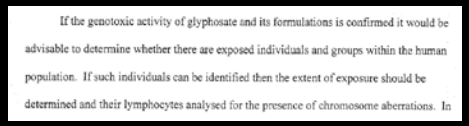

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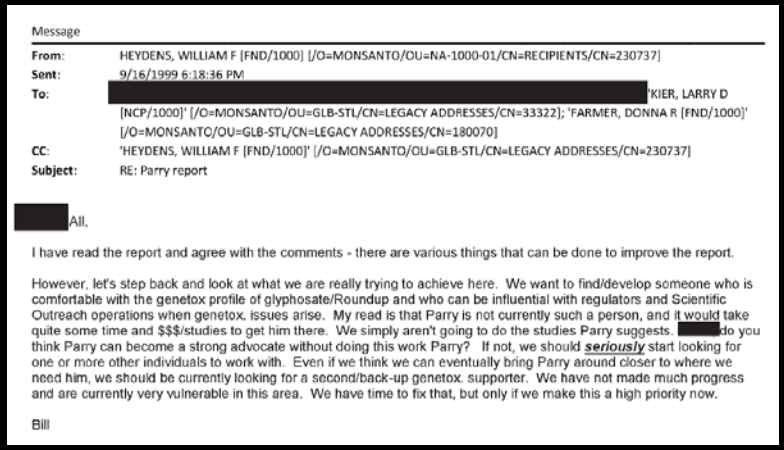

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Bill

Plaintiff Exhibit 0221

Apr 2000

Ghostwriting:

Dr. Heydens ghostwrites Williams paper.

Safety Evaluation and Risk Assessment of the Herbicide Roundup[1] and Its Active Ingredient, Glyphosate, for Humans

Gary M. Williams,* Robert Kroes,† and Ian C. Munro‡,§

*Department of Pathology, New York Medical College, Valhalla, New York 10595; †RITOX, Universiteit Utrecht, P.O. Box #0176, NL-3508 TD Utrecht Yalelaan 2, The Netherlands; and ‡Cantox Health Sciences International, 2233 Argentia Road, Suite 308, Mississauga, Ontario L5N 2X7, Canada

Received December 8, 1999

Plaintiff Exhibit 0377

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

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Apr 2000

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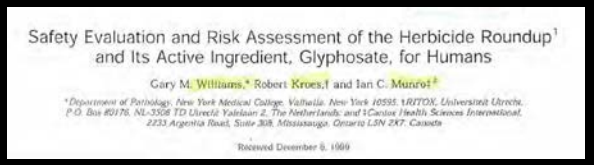
Ghostwriting:

When a company writes a favorable publication and pays a prestigious author to put their name on it.



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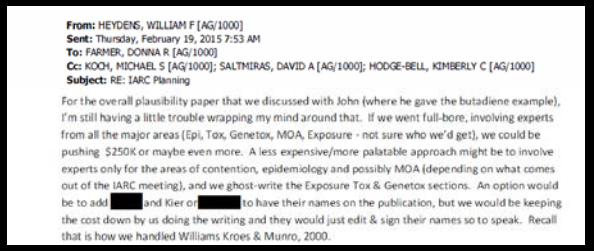

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Apr 2010

Ghostwriting:
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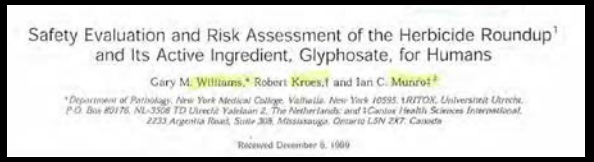

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Received December 8, 1999

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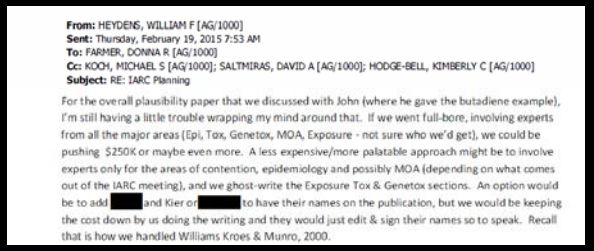

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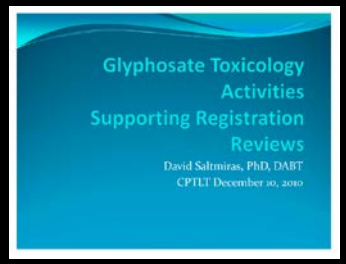
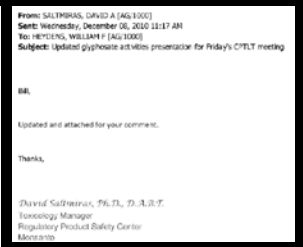


Glyphosate Toxicology Activities Supporting Registration Reviews

David Saltmiras, PhD, DABT
CPTLT December 10, 2010



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

Science

re facing regulatory reviews with increased focus on
r reviewed literature, irrespective of the quality of the science
t including activist researchers
on outcomes – e.g. POEAs in Germany
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rucial to facilitate scientifically robust and objective

Plaintiff Exhibit
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Ap
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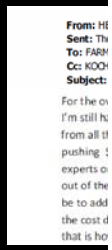
From: SALTMIRAS, DAVID A [AG/1000]
Sent: Wednesday, December 08, 2010 11:17 AM
To: HEYDENS, WILLIAM F [AG/1000]
Subject: Updated glyphosate activities presentation for Friday's CPTLT meeting

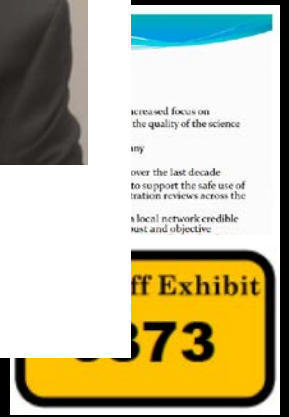
Bill,

Updated and attached for your comment.

Thanks,

David Saltmiras, Ph.D., D.A.B.T.
Toxicology Manager
Regulatory Product Safety Center
Monsanto





Apr 2000

Ghostwriting:
Dr. Heydens ghostwrites Williams paper.

Apr 2000

Ghostwriting:
The Williams paper "has served us well over the last decade."

Safety Evaluation and Risk Assessment of the Herbicide Roundup[1] and Its Active Ingredient, Glyphosate, for Humans

Gary M. Williams,* Robert Kroes,† and Ian C. Munro†,‡

*Department of Pathology, New York Medical College, Valhalla, New York 10595; †RITOX, Universiteit Utrecht, P.O. Box #0176, NL-3508 TD Utrecht Yalelaan 2, The Netherlands; and ‡Canton Health Sciences International, 2233 Argentia Road, Suite 308, Mississauga, Ontario L5N 2X7, Canada

Received December 8, 1999

Plaintiff Exhibit 0377

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

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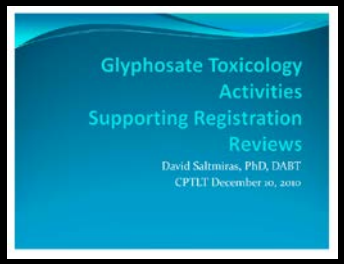
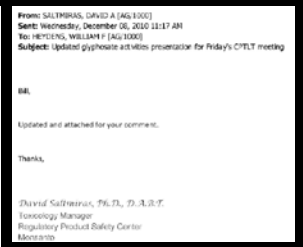




Glyphosate Toxicology Activities Supporting Registration Reviews

David Saltmiras, PhD, DABT

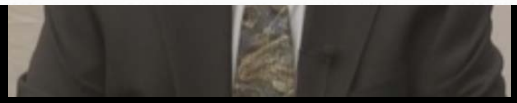
CPTLT December 10, 2010

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???

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*



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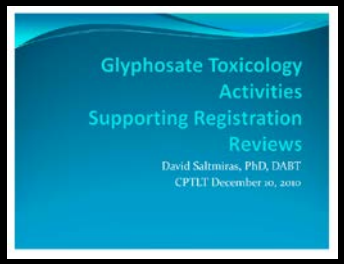
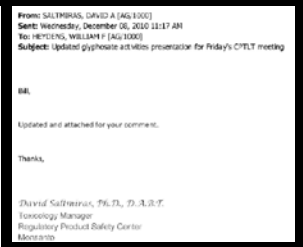
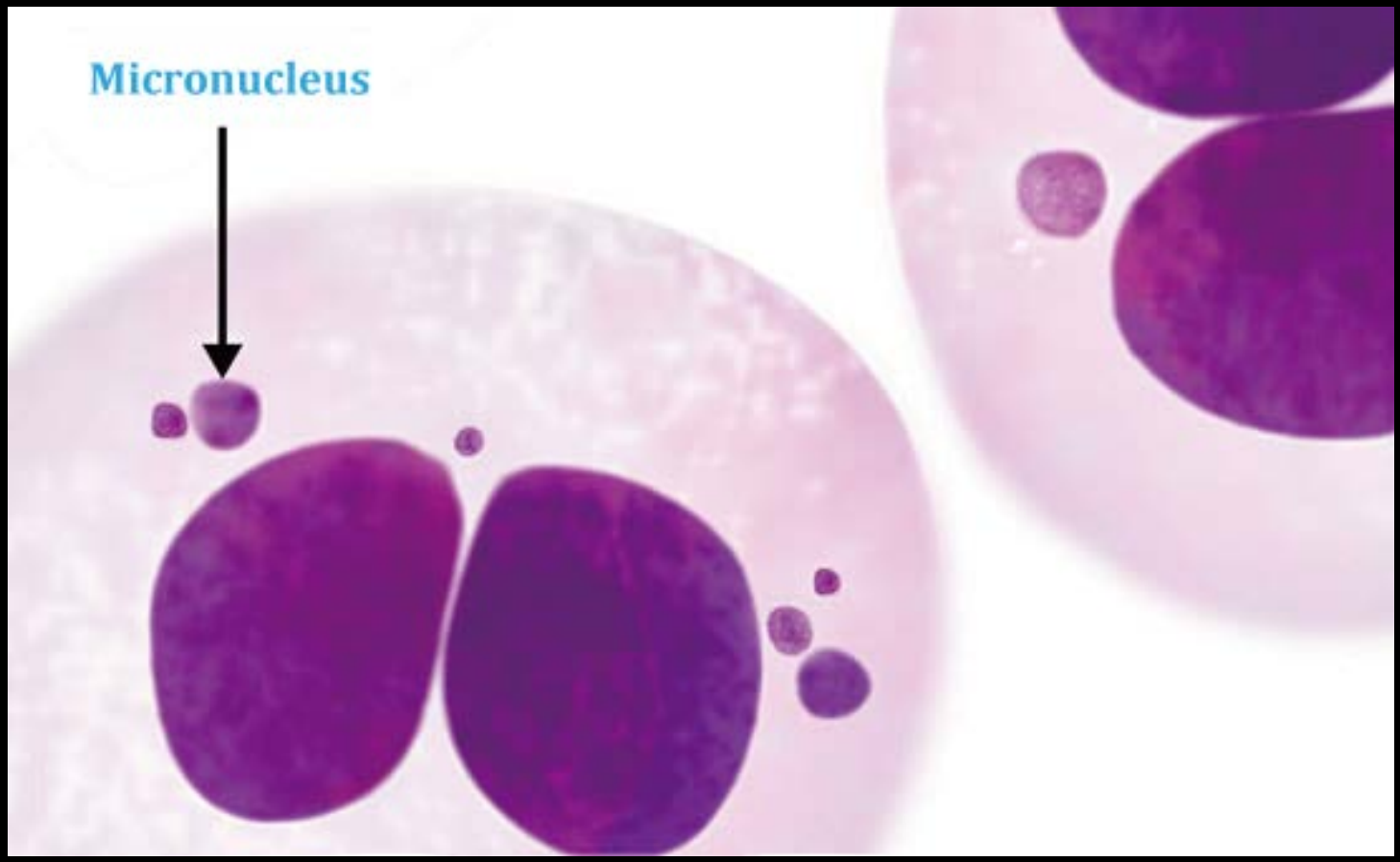




2. Can Roundup cause cancer?

2. Mechanistic Data

Recent Data Findings:



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Chemosphere 145 (2016) 42–54

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Does exposure to glyphosate lead to an increase in the micronuclei frequency? A systematic and meta-analytic review

Nédia de Castilhos Ghisi [a, b, *], Elton Celton de Oliveira [b], Alberto José Prioli [b]

[a] Programa de Pós-graduação em Ecologia de Ambientes Aquáticos e Continentais (PEA)/Nupélia, Universidade Estadual de Maringá (UEM), Av. Colombo, 5790, Zona 7, 87020-900, Maringá (PR), Brazil
[b] Universidade Tecnológica Federal do Paraná (UTFPR), Estrada para Boa Esperança, km 4, 85660-000, Dois Vizinhos (PR), Brazil

HIGHLIGHTS

- Systematic meta-analytical review correlating glyphosate exposure and micronuclei.
- Groups exposed to glyphosate formulations have increased formation of micronuclei.
- Significant difference among glyphosate (GLY) and its commercial formulations.
- Difference in MN formation among different exposure routes of GLY.
- Difference in MN formation among different groups of vertebrates.

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Handling Editor: Frederic Leusch

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Micronucleus
Mutagenesis
Pesticides
Roundup

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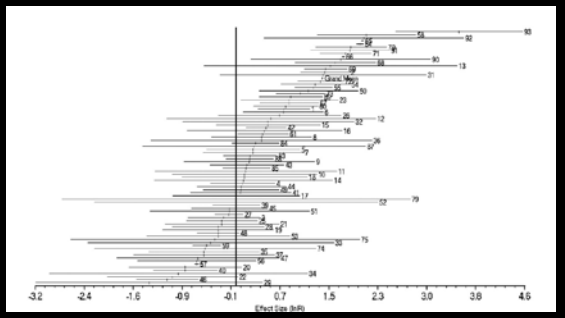

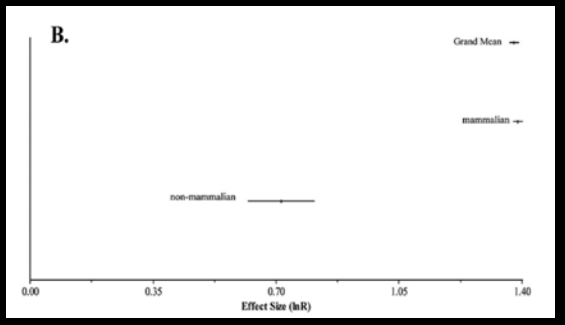

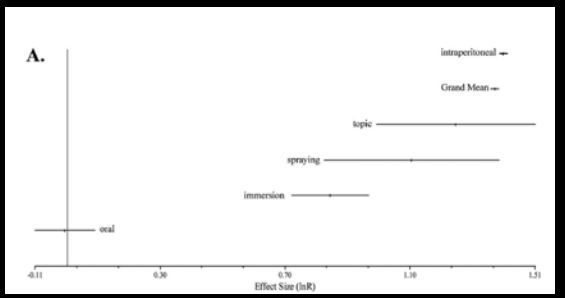

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Nédia de Castilhos

[a] Programa de Pós-graduação em
5790, Zona 7, 87020-900, Maring
[b] Universidade Tecnológica Federa

Meta-analysis:

A statistical approach that combines the results of multiple studies into a single summary estimate.

