







Not the first lawsuit:

Plaintiff COMPLAINT JURY TRIAL DEMANDED BIDEGAIN, CASE NO. Wig 0 5 4 4 5 1 5 5 MONSANTO COMPANY and JOHN DOES 1-50. JURY TRIAL DEMANDED Plaintiffs, COMPLAINT FOR TOXIC INJURIE ASSERTING CAUSES OF ACTION FOR; UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK UNITED STATES DISTRICT COURT Central DISTRICT OF CALIFORNIA JUDI FITZGERALD, Plaintiff, COMPLAINT Civil Action No. COMPLAINT Civil Action No.	DAVID W. COUTURE	District Court TOF MONTANA SUMMONS IN A CIVIL ACTION CASE NUMBER: CV-91-87-64- PC 49	IN THE COURT OF COMMON PLEAS OF MONTGOMERY COUNTY, PENNSYLVANIA CIVIL ACTION - LAW KEITH DEANGELIS VS. : No. 95-01922 E.I. DU PONT DE NEMOURS & : COMPANY, INC. and : MONSANTO COMPANY and : DOW CHEMICAL COMPANY ELANCO PRODUCTS COMPANY DIVISION OF ELI LILLY COMPANY :	
* 800 N. Lindbergh Blvd.	TO: Here and Address at Defendancy		COMPLAINT	
SUPERIOR COURT OF THE STATE OF CALIFORNIA EMANUEL RICHARD GIGLIO, Plaintiff Complaint JURY TRIAL DEMANDED STEVEN BIDEGAIN and YVETTE COMPLAINT COMPLAINT JURY TRIAL DEMANDED Complaintiffs, JUNITED STATES DISTRICT COURT Complaint K COMPLAINT JUDI FITZGERALD, COMPLAINT Plaintiff, COMPLAINT Complaint COMPLAINT Complaint COMPLAINT JUDI FITZGERALD, COMPLAINT Plaintiff, COMPLAINT Complaint Complaint Complaint Complaint Complaint Complaint Complaint Complaint	800 N. Lindbergh Blvd	400 Fuller Avenue	2010 AK (1900) 1212 -	
UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA FOR THE COUNTY OF SAN FRANCISCO EMANUEL RICHARD GIGLIO, Plaintiff Civil Action No.: '15CV2279 BTM NLS STEVEN BIDEGAIN and YVETTE BIDEGAIN, '15CV2279 BTM NLS CASE NO. CONCLAINT OF TOXIC INJURIE CASE NO. CONCLAINT FOR TOXIC INJURIE BIDEGAIN, '15CV2279 BTM NLS MONSANTO COMPANY and JOHN DOES 1-50. COMPLAINT JURY TRIAL DEMANDED Plaintiffs, '15CV2279 BTM NLS COMPLAINT FOR TOXIC INJURIE ASSERTING CAUSES OF ACTION FOR: JUDI FITZGERALD, Plaintiff, COMPLAINT Civil Action No. COMPLAINT Civil Action No. COMPLAINT Civil Action No. COMPLAINT Civil Action No.		Helena, MT 59601	SUPERIOR COURT OF THE STATE OF CALLEGENTE	
EMANUEL RICHARD GIGLIO, Civil Action No.: '15CV2279 BTM NLS. STEVEN BIDEGAIN and YVETTE CASE NO. OB 0 5 4 4 5 1 5 5 Plaintiff COMPLAINT DURY TRIAL DEMANDED Plaintiffs, COMPLAINT FOR TOXIC INJURIE ASSERTING CAUSES OF ACTION MONSANTO COMPANY and JOHN DOES 1-50. UNITED STATES DISTRICT COURT EASTERN JURY TRIAL DEMANDED UNITED STATES DISTRICT COURT CENTRAL DISTRICT OF CALIFORNIA JUDI FITZGERALD, COMPLAINT Civil Action No. COMPLAINT Civil Action No. COMPLAINT Civil Action No.				
UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK CENTRAL DISTRICT OF CALIFORNIA JUDI FITZGERALD, Plaintiff, COMPLAINT CHRISTINE SHEPPARD Civil Action No. CHRISTINE SHEPPARD	Plaintiff IONSANTO COMPANY and JOHN	<u>COMPLAINT</u>	- STEVEN BIDEGAIN and YVETTE BIDEGAIN, Plaintiffs, CASE NO.00005445155 COMPLAINT FOR TOXIC INJURIES ASSERTING CAUSES OF ACTION	
EASTERN DISTRICT OF NEW YORK CENTRAL DISTRICT OF CALIFORNIA JUDI FITZGERALD, COMPLAINT Plaintiff, Civil Action No.			UNITED STATES DISTRICT COURT	
Plaintiff, Civil Action No.			CENTRAL DISTRICT OF CALIFORNIA	
MONSANTO COMPANY, Defendant. JURY TRIAL DEMANDED Defendants.	Plaintiff, v. MONSANTO COMPANY,	Civil Action No.	Plaintiff, Case No.: 2:15-CV-8632 vs. JURY TRIAL DEMANDED MONSANTO COMPANY,	

How the trial works:

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

























Dr. Donna Farmer Product Protection Lead



Dr. Daniel Goldstein Medical Sciences and Outreach Dr. William Heydens Product Safety Assessment Strategy Lead



































Dr. Mark Martens Toxicology Director (former)



Dr. David Saltmiras Toxicology Manager



Dr. John Acquavella Epidemiologist (former)





























Daniel Jenkins Manager for Regulatory Affairs





David Heering Strategy, Compliance, Operations Lead





































Dr. Kirk Azevedo Sales Representative (former)



Steve Gould National Accounts Manager (includes California)



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?

Opening Statement Roadmap:

- 2. Can Roundup cause cancer?
- 3. Did Roundup cause Mr. Johnson's cancer?
- 4. What are Mr. Johnson's damages?
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ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine,	
in the form of its potassium salt	3.7%
OTHER INGREDIENTS:	1.3%
100	0.0%

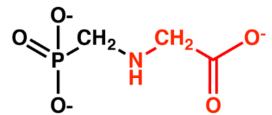


ACTIVE INGREDIENT:
*Glyphosate, N-(phosphonomethyl)glycine,
in the form of its isopropylamine salt
OTHER INGREDIENTS (including surfactant):
100.0%

Glyphosate

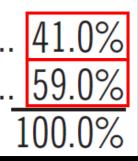


C glyphosate



Surfactant

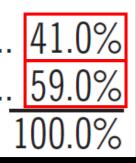
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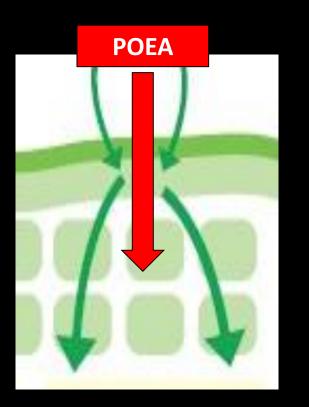
<u>POlyEthoxylated tallow Amine</u>

Surfactant

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

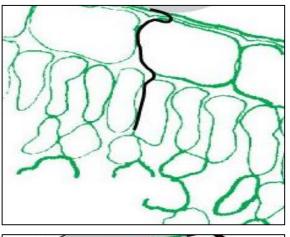


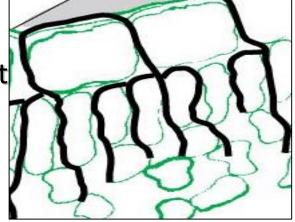




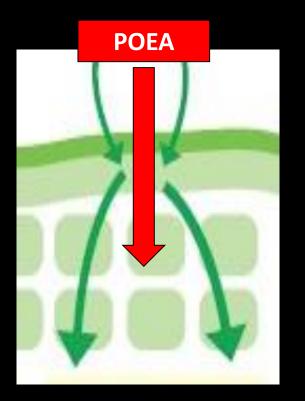
Without Surfactant

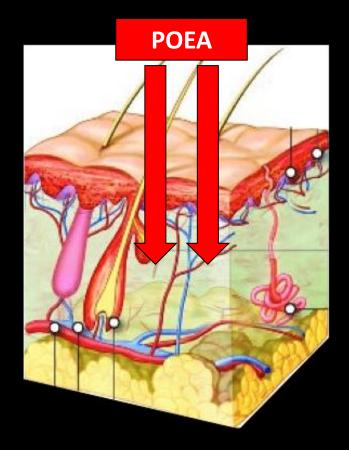
With Surfactant





Penetrates the surface of a leaf, but also human skin





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 [@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!!!







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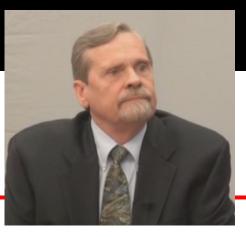
What do you think?



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Opening Statement Roadmap:

- 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?

Opening Statement Roadmap:

- 1. What is Roundup?
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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 twoyear 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



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
	4		

- 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.

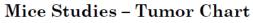
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1. Animal Carcinogenicity Studies

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		





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		Harderian gland adenoma		



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

1. Animal Carcinogenicity Studies



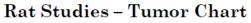


Glyphosate only

Long term – typically, 2 years

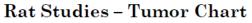
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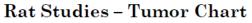
Lankas (1981)	Stout & Ruecker (1990)	Atkinson (1993)	Enemoto (1997)	Suresh (1996)	Brammer (2001)	Wood (2009)
Testicular interstitial cell tumors	Thyroid C-Cell carcinomas or adenomas	Thyroid follicular carcinomas or adenomas	Kidney carcinomas or adenomas		Hepatocellular carcinomas or adenomas	Skin kera-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





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1. Animal Carcinogenicity Studies



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Three Pillars of Cancer Science

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Three Pillars of Cancer Science

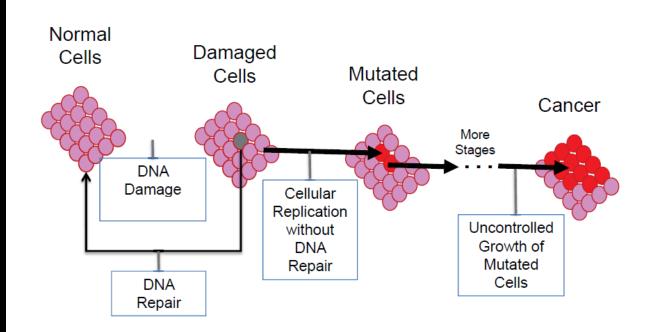
- 1. Animal Carcinogenicity Studies
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2. Mechanistic Data

Mechanistic Data:

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



2. Mechanistic Data

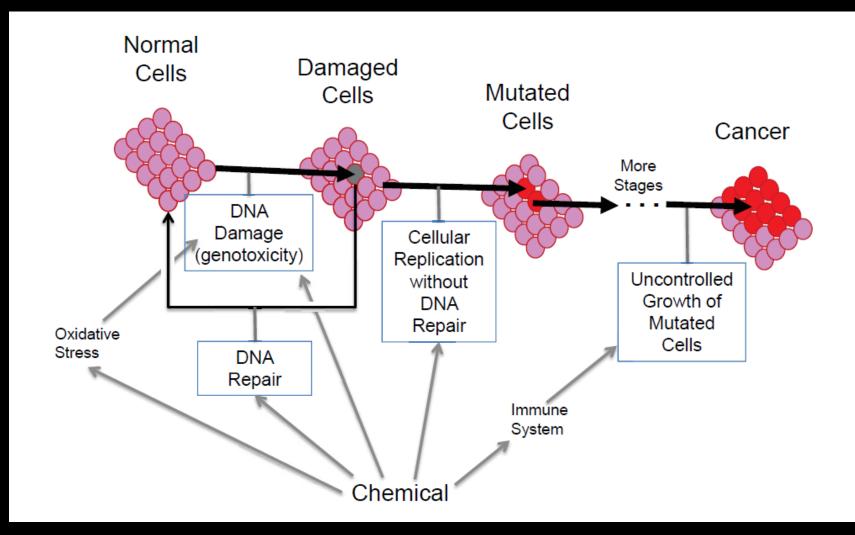
Genotoxicity:

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

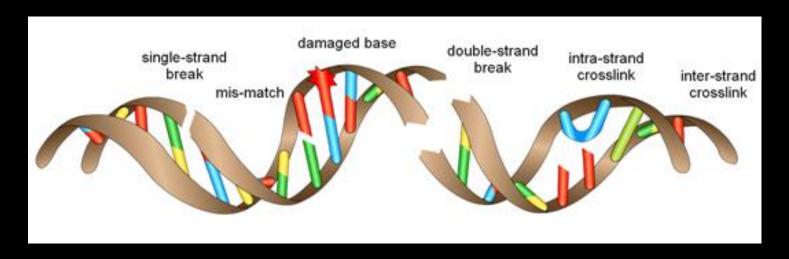
Oxidative Stress:

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

2. Mechanistic Data



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. 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.

ntion Brown A, 300 (2010-29-36 99) Elsovier Science Publishen B.V. All rights scienced 0015-1218/93/201600

MUTGEN OF

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 Department of Environment, Technology and Jonal Paulin Robble University, Downet (Bensited Visconie (PR)) (Journal of Visconie (PR))

Eyworde: Ronschep; Gigghonatz ingezegslamine; Genotanisky; Microandeux; Allian; Schmiedla

Summary

The generative potential of the herbick Roundup and in series appent, theybeards incorporation sets as used on a howe according a howe active massays. No chargen if effects over a host is the means howe nearest instantiation are not in the means howe nearest instantiation are the order of the two appendix and an effect of the potential sense or the based based on the probability of the set of

Roundup is a relatively new berbicide first	the future, when utility plants with resistant
arketed in the USA in 1976. The active agent in	phythesate are introduced on the market. Sp-
ionstaps is a glophosas: (w)-shouphonomethol	ing with Roundap on glyphomate-resistant of
lycine), which is considered almost non-tonic in	will make it possible to climitate all other
armeals ($\Omega_{D_{gen}}$ net oral = 4.3 g/kg) (Athiston,	warend plants on the field.
83). The hereincide Roundup is commonly used	The arcentonicity of Recendra and globh
a agriculture, forestry and numeries all over the orid and is expected to be used even more in	has been investigated in different assays (S 1977; Vigfusson and Vyse, 1980; Li and L 1988; Niagi and Gopolan, 1981; De Marco e 1992). The results from these studies are con
interpredence: Jete Rask, Department of Environment,	ing, and none of the investigators have to
inheology and Social Studies, Roskilde University, Box 201,	both Roundup and glyphosate in the same a
K-4000 Roskilde, Demark	In the present study we have examined

