

Extra, extra – read all about it!



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Disclosures

I work for Bayer Crop Science



Dilemma





Pesticide development very slow

- # 8-10 years to test, develop and register
- // Costs ~\$200 million (not including cost of building production facilities)

Difficult to balance concerns over pesticides and insect borne illnesses

Questionable reports allege associations between pesticide exposure an neurologic illness, cancer, ADHD, autism and many other diseases



Pesticides

Insecticides kill bugs – ticks, mosquitoes, fleas, lice, bed bugs

Herbicides kill weeds & invasive plants – kudzu, honeysuckle

Antibiotics kill bacteria – *Strep, Staph,* typhus, plague

Fungicides kill fungi – Athlete's foot, fungi that produce carcinogenic toxins





Newsweek

U.S. WORLD BUSINESS TECH & SCIENCE CULTURE SPORTS OPINION

STUDY FINDS 25 PERCENT HIGHER RATE OF AUTISM WHERE MOSQUITO KILLER IS SPRAYED FROM PLANES

BY ZOË SCHLANGER ON 4/30/16 AT 6:16 AM



99% of pesticides consumed are chemicals that are produced by plants to defend themselves

52 natural pesticides tested in this 1990 study

27 of these are rodent carcinogens

// Commonly found thousands of times higher than synthetic pesticides

Americans eat ~ 1.5 g of these natural pesticides/day

// ~10,000x higher than synthetic residues

Vegans likely eat more

"You are going to treat my kid with what?"





Acute Toxicity Studies





Hazard Assessment

Standard Battery of Studies

- Physical Properties
- **Residue Chemistry**
- // Environmental fate
 - // General fate
 - // Degradation/Metabolism
 - // Mobility/Dissipation
 - // Accumulation
- // Spray Drift
- // Non-Target Organisms
 - // Acute
 - // Chronic
- // Product Performance
- Applicator and Re-entry

HUMANS/DOMESTIC ANIMALS

- Acute oral, dermal & inhalation
- // Eye & skin irritation
- // Dermal sensitization
- 21-d dermal
- 90-day rat, mouse & dog
- 1-year dog chronic
- 18-mo. mouse oncogenicity
- 2-year rat chronic/ oncogenicity
- Genotoxicity battery
- // Developmental toxicity (rat & rabbit)
- 2-Gen. rat reproduction
- Acute neurotoxicity
- Subchronic neurotoxicity
- // Developmental neurotoxicity
- // Immunotoxicity
- // Rat ADME

\$ 200 million and 10 years

Findings Across the Database are Consistent

Toxicological studies demonstrate that glyphosate is:

Not acutely toxic – oral, dermal, inhalation

Not irritating to skin, not a sensitizer

Not genotoxic, not carcinogenic

Not a reproductive toxicant, not an endocrine disruptor, not a teratogen

Not neurotoxic, not immunotoxic

BAYER



Chronic Low-Level Exposures





Cancer Incidence among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study

<u>Anneclaire J. De Roos</u>,¹ <u>Aaron Blair</u>,² <u>Jennifer A. Rusiecki</u>,² <u>Jane A. Hoppin</u>,³ <u>Megan Svec</u>,¹ <u>Mustafa Dosemeci</u>,² <u>Dale</u> <u>P. Sandler</u>,³ and <u>Michael C. Alavanja</u>²

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applicators.					
			RR (95% CI) ^b		
				Adjusted for age,	
		Ever used	Effect estimates	demographic and	
	Total no.	glyphosate	adjusted for age	lifestyle factors,	
Cancer site	of cancers ^c	(% of total)	(n = 54,315) ^a	and other pesticides ^a	
All cancers	2,088	73.6	1.0 (0.9–1.1)	1.0 (0.9–1.2)	
Lung	204	72.1	1.0 (0.7–1.3)	0.9 (0.6–1.3)	
Oral cavity	59	76.3	1.1 (0.6–2.0)	1.0 (0.5–1.8)	
Colon	174	75.3	1.1 (0.8–1.6)	1.4 (0.8–2.2) ^e	
Rectum	76	77.6	1.2 (0.7-2.1)	1.3 (0.7-2.3)	
Pancreas	38	76.3	1.2 (0.6-2.5)	0.7 (0.3-2.0)	
Kidney	63	73.0	1.0 (0.6–1.7)	1.6 (0.7-3.8) ^e	
Bladder	79	76.0	1.2 (0.7–2.0)	1.5 (0.7–3.2) ^e	
Prostate	825	72.5	1.0 (0.8–1.1)	1.1 (0.9–1.3)	
Melanoma	75	84.0	1.8 (1.0-3.4)	1.6 (0.8-3.0)	
All lymphohematopoietic cancers	190	75.3	1.1 (0.8–1.5)	1.1 (0.8–1.6)	
NHL	92	77.2	1.2 (0.7-1.9)	1.1 (0.7–1.9)	
Leukemia	57	75.4	1.1 (0.6-2.0)	1.0 (0.5–1.9)	
Multiple myeloma	32	75.0	1.1 (0.5-2.4)	2.6 (0.7–9.4) ^f	

Table 2. Association of glyphosate exposure (ever/never used) with common cancers^a among AHS applicators.