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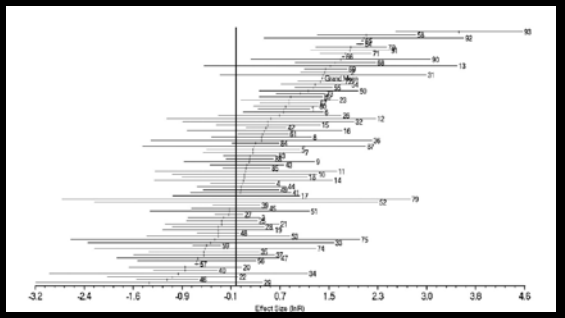

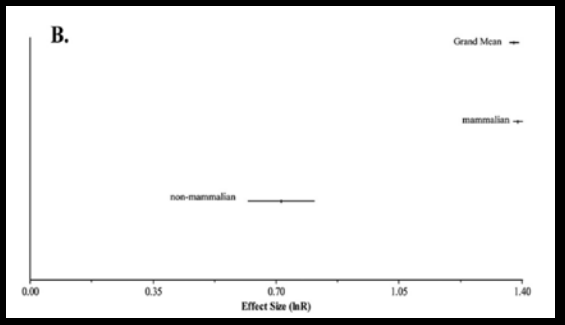

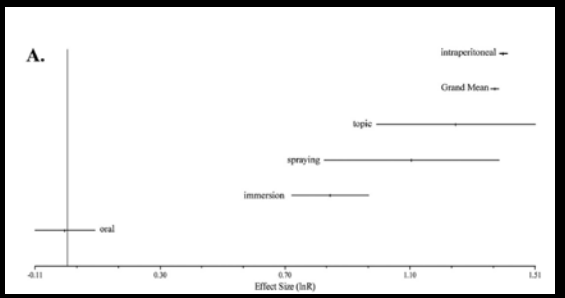

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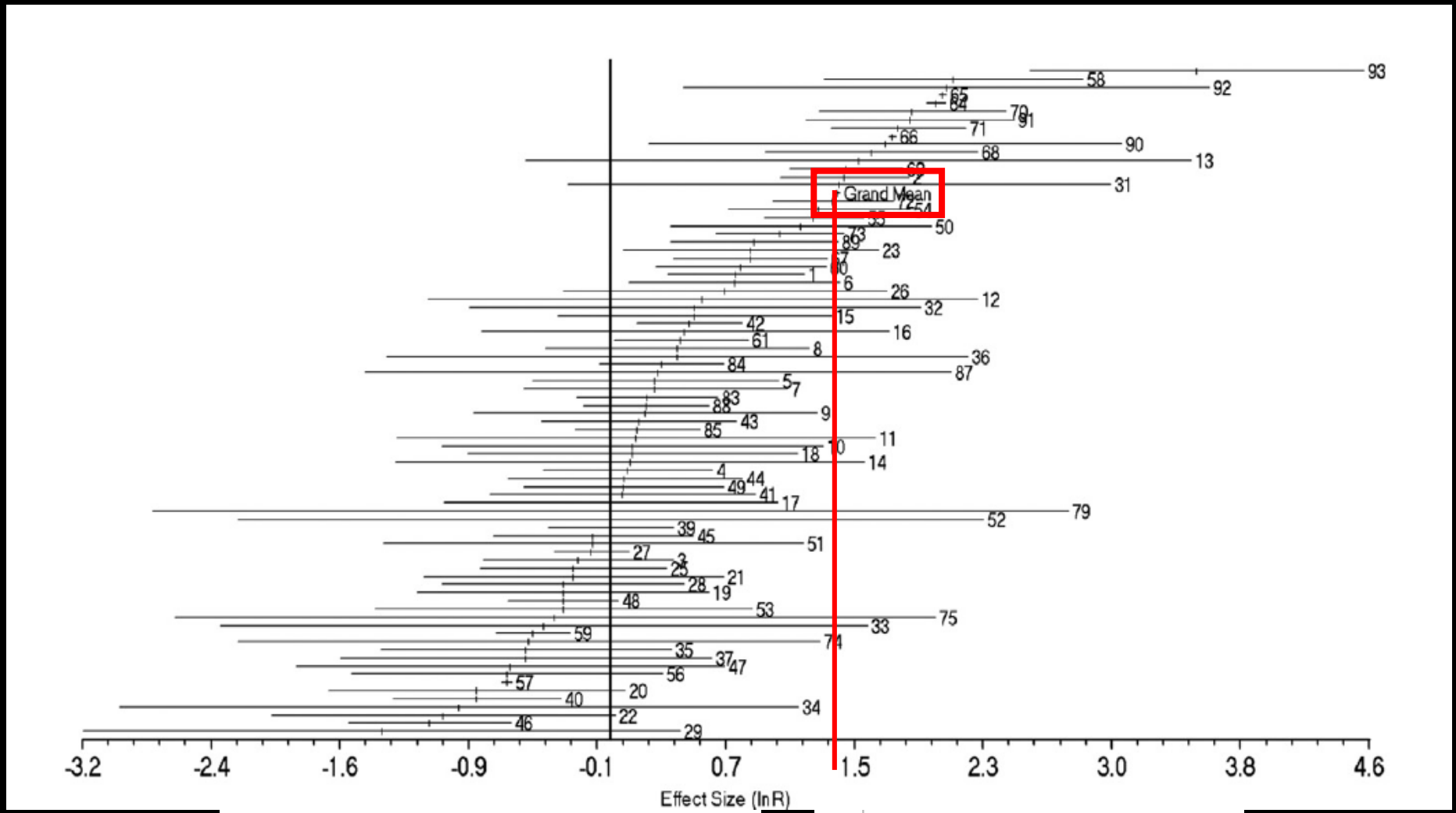

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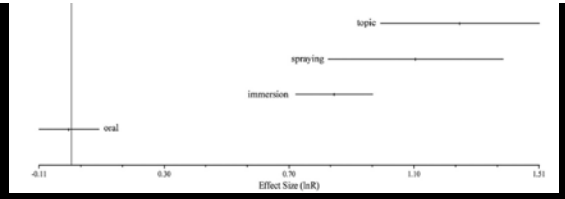

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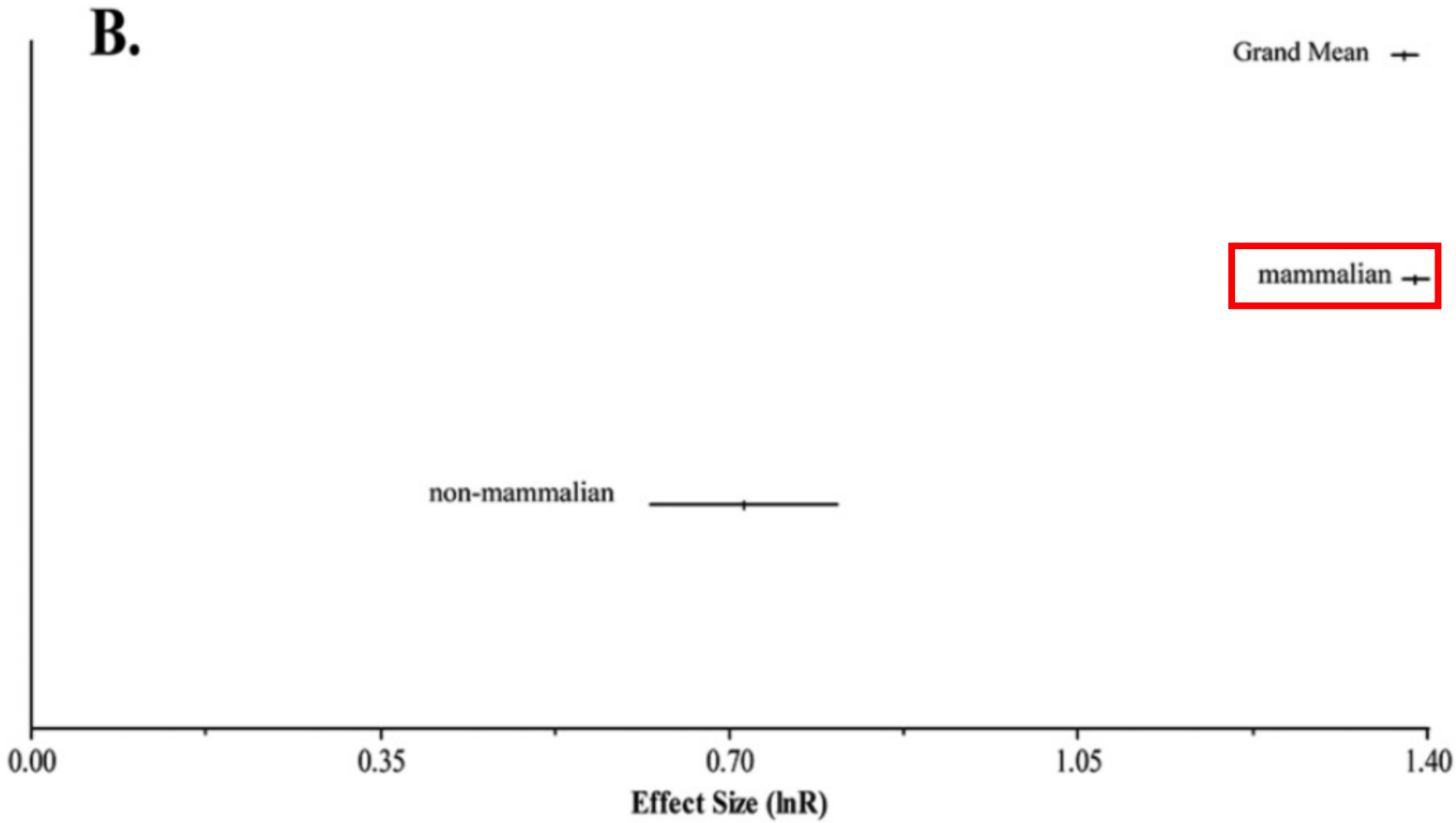


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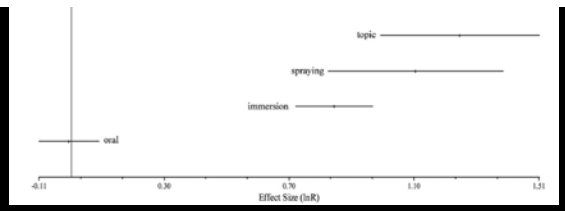

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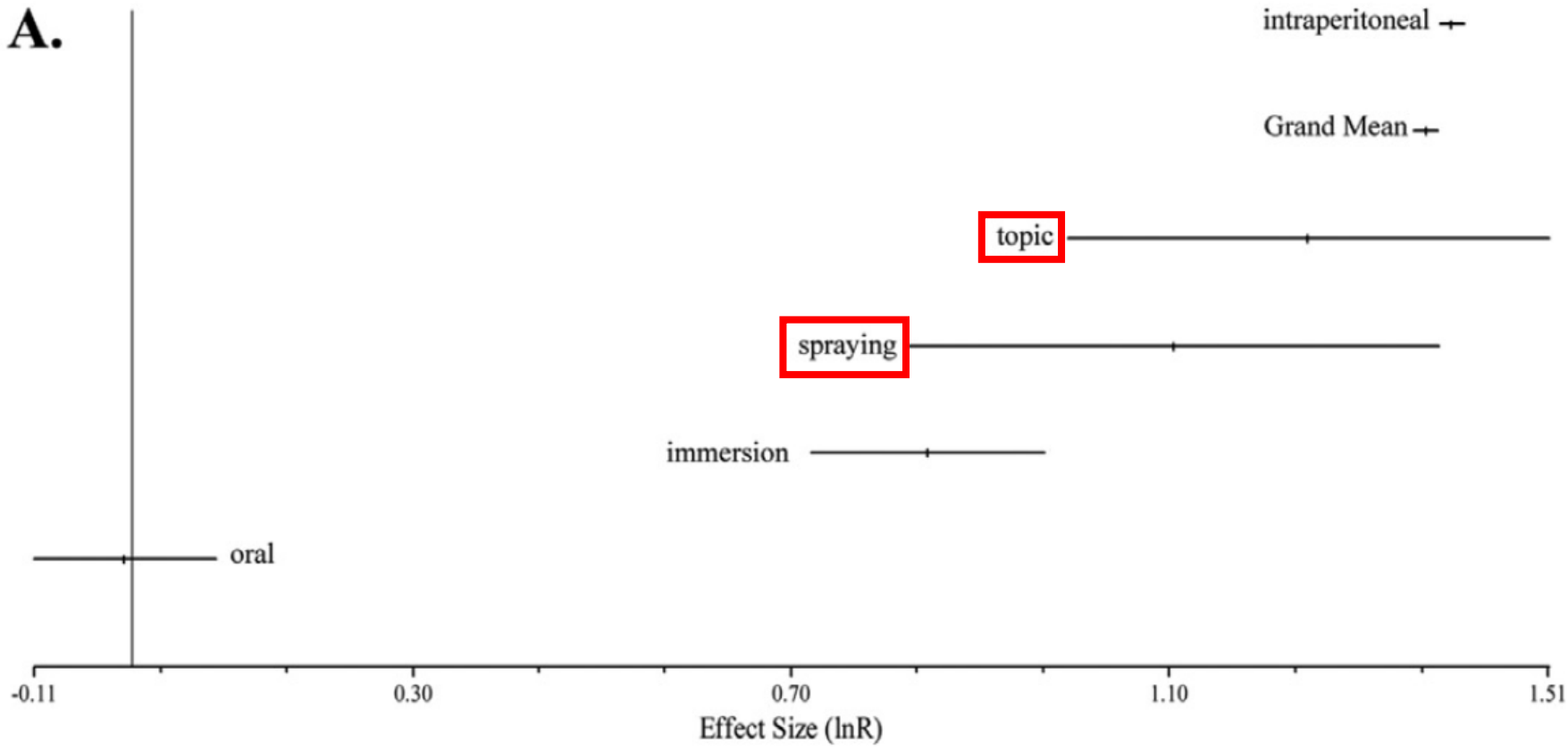

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2. Can Roundup cause cancer?

Three Pillars of Cancer Science

1. Animal Carcinogenicity Studies
2. Mechanistic Data
3. Epidemiology

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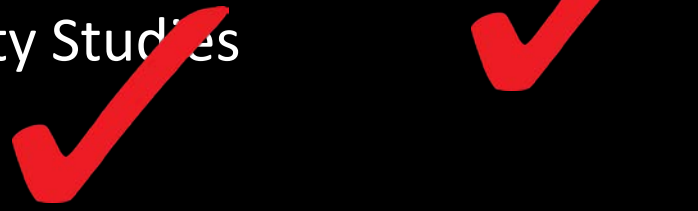


2. Can Roundup cause cancer?

3. Epidemiology

Epidemiology:

The study of the distribution and causes of disease in human populations.

Non-Hodgkin Lymphoma-specific

2. Can Roundup cause cancer?

3. Epidemiology

Non-Hodgkin Lymphoma:

A cancer that starts in white blood cells called lymphocytes, which are part of the body's immune system.