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Jan 1992

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

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*Author to whom correspondence should be an dressed (tritephnoc 38 010 5602235; fax 39 010 355573).	and/or coformal and the active ingre
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S. aphinorium TA98, TA100,	concerne.	Gene Muta shubosate	COOKS .		2500	Shiraw et al. (198
TAISIS, TAISIT, TAISIS	mutation	(not specified)				
S. ophinvarium TA98, TA100	mutation	glyphosate (not specified)		- (50 plant)	25	Wildeman and Natar (1982)
S. ophinvelue TA98, TA100, TA1535, TA1537, TA1538	mutation	glyphosate (18%)			2500	Li and Long (1988
5. ophinverium TA98	ownerse	Reartsp	+		180	Rank et al. (1993)
	mutation	(glyphoute 68%)				
S. ophinvarium TA100	mutation	Reservant		+	3930	Rank et al. (1993)
E. coll WP2 her	reverse				2500	Shirasu et al. (198
	mutation	(not specified)				
E. coltWP2	reverse modatan	glyphosate diffici			2500	L1 and Long (1988)
Chinese hamster ovary cells	COVECSE	ghybasate			22.5	Li and Long (1988)
	mutation	(18%)				
D. melangester	sex-linked	Enumber (not specified)				Copulan and Npag (1981)
	let hals					
		Chromosomal 3	Intations.			
L opa	chramosomal aberrations	Revendant (glyphenate 48%)	+	0	1440	Rank et al. (1993)
at bone marrow (22 vivi)	chromosomal	glyphosate		0	1000	Li and Long (1988
suman pertpheral blood	SCE	Frenchap	+	0	2500	Vigliances and
an entropheral blood	SCIU	(not specified) Ensandap		0	100	Vyse (1980) this paper
in sitre human peripheral blood	SCE	(glyphonate 30.0%) glyphonate	+	0	1000	this paper
an sitro V. Jaha (root tips)	microsocless	(90.9%) Solada		0	1400*	De Marco et al.
nouse bone marrow (22 +244)	test microsocieus	(glyphosate 21%) glyphosate		0	200	(1992) Rank et al. (1993)
nouse bone marrow (i.e.stari	test microtacieus	(not specified) Enverthep		0	200	Rank et al. (1993)
nouse bone marrow (22 stree)	test microsocieus	(glyphenate 48%) glyphenate	+	0	300	this paper
mouse hore macrow (in start	test mirmerikan	(99.990) Enversion			125	this paper
and the matrix for the	tand	(glyphosate S0.8%)			1.00	the paper
		DNA Dan	sage			
R. solutits	rec-assay	glyphosate (SWN)		-	1000	L1 and Long (1988
at qualocytes	UDS	altyphonate CBNG			125	Li and Long (1988
taxume (do vitro)	DNA single-strand	(50.9%)	+	0	300	this paper
Dourse (02 V2v3)	DNA DNA single-strand	Roundap (ghyphosate 30.8%)	+	0	270	this paper
moune (20 x7m8	breaks 8-OH4C	ghubusate	14	0	300	this paper
mouse (20 v/mb	8-OH4C	(99.9%) Fireadap	*		270	this paper
*+, positive: -, negative: 0, a selfective dose. * Expressed as a idney cells	ant tested. * Jo v	(glyphenate 50.6%) itro tests, agird.; in s	ivo tests, mg/	kg of bw. LED Itser cells. *Pr	lowest effect sitive results	ive dow; HID, high

sting of the herbicide Roundup and its active ingredient propylamine using the mouse bone marrow micronucleus a mutagenicity test, and Allium anaphase-telophase test

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

Roundap is a relatively new berbicide first arketed in the USA in 1974. The active agent in ioundap is glophosate (N-phosphonomethol joine), which is considered almost non-noic in armeals (LD _{ap} , net oral = 4.3 g/kgl (Athiston, S3). The hereincide Roundap is commonly used	the future, when utility plants with resistance to glyphosate are introduced on the market. Spray- ing with Rozardap on glyphosate-resistant crops will make it possible to climinate all other un- warred plants on the field. The zerostonicity of Resendue and gluphosate
agriculture, forestry and numeries all over the	has been investigated in different assays (Seiler,
orld and is expected to be used even more in	1977; Vigfusson and Vyse, 1980; Li and Long, 1988; Niagi and Gopolan, 1981; De Marco et al., 1992). The results from these studies are conflict-
terenpendence: Jette Rank, Department of Environment, inhoology and Social Studies, Roskilde University, Box 261, K-4000 Raskilde, Deamark	ing, and none of the investigators have tested both Roundep and glyphosate in the same assay. In the present study we have examined the

Plaintiff Exhibit



0686

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

We thank Patrizia Lupi, Car

Plaintiff Exhibit 0852

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 la 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 arting 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 to view and to vitro. Swiss CD1 mice were treated intraperitonenily with test substances, and the DNA damage was evaluated by alkaline elution technique and 8-bydroxydeoxyguanosine (8-OHdG) quantification in liver and kidney. The chromosomal damage of the two pesticide preparations was also evaluated in view in hone marrow of mice as micromiclet frequency and *to* 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 *to* view and *in vitro*. A weak increment of the genotoxic activity was evident using the technical formulation.

Keywords: Pesticide: in vivo generaticity; in vitro generativity: SCE: micromucleus test; alkaline elution: DNA axidative domage

INTRODUCTION

Roundup, an extremely effective norselective 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 dormatitis, rep in occupationally exposed agricultural workers () 1980).

The formulated commercial product, Roundup, a

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The formulated commercial product, Roundup, a

Jan 1992

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

J. Agric. Food Chem.	1997, 45, 1957-1952	1957 Olyphosale Genotoxicity				
Genotoxic Activity of Glyphosate a Roundup	nd Its Technical Formulation		Table 2. Summary of Result			
Claudia Bolognesi,* Stefania Bonatti, Pae Roberta Rabboni, Paola Benzi	to Degan, Elena Gallerani, Marco Poluso, eri, and Aranda Abhendaradola		text organisms	groet		
Centro Nazionale per lo Studio dei Turneri di Origi Cancro, Largo Rosanna Bes	as Ambientale, Intitute Nazionale per la Ravera sul		S. aphanoraum TA98, TA100, TA1535, TA1537, TA1538	mutat		
			S. optimication TA98, TA100 S. optimication TA98, TA100,	mutat		
Glyphosate (Nybosphonomethylglycine) is an effe amine acids in plants. The prostatic potential	of this herbicide luss been studied: the results		S. option view 1200, 12100, TA1535, TA1537, TA1538 S. options/som TA98	mutat		
available in the open literature reveal a weak act the formulated commercial product. Houndop, an				mutat		
same battery of assays for the induction of DNA wire. Swiss CD1 mice were treated introperitors	damage and chemenessenal effects as vivo and av		S. (gphteroritore TA100	mutat		
was evaluated by alkaline elution technique and 8 in liver and kidney. The chromosumal damage of	bydroxydeoxygianostne (#-OHdG) quantification		E. coli WP2 her	mutat		
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significant increase in chromosonal alterations w vitro. A weak increment of the genotoxic activity			D. melanquater	sex-ltri recess letha		
Keywords: Posticide: in vivo genotacicity; in vi elution: DNA middrive disman	trogroduktity: SCE mirronucleus test; alkallow		A. cepa	dyanos		
INTRODUCTION		00000	rat bone marrow (20 vivi)	aberrat chramos aberrat		
Roundup, an extremely effective normelactive poste-	1985), but Roundup has been identified as a ca Irritation physiomenon or contact dermatitis, re-	period	human pertpheral blood	SCE		
mergence herbickle, is a combination of an active ingredient, the toppropriamine salt of glyphusate, and	in occupationally exposed agricultural workers 1980).		hamon peripheral blood in stre	SCI		
a surface-active agent that enhances the spreading of	The formulated commercial product, Roundop,		human peripheral blood	SCE		
spray droplets when they contact foldage. Glyphosate (GLYPH), N-(phosphonomethy()glycine, is selectively	to be rather more toxic than the parent comp Clinical reports citing cases of acute paisoning in that the lung could be considered the target or	dicato	ito x80-0 V. flahs (root tips)	mit men land		
iasic in plants and relatively somitatic to animals. The mechanism of action of this herbicide is a competitive inhibition of the enalgemay/i shikimate phosphate sym-	Researchup texticity. The polymenery texticity of Ro- has been demonstrated in rats, after a direct tri- administration (Martinez et al., 1990; Martine	ar funal	mouse bone marrow (privite) mouse bone marrow (privite)	microdu lost microdu		
thase (ESP-synthese), an enzyme absent in animals, essential to the synthesis of aromatic amino acids in	Brown, 1991). This effect has been attributed to s active ingredients (Sawada et al., 1988); neveril	arfaxy	mouse bone marrow (2/1 stve)	microco		
plants (Amrhein et al., 1980; Hollander and Amrhein, 1980; Grossharil and Atkinson, 1985; Jawurski, 1972). Glyphesate has been reported to have a low acute.	n study on the interaction between glyphoset surfactants revealed an antagonistic effect (Baba 1980)	e and	mouse bere macrow (in stat)	mik rotat land		
testicity to different animal species with an oral LD _m ranging from 0.7 to 11.0 grieg of body weight (Worthing	The genotoxicity of glyphosate and its tec- formulations has been studied in different test ye	heatcal	B. solutits	rec-ase		
and Hance, 1991; EPA, 1982; FAO, 1980). The results of a number of tests on a variety of species have shown	The results obtained indicate no genotoxic activ	ity for	rat egatocytes	UD		
that glyphosate has, at the range of concentration normally used in agriculture, no chronic or neurotoxic efficits (Atkinson, 1985).	glyphosate and a weak effect for technical format The aim of our investigation is the evaluation genotoxic potential of this herbicide, testing	of the both	mouse (20 viru)	single-st break		
Chronic feeding studies did not evidence a carrino- penic activity of this berbicide in rats and dogs (FAO.	Roundop and glyphesate in the same battery of a Few data have been reported on the DNA-dam activity of this berbickle by site. We have eva-	usping	mouse (20 v2vi)	DN/ single-st		
1980: IPCS, 1904). In these studies the active ingredi- ent alsohosate demonstrated an organospecificity for the	the DNA damage in terms of single-strand break		maxuue (20 v2vil)	8-014		
one graphics an introducting an increase in prioritical renal infinity system, inducting an increase in prioritical renal inducts basephiliadropertrophy and in hyperplastic of the	8-hydroxydensyguanosine (8-OHIG).		mouse (20 v2vi)	8-019		
urinary bladder (FAO, 1986).	MATURIALS AND METHODS		*+, positive; -, negative; 0,	aut tested.		
No adverse effects on reproduction or fetal develop- ment have been observed in three generation studies on rate and to a developmental toatetty study on rubbits	Chemicals. Analytical grade glophonate ICAS Regin 1071-83-60 was parchased from Società Italiana C Rome, Italy. Parity declared by the producer was Reserving locendate 200.0% glyphonatel was from Me		anoffictive dose. " Expressed as a kadney cells	all a light of soil		
(Adkinson, 1985). Clyphosato is a mild skin and eye trritant (Mathach, 1986; California Department of Food and Agriculture,	Italiana, Milan, Italy. Methyl methanesufforate (MM Registry No. 69 27 32 and breast/alporess (RLdP, CAS R No. 50 32-8) severe obtained from Sagna Chemical Co. St	s, cas legatey Louis	The higher activity of tech ing toxic and genotoxic dam tal systems suggests a role	nage in di		
* Author to whom correspondence should be ad- dressed (trilephone 29 010 5600215; fax 29 010 355573).	MO. ICAS Registry No. source provided by the author. Int Vitro. SCE, Heparimized venues blood sample obtained from two healths female dezers. Whole blood		and/or coformulants in the the active ingredient.	potentiat		
\$3021-4841(94)(0081-6 CCC: \$14:00	# 1997 American Chemical Society	C1	Considering the wife us cultural and nonagricultura	al uses, se		

ble 2. Summary of Results on the Genotoxicity of Glyphosa			ree	ails.		
	grantic	compound	without exagences metabolic	with emgenous metabolic	dow ^a	
test organisms	effect	(purity)	system	system	13131000	references
		Gene Muta	Clocks .			
nphinogium TA98, TA100, TA1535, TA1537, TA1538	mutation	glyphosate (not specified)	-	-	2500	Shirasu et al. (198
ophinicram TA98, TA100	mutation	glyphosate (not specified)		- (59 plant)	25	Wildeman and Natar (1982)
ophinyarium TA98, TA100, TA1535, TA1537, TA1538	mutation	glyphowate (18%)			2500	Li and Long (1988)
tiphinverium TA98	CEVECKE	Reardsp	+		180	Rank et al. (1993)
	mutation	(glyphmate 48%)		+	360	Barris and a summer
ophievarium TA100	mutation	(gryphonate 48%)		+	3930	Rank et al. (1993)
col/WP2 her	OWNER	ghyphosate			2500	Shirana et al. (1983
	mutation	(not specified)				
codrWP2	reverse modatan	ghybosate			2500	L1 and Long (1988)
inese hamster ovary cells	coverse.	ghybosate			22.5	Li and Long (1988)
	mutation	68%				Compared (comp
melangester	sex-linked	Revendap .	0			Copulan and Nagt
	recessive lethals	(not specified)				(1981)
		Chromosomal N	la d'active au			
0004	chramosomal	Frenchop	+	0	1440	Rank et al. (1993)
	aberrations					
bone marrow (20 v/vi)	aberration	ghyphosate (58%)		0	1000	Li and Long (1988)
man pertpheral blood	SCE	Rearchap	+	0	2500	Vighneen and
0.100						Vyse (1980)
man peripheral blood in sitre	SCIU	Emerakap (glyphonate 30.8%)	+	D	100	this poper
nan peripheral blood	SCE		+	0	1000	this paper
in xithe						
fahs (root tips)	microsocieus tent	Solado (glyphonate 21%)		0	1400*	De Marco et al. (1992)
use bone marrow (co uneit	manuacieus		-		200	Rank et al. (1993)
		(not specified)				
use bone marrow (/n stor)	microsocless test	Enorskap (glyphenate 48%)		0	200	Rank et al. (1997)
use bone marrow (in stre)	microtecleus	glyphonate dena glyphonate (56.990)	+	0	300	this paper
one been marrow (in star)	microsov brow	Describer		0	135	this paper
	tand.	(glyphosate S0.8%)				
- Andrewski - A		DNA Dan	age		1000	I a send I among the send
solution	rec-assay	glyphosate (SWN)			1000	Lt and Long (1988)
epaixytes	UDS				125	Li and Long (1988)
ume (do schol)	DNA	(18%) phohosote			200	this second
use (20 V2H3)	single-strand	(30.3K)	+		300	this paper
une (00 v3vil)	DNA single-strand	Roundap (glyphosate 30.8%)	+	0	270	this paper
ume (pp youth	B-OH4C	ghubusate	14	0	300	these opport
		69.9%				
use (00 ¥848)	8-OHdG	Financkap (ghyphemate 30, 8%)	*	0	270	this paper
+, positive: -, negative: 0, i lective dose. * Expressed as j rey cells	not tested. * Jo v agig of soil. * Pos	itro tests, agind.; in a	no tests, mg/ n obtained in	kg of hw. 1.10). Inver cells, *Pe	kowest effect sitzvo results	ive dose; HID, high have been obtained

ts in the potentiation of the effects of mt. wide use of this heehicide for agriwide use of this heehicide for agriwide use of this heehicide for agrition of the state of the state of the state of the state of the Cheventum Measurement for intervised.