Two types:

- B-Cell (most common)
- T-Cell (less common)

2. Can Roundup cause cancer?

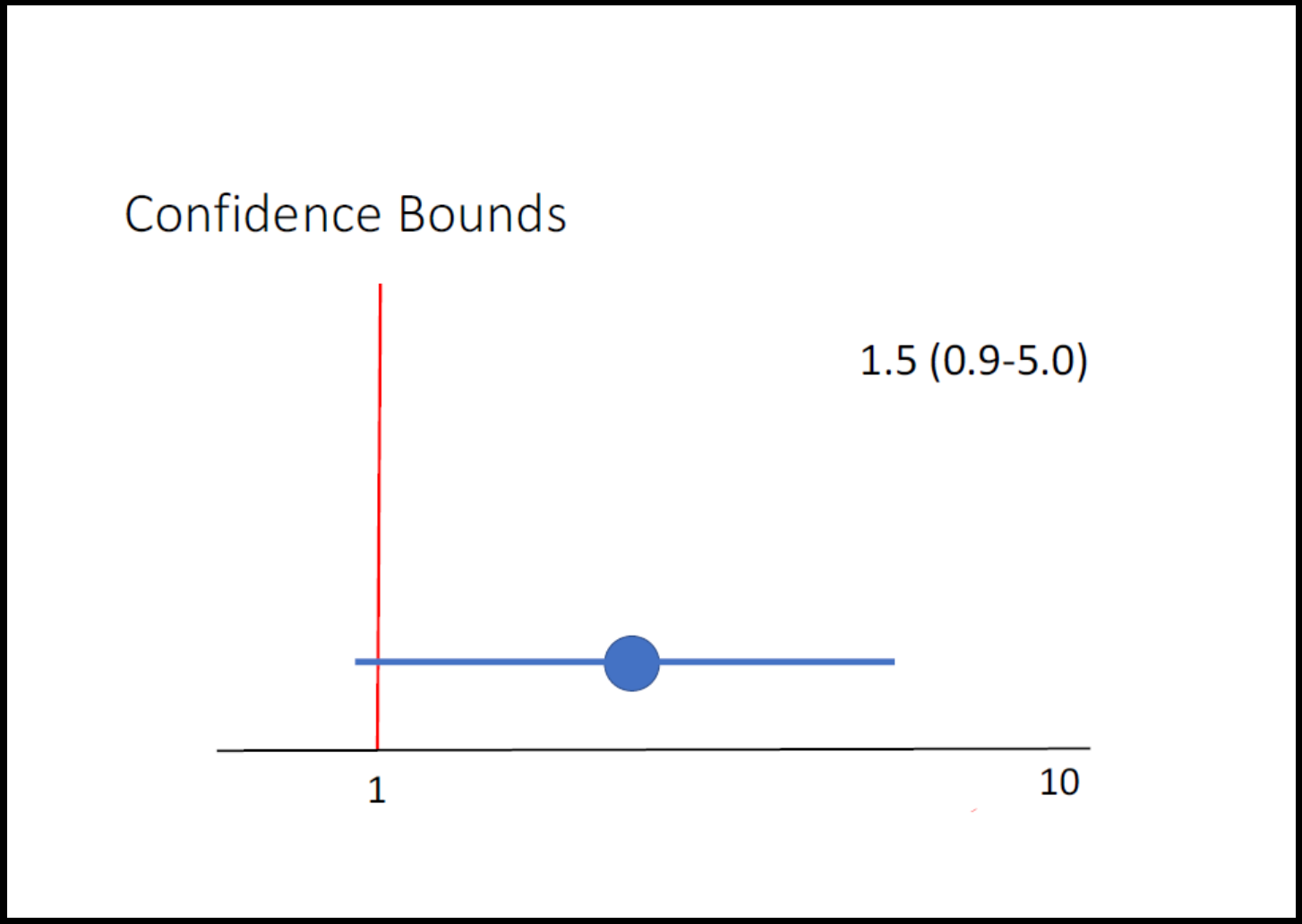
3. Epidemiology

Confidence Bound:

A range of values where there is a specified probability that the true value lies within it.

2. Can Roundup cause cancer?

3. Epidemiology



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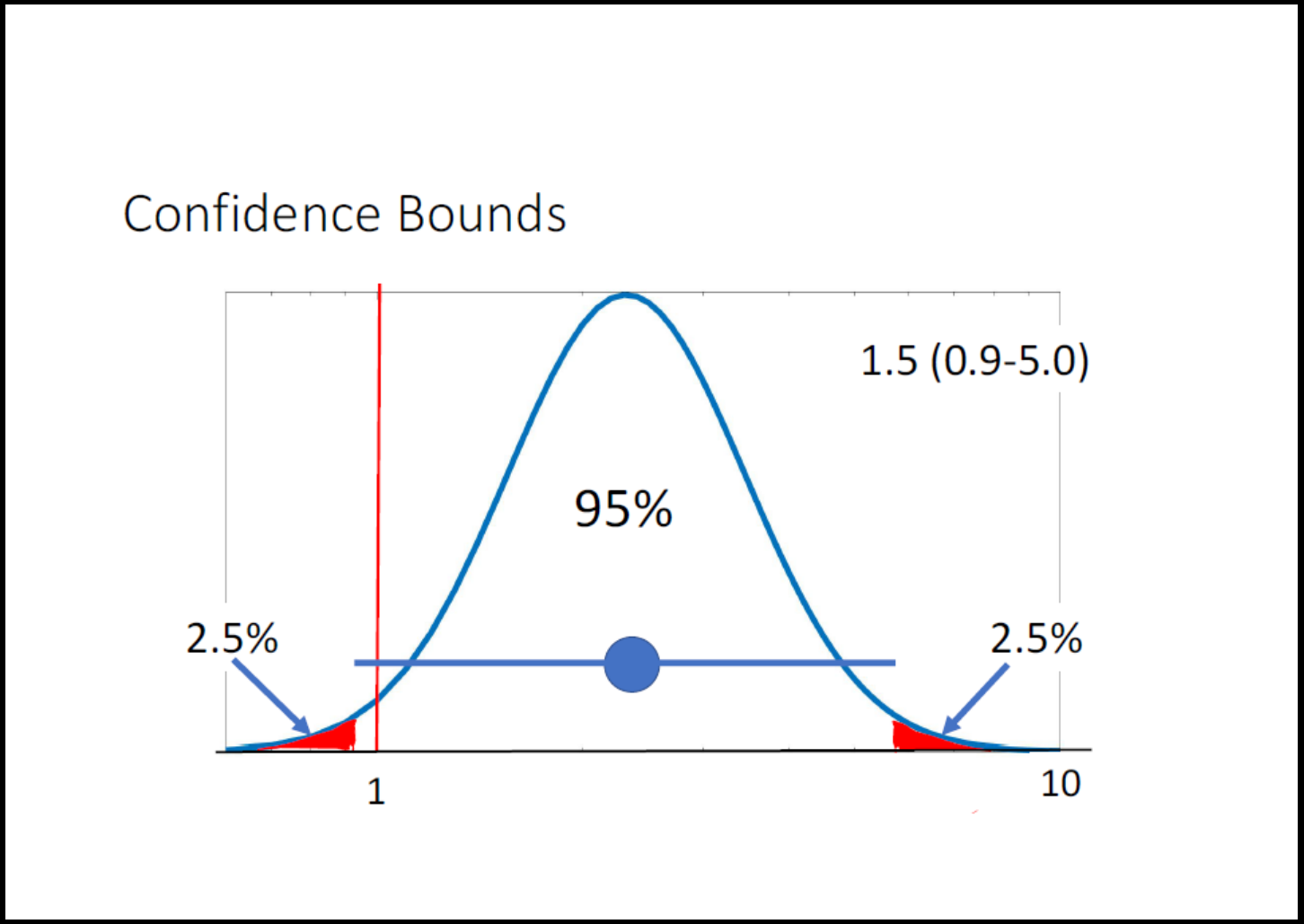
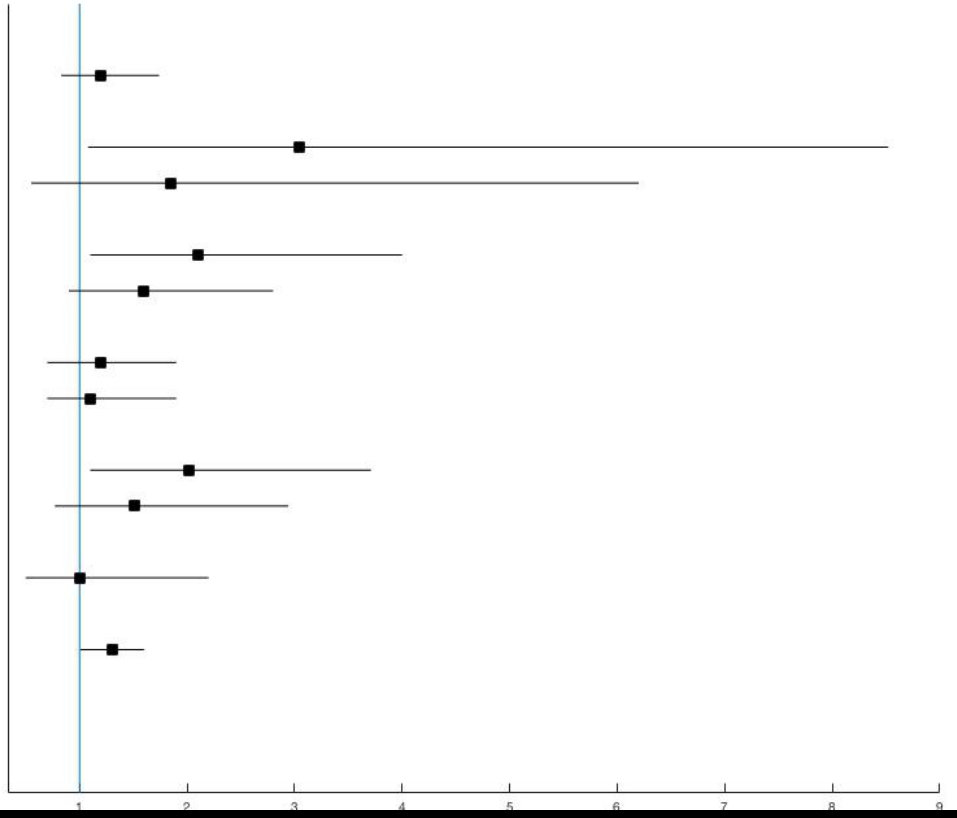


2. Can Roundup cause cancer?

3. Epidemiology

NHL – Never / Ever

Study	RR	Lower	Upper
McDuffie et al. (2001)			
no pesticide adjustment	1.20	0.83	1.74
Hardell et al. (2002)			
no pesticide adjustment	3.04	1.08	8.52
adjusted for pesticides	1.85	0.55	6.20
De Roos et al. (2003)			
adjusted for pesticides	2.10	1.10	4.00
Bayesian modeling	1.60	0.90	2.80
De Roos et al. (2005)			
no pesticide adjustment	1.20	0.70	1.90
adjusted for pesticides	1.10	0.70	1.90
Eriksson et al., (2008)			
no pesticide adjustment	2.02	1.10	3.71
adjusted for pesticides	1.51	0.77	2.94
Orsi et al. (2009)			
no pesticide adjustment	1.00	0.50	2.20
Meta-Analysis: Model 1			
most adjusted analysis	1.30	1.01	1.60
Andreotti et al. (2018)			
not provided			



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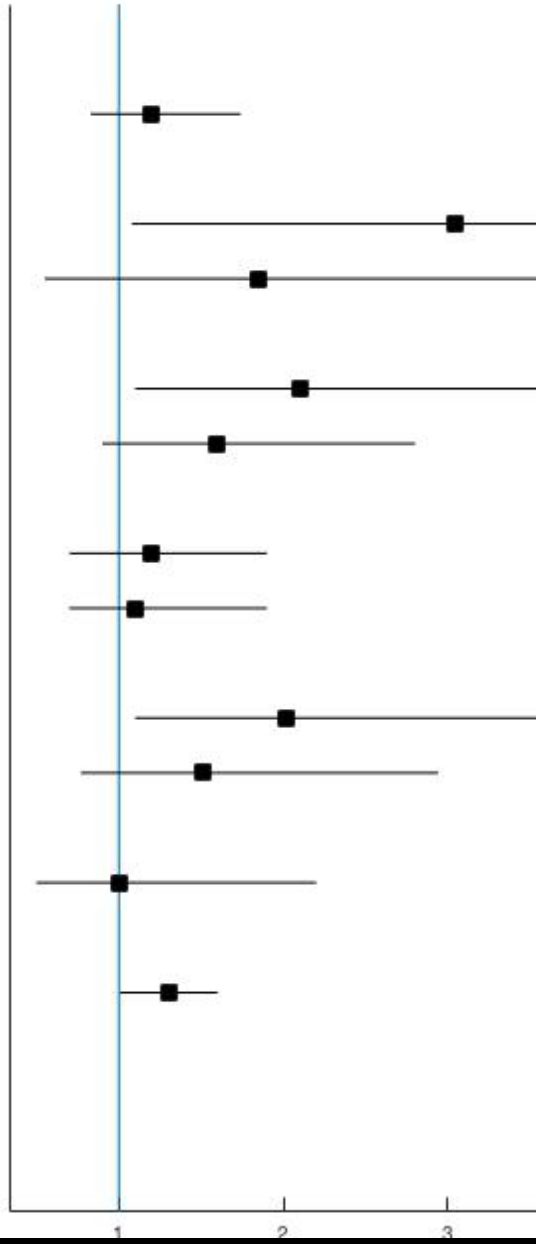

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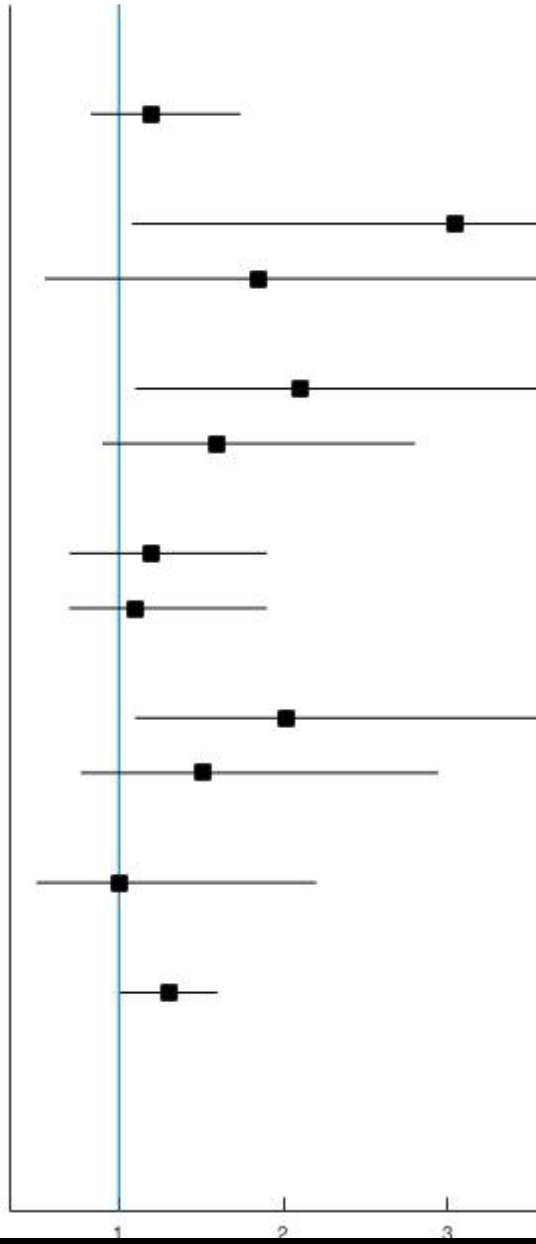
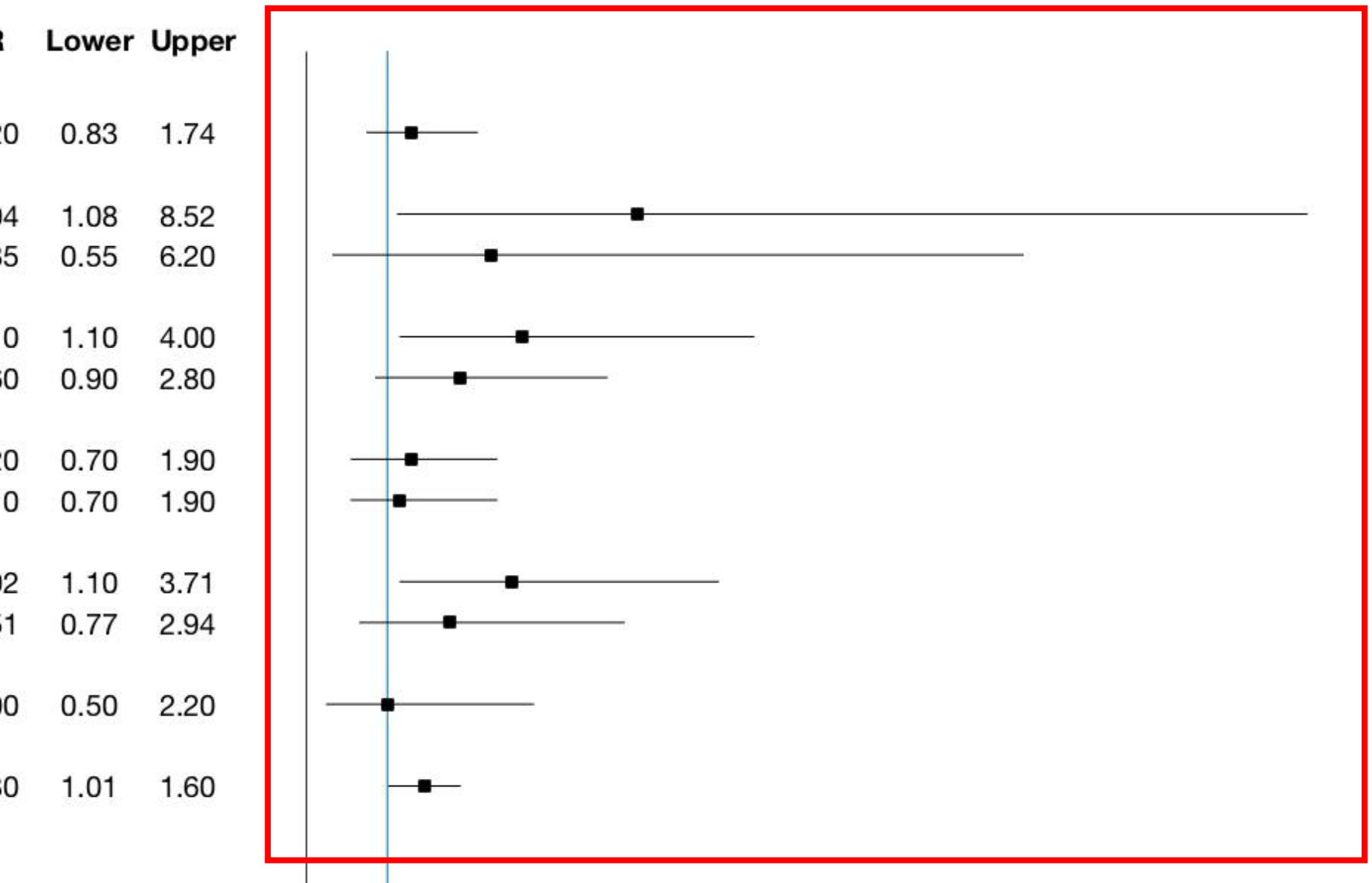


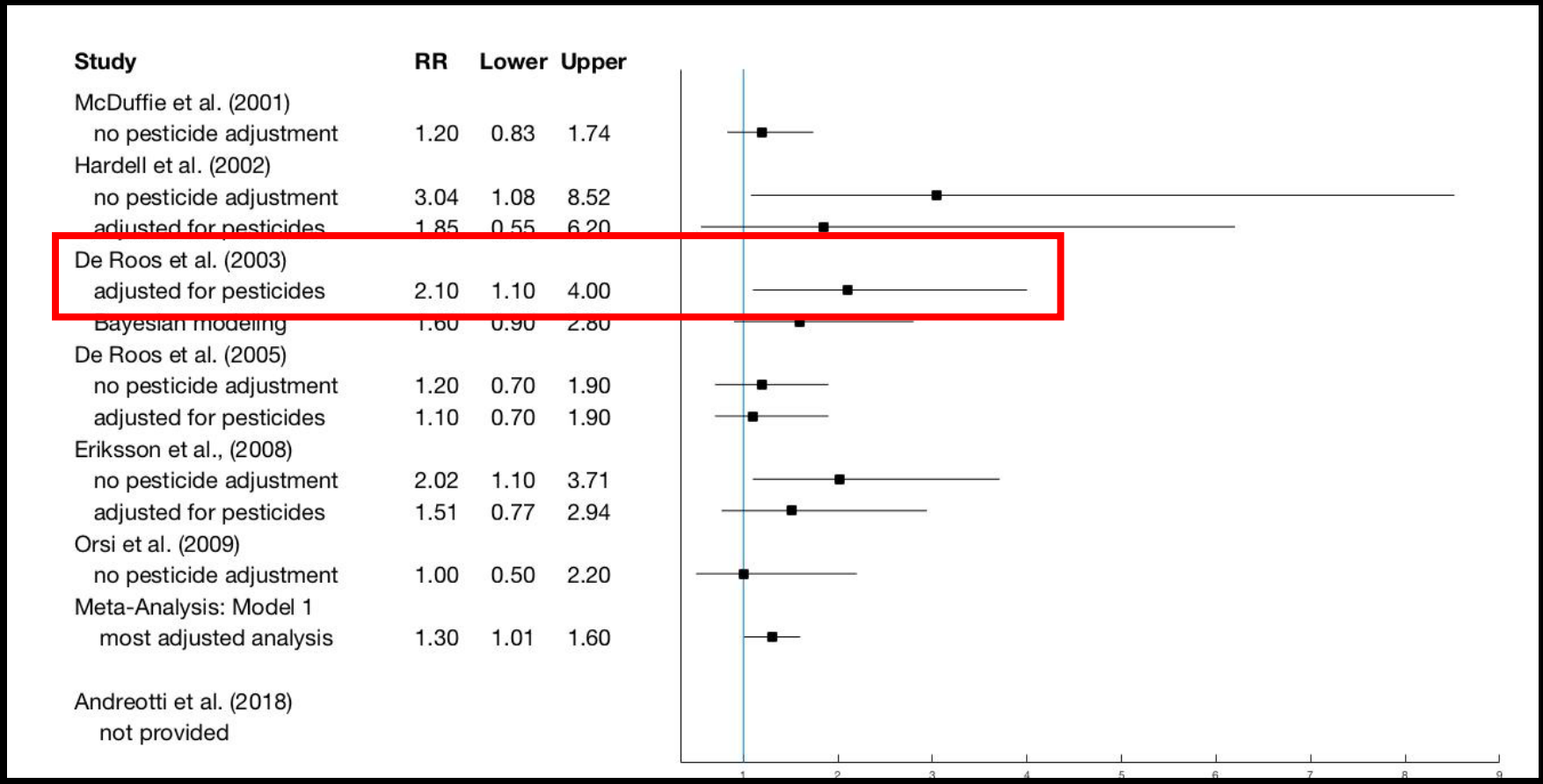
2. Can Roundup cause cancer?



2. Can Roundup cause cancer?

3. Epidemiology

NHL – Never / Ever



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3. Epidemiology

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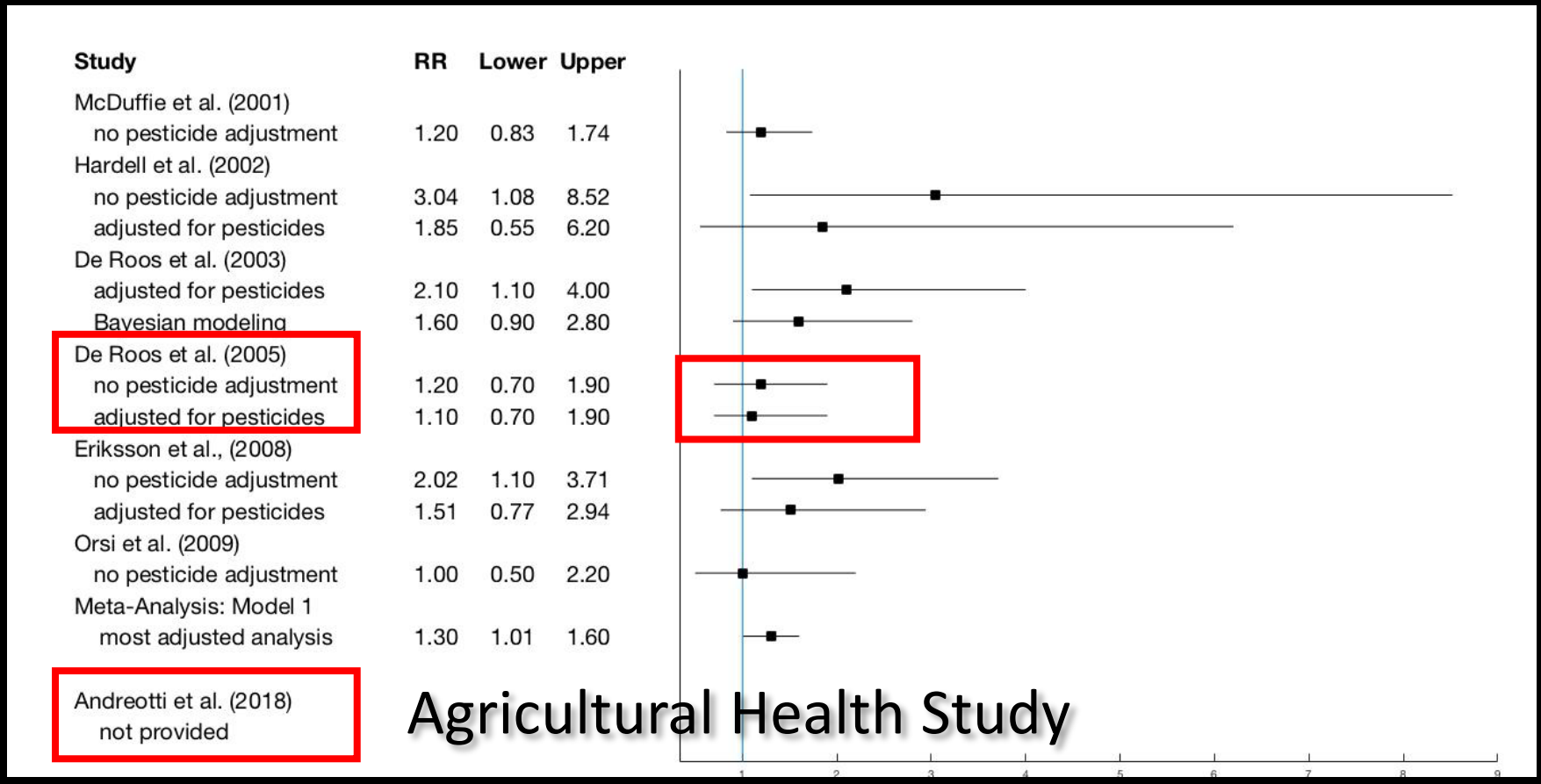


2. Can Roundup cause cancer?

3. Epidemiology

The Agricultural Health Study

- Large cohort study following pesticide applicators in North Carolina and Iowa
- Does not show any association for general NHL
- Does show association for T-cell NHL

2. Can Roundup cause cancer?

3. Epidemiology

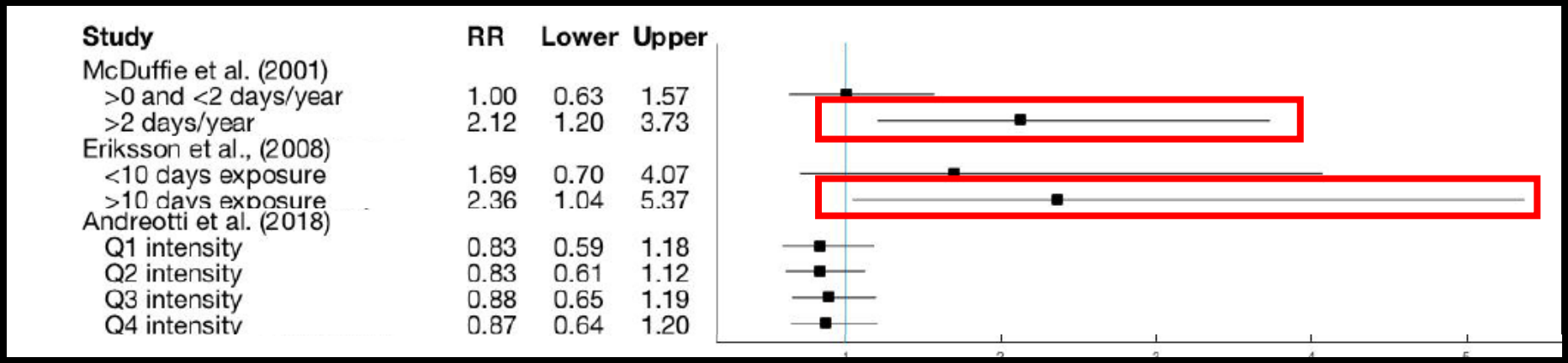
The Agricultural Health Study

- Deeply flawed study
  - Many pesticides being studied
  - Exposure classification
  - Imputation defects
  - AHS failed to detect other know carcinogens

2. Can Roundup cause cancer?

3. Epidemiology

NHL – Exposure Duration

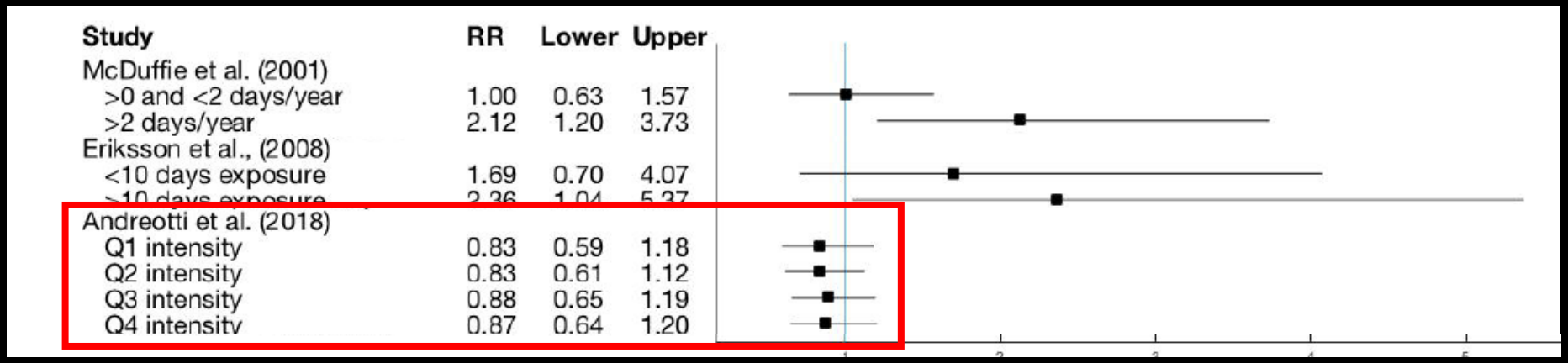


Study	RR	Lower	Upper
McDuffie et al. (2001)			
>0 and <2 days/year	1.00	0.63	1.57
>2 days/year	2.12	1.20	3.73
Eriksson et al., (2008)			
<10 days exposure	1.69	0.70	4.07
>10 days exposure	2.36	1.04	5.37
Andreotti et al. (2018)			
Q1 intensity	0.83	0.59	1.18
Q2 intensity	0.83	0.61	1.12
Q3 intensity	0.88	0.65	1.19
Q4 intensity	0.87	0.64	1.20

2. Can Roundup cause cancer?

3. Epidemiology

NHL – Exposure Duration



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Mar 1999

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Hardell study shows 230% increased risk of NHL for glyphosate formulation.