Interior Research, 300 (2003) 29-36

MUTGEN BIR

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 Dummer of Entroneou. Tethology on Social Justice Robitist University, Downet (Benzind 9 Suptraster (982)

iyworde: Roundop, Gipplenate koprogelanine; Genetativity; Micrometros; Alfan; Schninella

Sammary

The generatic pointial of the briefield Rounday and its across again, globours incorporalizations are instable in three different analys. No interpret effect were taken to be the source of the sour

Roundup is a mitatively see berblidle first marketetia the USA in 1974. The active agont in specific the USA in 1974. The active agont in specific which is creative of almost rose-state in specific the use of the USA in the USA in the USA in USA in the USA in the USA in the USA in the USA in agriculture, foreinly and numerics all over the orld and is expected to be used even more in	the future, when stillty plants with resistance to glythouse are introduced on the market. Spray- ing with Roards on glythour-resistant crops will make it possible to diminise all other are- used to the standard state of the state of the state The generativity of Roards and glythours has been investigated in different assay (Solitz, 1977; Vigfassen and Vys, 1996; Li and Long, 1988; Nagi and Capelta, 1981; De Marco et al., 1992; The results been three studies are conflic-
prospondence: Jette Rank, Department of Environment, chuokage and Social Studies, Roskilde University, Box 261, 6400 Enakluk, Donmark.	ing, and none of the investigators have tested both Roundup and glyphosate in the same assay. In the present study we have examined the

Name and the second sec

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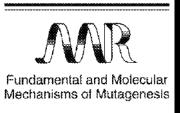
(g Date) (abs: Hen Kim, Tom, Tomari, B. (19-19). (Starthart, Sandart, Sandart, Sandart, Sandart, Sandart, Sandart, Sei, Sandart, Kathart, Sandart, Sandart, Sandart, Sandart, Sandart, Sandart, Kathart, Sandart, Sandar Mar 1997



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



Jul 1998



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



Dec 1998



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

Jul 1998



Fundamental and Molecular Mechanisms of Mutagenesis

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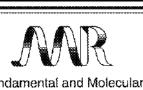


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Monsanto's Reaction:

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



etti 🛓	tians from12/37 Meeting on Mutagenicity
or:	/27/88 1131 PM
	Mix \$2276 - glyphonate - Mix \$253 (Endiger #227) and Taxes 25
	HDA 11012 - glyphonate - Occanesting and Artiflum All
- 1	- will contact the Tab, per protocols, request test
25	 will target to start the studies mid-tankary, but recognize we may alter the studies/and or text salarials hand or restard of areas assessed on subgestidies.
81.44	and to further discuss and develop "detergent meleoule" texting
1	will arrange this minimater. Theing after the receipt of the parameters mendant. Please let ne know your analighticly for the following days (se can always cancel the meeting of we have not haved yet):
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e) ag sevels	real an external glabal returns of perchas asperts words to im-
8.0 90 21 81	As has an imputing year and is a critical area new it was need that the second avails contact by, warry near work to cause with firs his participation to the support of glyphosate, phonone-based ***forwalization*** periods forwar.
	ofter stilled costers, if for, terry is agreenable then will be trabade to discontine to multime inseriments etc.
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- IS proble galax	is a real concern that these papers may create as even bigger in far as Duet the District ager. Therefore we do sume things (r)
	results of the human 'symplectyte test by the set agree with story and data in the human 'yespicovis story' consisted by an at 9000.
Recom	widetfore:
EPAN BUAN	it the authors, make a Tether saft from Hersants Stalp or Is and saying semething about:
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the metric leafe

MI UTI

	Reply Separator
	Actions from12/17 meeting on Mutagenicity
Author: Date:	12/22/000 1-22 000
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12 Agreed an external glabal network of genetox experts words to de days1coatt. As Ed has an immediate read and is a critical area now it was agreed that an anald contact br. Parry next week to discuss with his his participation in the support of glyphonate. glyphonate-based +++formulation+++ pentox feaunc. After withal covers, if Dr. Party is appeared to that will be included in discussion to mulling issue/needs where. For North America will be here to early February as part of the tANFOR project. as practicusly apreset to Sols is those discussions.

2) infortunately our time rain out but papers:

 The data are very unusual and suspect (i.e. the results may reflect an artifact of some procedural error and/or imexperiance in scoring) but may be estremely difficult to refute based simply on the contents of the paper.

- It is a real concern that these papers may create as even bigger problem for us that the property caper. Therefore we do some things publicity!

- The results of the huses typehocyte test by and do not agree with

Dec 1998

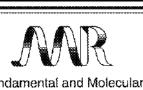


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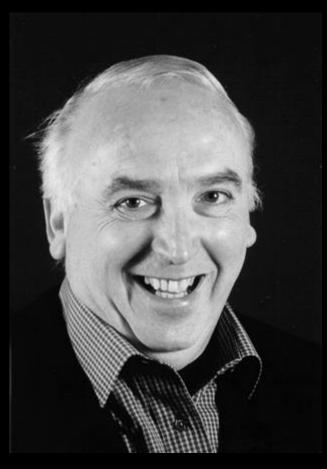
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81.44	and to further discuss and develop "detergent meleoule" texting
1	will arrange this minimater. Theing after the receipt of the parameters mendant. Please let ne know your analighticly for the following days (se can always cancel the meeting of we have not haved yet):
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	2/19 2/19 2/19 1/11 1/11
e) ag sevels	real an external glabal returns of perchas asperts words to im-
84 00 21 8	As has an imputing year and is a critical area new it was need that the second avails contact by, warry near work to cause with firs his participation to the support of glyphosate, phonone-based ***forwalization*** periods forwar.
	ofter stilled costers, if for, terry is agreenable then will be trabade to discontine to multime inseriments etc.
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	fortunately our time rate out to
	data are very unusual and support (i.e. the results my it as artifact of some procedural error and/or imsperience in g) but my be extremely difficult to refuse based singly or interts of the paper.
- IS proble galax	is a real concern that these papers may create as even bigger in far as Duat the District ager. Therefore we do sume things (r)
	results of the human hyperacyte test by the set agree with story and data to the human hyperacyte story consisted by an at 9000.
Recom	widetfore:
EPAN BUAN	it the authors, make a Tether saft from Hersants Stalp or Is and saying semething about:
- The	data doesn't opree with other data as have - the agriches study where as are interested in investigating the discretance.

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





External global network of genotox experts:

- EU

- NA

 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 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 , no further contact will be made at this time. When a clear role has been identified for Alan will contact him.
 Money for this initial consultation will come from budget. A bigger initiative will require additional funds to be located.

 Expanded discussions with Dr. Gary Williams on genotox issues will occur as part of the CANTOX meetings (2/5,647). 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
- While there is \$90K in the glyphosate toxicology testing budget for mutagenicity testing, this may not be enough. Further

External global network of genotox experts:

- EU



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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

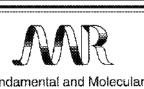


Dec

1998

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

Jul 1998



Fundamental and Molecular Mechanisms of Mutagenesis

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



Monsanto's Reaction:

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



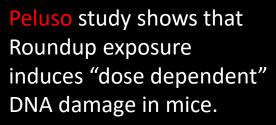
Sub Sect i	Actions from12/32 meeting an Mutagenicity
Author: Dete:	12/27/98 1:31 PM
	MDW 52278 - g7yphonate = MOA 8252 (Endigen 4022) and Tamen 28
	904 31012 - glyphosate - Occupation and Arctifium All
	- will contact the Tab, put protocols, request text material atc.
	 In still target to start the studies sid-tanary, but recognize see may allow the cludies/and or best salerials based or resoluted of permata assessment on subspecifility
80	Agreed to further discuss and develop "detergent selecule" testing groupse
	 will arrange this stocastor. Theing after the receipt of the person senders: . Hence let ne tree your availability for the following days (se can always cancel the meeting the have not send will).
	an of)
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62 89	Agreed an external glabal returns of provins apports woods to in without
	as in his so insufficts read and is a critical area new it ass squeet that because off asside contact in . Party next sets to discuss with the the participation is the support of glypheasts, glypheast-based envelopmentations perms forms.
	after scilled contact, if Dr. Navry is agreents than the following will be included in discounter to motion issue/heads
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22	ordertowately our time rate out but presented and the tayout a till will be taken a
	The data are very unusal and suspect (i.e. the resalts may flect an artifact of same procedural error and/or impactance in oring) but may be extremely difficult to rafue based simply on a contexts of the spare.
-	It is a real concern that there papers may create as even bigger of an for us that the structure paper . Therefore we do sume things inty?
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100	when the authors, rease a fatter safe from Hersants Stalp or seachs and saying essenthing about:
	The data discut's agree with other data as have - the agriches study therefore us are interested in investigation the discrements

Dec 1998

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Jul 1998



Fundamental and Molecular Mechanisms of Mutagenesis

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



Monsanto's Reaction:

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



	12/27/98 1111 99
	Min 52276 - allyphonete - Min 8552 (Indigen 4822) and Taxen 25
	NDs 11012 - glyphonate - documentar and Anti-fluor All
	- will contact the Tab, per protocols, request test
	in all target to start the studies ald-basary, but reception as my alter the studies and the state-talk based on receipt of genus annihiert on subgeniting.
11.1	spread to further discuss and develap "detergent selecule" testing program
	will arrange this discussion. Theirs after the receipt of the person senders. Please let me know your acallability for the following days the can always cancel the meeting if we have not mean year).
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ferre	spend an external global research of genetics experts works to im found. In all has an immuting read and is a critical area new it was opened that the second contact an reary mass work to found with the file activitation to the support of alsophones.
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22	infortunately our time rate and but groupers and the tayed a tayed a
raft area	e data are very unusual and support (i.e. the results my lect as artifact of sum procedural error and/or imogeniance in ing) but may be extremely difficult to refute based singly or conterns of the super.
- It prot exit	t is a real concern that them papers may create as even bigger las for as that the particul paper. Therefore we do same things (1)
	is results of the house, beginning test to the set of the set agree with territing and data in the house Treprogram study consisted by case at 40000.
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	e data disex's agree with other data as knot The agriches study arefore as are interested in investigating the discrepancy much this pandes of what they terms for explories.

Reply Separator

Feb 1999

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



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Managanto Europe Parc Scientifique Fleming Ros Laid Barriet 5 B-1348 Lournin La-Neuve Delgion

11 February 1999

Dee

You will find endorsed my unitation of the Sour papers you provided concerning the potential genetonisity of glyphonese and Roomhap. Although each of the papers have vacakasesee, I have anothed a report which amongto to flotus apon these weakarooes. Rather, I have anothed to "poll real" the data which provide an aid to the understanding of the potential mechanisms of glyphonese genotonicity and indicated how you might clarify these mechanisms. It has been my experience with Regulatory Agencies that a positive attaude to published data is a more productive approach then just articleing individual studies.

I essues that you will already have in house data for some of the suggested experiments. In my view the in view micrometicus work suggerent would be the most productive was of clarifying the question of mechanisms. I would be happy to provide you with further suggestions to detailed protocols for such studies. They would make a ratios nice Ph.D project for a graduate coders if you could fied the funding.

I have enclosed my investor for the evaluation.

- Ju Com

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at opsivalest concentrations to that in Rounday, failed to increase adducts. These data provide some evidence to support the concept that say in vice activity of Gippivaphate map be prioritized by other components of the Rounday mixture.

The overall data provided by the four publications provide coldence to support a cooled data Glyphonete is sepable of producing processicily both in who and in view by a mechanism based open the production of unitaries datange. X-confirmed, such a mechanism of generic damage would be expected to be produced at high concentrations of the harbicide and would be solevant only when the anti-outdoor protective machanisms of the well are overwhelmed. Thus, I would construct that if the mechanism of action can be proved to be based upon onidative memory data the set out if the mechanism of action can be proved to be based upon onidative memory data based and risk meconeses readd be based upon a notlinear model with a doubled of activity at low does.

Quartiess raised by the studies

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D Bois of components of minute which traits to high levels of activity of Revailant?

2) Is the generator entropy alwarved due to evidentive damage?

10 Can the processis activity he subset by anti-onidates?

Recommendations for further work to clarify the patential processic activity of

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based upon exidation demage then based and risk successes could be based upon a net-

linese model with a doubload of serivity as low does.

Questions raised by the studies D Bois of components of mixture which itsels to high lovals of activity of Rousiky? D to be genetoxic activity elearved due to orderive damage? D Can the generously activity by and/ord by anti-orderat?

Recommendations for further work to clarify the patential processic activity of Glephonets

Barteria

L reconstructed a repose of Subscendle studies particularly with Roundup minutes. 1 writin be surprised if there does are not already available in forms.

Cytogenetics

I reportment as in view microstation usely periodily in homes lymphocycs. If combined with analyses of the microstatic for the presence and strenger of contraling the this many would indicate whether Glyphoeste induces predominantly thromotooss structured

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- s). The assessment of the potential influence of anti-excitents upon the percental: portraid
 - of Chydronau Note the measurements of the effect of and-cubites or a ground

andpoint is a settical deficiency in the Lot or al (1998) shalp-

b) Assessment of the individual components of the Roundep Misense to committee whether thats is an componential edich to sprangislically in increase the powerful genoreality of Clippicents. Such studies could be designed to invasignee a peopl of mineurus larving not any component of the mile for each individual superinteet.

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is would be worth repeating the study to a more compatibately e design.

To rented both the DNA smand books and advant work, would require very large

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As a following Mark will gestagt by . Parry, discuss with his the existence of additional data and ask his to evaluate the full package, mark will also wather his interest Of the can turn his spintan wound is being a sockeaperion for un for these type of lamas. carry as well as others will be soullable to discuss the data with Parry as median by e-wall, place or in person or all the above. The panel concluded that plyphonate and Kanadap metering mataparts. That is the each parties of these types of studies primers about the each one front in the each estimation to shark makes an acceptable study and what does not - this is to be included in the managements as well as of earliering environment An analysis of whit was tested in the Lisi studies was deemed important. Therefore it was recommended that measure by an Italy contact that and try its pet a sumple of bett, they seed in their pit

Plaintiff Exhibit 0264

4) 61sb	all experts Review Dr. Harry's analyts - what is our west step? Dr. Harry concluded on his evaluation of the four- articles that glyphusate is capable of producing generatoricity both to viso and in vitro by a mechanism based upon the production of outdative 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 Wim to critically evaluate the spallity of all the data including the open literature studies.
	As a followap Mark will used and Dr. Parry, discuss with him the existance of additional data and ask into to evolvate the full peckage. Mark will also explore his interest (if we can turn his opinion around) in being a spokesperson for us for these type of issues.
	carry as well as others will be ovsilable to discuss the data with Farry as needed by e-mail, phone or in person or all the above.
	dr. williams - discuss the subcase of the cautox meeting
	The purel concluded that glyphicate and Kountup more rot mutagents. That in the evaluation of these types of studio priteria abould be set up frowt in the evaluation process to what makes an acceptable study and what does not - this be included in the manuscript as well as a weight of evider approach.

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An analysis of whit was tested in the List studies wie deemed (apertant, Therefore it was recommended that Messanis Disr Tlay contact list and try is pet a comple of what they used in their vis

Plaintiff Exhibit 0264



Dr. Parry submits second comprehensive report.

Dr. Parry submits second comprehensive report.

Clastogen:

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

Dr. Parry submits second comprehensive report.

Dr. Parry concludes glyphosate is clastogenic.

12

- 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 Lin *et al* (1998a and 1998b) i conclusite that glaphonus is a potential classropeic *invivo*. The tudy of Bolgment *et al* (1997) indicates that this contagonic activity **may** be reproduced in vivo is somatic settle. However, the dominant lends assay (of limited sensitivity) indicates that this generatic activity is not reproduced in grow cettle. The work of Bolgment *au* (1997) and Lio *et al* (1998a and 1998b) suggest that the generaticity observed may be derived from the generation of existivity damage in the presence of glyphonate.

Specific evaluation of genotoxicity of glyphosate mixtures

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Plaintiff Exhibit **0220**

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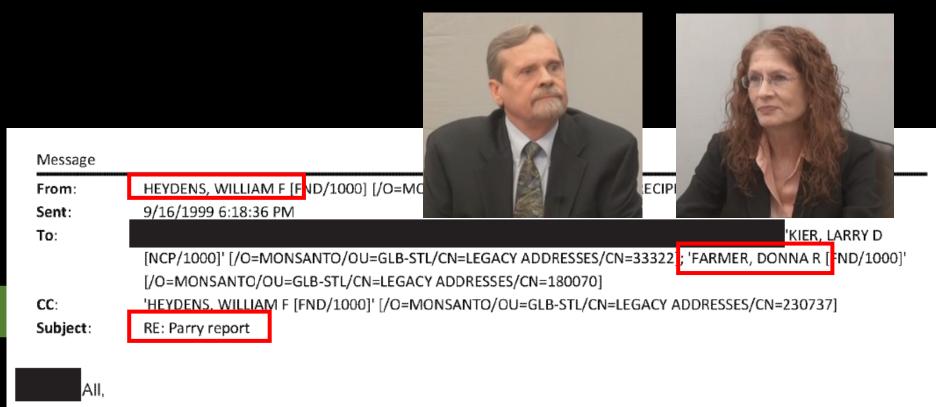
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- None of the surfactants demonstrated any mutagenic activity in bacteria.
- 18) There are no adequate data to evaluate the in vitro clastogenic activity of surfactants
- 19) One limited bone marrow micronucleus assay failed to detect any micronucleus

inducing activity with the surfactant MON0818.

Specific evaluation of the genotoxicity of glyphosate

On the basis of the analy of Ll (*i*e *ed* (1998a and 1998b)) conclude that glaphones is a potential extangenic in vitro. The multy of Bolympi *et al* (1997) indicates that this contagonic activity may be reproduced in vitro in somatic efficie. However, the dominant lends assay (of limited sensitivity) indicates that this genomeic activity is not reproduced in gram eitht. The work of Bolympi *et al* (1997) and Lio *et al* (1997a and 1998b) suggests that the genomecicity observed may be derived from the generation of existive damage in the presence of glyphonte.

Specific evaluation of genotoxicity of glyphosate mixtures

In view of the absence of adequate data no evaluation of the clastogenic potential in vitro of glyphonene mixtures is possible. In the absence of a microauclion and/s to the protocol of the taused by Bologeneii et al (1997) to a dequate assessment of the potential activity of glyphonene mixtures in bone marrow is possible. The available matlers do not provide any ovidence of productivity in other to marrow the interview of the Demosphila to suggest that glyphonete mixtures may have some germ cell activity.

The studies of Bolognesi et al (1997) suggests that glyphoate mixtures may be capable of inducing oxidative damage in vivo. Specific evaluation of surfactants

Plaintiff Exhibit

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ansate aduation of the classopsnic potential is aduation of the classopsnic potential is or a micromulcus study to the inquire assessment of the potential 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?
- 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?

Key Issues concerning the potential genotoxicity of glyphosate, glyphosate formulations

James M. Parry

Centre for Molecular Genetics and Toxicology

School of Biological Sciences

University of Wales Swansea

Swansea SA2 8PP, UK

Is glyphosate an in vivo clastogen? Can the positive studies of Bolognesi et al (1997)

If glyphosate is an in vitro and in vivo clastogen, what is its mechanism of action and

1. Is glyphosate an in vitro clastogen? Can the positive studies of Lioi et al (1998a,

- 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

Message From HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737] 9/16/1999 6:18:36 PM Sent To: '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] RE: Parry report Subject 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. do vou 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.



Sept

1999





Ghostwriting: Dr. Heydens ghostwrites Williams paper.

Safety Evaluation and Risk Assessment of the Herbicide Roundup¹ and Its Active Ingredient, Glyphosate, for Humans

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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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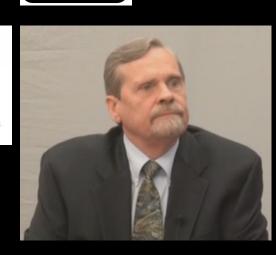
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Updated and attached for your commer

Thanks,

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



Science

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Bill,

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Safety Eva al

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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 <u>weight</u> of evidence be measured by <u>number</u> 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





Apr 2000

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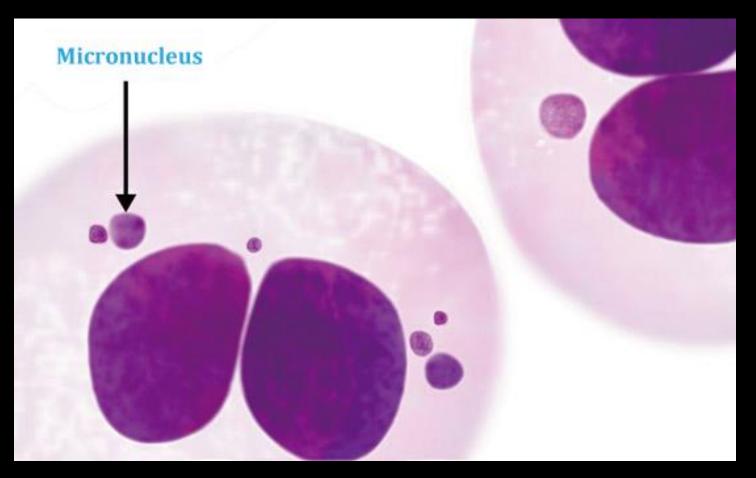
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- 2. Can Roundup cause cancer?
 - 2. Mechanistic Data

Recent Data Findings:



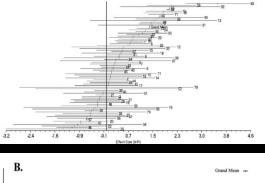
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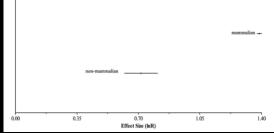
Recent Data Findings: Ghisi (2016)

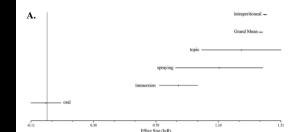


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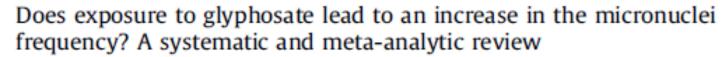


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Review





Chemosphere

5

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

* Programa de Pós-graduação em Ecologia de Ambientes Aquáticos e Continentais (PEA) Nupélia, Universidad e Estadual de Maringá (UEM), Av. Colombo, 5790, Zona 7, 87020-900, Maringá (PR), Brazil

^b Universidad e 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.

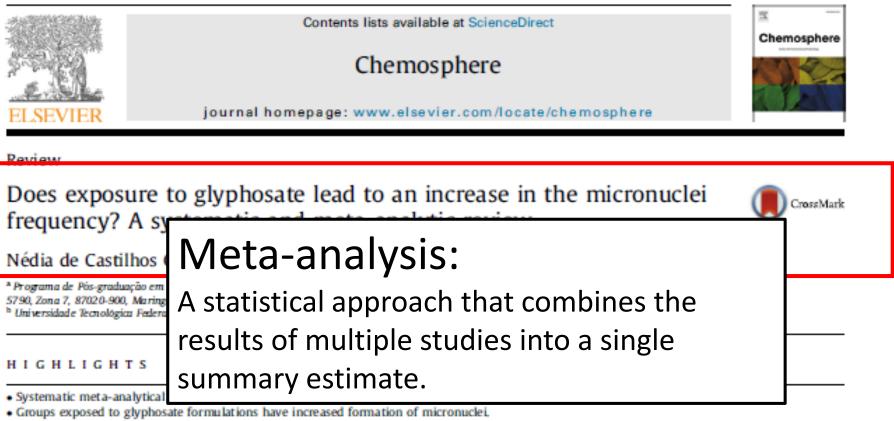
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Handling Editor; Frederic Leusch

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Glyphosate-based herbicides are among the most used pesticides worldwide. Reviews on the safety of glyphosate have been conducted by several regulatory agencies and researches centers, many times with contradictory results. This study is a systematic meta-analytical review of experimental studies on the relationship between exposure to the glyphosate (GLY) and its formulations with the formation of micronuclei (MN) to establish a quantitative estimate of the environmental risks. The natural logarithm (ln) of the estimated response ratio was calculated from 81 experiments. A meta-analysis was performed on the complete data set, and individual meta-analyses were conducted after stratification by test system, class of vertebrate, exposure route, gender, endpoints, type of literature, formulation, GLY dose and



- Significant difference among glyphosate (GLY) and its commercial formulations.
- Difference in MN formation among different exposure routes of GLY.
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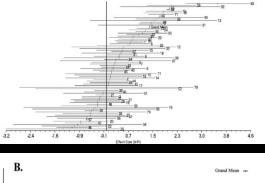
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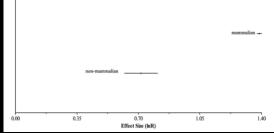
Recent Data Findings: Ghisi (2016)

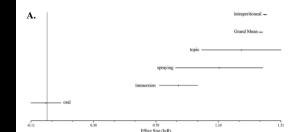


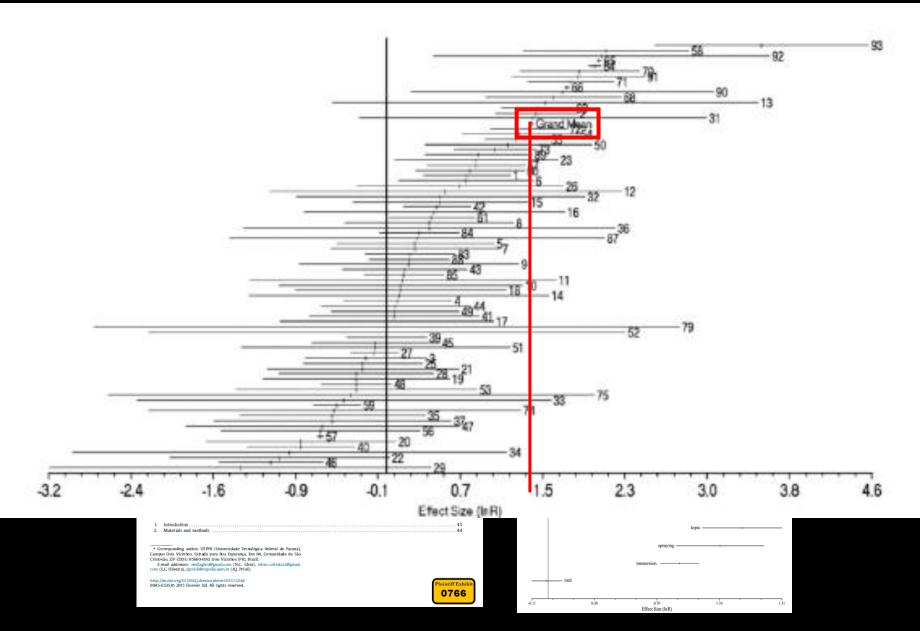
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http://dx.doi.org/10.1016/j.chemosphere.2015.11.099 0045-6535/t0 2015 Elsevier Izd. All rights reserved.

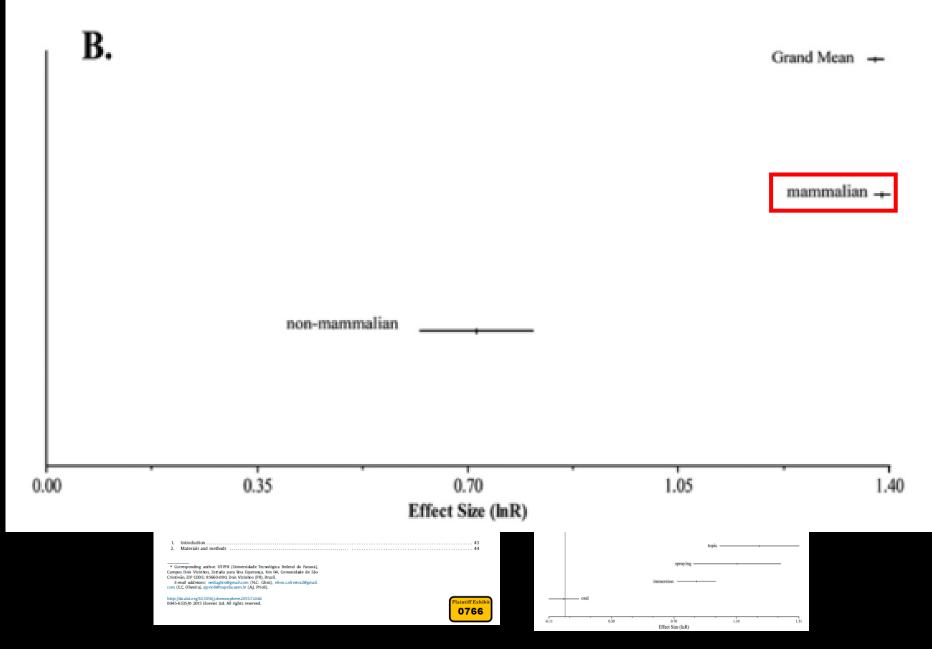


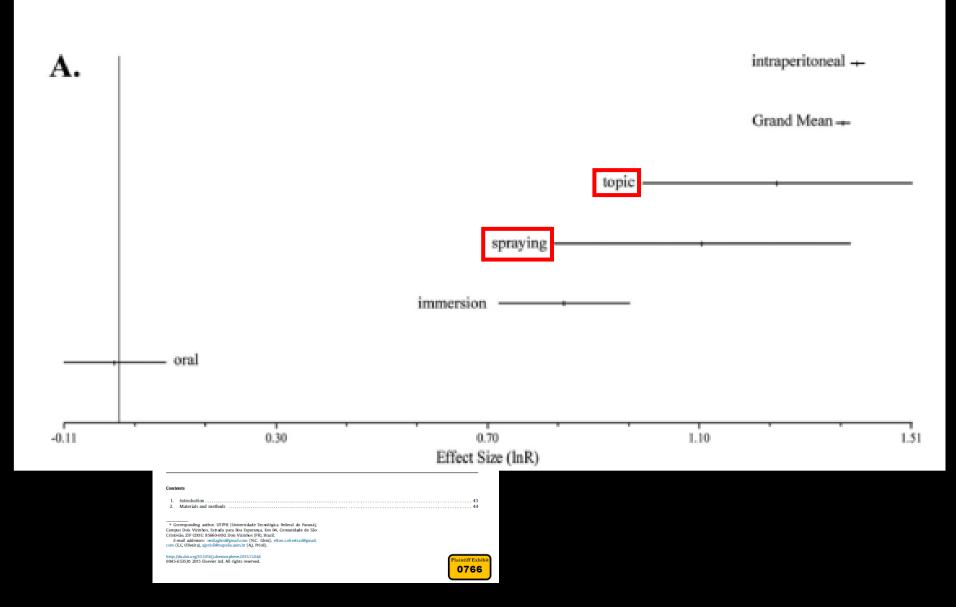












Three Pillars of Cancer Science

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



Three Pillars of Cancer Science

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



3. Epidemiology

Epidemiology:

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

Non-Hodgkin Lymphoma-specific

3. Epidemiology

Non-Hodgkin Lymphoma:

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

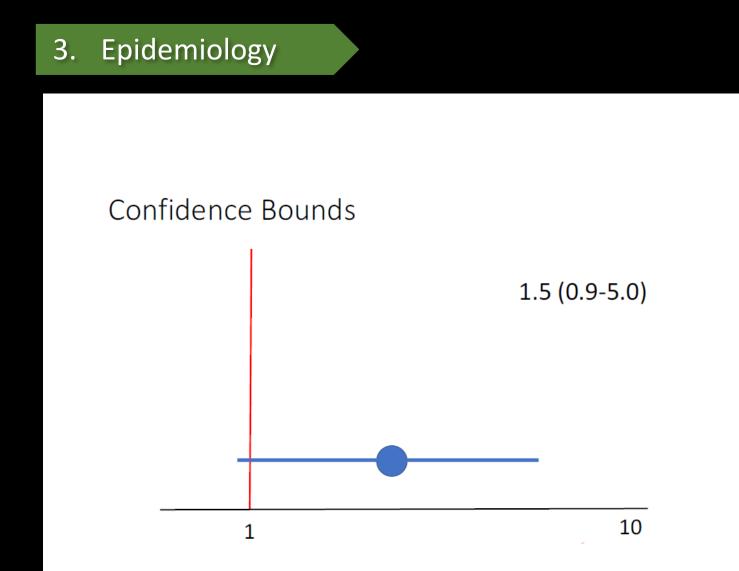
Two types:

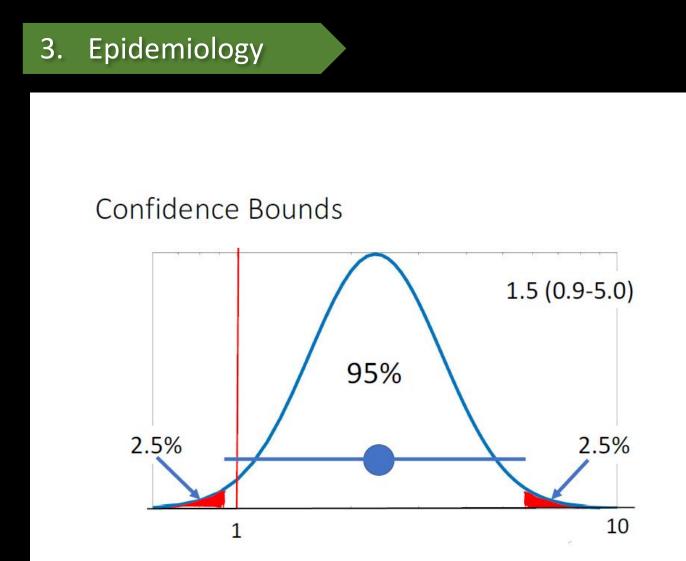
- B-Cell (most common)
- T-Cell (less common)

3. Epidemiology

Confidence Bound:

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





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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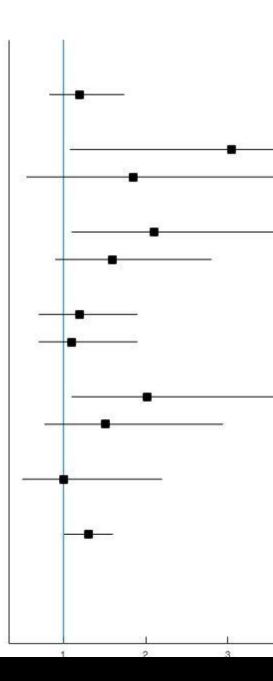
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Study

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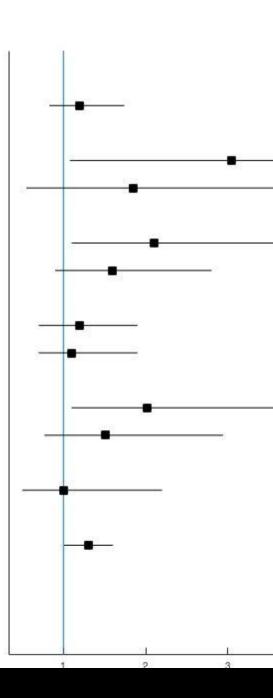
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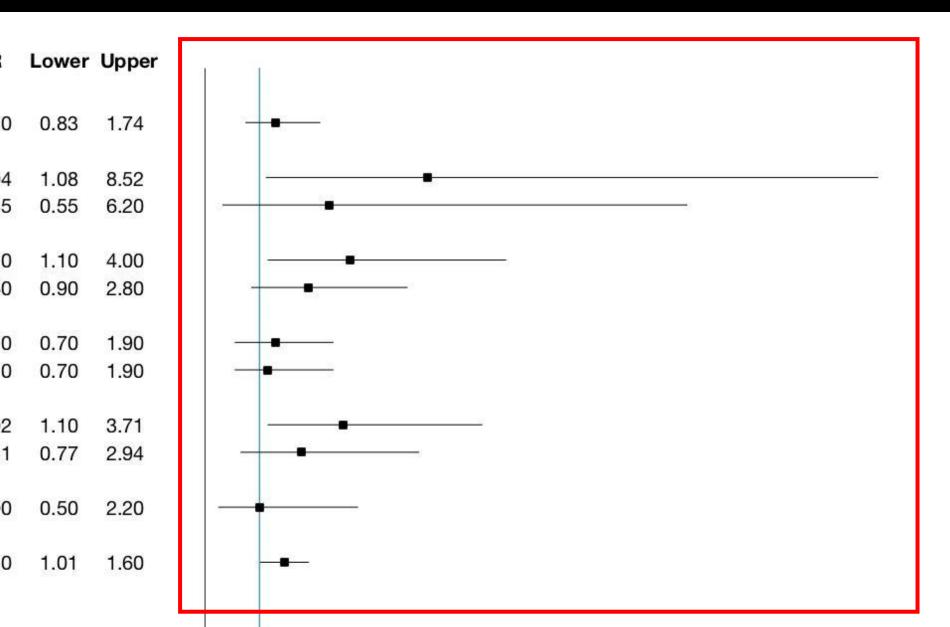
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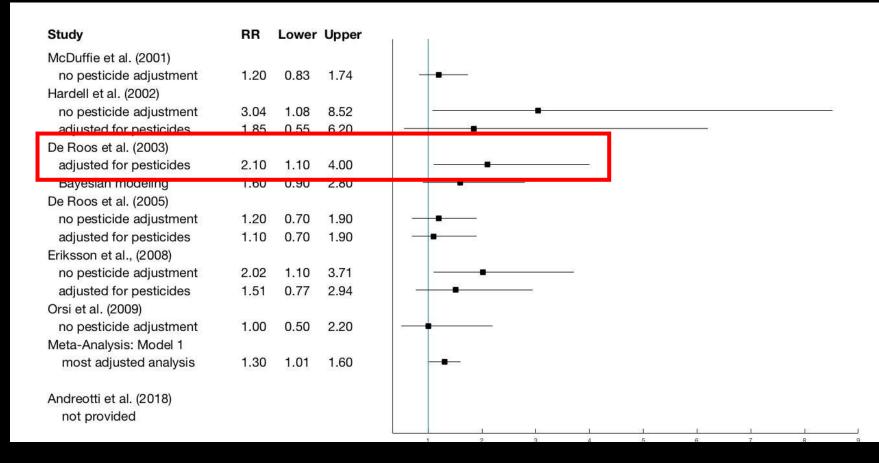
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Andreotti et al. (2018)	Ag	ric	ultu
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3. Epidemiology

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

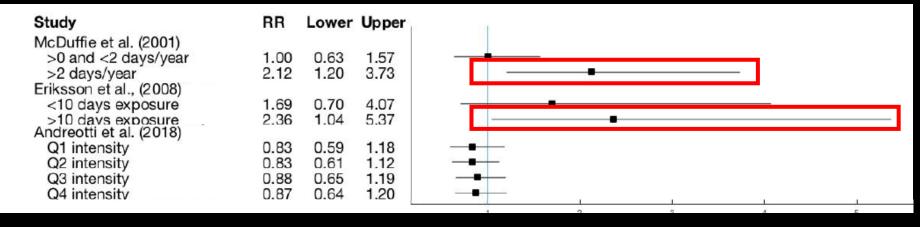
3. Epidemiology

The Agricultural Health Study

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

3. Epidemiology

NHL – Exposure Duration



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 26	1 04	5 27	
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	

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John Acquavella, PhD, and Donna Fanner, PhD Monsanto Company April 14, 1999



specific pesticities, the poisitistity or recail bias, the refusice 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 clevated 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-matagenic and noncareinogenic 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 physhesate in



In conclusion, the study by Hanlell 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 concerns" for glyphosate in fature agricultural epidemiologic studies.

References

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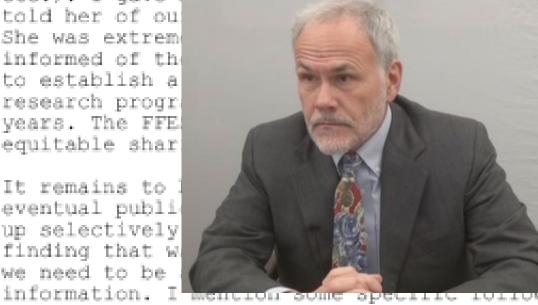
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etc.). I gave i told her of ou She was extrem informed of the to establish a research progr. years. The FFE equitable shar

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Aug 2001

Monsanto:

Dr. Acquavella learns that Dr. Helen McDuffie plans to publish article showing NHL risk with glyphosate.







Apr 1999

Hardell L, Enkoson M. A Case-control Study of non-Hedgkin Lymphonu an Porticides. Conver 1999, 85:1351-1360.

> (OR = 2.7). The maps limitations of this star councerted exposure) information, the small is the possibility of recall bias, the reliance on it

and was based on only four "exposed" cases and the abated in light of the limitations of the study, mention in that has resulted in glyphosate being judged to be in

and Erikkom conducto a case control study to took for association servicen re 1 non-Hodgkin is braphona (NHL). The study included 404 NHL cases and 741 assure of association in this study was the odds ratio (OR), a statistic the estima se rates (in this case NHL rates) for exposed and unexposed populations.

John Acquavella, PhD, and Donna Farmer. PhD Monunto Company April 14, 1999 Monsanto's Reaction: Hardell study raises "index of concern."

Inste's acidity; sufficient was not mutagenic in this assay when the pH was adjusted to a subspicel level.¹⁹ Also, EPA characterized the sufficient means carcinogeneity stab²⁰ as using ", ne evidence of carcinogeneity : at the down tented" and classified sufficient as room. If , ne reviewer for carcinogeneity is themasy.

To see alphanata isotologi andig cala²⁴ showed scale positive fadings for size dround advances in human isopologi sa si uto. This and human is minimum cala mareness, non secolds, malganoids anoy hao en thoses positive search for glyphonar.¹⁶ Extension relative searches in the second scale drough the fast LS. Enterioremult processing searches and the second scale drough the fast LS. Enterioremult processing searches and the second scale drough the fast LS. Enterioremult processing searches are seen as the second scale drough the fast LS. Enterioremult processing searches are set to be addrough processing and the second scale drough the properties of the second scale drough the second scale drough the second scale of the second scale drough the second scale drough the scale drough the second scale drough the second scale drough the scale drough the second scale drough the second scale drough the scale drough the second scale drough the scale drough the second scale drough the scale drough the second scale drough the scale drough the second scale drough the second scale drough the scale drou

In conclusion, the study by Handil and Erkinsten found a modera association between VME and lower dhemical generation—ness results (NMCR Are dis (no solitosis) argue of finguzidato. The respond weak to moderate associations for glyphones are ness resteriably significant and could be due to modere or to real or motionating bass. It is cals, however, that have windeproved and glyphones and concerns from glyphones in finance applicables for farmers and their families will make the "index of concerns" for glyphones in finance applicables of a glyphone index.

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- Handell L, Erikason M. A Case-control Study of non-Hodgkin Lymphonus and Exposure to Penterdes. Cancer 1999;85:1353–1360.
- Hardell L, Malignant lymphornas of the histocytic type and exposure to phenoxyacetic chlorophenolis. Lancet 1979;155:56.
- Hardell L, Erikasor M, Lerner P, Landgron E. Malignant hyrephorma and evouus to chemicals, especially organic volvants, eldosophenelis, and phonony acids: a case cortrol study. Briel J. Cancer 1981;43:169–176.
- Hoar SK, Blair A, Holmes FF, et al. Agricultural horbicide use and risk of lymphona and soft in sarroras. JAMA 1986;255:1141-1147
 Hoar Zahm S. Weisenburgt DD. Babbit PA, et al. A case control study of non-Haddkin's
- lymphoria and the herbicide 2,4-dichlorephenoxy acitic acid (2,4-0) in eartern No Epidemiology 1990;1:349-356
 - Environmental Postection Agency, An SAB Report: Assessment of potential 24-D carcinogeneity Review of the epidemiological and other data on potential carcinogeneity of 24-D by the 8AB5A2 joint committine: EPA-SABE-DBC-96-400, Washington, DC: US EPA, 1994.
 Marmeen OS: Theoretical Epidemiology: Julia Wiley & Seen, New York, 1985.
 - Rothman KJ, Greenland S. Modern Epidemiology: Second Edition. Lippincott-Raven, Philadelphia,

risk of NHL including mecogrop, malathion, GOT, acaharyi, aldrin, ad Linden, Rhen he authors controlled for personal factors including antecedent cancer, family history of cancer, personal history of measies, and allorgy and the second second second second second second significantly related to NHL was mecogrop (a.k.s. MCFP 2-(dchlor2-methylphenoxy) promotic acid).

Additional analyses found significant relationships for more than 2 days use/year for glyphosate (odds ratio 2.1, 95) CI full range of confounding factors was not considered in these analyses, but one presumes that again only mecoprop would remain associated with NRL 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

deean't seem to have any preconcived notions about djymboats. Be agreed to share her paper with me when it is ready for submission for publication. She also agreed to come etc.). I gave her a copy of the cantox glyphosate review and told her of our ongoing Parm Family Exposure Study (FFSS) he was extremely interstell in the FESS and asked to be kept to establish a relationship with Dr. McDuffse because her to establish a relationship with Dr. McDuffse hences here to see a super set of the set of the set of the set for the set of the to establish a relationship with Dr. McDuffse because her

osa analysis was to look for regior relationships between pesticide showed variable findings by pro authors reported a significant

Plaintiff Exhibi

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Hod ces" the British Journal of Cancer (1998) 77(11), 2048–2052 © 1998 Cancer Research Campaign



Nov 2001

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



Nov 2001

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Nov 2001





Monsanto's Reaction:

11/29/2002 22:07.23 PM GGUISTEL, JARJONEJ UGU-MOREMATO/DU-HA-1000-01/CH-RECHENTI/CH-355265] GGUISTEL, JARIEL A. JAC/2002 UGU-MOREMATO/DU-HA-1000-01/CH-RECPRENTI/CH-5727245], ARMSTRO JARKE M. JAC/12001 UGU-MACKSARTO/DU-HA-1000-01/CH-RECPRENTS/CH-59737], HEYDENS, WILLIAM F JAG/20030 UGU-MARKSARTO/DU-HA-1000-01/CH-RECPRENTS/CH-201737]

w yet what is says in the "small print" - but the fact that glyphosate is no longer mentioned in the lan forward - it removas it from being picked up to abstract searched.

RE: the McDuffee article appears - glyphosate not mentioned in the abstract

Thursday, November 29, 20 FARMER, DONNA R (AG/10) GOLDSTEIN, DANIEL A (AG

Celebrate the fact that glyphosate is not mentioned in the abstract.

laintiff Exhibi

0312

Original	Message
From:	ACQUAVELLA, JOHN F [AG/1000]
Sent:	TOURSDAY NOVEMBER 29 ZOOL 7:54 AM
To: Cc:	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."





Message	
From:	FARMER, DONNA R [#G/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]
Sent:	11/29/2001 2:07:23 PM
Te:	ACQUAVELLA, JOHN F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=145465]
CC:	GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=527246]; ARMSTRONG,
	JANICE M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=597137]; HEYDENS, WILLIAM F
	[AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
Subject:	RE: the McDuffee article appears - glyphosate not mentioned in the abstract

John,

I know we don't know yet what is says in the "small print" - but the fact that glyphosate is no longer mentioned in the abstract is a huge step forward - it removes it from being picked up by abstract searches!

Donna

----Original Message-----From: ACQUAVELLA, JOHN F [AG/1000] Sent: Thursday, November 29, 2001 7:54 AM To: FARMER, DONNA R [AG/1000] Cc: GOLDSTEIN, DANIEL A [AG/1000]; ARMSTRONG, JANECE M [AG/1000]; HEYDENS, W Subject: the McDuffee article appears - glyphosate not mentioned in the abstract Importance: High



The McDuffee article appeared in the November (see journal Cancer Epidemiology, Biomarkers, and Prevention (see



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:

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laintiff Exhibi

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



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.

me Industry Data Educing (Construction Construction Const

The McDuffee article ap journal Cancer Epidemic abstract below). Unlike International Society f August 1999, Glyphosate factor in the abstract. what it says in "the smarr

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Plaintiff Exhibit

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British Journal of Cancer (1998) 77(11), 2048-2052 © 1998 Cancer Research Campaign

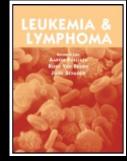


Nov 2001

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May 2002 **Epidemiology:** Another Hardell study shows 306% increased risk of NHL for Roundup.