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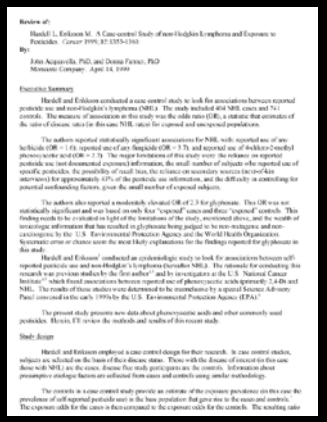
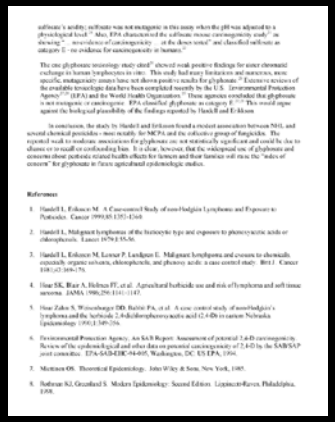
Plaintiff Exhibit
0139

Apr 1999

Monsanto's Reaction:
Hardell study raises "index of concern."





Mar 1999

Review of:

Hardell L, Eriksson M. A Case-control Study of non-Hodgkin Lymphoma and Exposure to Pesticides. *Cancer* 1999; 85:1353-1360.

By:

John Acquavella, PhD, and Donna Farmer, PhD
Monsanto Company. April 14, 1999

Exe case contr etween reported pest a (NHL). s and 741 con s study w at estimates of the rates) for ns.

ignificant d use of any herb ungicide (hloro-2-methyl phe limitatio n reported pest formatio o reported use of specific pesticides, the possibility of recall bias, the reliance on secondary sources (next-of-kin interviews) for approximately 43% of the pesticide use information, and the difficulty in controlling for potential confounding factors, given the small number of exposed subjects.

The authors also reported a moderately elevated OR of 2.3 for glyphosate. This OR was not statistically significant and was based on only four "exposed" cases and three "exposed" controls. This finding needs to be evaluated in light of the limitations of the study, mentioned above, and the wealth of toxicologic information that has resulted in glyphosate being judged to be non-mutagenic and non-carcinogenic by the U.S. Environmental Protection Agency and the World Health Organization. Systematic error or chance seem the most likely explanations for the findings reported for glyphosate in

sulfosate's acidity; sulfosate was not mutagenic in this a… in this assay when the pH was adjusted to a physiolog… the sulfos… as showing … at the do… e as category … humans.[2]

The one … owed we… omatid exchang… s study ha…, more specific… positive r… reviews of the avail… leted rece… Protection Agency[2] … nization.[2] …lyphosate is not m… ied glyph… ld argue against the biological plausibility of the findings reported by Hardell and Erikkson.

In conclusion, the study by Hardell and Eriksson found a modest association between NHL and several chemical pesticides - most notably for MCPA and the collective group of fungicides. The reported weak to moderate associations for glyphosate are not statistically significant and could be due to chance or to recall or confounding bias. It is clear, however, that the widespread use of glyphosate and concerns about pesticide related health effects for farmers and their families will raise the "index of concern" for glyphosate in future agricultural epidemiologic studies.

References

1. Hardell L, Eriksson M. A Case-control Study of non-Hodgkin Lymphoma and Exposure to Pesticides. Cancer 1999;85:1353-1360.

2. Hardell L, Malignant lymphomas of the histiocytic type and exposure to phenoxyacetic acids or chlorophenols. Lancet 1979;I:55-56.

3. Hardell L, Eriksson M, Lenner P, Lundgren E. Malignant lymphpoma and exousre to chemicals,

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Epidemiology:
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Plaintiff Exhibit
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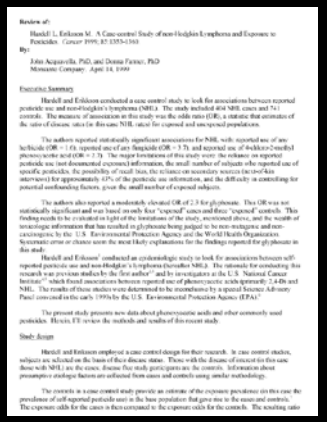

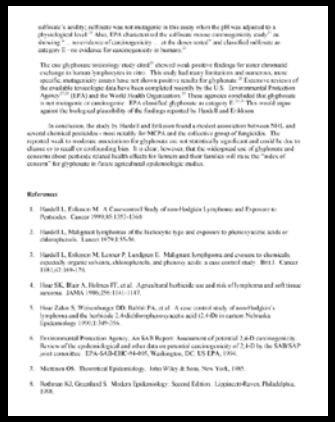

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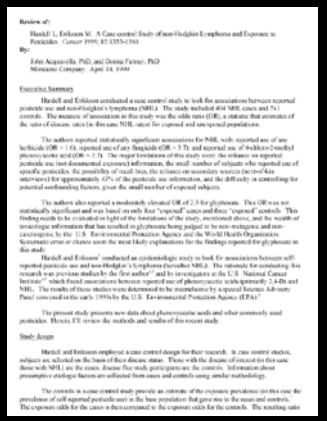

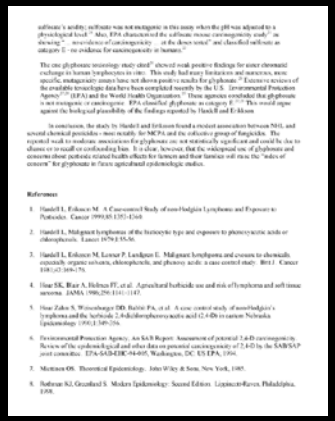

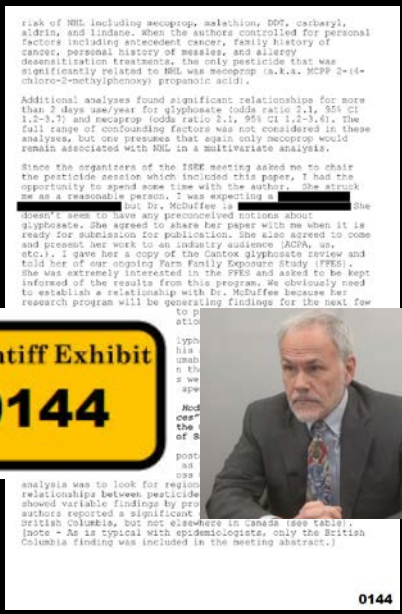
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Additional analyses found significant relationships for more than 2 days use/year for glyphosate (odds ratio 2.1, 95% CI 1.2-3.7) and mecoprop (odds ratio 2.1, 95% CI 1.2-3.6). The full range of confounding factors was not considered in these analyses, 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, ag, 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

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0144

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It remains to [redacted]eated in the eventual publi[redacted]ether anyone picks up selectively [redacted]ded glyphosate finding that w[redacted]bstract. Obviously, we need to be [redacted] limited information. I mention some specific follow-up plans below.

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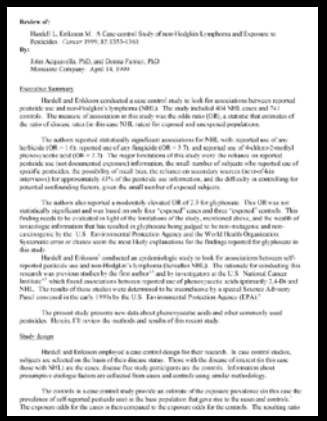

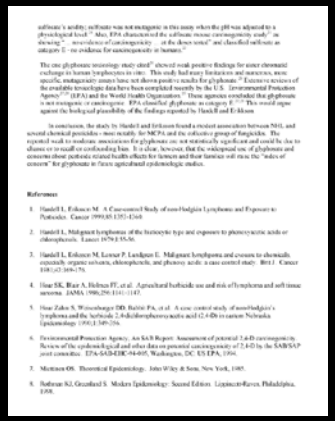

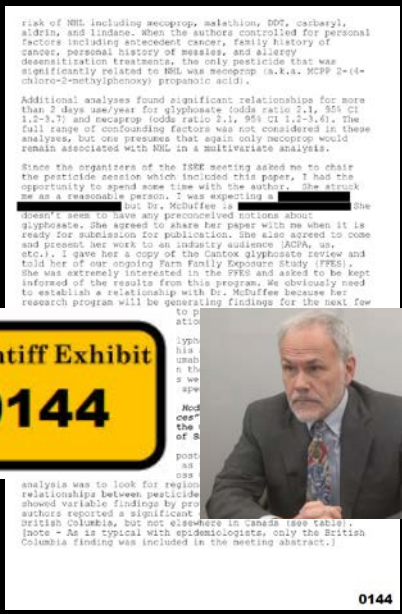
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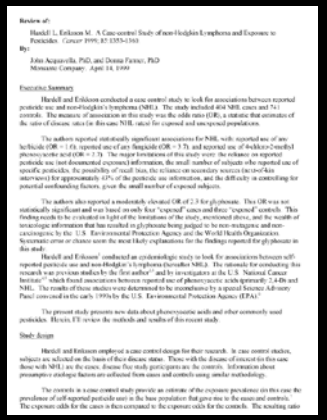

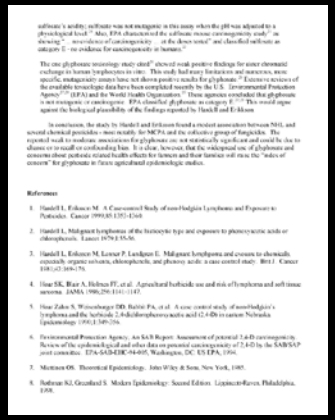

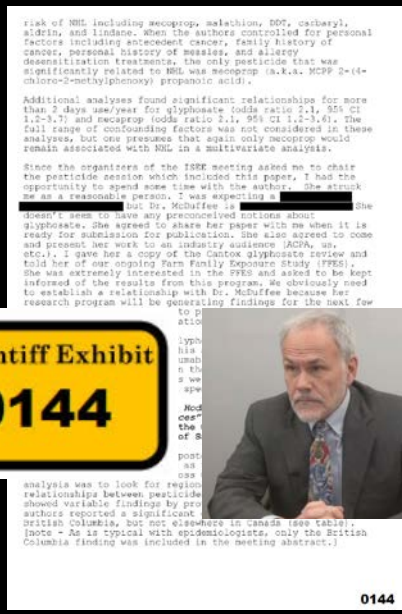

British Journal of Cancer (1998) 77(11), 2048–2052

Nov 2001

Epidemiology:
McDuffie study shows 212% increased risk of NHL when using Roundup more than 2 days a year.

British Journal of Cancer (1998) 77(11), 2048–2052
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Plaintiff Exhibit
0818

Nov
2001

Epidemiology:
McDuffie study shows
212% increased risk of NHL
when using Roundup more
than 2 days a year.

Nov
2001

Monsanto's Reaction:
Celebrate the fact that
glyphosate is not
mentioned in the abstract.

Plaintiff Exhibit
0312

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

British Journal of Cancer (1998) 77(11), 2048–2052

Plaintiff Exhibit
0818

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

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© 1998 Cancer Research Campaign

Plaintiff Exhibit
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British Journal of Cancer (1998) 77(11), 2048–2052

Plaintiff Exhibit 0818

Nov 2001

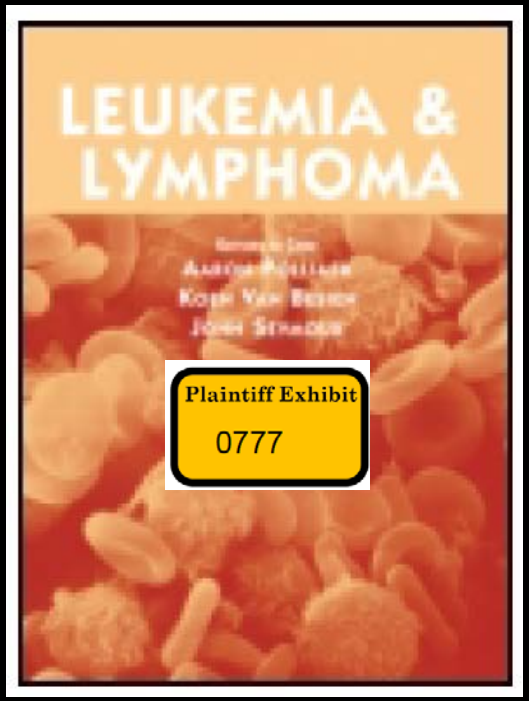
Epidemiology:
McDuffie study shows 212% increased risk of NHL when using Roundup more than 2 days a year.

May 2002

Epidemiology:
Another Hardell study shows 306% increased risk of NHL for Roundup.

Nov 2001

Monsanto's Reaction:
Celebrate the fact that glyphosate is not mentioned in the abstract.



British Journal of Cancer (1998) 77(11), 2048–2052

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Nov 2001

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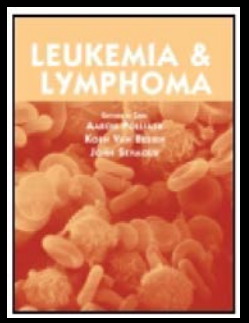
McDuffie study shows 212% increased risk of NHL when using Roundup more than 2 days a year.

May 2002

Epidemiology:
Another Hardell study shows 306% increased risk of NHL for Roundup.

Plaintiff Exhibit 0777



Nov 2001

Monsanto's Reaction:
Celebrate the fact that glyphosate is not mentioned in the abstract.

Mar 2003

Epidemiology:
shows 210% increased risk of NHL for glyphosate formulation.
Controlled for 60 other pesticides.

Plaintiff Exhibit 0710

a cytogenetic mechanism.[14] However, there is only very limited evidence for genotoxicity of atrazine, although there are no studies in humans.[48] A small number of studies of atrazine on immune function in rodents and in vitro suggest a decreased lymphocyte count and cytokine production following expo-

50 **Williams GM**, Kroes R, Munro IC. Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans. *Regul Toxicol Pharmacol* 2000;**31**:117–65.

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Much attention in NHL research has focused on the herbicide 2,4-D as a potential risk factor, and several studies have observed positive associations with 2,4-D exposure.[6 8 9] Whereas an indicated effect of 2,4-D exposure on NHL was reported in NCI's Nebraska and Kansas studies[5,7] of the pooled data found no association with h 2,4-D. The null association does not result from other pesticides, missing data, or from t

Plaintiff Exhibit 0710

British Journal of Cancer (1998) 77(11), 2048–2052

Plaintiff Exhibit 0818

Nov 2001

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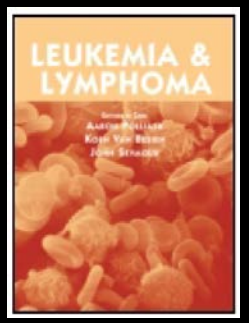
Plaintiff Exhibit 0777



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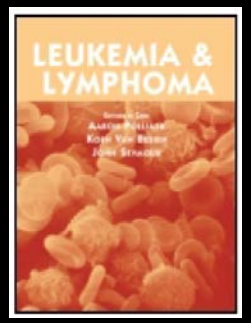

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Sept 2003

Monsanto's Reaction:

Dr. Acquavella warns that the De Roos study could add fuel to the fire.

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From: ACQUAVELLA, JOHN F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=145465]
Sent: 9/3/2003 2:29:00 PM
To: CARR, KATHERINE H [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=43435]; GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=527246]; FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]; [redacted] KRONENBERG, JOEL M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=501517]
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John

Plaintiff Exhibit

0482

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0482

Plaintiff Exhibit
0758

Jul
2008

Epidemiology:
Eriksson study shows 202% increased risk of NHL for Roundup. Also shows 236% increased risk of NHL when used for more than 10 days a year.

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Oct
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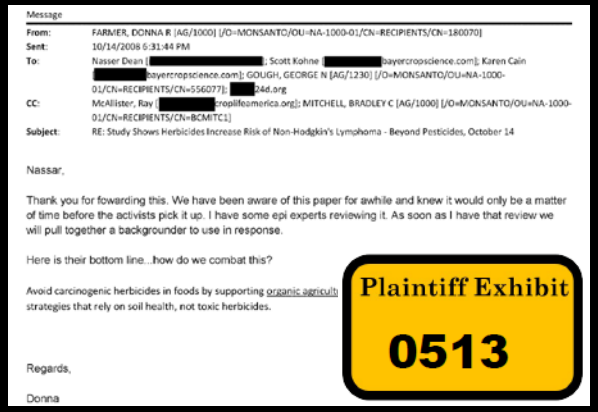
Monsanto's Reaction:
"How do we combat this?"



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To: Nasser Dean [redacted]; 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]; [redacted]24d.org
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Subject: RE: Study Shows Herbicides Increase Risk of Non-Hodgkin's Lymphoma - Beyond Pesticides, October 14

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Here is their bottom line...how do we combat this?

Avoid carcinogenic herbicides in foods by supporting organic agricult strategies that rely on soil health, not toxic herbicides.

Plaintiff Exhibit
0513

Regards,

Donna

Plaintiff Exhibit

Epidemiology:

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0513

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0758

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2008

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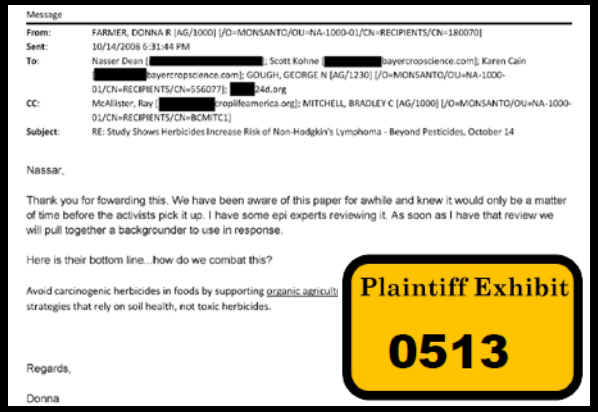

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Plaintiff Exhibit
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Plaintiff Exhibit 0758

Jul 2008

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International Journal of Environmental Research and Public Health

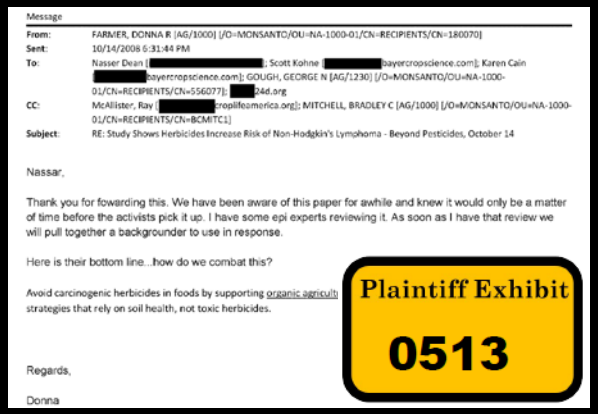
Plaintiff Exhibit 0861

Apr 2014

Epidemiology:
Schinasi & Leon meta analysis reveals Roundup increases overall NHL risk by 150%.

Oct 2008

Monsanto's Reaction:
"How do we combat this?"



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Plaintiff Exhibit 0513

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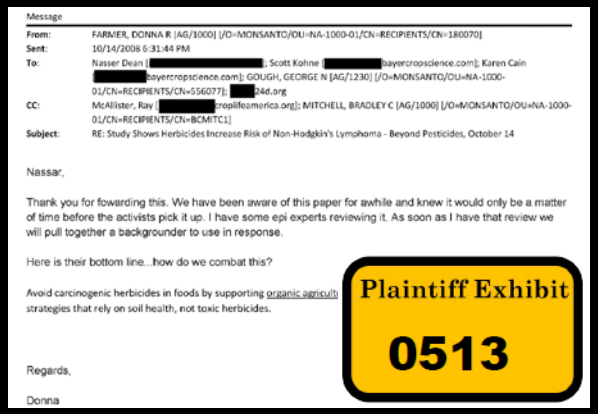

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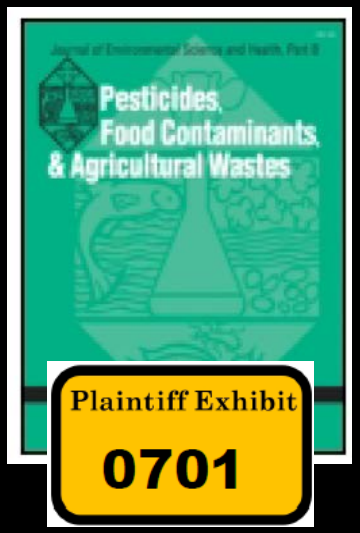
Monsanto-sponsored meta-analysis shows a 130% increased risk of NHL from Roundup use.



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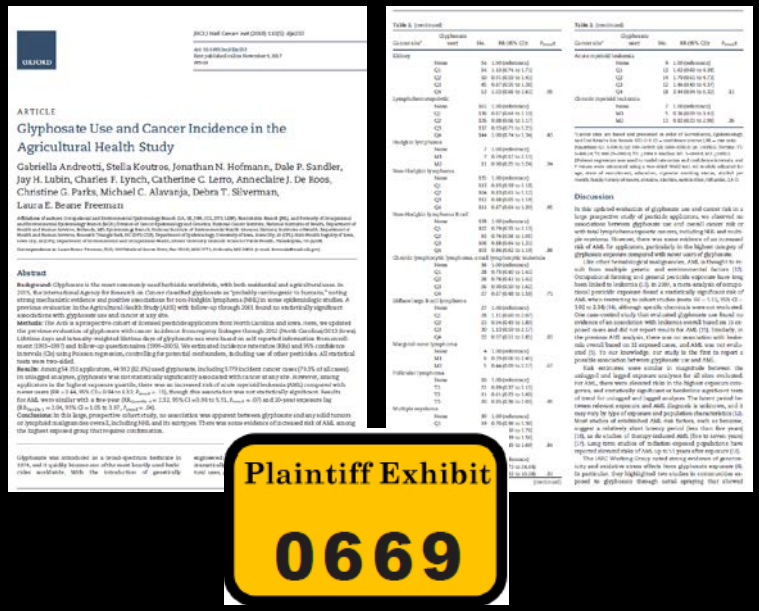
Nov 2017

Epidemiology:
Latest version of the AHS is published using unreliable imputed data. Shows no overall NHL risk.



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Q2	126	0.88 (0.66 to 1.17)	
Q3	137	0.93 (0.71 to 1.23)	
Q4	144	1.00 (0.74 to 1.34)	.43
Hodgkin lymphoma			
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M1	7	0.59 (0.17 to 2.11)	
M2	11	0.90 (0.25 to 3.24)	.94
Non-Hodgkin lymphoma			
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Q1	113	0.83 (0.59 to 1.18)	
Q2	104	0.83 (0.61 to 1.12)	
Q3	112	0.88 (0.65 to 1.19)	
Q4	111	0.87 (0.64 to 1.20)	.95
Non-Hodgkin lymphoma B cell			
None	128	1.00 (reference)	
Q1	102	0.79 (0.55 to 1.13)	
Q2	93	0.76 (0.56 to 1.05)	
Q3	106	0.88 (0.64 to 1.21)	
Q4	103	0.86 (0.62 to 1.19)	.86
Chronic lymphocytic lymphoma, small lymphocytic leukemia			
None	36	1.00 (reference)	
Q1	28	0.75 (0.40 to 1.41)	
Q2	26	0.76 (0.41 to 1.41)	
Q3	26	0.90 (0.50 to 1.62)	
Q4	27	0.87 (0.48 to 1.58)	.71
Diffuse large B cell lymphoma			
None	27	1.00 (reference)	
Q1	28	1.11 (0.60 to 2.07)	
Q2	23	0.94 (0.49 to 1.80)	
Q3	30	1.13 (0.59 to 2.17)	
Q4	22	0.97 (0.51 to 1.85)	.83
Marginal-zone lymphoma			
None	4	1.00 (reference)	
M1	6	0.39 (0.06 to 2.45)	
M2	5	0.44 (0.09 to 2.17)	.67
Follicular lymphoma			
None	7	1.00 (reference)	
M1	5	0.36 (0.09 to 1.43)	
M2	11	0.82 (0.23 to 2.98)	

*Cancer sites are based and presented in order of Surveillance, Epide
and End Results Site Recode ICD-O-3. CI = confidence interval; RR = rat
†Quartiles: Q1: 1–598.9; Q2: 599–1649.9; Q3: 1650–4339.9; Q4: ≥4340.0. Te
1–866.24; T2: 866.25–2963.9; T3: ≥2964.0. Median: M1: 1–1649.9; M2: ≥165
‡Poisson regression was used to model rate ratios and confidence inter
P values were calculated using a two-sided Wald test. All models adj
age, state of recruitment, education, cigarette smoking status, alc
month, family history of cancer, atrazine, alachlor, metolachlor, trifluralin

Discussion

In this updated evaluation of glyphosate use and cancer r
large prospective study of pesticide applicators, we obser
associations between glyphosate use and overall cancer
with total lymphohematopoietic cancers, including NHL and
ple myeloma. However, there was some evidence of an in
risk of AML for applicators, particularly in the highest cate
glyphosate exposure compared with never users of glyphos

Like other hematological malignancies, AML is though
sult from multiple genetic and environmental facto
Occupational farming and general pesticide exposure ha
been linked to leukemia (13). In 2007, a meta-analysis of
tional pesticide exposure found a statistically significant
AML when restricting to cohort studies (meta RR = 1.55, 9
1.02 to 2.34) (14), although specific chemicals were not eva
One case–control study that evaluated glyphosate use fo
evidence of an association with leukemia overall based o
posed cases and did not report results for AML (15). Simi
the previous AHS analysis, there was no association with
mia overall based on 32 exposed cases, and AML was no
ated (5). To our knowledge, our study is the first to r
possible association between glyphosate use and AML.

Risk estimates were similar in magnitude betwe
unlagged and lagged exposure analyses for all sites eva

Q2	23	0.94 (0.49 to 1.80)	
Q3	30	1.13 (0.59 to 2.17)	
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Marginal-zone lymphoma			
None	4	1.00 (reference)	
M1	6	0.39 (0.06 to 2.45)	
M2	5	0.44 (0.09 to 2.17)	.67
Follicular lymphoma			
None	16	1.00 (reference)	
T1	21	0.89 (0.37 to 2.15)	
T2	11	0.61 (0.23 to 1.60)	
T3	20	0.85 (0.36 to 2.03)	.95
Multiple myeloma			
None	30	1.00 (reference)	
Q1	19	0.70 (0.36 to 1.36)	
Q2	26	0.94 (0.50 to 1.76)	
Q3	19	0.78 (0.39 to 1.56)	
Q4	24	0.87 (0.45 to 1.69)	.84
Non-Hodgkin lymphoma T cell			
None	2	1.00 (reference)	
M1	14	4.25 (0.73 to 24.64)	
M2	6	1.53 (0.23 to 10.38)	.31

425%

(continued)

evidence of an association with leukemia overall based o
posed cases and did not report results for AML (15). Simi
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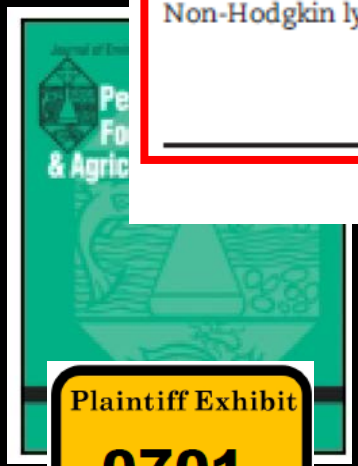
Risk estimates were similar in magnitude betwe
unlagged and lagged exposure analyses for all sites eva
For AML, there were elevated risks in the highest exposu
gories, and statistically significant or borderline significa
of trend for unlagged and lagged analyses. The latent pe
tween relevant exposure and AML diagnosis is unknown
may vary by type of exposure and population characterist
Most studies of established AML risk factors, such as b
suggest a relatively short latency period (less than five
(16), as do studies of therapy-induced AML (five to seven
(17). Long-term studies of radiation-exposed population
reported elevated risks of AML up to 55 years after exposu

The IARC Working Group noted strong evidence of g
icity and oxidative stress effects from glyphosate expos
In particular, they highlighted two studies in communi
posed to glyphosate through aerial spraying that



Plaintiff Exhibit
0701

Christine G. Parks, Michael C. Alavanja, Debra T. Silverman, Laura E. Beane Freeman

Abstract

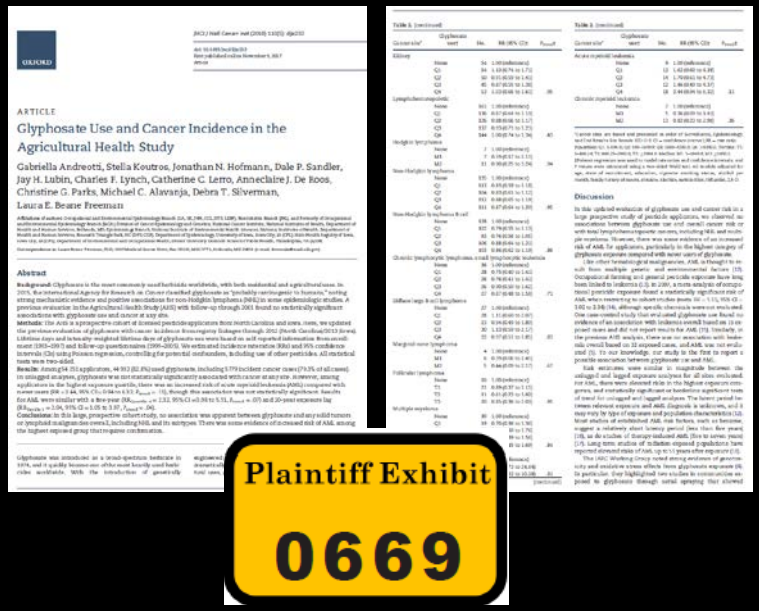
Plaintiff Exhibit
0669

Oct 2016

Epidemiology:
Monsanto-sponsored meta-analysis shows a 130% increased risk of NHL from Roundup use.