Plaintiff Exhib 0777

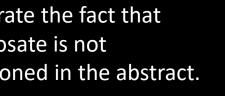


Nov 2001





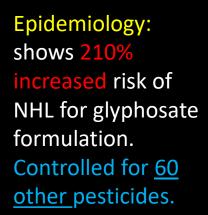
Monsanto's Reaction: Celebrate the fact that glyphosate is not mentioned in the abstract.







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or knowledge about how pestion to the risk of NHL Both its carises with the number of ictules used, but the relativeurbeantially different---25.9

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1254

a cytogenetic mechanism." However, there is only very limited evidence for genotoxicity of anazine, although there are no studies in humans." A small member of studies of atrazing on immune function in ordents and in vitro suggest a decreased lymphocyte count and cytoking production following expo-



e

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.

DAY COMPUTERD Vevertheless, some previous shar to confounding by correrticular, a previously reported I" was not replicated in the vis here revealed that carburyl sochried (p < 0.001), and pref different carbaryl measures w adjustment for diazinon. handling of carbaryl, and use vious analysis, estimates were ides, including a group for but adjustment for specific results. Similarly, previous isk associated with use of the tetrachiorytrohos" were neg-IP intenticides in the model. reportance of considering cor-

risk associated with the use of ng coumaphos, diazinon, and

Glyphosate, commercially sold as Roundum is a commonly used herbicide in the United States, both on crops and on non-cropland areas." An association of glyphosate with NHL was observed in another case-control study, but the estimate may based on only four exposed cases." A recent study across a large region of Canada lotand an increased risk of NHL assoclaued with glyphesate use that increased by the number of days used per year." These lew suggestive findings provide some impetus for further investigation into the potential health effects of glyphosate, even though one review concluded that the active ingredient is non-carcinogenic and non-genetistic."

Much attention in NHL research has located on the herbicide 2.4-D as a potential risk factor, and several studies have observed positive associations with 2,4-0 caposine."" Whereas an indicated effect of 2,4-D exposure on NHL was reported in NCF's Nebtaska and Karisas studie **Plaintiff Exhibit** of the pooled data found no association with h 0710 2,4-D. The null association does not result from other pesticides, missing data, or from a

British Journal of Cancer (1998) 77(11), 2048-2052 © 1998 Cancer Research Campaign

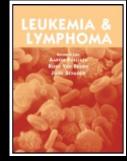


Nov 2001

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Plaintiff Exhib 0777

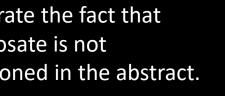


Nov 2001





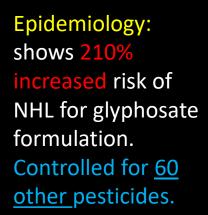
Monsanto's Reaction: Celebrate the fact that glyphosate is not mentioned in the abstract.







Mar





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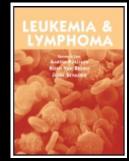


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Nov 2001





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 <u>60</u> other pesticides.



Monsanto's Reaction:

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





[/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]; DANHAUS, ROY G [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=218231] RE: Article r: NHL and BuyNosate. alasholor

The authors spent an entire paragraph in the discussion on glyphosate, specifically mentioning the Hardell and McDuffie studies:

Anote sometrate commercially and an Romday, is a commonly used herbiside in the United States, both on crops and non-croptand areas...An association of glyphostar with MHL was observed an another case-control dusly, but the estimate was based on only form exposed cases. As result and parson large region of Chanda from the morecond risk of MHL associated with glyphostane on this means of the number days used per year. These few suggestive findings provide some impects for further investigation into the potontial health effects of glyphostae, even though one review concluded but the active suppreducts in some circumgare in the supgestion into the potontial health effects of glyphostae, even though one review concluded but the active suppreducts in some circumgare in the supgestion into the potontial health effects of glyphostae, even though one preview concluded but the active suppreducts in some circumgare in the support of the super support of the support of the super support of the support of th

I'm afraid this could add more fuel to the fire for Hardell et al.

I'm going to see one of the authors of this paper this weekend at the American College of Epidemiology meeting. I'll ask him about some of these issues.

It looks like NHL and other lymphopoietic cancers continue to be the main cancer epidemiology issues both for glyphosate and alachlor. We're assembling a panel of experts to work on this.

Regards, John

Subject:



From:		/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=145465]
Sent:	9/2/2003 2:29:00 PM	
To:	Construction in the hospital	D=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=43435 ; GOLDSTEIN, DANIEL
	A	=NA-1000-01/CN=RECIPIENTS/CN=527246; FARMER, DONNA R [AG/1000]
	L	/CN=RECIPIENTS/CN=180070];
	- And	KRONENBERG, JOEL M [AG/1000]
		/CN=RECIPIENTS/CN=501517]
CC:		/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=119523];
		HEYDENS, WILLIAM F [AG/1000]
		/CN=RECIPIENTS/CN=230737]; DANHAUS, ROY G [AG/1000]
		ICAL DECIDIFATE (CAL DIGDDI)
Subject:	RE: Article re: NHL and glyphosate	

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Se 20

Monsanto's Reaction:

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[/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]; DANHAUS, ROY G [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=218231] RE: Article r: NHL and BuyNosate. alasholor

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Monsanto's Reaction:

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Jan 2005

Epidemiology:

De Roos publishes first iteration of the AHS, showing no association between Roundup and NHL.



ACQUAVELLA, JOHN F [AG/1000] [/O=MIONSANTD/OU=NA-1000-01/CN=RECIPIENTS/CN=145465] 9/2/2003 2:29:00 PM

CARR, KATHERINE H [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=REDPIENTS/CN=3435]; GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=REDPIENTS/CN=327246]; FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=32070];

KRONENBERG, JOEL M [AG/1000 [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=501517]

WRATTEN, STEPHEN J [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=119523];

HEYDENS, WILLIAM F [AG/1000 [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]; DANHAUS, ROY G [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=218231] RE: Article re: NHL and alvohosate, alachlor

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Sent:

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Jan 2005

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KRONENBERG, JOEL M [AG/1000 NA-1000-01/CN=RECIPIENTS/CN=50151

WRATTEN_STEPHEN [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=119523]:

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Sent:

cc

Subject



Jul 2008

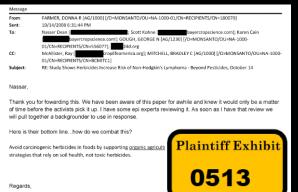
Epidemiology: Eriksson study shows 202% increased risk of NHL for Roundup. Also shows 236% increased risk of NHL when used for more than 10 days a year.

Jul 2008

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Oct 2008

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





Donna

Plaintiff Exhibit Epide

Epidemiology:

Message		
From:	FARMER, DONNA R AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]	
Sent:	10/14/2008 6:31:44 PM	
To:	Nasser Dean []; Scott Kohne []; Scott Kohne []; Scott Kohne []; Scott Kohne []; Karen Ca	
	bayercropscience.com]; GOUGH, GEORGE N [AG/1230] [/O=MONSANTO/OU=NA-1000-	
	01/CN=RECIPIENTS/CN=556077]; 24d.org	
CC:	McAllister, Ray [croplifeamerica.org]; MITCHELL, BRADLEY C [AG/1000] [/O=MONSANTO/C	1
	01/CN=RECIPIENTS/CN=BCMITC1]	
Subject:	RE: Study Shows Herbicides Increase Risk of Non-Hodgkin's Lymphoma - Beyond Pesticides, October 14	
		- Alter I



Thank you for fowarding this. We have been aware of this paper for awhile and knew it would only be a matter of time before the activists pick it up. I have some epi experts reviewing it. As soon as I have that review we will pull together a backgrounder to use in response.

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

Avoid carcinogenic herbicides in foods by supporting <u>organic agriculture</u>, and on <u>lawns</u> by using non-toxic land care strategies that rely on soil health, not toxic herbicides.

Regards,

Donna

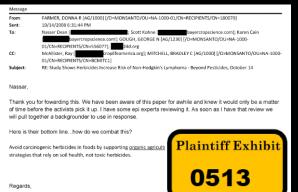


Jul 2008

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.

Oct 2008

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





Donna

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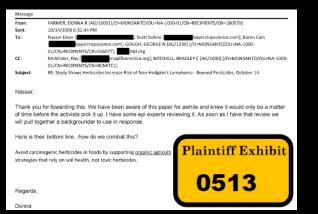
Apr 2014

Epidemiology:

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

Oct 2008

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





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. International Journal of Environmental Research and Public Health



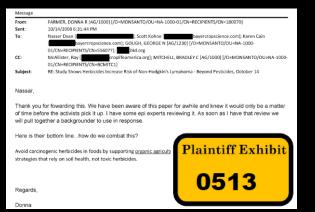
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Oct 2016

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



Oct 2016

Epidemiology: Monsanto-sponsored metaanalysis shows a 130% increased risk of NHL from Roundup use. Nov 2017

oxro

ARTIC

Glyp Agrid Gabrie Jay H. I Christi Laura

Abstract Eackgroun 2015, the fistrong near previous eassociation Methode: 1 the previous 1 the abstract of the ABL we of lymphat the highest

Epidemiology:

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



N											
N		Table 2, (cost)	mand				Table 2. (conti-	mand			
	CI / Natl Carver Inst (2018) 120(5): djs223		Gypbosate					Gyphosate			
	1111003-04/46201	Canoer site*	unt	No.	NR (95% C)(Panult	Cancer site*	sole?	No.	\$3.(35% CI))	Parad
	st published online Nowmber 6, 2017 tota	Kidney	None		1.00 (mfirmace)		Acute myeloid	leukeenia Nitzer		1.001seference1	
a	591 5-5		Q1	54	3.33 (0.74 to 1.71)			Q1	13	1.62(0.60 to 4.98)	
			Q2 Q3		0.95 (0.59 to 1.41) 0.87 (0.55 to 1.38)			02		1.70(061 to 4.7)) 1.46(0.49 to 4.37)	
			03		0.87 (0.55 to 1.38) 1.03 (0.66 to 1.61)	.95		Q3 Q4		2.44 (0.94 to 6.37)	.11
		Lymphobema	topoletic				Channic myelo	id beakiemila			
E			None O1		1.00 (reference) 0.87 (0.64 to 1.27)			None MI		1.00 (welevence) 0.36 (0.09 to 1.43)	
			02		0.88 30.96 to 1.171			M2		0.82(0.23 to 2.90	36
hosate Use and Cancer In	cidence in the		43	137	0.93 (0.71 to 1.22)					fer of hutstilleens.	
		Hodgkin herea	Q4 home	244	1.00 (0.74 to 1.34)	.43	and End Lemits	Sie Retoile KID-0-5	Q - 000	Adence marval, \$3 -	rate rate.
cultural Health Study			None		1.00(mfenesce)					0-410 5 QE 24140	
			MI		0.59 (517 to 2.11) 0.90 (525 to 3.24)	.94	philmon regressi	in was used to min	tel cane ci	tox and confidence	intervals, as
lla Andreotti, Stella Koutros, Jonath		Non-Hodgkin								Weld test, All exadels of the second status	
Lubin, Charles F. Lynch, Catherine	C. Lerro, Anneclaire J. De Roos,		None		1.00 (reference)		month, the soly his	may of conser, straid	in, shid	ire memischer, till	min, 2,4-D.
ne G. Parks, Michael C. Alavania, D			01		0.83 (0.99 to 1.58) 0.83 (0.61 to 1.12)						
	eora i . Suverman,		03		0.88 (0.65 to 1.19)		Discussion	8			
E. Beane Freeman		Transfer to Apple Providence	Q4	111	0.87 (0.64 to 1.20)	.95	In this update	d evaluation of ;	deples	ate use and care	er risk in.
authors: O experienced and Territors exertial Epidemiology Branch \$55, 55,75	6, CCL, DDS, 12395, Sectorization Result (NR), and Parenarily of Comparisonal	Non-Hodgkin	lymphoma 8 cell None		1.00 (reference)					applicators, we o	
ented Epideminings Branch SHOA, SWitt in of Calcor Epidemiology and Gen main ferrores, Berbergh, MD Epidemiology Tanach, Natural Institute of Epi	artics, Historgal Caster Institute, Network Institutes of Health, Department of departmental Neulth Informers, Network Institutes a Mealth, Department of		Q1	302	0.791055 to 1.12					and overall car	
man Services, Recearch Triangle Pack, NC (2016, COF), Department of Spider	elements in Machin Balencers, National Institutes of Health, Department of the logs University of lows, Jown City, 14 (2013) state wealth Registry of lows,		Q2	93	0.76 (0.58 to 1.05)		with total lyrs	phohematopolet	k and	ers, including NHI me esidence of a	and mult
(N) Department of Devicemental and Colepatibelai MoRA, Devici Dilete are to Laura Bears Promos, 2012, 0021Matteral General Trees, Rev 60216, Mile			Q3 04	206	0.88 (0.64 to 1.21) 0.86 (0.62 to 1.29)	1.22	risk of AML in	e applicators, pa	rticalar	by in the highest	nate goey o
IN THE CASES MEANING PROPERTY AND A DESCRIPTION OF THE ADDR. NO.	And the start and the start presentation of the	Channels hereit			0.88-(042 to 1.29) lymphocytic leake	.85	ghybosate exp	postes compared	with a	ever users of gbyp	house.
		canada () any	None	36	1.00(reference)					ncies, AML is the revisionmental fit	
			QJ	28	0.75 (0.40 to 1.41)					esticide exposure	
d: Glyphosate is the most commonly used herbicide worl	dwide, with both residential and acricultural uses. In		02		0.76(541 to 1.41) 0.90(0.57 to 1.42)					a meta-analysis	
stemational Agency for Research on Osnovr classified gly	phosate as "probably carcinogenic to humans," noting	1997	Q4		0.87 (0.48 to 1.56)					stistically signific	
hanistic evidence and positive associations for non-Hod	gkin lymphoma (NHL) in some epidemiologic mudies. A	Diffuse large 1	cell lymphema							es (mota IOI = 1.5	
valuation in the Agricultural Health Study (AHS) with full is with glyphosate use and cancer at any site.	on-ob cusoids that mont to respected effermant		None		1.00 (reference) 1.11 (0.60 to 2.07)		000 (000 (000	not enable that a	anc cri	emicals were not ed glaphosate us	evaluated in
	icators from North Carolina and Jows. Here, we updated		02		0.943049 to 1.80		evidence of an	association with	th letaks	ernía overall base	d on 15 es
as evaluation of glyphosate with cancer incidence from r	egistry linkages through 2012 (North Carolina)/2013 (iows).		Q3		1.13 (0.59 to 2.17)					ts for AML (15). S	
eys and intensity-weighted lifetime days of glyphosate us	as were based on self-reported information from enroll-	Marginal-ion	Q4	22	0.57 (151 to 1.85)	.83				es, and AML was	
-1997) and follow-up question naires (1999-2005). We est	mated incidence rate ratios (KR) and 95% considence afounders, including use of other pesticides. All statistical	and free seasons	None	4	1.00 (inference)					sdy is the first t	
repeated.	inclusive, accounting the or other processive set extension		261		0.39 (0.06 to 2.45)		possible assoc	sation between p	(hyphos	rate use and AML	
nong 54 251 applicators, 44 932 (82.8%) used glyphosate, i	ncluding 5779 incident cancer cases (79.3% of all cases).	Thillic slar lyrn	MS	- 2	0.44 (0.09 to 2.37)	67	Risk estin	usten were sice	iler k	magnitude be	tween th
d analyses, glyphosate was notatatistically significantly			None	26	1.00 (mfammes)		unlagged and	pilling exhoen	te anal	yses for all sites the highest exp	eveluated
in the highest exposure quartile, there was an increased a $(88 - 2.46, 95\% \text{ Cl} = 0.94$ to $6.32, P_{percl} = .10$, though this			T3		0.29 (0.37 to 2.15)		gories, and sh	e were elevated	cant of	r borderline signi	ficant test
ere similar with a five-year (RR _{inemia 4} = 2.32, 95% CI =0	98 to 5.53, F		17		0.65 (0.23 to 1.60) 0.85 (0.36 to 2.03)	.95	of trend for w	slagged and lag	erd and	dynes. The latent	period be
-2.04, 95% CI = 1.05 to 3.97, P _{mand} = .040.	김 방법 양가 비행 방법 영향 위해 방법 방법 방법에 들었다. 그는 것	Multiple mysl								iagnosis is unkn	
	was apparent between glyphosate and any solid tumors	CHICK OF SPACE	None	30	1.00(selerence)					polation characte k factors, such a	
id malignancies overall, including NHL and its subtypes." t opposed group that requires confirmation.	There was some evidence of increased risk of AML among		Q1	29	0.70 (0.36 to 1.34) 17 to 1.76					eriod (less than	
capture group the tracket are can annalise.				-	12 to 1.50		(16), as do sta	dies of therapy	indua	d AML (five to se	wen years
					15 10 1.69	.84	(17). Long-tee	m studies of m	distion	exposed popula	tions have
	ginered .				femarel		The LANC	and runks of AM.	up as : reard	15 years after exp strong evidence of	insure (18) 6 apressos
was introduced as a broad-spectrum behicide in en	match To 1	· • • •	• 1	۰.	13 to 24 Feb		leity and oxid	lative stress effe	ets foo	m glyphosate en	poppere 14
quickly became one of the most heavily used herbi-dr					13 to 10.36					studies in comm	
quickly became one of the most heavily used herbi-dr	Plaintiff										
quickly became one of the most heavily used herbi-dr		EX	110	ıι	1	continent				tal spraying the	
quickly became one of the most heavily used herbi-dr	Plaintiff	EXI	110	ц	/	Continued					

	None	361	1.00(reletence)	
	Q1	136	0.87 (0.64 to 1.19)	
	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)	.40
Hodgkin hr	sphone			
	Nome	1	1.00 (missisce)	
	MI	12	0.55 (0.17 to 2.11)	
	MC	11	0.90 (0.25 to 3.24)	.94
Nom-Hodgki	in lymphoma			
	14ome	135	1.00 (reference)	
	01	113	0.83 (0.59 to 1.58)	
	Q0	304	0.83 (0.61 to 1.12)	
	Q3	312	0.88 (0.65 to 1.39)	0.07 (244
Concernation and Automatical	Q4	111	0.87 (0.64 to 1.20)	.95
Nos-Hodge	in lymphonia 8 ceil	140		
이 가지 않으며 생각	None	\$28	1.00 (reference)	
	Q1	302	0.79 (0.55 to 1.13)	
	Q2	93	0.78 (0.50 to 1.05)	
	Q)	206	(LR8-(0.64 to 1.21)	
	Q4	103	0.86 (0.62 to 1.39)	.86
Channic lym	phocytic lymphama	, small	lymphocytic leolorn	alia.
	Nome	36	1.00 (reference)	
	QI	28	0.75-(0.40 to 1.40)	
	02	26	0.76 (0.41 to 1.41)	
	Q3	-26	0.90 (0.50 to 1.42)	
	Q4	27	0.87 (0.48 to 1.58)	
Diffuse larg	s B cell lymphona			
	None	27	1.00 (selemance)	
	Q1	28	£.33 (0.60 to 2.07)	
	02	23	0.94 (0.49 to 1.80)	
	Q3	30	1.13 (0.59 to 2.17)	
	Q4	22	0.57 (0.51 to 1.85)	.83
Marginal-az	ne lymphoma			
10	Monar	- 4	1.00 (reference)	
	261	- 6	0.39 (0.06 to 2.45)	
	MO	- 5	0.44 (0.09 to 2.17)	.67
Follic ular ly	mph oma			
	The second	100.00	A DOMESTIC AND A DOMESTICA AND A DOMES	

None	9	1.00 (reference)
-M1	5	0.36 (0.09 to 1.43)
547	11	0.82(0.23 to 2.98)

"Conter oldes are based and presented in other of Surveillance, Epide and End Results Site Recode KD-D-S. CI = confidence interval, R8 = nat (Quartiles: Q1: 1-888-9; Q2: 598-5049.5; Q3: 1400-4339.9; Q6: 24340.0; Tr 1-888-24, T2: 888-25-2980.8; T3: 22884.0; Mediau M0; 1-1449.9; M2: 2144 (Polsson regression was used to model rate ratios and confidence inter P values were calculated using a two-sided Weld test. All models ad; age, state of recodment, education, rigarette models (M2: alloc, different, all month; family history of mozer, structure, slacitize, metolaction; tillaratio

Discussion

In this updated evaluation of glyphosate use and cancer to large prospective study of pesticide applicators, we obser associations between glyphosate use and overall cancer with total lymphohematopoietic cancers, including NHL an ple myeloma. However, there was some evidence of an in risk of AML for applicators, particularly in the highest can 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 ev One case-control study that evaluated glyphosate use fit evidence of an association with leukemia overall based of posed mass and did not report results for AML (15). Simithe previous AIES analysis, there was no association with mis 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 betwee unlagged and lagged exposure analyses for all sites ev-

			and a particular second s	
	02	23	0.94 (0.49 to 1.80)	
	Q3	30	1.13 (0.59 to 2.17)	
	Q4	22	0.57 (0.51 to 1.85)	.83
Marginal	-zone lymphoma			
10	Mone	- 4	1.00 (reference)	
	261	- 6	0.39 (0.06 to 2.45)	
	MO	- 5	0.44 (0.09 to 2.57)	.67
Follic ula	r tyrngb.oena			
	None	- 26	1.00 (mfemace)	
	T1	21	0.89 (0.37 to 2.15)	
	T2	11	0.61 (0.23 to 1.60)	
	T3	20	0.85 (0.96 to 2.03)	95
Multiple	mysioma.		No. 20 Acres and a	
200-059	None	30	1.00 (reference)	
	Q1	29	(0.70 (0.36 to 1.36)	
	Q2	26	0.94 (0.50 to 1.76)	
	Q3	29	0.78 (0.39 to 1.56)	
	04	- 24	0.87 (0.45 to 1.69)	84
Non-Hod	igkin lymphoma T call	- 55	120/	
	None	2	425%	
	MI	- 14	4.25 (0.73 to 24.64)	
	MD	- 6	1.53 (0.23 to 10.38)	31

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evidence of an association with leukemia overall based or posed cases and did not report results for AML [15]. Simil the previous AHS analysis, there was no association with mis 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.

Rink estimates were similar in magnitude betwee unlagged and lagged exposure analyses for all sites evfor AME, there were elevated risks in the highest exposugories, and statistically significant or borderline significaof trend for unlagged and lagged analyses. The latent petween relevant exposure and AML diagnosis is unknown may vary by type of esposure and population characterial Most studies of established AML risk factors, such as bsuggest a relatively short latency period (less than file (36), 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 35 years after exposu-

The LARC Working Group noted strong evidence of g icity and oxidative stress effects from glyphosate exposiin particular, they highlighted two studies in communiposed to glyphosate through aerial spraying that



Oct 2016

Epidemiology: Monsanto-sponsored metaanalysis shows a 130% increased risk of NHL from Roundup use. Nov 2017

oxro

ARTIC

Glyp Agrid Gabrie Jay H. I Christi Laura

Abstract Eackgroun 2015, the fistrong near previous eassociation Methode: 1 the previous 1 the abstract of the ABL we of lymphat the highest

Epidemiology:

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



N											
N		Table 2, (cost)	mand				Table 2. (conti-	mand			
	CI / Natl Carver Inst (2018) 120(5): djs223		Gypbosate					Gyphosate			
	111100/360/46201	Canoer site*	unt	No.	NR (95% C)(Panult	Cancer site*	son f	No.	\$3.(35% CI))	Parad
	st published online Nowmber 6, 2017 tota	Kidney	None		1.00 (mfirmace)		Acute myeloid	leukeenia Nitzer		1.00(peference)	
a	591 5-5		Q1	54	3.33 (0.74 to 1.71)			Q1	13	1.62(0.60 to 4.98)	
			Q2 Q3		0.95 (0.59 to 1.41) 0.87 (0.55 to 1.38)			02		1.70(061 to 4.7)) 1.46(0.49 to 4.37)	
			03		0.87 (0.55 to 1.38) 1.03 (0.66 to 1.61)	.95		Q3 Q4		2.44 (0.94 to 6.37)	.11
		Lymphobema	topoletic				Channic myelo	id beakiemila			
E			None O1		1.00 (reference) 0.87 (0.64 to 1.27)			None MI		1.00 (welevence) 0.36 (0.09 to 1.43)	
			02		0.88 30.96 to 1.171			M2		0.82(023 to 2.98)	36
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		Hodgkin herea	Q4 home	244	1.00 (0.74 to 1.34)	.43	and End Lemits	Sie Retoile KID-0-5	Q - 000	Adence marval, \$3 -	rate rate.
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Lubin, Charles F. Lynch, Catherine	C. Lerro, Anneclaire J. De Roos,		None		1.00 (reference)		month, the soly his	may of conser, straid	in, shid	ire memischer, till	min, 2,4-D.
ne G. Parks, Michael C. Alavania, D			01		0.83 (0.99 to 1.58) 0.83 (0.61 to 1.12)						
	eora i . Suverman,		03		0.68 (0.65 to 1.19)		Discussion	8			
E. Beane Freeman		Transfer to Apple Providence	Q4	111	0.87 (0.64 to 1.20)	.95	In this update	d evaluation of ;	deples	ate use and care	er risk in.
authors: O experienced and Territors exertial Epidemiology Branch \$55, 55,75	6, CCL, DDS, 12395, Sectorization Result (NR), and Foreworks of Comparisonal	Non-Hodgkin	lymphoma 8 cell None		1.00 (reference)					applicators, we o	
ented Epideminings Branch SHOA, SWitt in of Calcor Epidemiology and Gen main ferrores, Berbergh, MD Epidemiology Tanach, Natural Institute of Epi	artics, Historgal Caster Institute, Network Institutes of Health, Department of departmental Neulth Informers, Network Institutes a Mealth, Department of		Q1	302	0.791055 to 1.12					and overall can	
man Services, Recearch Triangle Pack, NC (2016, COF), Department of Spider	elements in Machin Released, National Institutes of Meddin, Department of No.log. University of lower, Sowie City, 14 (2013) state wealth Registry of lower,		Q2	93	0.76 (0.58 to 1.05)		with total lyrs	phohematopolet	k and	ers, including NHI me esidence of a	and mult
(N) Department of Devicemental and Colepatibelai MoRA, Devici Dilete are to Laura Bears Promos, 2012, 0021Matteral General Trees, Rev 60216, Mile			Q3 04	206	0.88 (0.64 to 1.21) 0.86 (0.62 to 1.29)	1.22	risk of AML in	e applicators, pa	rticalar	by in the highest	nate goey o
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		Constant () and	None	36	1.00(reference)					ncies, AML is the revisionmental fit	
			QJ	28	0.75 (0.40 to 1.41)					esticide exposure	
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stemational Agency for Research on Osnovr classified gly	phosate as "probably carcinogenic to humans," noting	100000000000000000000000000000000000000	Q4		0.87 (0.48 to 1.56)					stistically signific	
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valuation in the Agricultural Health Study (AHS) with full is with glyphosate use and cancer at any site.	on-ob cusoids that mont to respected effermant		None		1.00 (reference) 1.11 (0.60 to 2.07)		000 (000 (000	not enable that a	anc cri	emicals were not ed glyphosate us	evaluated in
	icators from North Carolina and Jows. Here, we updated		02		0.943049 to 1.801		evidence of an	association with	th letaks	enía overall base	d on 15 es
as evaluation of glyphosate with cancer incidence from r	egistry linkages through 2012 (North Carolina)/2013 (iows).		Q3		1.13 (0.59 to 2.17)					ts for AML (15). S	
eys and intensity-weighted lifetime days of glyphosate us	as were based on self-reported information from enroll-	Marginal-ion	Q4	22	0.57 (151 to 1.85)	.83				es, and AML was	
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d analyses, glyphosate was notatatistically significantly			None	26	1.00 (mfammes)		unlagged and	pilling exhoen	te anal	yses for all sites the highest exp	eveluated
in the highest exposure quartile, there was an increased a $(88, -2.46, 95\% \text{ Cl} = 0.94$ to 6.32 , $P_{percl} = .10$, though this			T3		0.29 (0.37 to 2.15)		gories, and sh	e were elevated	cant of	r borderline signi	ficant test
ere similar with a five-year (RR _{inemia 4} = 2.32, 95% CI =0	98 to 5.53, F		17		0.65 (0.23 to 1.60) 0.85 (0.36 to 2.03)	.95	of trend for w	slagged and lag	erd and	dynes. The latent	period be
- 2.04, 95% CI = 1.05 to 3.97, P _{mand} = .040.	김 방법 양가 비행 방법 방법 방법 방법 방법 방법에 들었다. 그는 것	Multiple mysl								iagnosis is unkn	
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id malignancies overall, including NHL and its subtypes." t opposed group that requires confirmation.	There was some evidence of increased risk of AML among		Q1	29	0.70 (0.36 to 1.34) 17 to 1.76					eriod (less than	
capture group the tracket are can annalise.				-	12 to 1.50		(16), as do sta	dies of therapy	indua	d AML (five to se	wen years
					15 10 1.69	.84	(17). Long-tee	m studies of m	distion	exposed popula	tions have
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Three Pillars of Cancer Science

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

International Agency Research on Cancer











Message	
From:	HEYDENS, WILLIAM F [AG/1000] [@ monsanto.com]
Sent:	10/15/2014 9:08:37 PM
To:	@monsanto.com]
CC:	@monsanto.com]; FARMER, DONNA R [AG/1000]
	@monsanto.com]; SALTMIRAS, DAVID A [AG/1000] [@monsanto.com]; KOCH,
	MICHAEL S [AG/1000] [@monsanto.com]
Subject:	IARC Evaluation of Glyphosate

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 liming 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 LARC 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





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Thanks.

Bill



- 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

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

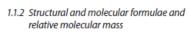
GLYPHOSATE

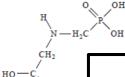
1. Exposure Data

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).





Molecular formula: C₃H, Relative molecular mass Additional information ture is also available in the P database (<u>NCBI</u>, 2015).

1.1.3 Chemical and physica pure substance

> Description: Glyphosate actu is a coourless, 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



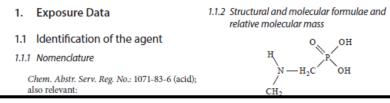
Three Pillars of Cancer Science

- 1. Animal Carcinogenicity Studies
- 2. Mechanistis Daticient

6.2 Cancer in experimental animals

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

GLYPHOSATE



Three Pillars of Cancer Science

- 1. Animal Carcinogenicity Studies
- 2. Mechanisti Sofficient

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

Yerbimat (Farm Chemic 2015). 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



GLYPHOSATE

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 - sold worldwide under numeroust including: Abundit Extra; Crec Glifonox; Glyphogan; Ground-Roundup; Touchdown; Tragli; Yerbimat (<u>Farm Chemicals Ir</u> 2015).