Nov 2017

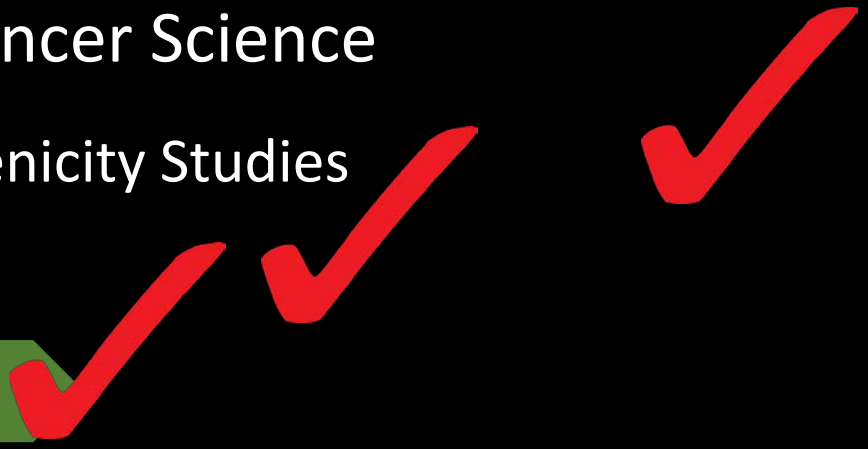
Epidemiology:
Latest version of the AHS is published using unreliable imputed data. Shows no overall NHL risk.



2. Can Roundup cause cancer?

Three Pillars of Cancer Science

1. Animal Carcinogenicity Studies
2. Mechanistic Data
3. Epidemiology



2. Can Roundup cause cancer?

International Agency Research on Cancer

World Health Organization

2. Can Roundup cause cancer?

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

MONGLY00989918

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Thanks.

Bill

2. Can Roundup cause cancer?

- Leading world experts on cancer
- 17 scientists from the EPA, California EPA, and worldwide
- Over six months reviewing all peer-reviewed science on glyphosate
- Held a week-long meeting
- Unanimous vote

2. Can Roundup cause cancer?

Participants

- Members:
  - Aaron Blair, National Cancer Institute, USA (Overall Chair)
  - Charles W. Jameson, CWJ Consulting, LLA, USA
  - Matthew T. Martin, U.S. Environmental Protection Agency, USA
  - Lauren Zeise, California Environmental Protection Agency, USA
  - Matthew K. Ross, Mississippi State University, USA
- Invited Specialists
  - Christopher J. Portier, Agency for Toxic Substances and Disease Registry, USA
- Representatives of National and International Health Agencies
  - Jesudoss Rowland, U.S. Environmental Protection Agency, USA
- Observers
  - Thomas Sorahan, for Monsanto Company, USA
  - Patrice Sutton, for the University of California, San Francisco, Program on Reproductive Health and the Environment

2. Can Roundup cause cancer?

GLYPHOSATE

1. Exposure Data

1.1 Identification of the agent

1.1.1 Nomenclature

Chem. Abstr. Serv. Reg. No.: 1071-83-6 (acid); also relevant:
38641-94-0 (glyphosate-isopropylamine salt)
40465-66-5 (monoammonium salt)
69254-40-6 (diammonium salt)
34494-03-6 (glyphosate-sodium)
81591-81-3 (glyphosate-trimesium)

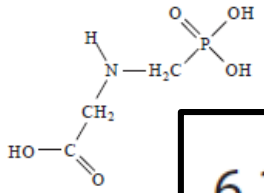
Chem. Abstr. Serv. Name: *N*-(phosphonomethyl)glycine

Preferred IUPAC Name: *N*-(phosphonomethyl)glycine

Synonyms: Gliphosate; glyphosate; glyphosate hydrochloride; glyphosate [calcium, copper (2+), dilithium, disodium, magnesium, monoammonium, monopotassium, monosodium, sodium, or zinc] salt

Trade names: Glyphosate products have been sold worldwide under numerous trade names, including: Abundit Extra; Credit; Xtreme; Glifonox; Glyphogan; Ground-Up; Rodeo; Roundup; Touchdown; Tragli; Wipe Out; Yerbimat (Farm Chemicals International, 2015).

1.1.2 Structural and molecular formulae and relative molecular mass



Molecular formula: $C_3H_$
Relative molecular mass:
Additional information
ture is also available in the P
database (NCBI, 2015).

1.1.3 Chemical and physic pure substance

Description: Glyphosate acid is a colourless, odourless, crystalline solid. It is formulated as a salt consisting of the deprotonated acid of glyphosate and a cation (isopropylamine, ammonium, or sodium), with more than one salt in some formulations.

Solubility: The acid is of medium solubility at 11.6 g/L in water (at 25 °C) and insoluble in common organic solvents such as acetone, ethanol, and xylene; the alkali-metal and

Plaintiff Exhibit
0784

Three Pillars of Cancer Science

1. Animal Carcinogenicity Studies

2. Mechanistic Data: Sufficient

6.2 Cancer in experimental animals

There is *sufficient evidence* in experimental animals for the carcinogenicity of glyphosate.

2. Can Roundup cause cancer?

GLYPHOSATE

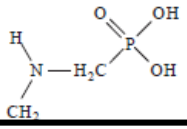
1. Exposure Data

1.1 Identification of the agent

1.1.1 Nomenclature

Chem. Abstr. Serv. Reg. No.: 1071-83-6 (acid); also relevant:

1.1.2 Structural and molecular formulae and relative molecular mass



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Plaintiff Exhibit 0784

Three Pillars of Cancer Science

1. Animal Carcinogenicity Studies
2. Mechanistic Data: Sufficient

Sufficient evidence of carcinogenicity: The Working Group considers that a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) two or more independent studies in one species carried out at different times or in different laboratories or under different protocols. An increased incidence of tumours in both sexes of a single species in a well-conducted study, ideally conducted under Good Laboratory Practices, can also provide *sufficient evidence*

2. Can Roundup cause cancer?

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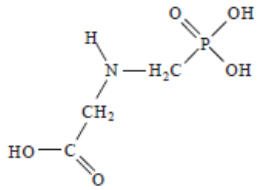
sate hydrochloride; glyphosat
copper (2+), dilithium, disodiu
sium, monoammonium, mon
monosodium, sodium, or zinc] s

Trade names: Glyphosate produc
sold worldwide under numerous t
including: Abundit Extra; Cre
Glifonox; Glyphogan; Ground-
Roundup; Touchdown; Tragli;
Yerbimat (Farm Chemicals In
2015).

1.1.2 Structural and molecular formulae and relative molecular mass



Molecular formula: $C_3H_8NO_5P$
Relative molecular mass: 169.07
Additional information on chemical structure is also available in the PubChem Compound

ethanol, and xylene; the alkali-metal and

Plaintiff Exhibit
0784

Three Pillars of Cancer Science

1. Animal Carcinogenicity Studies
2. Mechanistic Data — Sufficient
3. Epidemiology — Strong

> Overall, the mechanistic data provide strong evidence for genotoxicity and oxidative stress. There is evidence that these effects can operate in humans.

2. Can Roundup cause cancer?

GLYPHOSATE

1. Exposure Data

1.1 Identification of the agent

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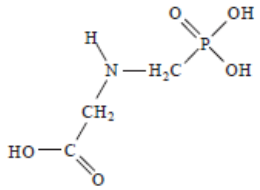


Molecular formula: $C_3H_8NO_5P$
Relative molecular mass: 169.07
Additional information on chemical structure is also available in the PubChem Compound database (NCBI, 2015).

1.1.3 Chemical and physical properties of the pure substance

Description: Glyphosate acid is a colour-

Plaintiff Exhibit
0784

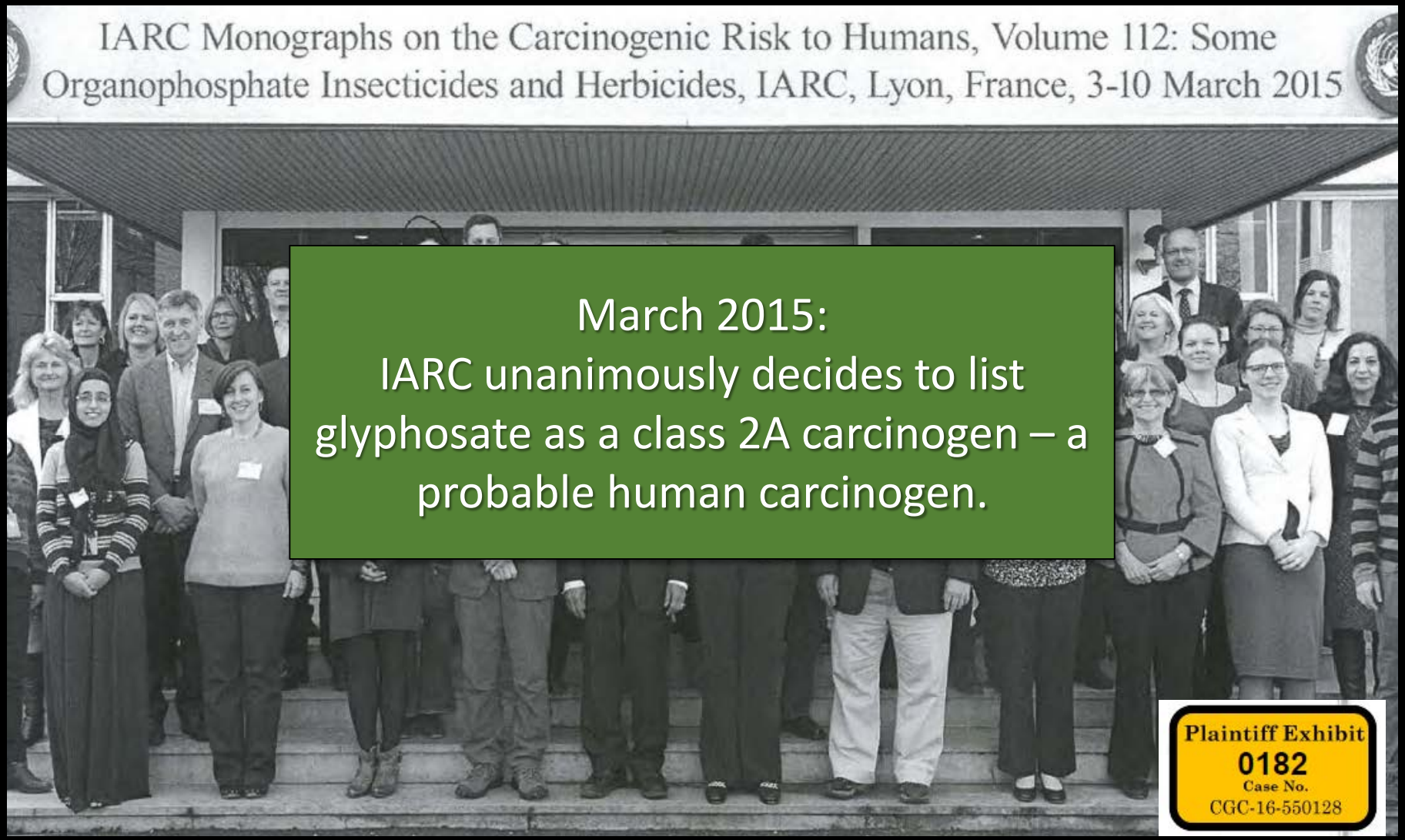
Three Pillars of Cancer Science

1. Animal Carcinogenicity Studies
2. Mechanistic Data — Sufficient
3. Epidemiology — Strong

Limited

Limited evidence of carcinogenicity: A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.

2. Can Roundup cause cancer?



2. Can Roundup cause cancer?

Monsanto's Response to IARC

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
     - 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

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

February 23, 2015

        - 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
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2. Can Roundup cause cancer?

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2. Can Roundup cause cancer?

Nearly 100 scientists from all over the world endorse IARC's assessment of glyphosate

Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)

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The International Agency for Research on Cancer (IARC) Monographs Programme identifies chemicals, drugs, mixtures, occupational exposures, lifestyles and personal habits, and physical and biological agents that cause cancer in humans and has evaluated about 1000 agents since 1971. Monographs are written by ad hoc Working Groups (WGs) of international scientific experts over a period of about 12 months ending in an eight-day meeting. The WG evaluates all of the publicly available scientific information on each substance and, through a transparent and rigorous process,[1] decides on the scientific evidence supports that substance's potential to cause or not cause cancer in humans.

For Monograph 112,[2] 17 expert scientists evaluated the carcinogenic hazard for four insecticides and the herbicide glyphosate.[3] The WG concluded that the data for glyphosate meet the criteria for classification as a *probable human carcinogen*.

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Serious flaws in the scientific evaluation in the RAR incorrectly characterise the potential for a carcinogenic hazard from exposure to glyphosate. Since the RAR is the basis for the European Food Safety Agency (EFSA) conclusion,[4] it is critical that these shortcomings are corrected.

THE HUMAN EVIDENCE

EFSA concluded 'that there is very limited evidence for an association between glyphosate-based formulations and non-Hodgkin lymphoma (NHL), overall inconclusive for a causal or clear associative relationship between glyphosate and cancer in human studies'. The BfR Addendum (p. ii) to the EFSA report explains that 'no consistent positive association was observed' and 'the most powerful study showed no effect'. The IARC WG concluded there is *limited evidence of carcinogenicity in humans* which means "A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence."[1]

The finding of *limited evidence* by the IARC WG was for NHL, based on high-quality case-control studies, which are

For numbered affiliations see end of article.

Correspondence to Dr Christopher J Portier, Environmental Health Consultant, Thun, CH-3600, Switzerland; cportier@in

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2. Can Roundup cause cancer?

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The finding of *limited evidence* by the IARC WG was for NHL, based on high-quality case-control studies, which are

The most appropriate and scientifically based evaluation of the cancers reported in humans and laboratory animals as well as supportive mechanistic data 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.

Plaintiff Exhibit
0293
Case No.
CGC-16-550128

2. Can Roundup cause cancer?

npic NATIONAL PESTICIDE INFORMATION CENTER

American Cancer Society®

Known and Probable Human Carcinogens

In most cases, the ACS does not directly evaluate whether a certain substance or exposure causes cancer. Instead, the ACS looks to national and international organizations such as the NTP and IARC, whose mission is to evaluate environmental cancer risks based on evidence from laboratory and human research studies.

Plaintiff Exhibit
0306

2. Can Roundup cause cancer?

Glyphosate v. Roundup

No one tests “Roundup”

2. Can Roundup cause cancer?

Charles Benbrook, PhD.

- B.A. in Economics from Harvard University (1971) and Ph.D. in Agricultural Economics from the University of Wisconsin (1980).
- Former Staff Director of the Subcommittee on Department Operations, Research, and Foreign Agriculture ("DOFRA") of the House Committee on Agriculture.
- Organized several DOFRA hearings on pesticide issues, and worked with Members of Congress in drafting potential changes in federal laws impacting the Environmental Protection Agency's ("EPA") Office of Pesticide Programs ("OPP").

2. Can Roundup cause cancer?

1. The EPA does not test anything.
2. Vulnerable to political shifts.
3. EPA's "Scientific Advisory Panel" split.
4. EPA's Office of Research and Development disagrees.

Opening Statement Roadmap:

1. What is Roundup?
2. Can Roundup cause cancer? Yes.
3. Did Roundup cause Mr. Johnson's cancer?
4. What are Mr. Johnson's damages?
5. Should Monsanto be punished for its conduct?