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

Three Pillars of Cancer Science

- 1. Animal Carcinogenicity Studies
- 2. Mechanisti Softicient
- 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.

ethanol, and xylene; the alkali-metal and



GLYPHOSATE

1. Exposure Data

1.1 Identification of the agent

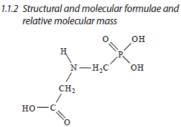
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 $\begin{array}{l} Molecular \ formula: \ C_3H_8NO_5P\\ Relative \ molecular \ mass: \ 169.07\\ Additional \ information \ on \ chemical \ structure \ is also available \ in the PubChem \ Compound \ database \ (NCBI, \ 2015). \end{array}$

1.1.3 Chemical and physical properties of the pure substance

Description: Glyphosate acid is a colour-

Three Pillars of Cancer Science

- 1. Animal Carcinogenicity Studies
- 2. Mechanisti Sofficient
- 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.

0784

IARC Monographs on the Carcinogenic Risk to Humans, Volume 112: Some Organophosphate Insecticides and Herbicides, IARC, Lyon, France, 3-10 March 2015

March 2015: IARC unanimously decides to list glyphosate as a class 2A carcinogen – a probable human carcinogen.

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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
- <u>Tier 1:</u> Crop Life International / European Crop Protection Association / GMO Answers / BIO identify committees that are best to engage
- <u>Tier 2:</u> Academics (AgBioChatter), Biofortified, Sense About Science, Genetic Literacy Project, Academics Review
- <u>Tier 3:</u> 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
- <u>Tier 4:</u> 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



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POST-IARC

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 - [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

Plaintiff Exhibit

0292

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

Christopher J Portier, ¹ Bruce K Armstrong, ² Bruce C Baguley, ³ Xaver Baur,⁴ Igor Belyaev,⁵ Robert Bellé,⁶ Fiorella Belpoggi, Annibale Biggeri,⁸ Maarten C Bosland,⁹ Paolo Bruzzi,¹⁰ Lygia Therese Budnik,¹¹ Merete D Bugge,¹² Kathleen Burns,¹³ Gloria M Calaf,¹⁴ David O Carpenter,¹⁵ Hillary M Carpenter,¹⁶ Lizbeth López-Carrillo, 17 Richard Clapp, 18 Pierluigi Cocco, Dario Consonni, 20 Pietro Comba, 21 Elena Craft, 22 Mohamed Aqiel Dalvie,²³ Devra Davis,²⁴ Paul A Demers,²⁵ Anneclaire J De Roos,²⁶ Jamie DeWitt,²⁷ Francesco Forastiere,²⁸ Jonathan H Freedman, 29 Lin Fritschi, 30 Caroline Gaus, 31 Julia M Gohlke, ³² Marcel Goldberg, ³³ Eberhard Greiser, ³⁴ Johnni Hansen, ³⁵ Lennart Hardell, ³⁶ Michael Hauptmann, ³⁷ Wei Huang, 38 James Huff, 39 Margaret O James, 40 C W Jameson, 41 Andreas Kortenkamp, ⁴² Annette Kopp-Schneider,⁴³ Hans Kromhout,⁴⁴ Marcelo L Larramendy,⁴⁵ Philip J Landrigan,⁴⁶ Lawrence H Lash,⁴⁷ Dariusz Leszczynski,⁴⁸ Charles F Lyndr,⁴⁹ Corrado Magnani,⁵⁰ Daniele Mandrioli,⁵¹ Francis L Martin,⁵² Enzo Merler,⁵³ Paola Michelozzi,⁵⁴ Lucia Miligi,⁵⁵ Anthony B Miller,⁵⁶ Dario Mirabelli,⁵⁷ Franklin E Mirer,⁵⁸ Saloshni Naidoo,⁵⁹ Melissa J Perry,⁶⁰ Maria Grazia Petronio,⁶¹ Roberta Pirastu,⁶² Ralph J Portier,⁶³ Kenneth S Ramos,⁶⁴ Larry W Robertson,⁶⁵ Theresa Rodriguez,⁶⁶ Martin Röösli,⁶⁷ Matt K Ross,⁶⁸ Deodutta Roy,⁶⁹ Ivan Rusyn, 70 Paulo Saldiva, 71 Jennifer Sass, 72 Kai Savolainen, 73 Paul T J Scheepers,⁷⁴ Consolato Sergi,⁷⁵ Ellen K Silbergeld,⁷⁶ Martyn T Smith,⁷⁷ Bernard W Stewart,⁷⁸ Patrice Sutton,⁷⁹ Fabio Tateo,⁸⁰ Benedetto Terracini,⁸¹ Heinz W Thielmann,⁸² David B Thomas,⁸³ Harri Vainio,⁸⁴ John E Vena,⁸⁵ Paolo Vineis,⁸⁶ Elisabete Weiderpass, 87 Dennis D Weisenburger, 88 Tracey J Woodruff, 89 Takashi Yorifuji, 90 II Je Yu, 91 Paola Zambon, 92 Hajo Zeeb,93 Shu-Feng Zhou94

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

ientific evidence

v Health Month 2016

iced by BMJ P

The International Agency for Research on agents that cause cancer in humans and Cancer (IARC) Monographs Programme has evaluated about 1000 agents since identifies chemicals, drugs, mixtures, 1971. Monographs are written by ad hoc occupational exposures, lifestyles and personal habits, and physical and biological scientific experts over a period of about

For numbered affiliations see end of article.

Correspondence to Dr Christopher J Portier, Environmental Health Consultant: Thus: CH-3600 Switzerland; cportier@n

BMJ Copyright Ar 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. The European Food Safety Authority (EFSA) is the primary agency of the European Union for risk assessments regarding food safety. In October 2015, EFSA reported⁴ on their evaluation of the Renewal Assessment Report⁵ (RAR) for glyphosate that was prepared by the Rapporteur Member State, the German Federal Institute for Risk Assessment (BfR), EFSA concluded that 'glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential'. Addendum 1 (the BfR Addendum) of the RAR⁵ discusses the scientific rationale for differing from the IARC WG conclusion.

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 highquality case-control studies, which are particular valuable for determining the



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supports that a cause or not cau For Monograp

tists evaluated th four insecticides sate.³ The WG for glyphosate m fication as a prob

The European (EFSA) is the European Unio regarding food EFSA reported* Renewal Assess glyphosate that Rapporteur Mer Federal Institut (BfR), EFSA con unlikely to pose humans and t support classific carcinogenic pot BfR Addendum) scientific rational IARC WG concl

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The International Agency for Research on agents that cause cancer in humans and

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THE HUMAN EV EFSA concluded evidence for a glyphosate-based non-Hodgkin ly inconclusive for tive relationship cancer in hun Addendum (p. explains that 'no ciation was ob powerful study IARC WG cond dence of carcino means "A positi observed betwee and cancer for a ation is consider to be credible, I founding could 1 sonable confiden

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)

Christopher J Portier, ¹ Bruce K Armstrong,² Bruce C Baguley,³ Xaver Baur,⁴ Igor Belyaev,⁵ Robert Bellé,⁶ Fiorella Belpoggi,⁷ Annibale Biggeri,⁸ Maarten C Bosland,⁹ Paolo Bruzzi,¹⁰ Lygia Therese Budnik,¹¹ Merete D Bugge,¹² Kathleen Burns,¹³ Gloria M Calaf,¹⁴ David O Carpenter,¹⁵ Hillary M Carpenter,¹⁶ Lizbeth López-Carrillo,¹⁷ Richard Clapp,¹⁸ Pierluigi Cocco,¹⁹ Dario Consonni,²⁰ Pietro Comba,²¹ Elena Craft,²²

The most appropriate and scientifically based evaluation of the cancers reported omhout.44 in humans and laboratory animals as well as supportive mechanistic data is that glylutta Roy.⁶⁹ phosate is a probable human carcinogen. On the basis of this conclusion and in the $\frac{1}{1}$ ambon.⁹² absence of evidence to the contrary, it is n humans and reasonable to conclude that glyphosate 0 agents since tten by ad hoc international eriod of about an eight-day formulations should also be considered ates all of the information on a transparent ecides on the ntific evidence likely human carcinogens. Health Month 2016 ed by BMJ P

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. The European Food Safety Authority (EFSA) is the primary agency of the European Union for risk assessments regarding food safety. In October 2015, EFSA reported⁴ on their evaluation of the Renewal Assessment Report⁵ (RAR) for glyphosate that was prepared by the Rapporteur Member State, the German Federal Institute for Risk Assessment (BfR). EFSA concluded that 'glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential'. Addendum 1 (the BfR Addendum) of the RAR⁵ discusses the scientific rationale for differing from the IARC WG conclusion.

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 highquality case-control studies, which are everyoutle velocities for determining the



101C **PESTICIDE INFORMATION**

American Cancer Society®

Known and Probable Human Carcinogens

0306

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 . Plaintiff Exhibi environmental cancer risks based on evidence from laboratory and human research studies.



Glyphosate v. Roundup No one tests "Roundup"

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").



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

Yes.

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?

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.

William Sawyer, PhD.



 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.

2012 – New Job at Benicia School District



Pest Management







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.

2007-1

41.0%

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



Complete Directions for Use

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

EPA Reg. No. 524-517

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 REPACKACING LIMITATIONS

1.0 INGREDIENTS

ACTIVE INCREDIENT Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt. OTHER INGREDIENTS (including surfactant):

. <u>59.0%</u> 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 FYE IRRITATION

Avoid contact with eyes or clothing FIRST AID: Call a poison control center or doctor for treatment advice.

IF IN FACE a Held are seen and since shock, and worth with vertex for 17 - 20

 nou eye oper and mise sowny and genuy with water for 15 - 20 minutes. Remove contact lenses if present after the first 5 minutes then continue rinsing eye.
roduct container or label with you when calling a poison control center r going for treatment.
so contact (314) 694-4000, collect day or night, for emergency medical information.
uct is identified as Ranger PRO® herbicide, EPA Registration 17.

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

lisers shore · 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.

The Label:

Keep out of reach of children.

CAUSES EYE IRRITATION.

Avoid contact with eyes or clothing.

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

- 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.
- \bullet This product is identified as Ranger PRO $^{\circledast}$ 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.

3. Did Roun • Have th or doct • You ma treatme • This p

The Label:

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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.

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.

Personal Protection





Multiple Heavy Exposures Nov. 2014: Reports to Monsanto

Message From: GOLDSTE Sent: 11/11/20 To: BIEHL, PA Subject: RE: Range

GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=527246] 11/11/2014 8:19:51 PM BIEHL, PATRICIA M [AG-Contractor/1045] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=208718] 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 @

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

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From: Sent:	GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-10 11/11/2014 8:19:51 PM	00-01/CN=RECIPIENTS/CN=527246]
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Patricia Biehl Product Support Specialist

Multiple Heavy Exposures Mar. 2015: Reports Problem Again

Message			
From:	Thompson, Joy [
Sent:	4/15/2015 7:04:57 PM		
To:	GRANETO, MATTHEW J [AG/1000] [
CC:	GOLDSTEIN, DANIEL A [AG/1000] [management of monsanto.com]; NYANGULU, JAMES M [AG/8070]		
	@monsanto.com]; THURSTON, RUTH M [AG/8070] [@monsanto.com]; WHITE,		
	ERIN [AG/1000] [@monsanto.com]; SEIFERT-HIGGINS, SIMONE [AG/1000] [
	@monsanto.com]; Weber, Julie [@ssmhc.com]		
Subject	March 2015 FIFRA 6(a)(2) Reports		
Attachments:	FIFRA March 2015.docx		
Flag:	Follow up		
Good after	noon Matt,		
	e the FIFRA 6(a)(2) Reports for the Monsanto Lawn & Garden and Monsanto Agricultural products h of March 2015.		
Please call r	me at 314 f you have any questions.		
Thank you,			
Joy Thomps	ion RN, CSPI		
Industry liais	son		
Missouri Poi	ison Center		
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Human Exposure / Adverse Effect Incidents Involving Monsanto Agricultural Products

Reporting Categories: H-A, H-B, H-C Reporting Period: March 1, 2015 – March 31, 2015

Substance:	Ranger Pro Herbicide from Monsanto
Serial Number:	32283189
Date:	03/27/2015
Medical Outcome:	Major Effect H-B
EPA Reg. No.	524-517
Active Ingredients:	Glyphosate 41%
State:	California
History and Notes:	Caller states he has been using Ranger Pro as part of his job for 2 to 3 years. He has recently been diagnosed with cutaneous T cell lymphoma. He has concerns about continuing to use Roundup as part of his job and questions if Roundup could be a source of his cancer. As the call progressed, caller said that doctors are unsure as to how to treat his condition and they are not even sure if it is cancer. Caller states that he works with Ranger Pro using a 50 gallon tank and also using a backpack sprayer. He dilutes 10 ounces of the Roundup per gallon (3.0%) for the 50 gallon tank and 4 ounces of Roundup per gallon (1.25%) when using the backpack sprayer. He recalls having been exposed to Roundup twice in the past 2 to 3 years, both from the backpack leaking/malfunctioning. In one case, he was wearing personal protective equipment (PPE) but it soaked through the PPE and his clothing. Recently, he has had a swollen foot and the MD's cannot figure out what is going on. The caller's level of fear is rising over his continued use of Ranger Pro. He states he continues to get unexplained rashes and nodules over his body. MRPC discussed the product toxicity. The symptoms are not an expected response from the product. Advised MRPC is available, if the treating MD has any questions.

Message

From:	Thompson, Joy [.
Sent:	4/15/2015 7:04:57 PM
To:	GRANETO, MATTHEW J [AG/10
CC:	GOLDSTEIN, DANIEL A [AG/100
	@monsant
	ERIN [AG/1000] [@r
	@monsanto.com]; Web
Subject:	March 2015 FIFRA 6(a)(2) Repo
Attachments:	FIFRA March 2015.docx
Flag:	Follow up



AMES M [AG/8070] @monsanto.com]; WHITE,

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 for the former of the second second

Thank you,

Joy Thompson RN, CSPI

Industry liaison

Missouri Poison Center

Human Exposure / Adverse Effect Incidents Involving Monsanto Agricultural Products

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Multiple Heavy Exposures 2015: Reports Problem Again

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Sent: To:	4/15/2015 7:04:57 PM GRANETO, MATTHEW J [AG/1000] [
CC:	GOLDSTEIN, DANIEL A [AG/1000] [monsanto.com]; NYANGULU, JAMES M [AG/8070]
	@monsanto.com]; THURSTON, RUTH M [AG/8070] @monsanto.com]; WHITE, ERIN [AG/1000] @monsanto.com]; SEIFERT-HIGGINS, SIMONE [AG/1000] [@monsanto.com]; Weber, Julie [@ssmhc.com]
Subject:	March 2015 FIFRA 6(a)(2) Reports FIFRA March 2015.docx
Attachments:	FIFKA March 2015.dock
Flag:	Follow up
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Please call i	me at 314-
Thank you,	
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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.







Issues to Consider

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

- 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?

Yes.

Yes

- 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?

- Economic damages
- Non-economic damages
 - physical pain



- Economic damages
- Non-economic damages
 - physical pain
 - mental suffering
 - loss of enjoyment of life



- Economic damages
- Non-economic damages
 - physical pain
 - mental suffering
 - loss of enjoyment of life
 - disfigurement
 - physical impairment



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





- 1. What is Roundup?
- 2. Can Roundup cause cancer? Yes.
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- 5. Should Monsanto be punished for its conduct?

Net Worth: \$6.6 Billion



Message		
From:	FARMER, DONNA R [AG/1000]	/O=MONSANTO/OU=NA-1000-01/CN=F
Sent:	9/21/2009 5:12:07 PM	
То:	COMBEST, JOHN C [AG/1000]	@Monsanto.com]
Subject:	RE: Roundup article in Fremant	le 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.

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.

- 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?

Dr. Kirk Azevedo Sales Representative (former)

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



- 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?

Yes.