Opening Statement Roadmap:

1. What is Roundup?
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3. Did Roundup cause Mr. Johnson's cancer?
4. What are Mr. Johnson's damages?
5. Should Monsanto be punished for its conduct?

3. Did Roundup cause Mr. Johnson's cancer?

Chadi Nabhan, M.D.

THE UNIVERSITY OF CHICAGO

- Board-Certified hematologist and medical oncologist specializing in Non-Hodgkin Lymphoma ("NHL").
- Vice President and Chief Medical Officer of Cardinal Health Specialty Solutions.
- Former Medical Director of the Clinical Cancer Center at the University of Chicago.
- Treated thousands of lymphoma patients.

3. Did Roundup cause Mr. Johnson's cancer?

William Sawyer, PhD.

INDIANA UNIVERSITY

- Ph.D. in toxicology from Indiana University School of Medicine (1983).
- Diplomate of the American Board of Forensic Medicine with more than 28 years of experience in public health and forensic toxicology, including five years of governmental service.
- Former Assistant Professor (23 years) at the Department of Medicine, Upstate Medical University, Syracuse, New York.
- 14 years of experience as a licensed clinical and environmental laboratory director.

3. Did Roundup cause Mr. Johnson's cancer?

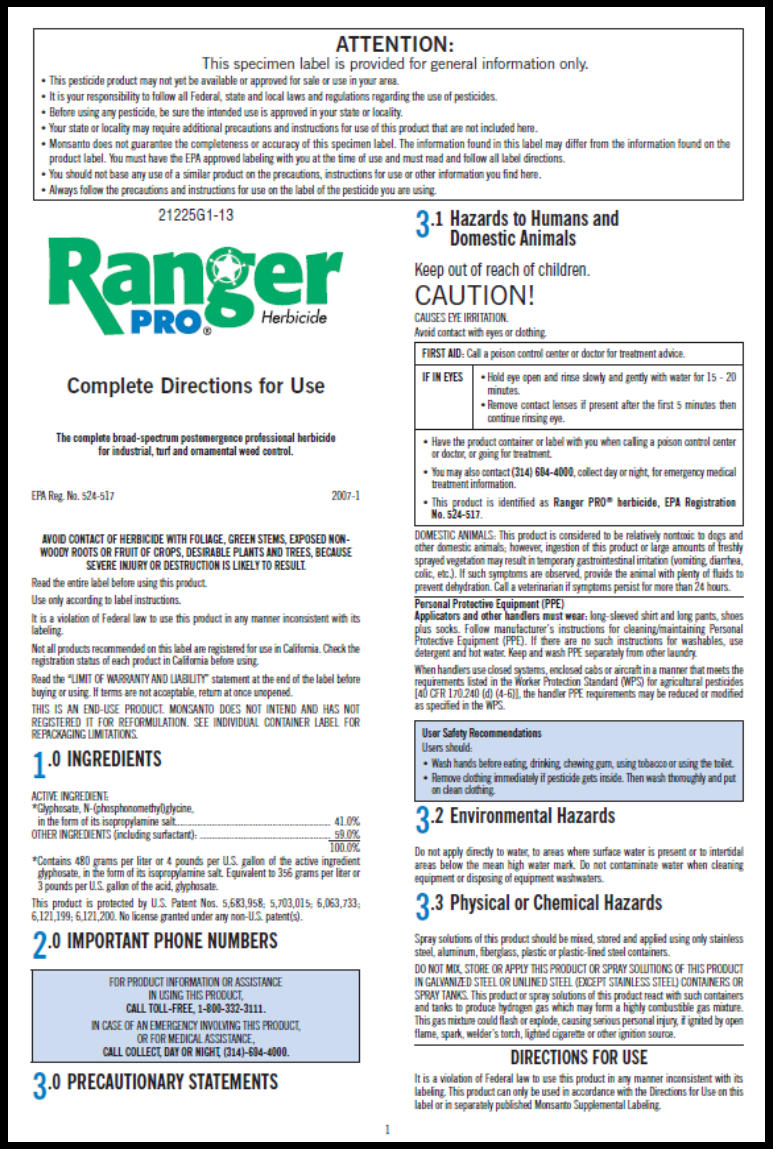
2012 – New Job at Benicia School District

3. Did Roundup cause Mr. Johnson's cancer?

Pest Management

3. Did Roundup cause Mr. Johnson's cancer?

The Label:



ATTENTION:
This specimen label is provided for general information only.

- This pesticide product may not yet be available or approved for sale or use in your area.
- It is your responsibility to follow all Federal, state and local laws and regulations regarding the use of pesticides.
- Before using any pesticide, be sure the intended use is approved in your state or locality.
- Your state or locality may require additional precautions and instructions for use of this product that are not included here.
- Monsanto does not guarantee the completeness or accuracy of this specimen label. The information found in this label may differ from the information found on the product label. You must have the EPA approved labeling with you at the time of use and must read and follow all label directions.
- You should not base any use of a similar product on the precautions, instructions for use or other information you find here.
- Always follow the precautions and instructions for use on the label of the pesticide you are using.

21225G1-13

Ranger PRO® Herbicide

Complete Directions for Use

The complete broad-spectrum postemergence professional herbicide for industrial, turf and ornamental weed control.

EPA Reg. No. 524-517 2007-1

AVOID CONTACT OF HERBICIDE WITH FOLIAGE, GREEN STEMS, EXPOSED NON-WOODY ROOTS OR FRUIT OF CROPS, DESIRABLE PLANTS AND TREES, BECAUSE SEVERE INJURY OR DESTRUCTION IS LIKELY TO RESULT.

Read the entire label before using this product.

Use only according to label instructions.

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Not all products recommended on this label are registered for use in California. Check the registration status of each product in California before using.

Read the "LIMIT OF WARRANTY AND LIABILITY" statement at the end of the label before buying or using. If terms are not acceptable, return at once unopened.

THIS IS AN END-USE PRODUCT. MONSANTO DOES NOT INTEND AND HAS NOT REGISTERED IT FOR REFORMULATION. SEE INDIVIDUAL CONTAINER LABEL FOR REPACKAGING LIMITATIONS.

1.0 INGREDIENTS

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt	41.0%
OTHER INGREDIENTS (including surfactant):	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds per U.S. gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent Nos. 5,683,958; 5,703,015; 6,063,733; 6,121,199; 6,121,200. No license granted under any non-U.S. patent(s).

2.0 IMPORTANT PHONE NUMBERS

FOR PRODUCT INFORMATION OR ASSISTANCE IN USING THIS PRODUCT, **CALL TOLL-FREE, 1-800-332-3111.**

IN CASE OF AN EMERGENCY INVOLVING THIS PRODUCT, OR FOR MEDICAL ASSISTANCE, **CALL COLLECT, DAY OR NIGHT, (314)-694-4000.**

3.0 PRECAUTIONARY STATEMENTS

3.1 Hazards to Humans and Domestic Animals

Keep out of reach of children.

CAUTION!

CAUSES EYE IRRITATION.
Avoid contact with eyes or clothing.

FIRST AID: Call a poison control center or doctor for treatment advice.

IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. • Remove contact lenses if present after the first 5 minutes then continue rinsing eye.

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
- You may also contact **(314) 694-4000**, collect day or night, for emergency medical treatment information.
- This product is identified as **Ranger PRO® herbicide, EPA Registration No. 524-517.**

DOMESTIC ANIMALS: This product is considered to be relatively nontoxic to dogs and other domestic animals, however, ingestion of this product or large amounts of freshly sprayed vegetation may result in temporary gastrointestinal irritation (vomiting, diarrhea, colic, etc.). If such symptoms are observed, provide the animal with plenty of fluids to prevent dehydration. Call a veterinarian if symptoms persist for more than 24 hours.

Personal Protective Equipment (PPE)
Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining Personal Protective Equipment (PPE). If there are no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations
Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

3.2 Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

3.3 Physical or Chemical Hazards

Spray solutions of this product should be mixed, stored and applied using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX, STORE OR APPLY THIS PRODUCT OR SPRAY SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS. This product or spray solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product can only be used in accordance with the Directions for Use on this label or in separately published Monsanto Supplemental Labeling.

1

3. Did Roundup cause Mr. Johnson's cancer?

The Label:

Keep out of reach of children.

CAUTION!

CAUSES EYE IRRITATION.

Avoid contact with eyes or clothing.

FIRST AID: Call a poison control center or doctor for treatment advice.	
IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. • Remove contact lenses if present after the first 5 minutes then continue rinsing eye.
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3. Did Roundup cause Mr. Johnson's cancer?

Admission No. 13

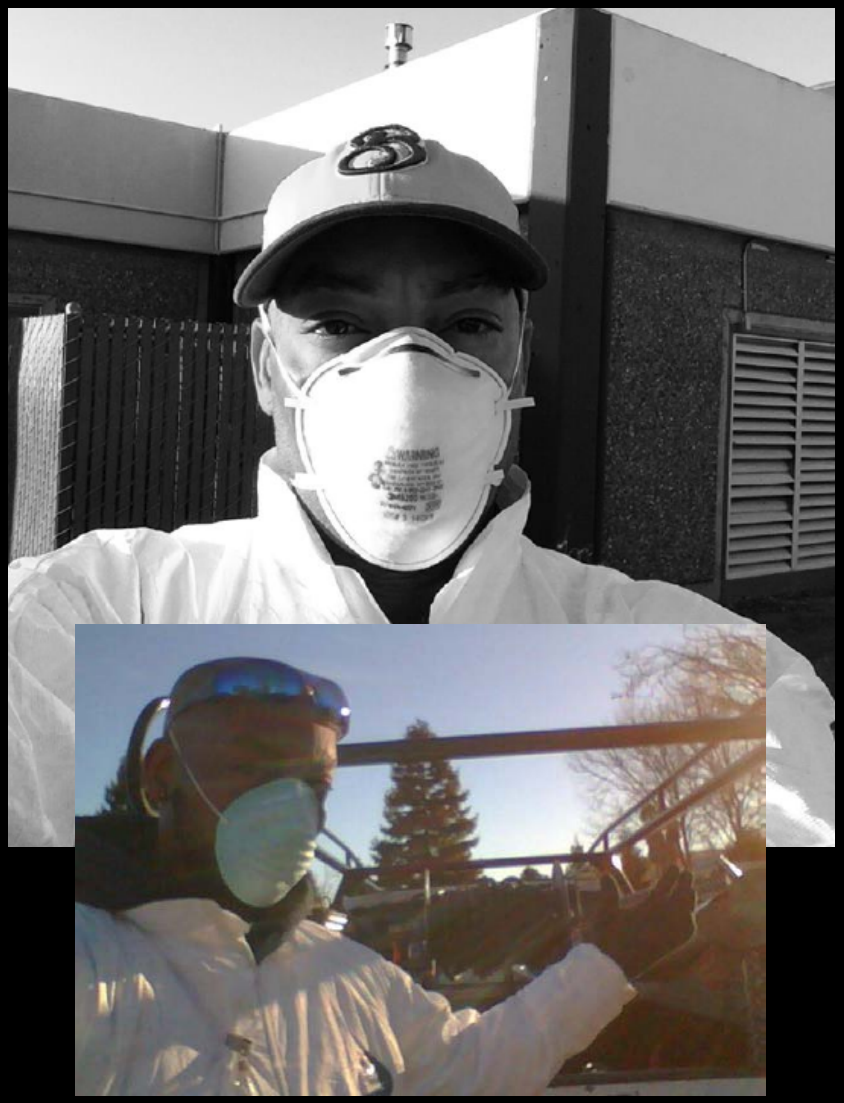
Monsanto admits that it has never warned any consumer that Roundup could cause cancer

Admission No. 14

Monsanto admits that it has never warned Mr. Johnson that Roundup could cause cancer.

3. Did Roundup cause Mr. Johnson's cancer?

Personal Protection



3. Did Roundup cause Mr. Johnson's cancer?

Multiple Heavy Exposures
Nov. 2014: Reports to Monsanto

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
[redacted]

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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
[redacted]

3. Did Roundup cause Mr. Johnson's cancer?

Multiple Heavy Exposures
Mar. 2015: Reports Problem Again

Message

From: Thompson, Joy [redacted]
Sent: 4/15/2015 7:04:57 PM
To: GRANETO, MATTHEW J [AG/1000] [redacted]
CC: GOLDSTEIN, DANIEL A [AG/1000] [redacted]monsanto.com]; NYANGULU, JAMES M [AG/8070] [redacted]@monsanto.com]; THURSTON, RUTH M [AG/8070] [redacted]@monsanto.com]; WHITE, ERIN [AG/1000] [redacted]@monsanto.com]; SEIFERT-HIGGINS, SIMONE [AG/1000] [redacted]@monsanto.com]; Weber, Julie [redacted]@ssmhc.com]
Subject: March 2015 FIFRA 6(a)(2) Reports
Attachments: FIFRA March 2015.docx

Flag: Follow up

Good afternoon Matt,

Attached are the FIFRA 6(a)(2) Reports for the Monsanto Lawn & Garden and Monsanto Agricultural products for the month of March 2015.

Please call me at 314[redacted]f you have any questions.

Thank you,

Joy Thompson RN, CSPI

Industry liaison

Missouri Poison Center

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.

3. Did Roundup cause Mr. Johnson's cancer?

Message

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To: GRANETO, MATTHEW J [AG/1[redacted]
CC: GOLDSTEIN, DANIEL A [AG/100[redacted]AMES M [AG/8070]
[redacted]@monsant[redacted]@monsanto.com]; WHITE,
ERIN [AG/1000] [redacted]@r[redacted]
[redacted]@monsanto.com]; Web[redacted]
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2015: Reports Problem Again

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3. Did Roundup cause Mr. Johnson's cancer?

While Mr. Johnson was waiting for a response from Monsanto, he continued to use Roundup and Ranger Pro for another spraying season.

His cancer got worse and worse.

Why?

Roundup can promote cancer.

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Issues to Consider

1. Exposure
2. Latency
3. Other possible causes
4. Warning

Opening Statement Roadmap:

1. What is Roundup?
2. Can Roundup cause cancer? Yes.
3. Did Roundup cause Mr. Johnson's cancer? Yes.
4. What are Mr. Johnson's damages?
5. Should Monsanto be punished for its conduct?

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Compensatory Damages

- Economic damages
- Non-economic damages
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- Non-economic damages
  - physical pain
  - mental suffering
  - loss of enjoyment of life
  - disfigurement
  - physical impairment
  - grief
  - anxiety
  - humiliation
  - emotional distress


REPUBLIC

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Net Worth:

$6.6 Billion

5. Should Monsanto be punished for its conduct?

Message

From: FARMER, DONNA R [AG/1000] /O=MONSANTO/OU=NA-1000-01/CN=R
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 that is taken up it is glyphosate. It stops the synthesis of 3 amino 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

5. Should Monsanto be punished for its conduct?

1. Why did no one from Monsanto call Mr. Johnson back, even after IARC?
2. Why did Monsanto not send the Perry reports to the EPA and, instead, ghostwrite the Williams paper?
3. Why did Monsanto refuse to study the Roundup formulation, like Dr. Parry suggested 20 years ago?
4. Why did Monsanto feel the need to combat published articles raising concerns about the safety of Roundup?

5. Should Monsanto be punished for its conduct?

Dr. Kirk Azevedo
Sales Representative (former)

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"We're about making money, so get it straight."

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SOCCER