^aCancers for which at least 30 subjects had sufficient information for inclusion in age-adjusted analyses. ^bRRs and 95% Cls from Poisson regression models. ^cFrequencies among subjects included in age-adjusted analyses. ^dNumbers of sub-

De Roos AJ, Blair A, Rusiecki JA, et al. Cancer Incidence among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study. *Environmental Health Perspectives*. 2005;113(1):49-54. doi:10.1289/ehp.7340









Worldwide Regulatory Reviews

Have repeatedly concluded that glyphosate is **not genotoxic** and is **not a carcinogenic** hazard to humans

	EU ECHA RAC Classification
2017	Canada PMRA
	Australia APVMA
	US EPA Registration
2016	New Zealand EPA
	WHO/JMPR
	Japan FSC
	US EPA CARC Report
2015	EU EFSA Peer Review
	EU Annex I Renewal (BFR)
	Canada PMRA Registration Rev. (draft published)
2012	WHO/IARC
2013	
2012	US EPA Human Health RA
2011	US EPA Effects Determination
2008	
2007	Brazil ANVISA (ongoing)
	ОЕННА
2005	WHO/Water Sanitation Health
2004	WHO/JMPR
2002	EU Annex I
2000	FAO Specifications
1999	Japan FSC
1994	WHO/IPCS
1993	US EPA RED
1991	Canada PMRA
1987	WHO/JMPR

Glyphosate Use and NHL



199	6		
	Data	Observed Rate	Modeled Rate
	New Cases	19.4	19.3
	Deaths	8.8	8.8

201	6		
	Data	Observed Rate	Modeled Rate
	New Cases	19.0	19.1
	Deaths	5.4	5.4

NHL data U.S. 1992-2016



http://seer.cancer.gov/statfacts/html/nhl.html





Article Navigation

Glyphosate Use and Cancer Incidence in the Agricultural Health Study

Gabriella Andreotti, Stella Koutros, Jonathan N Hofmann, Dale P Sandler, Jay H Lubin, Charles F Lynch, Catherine C Lerro, Anneclaire J De Roos, Christine G Parks, <u>Michael C Alavanja</u>, ... Show more

JNCI: Journal of the National Cancer Institute, Volume 110, Issue 5, 1 May 2018, Pages 509–516, https://doi.org/10.1093/jnci/djx233



"In this updated evaluation of glyphosate use and cancer risk....we observed no associations between glyphosate use and overall cancer risk or with total lymphohematopoetic cancers including NHL and multiple myeloma"







News Releases from Headquarters > Chemical Safety and Pollution Prevention (OCSPP)

EPA Takes Next Step in Review Process for Herbicide Glyphosate, Reaffirms No Risk to Public Health

04/30/2019

Contact Information:

EPA Press Office (press@epa.gov)



The Safety of

GLYPHOSATE

What is Glyphosate?

Organophosphonate (not organophosphate)



//Not an insecticide.

//Works by preventing plants from making certain amino acids needed for growth.

//BUT, animals and humans are not affected, as they do not have this enzyme.



Formulations are simple:

- // Glyphosate
- // Surfactant (a detergent, like shampoo)
- // Anti-foam (like simethicone for intestinal gas)
- // Sometimes colorant (food coloring).
- // Water



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Most surfactant exposure comes from shampoos, soaps, and detergents at home.

Globally, glyphosate from major producers meets the FAO standard for purity.

Properties of Glyphosate



Glyphosate...

//Has relatively high water solubility and low
fat solubility -

//Does not bioaccumulate

//Has low absorption through the skin

//It is not metabolized -

//Quickly eliminated from the body.



Glyphosate

Myths



MYTH

Glyphosate is found in breast milk.

FACT

- This claim was made by an activist group that used an unvalidated test on breast milk.
- When the study was conducted using a validated test, no glyphosate was detected in breast milk.



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Issues

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Volume 103, Issue 5

Glyphosate and aminomethylphosphonic acid are not detectable in human milk a

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Michelle K McGuire ➡, Mark A McGuire, William J Price, Bahman Shafii, Janae M Carrothers, Kimberly A Lackey, Daniel A Goldstein, Pamela K Jensen, John L Vicini Author Notes

The American Journal of Clinical Nutrition, Volume 103, Issue 5, 1 May 2016, Pages 1285–1290. https://doi.org/10.3945/aicn.115.126854



MYTH

• Glyphosate disrupts the gut microbiome

FACT

- Glyphosate works by inhibiting EPSPS enzyme which is found in some microbes
- Plants use enzyme to make certain amino acids
- Gut flora are bathed in amino acids so microbes can live without it
- Tiny amount of glyphosate compared to gut microbes

Glyphosate and the Gut Microbiome





MYTH

Glyphosate (Roundup[®]) causes a wide variety of human health issues:

- Autism
- Celiac disease
- Parkinson's disease
- Obesity

FACT

These are SPECULATIVE relationships based on a mixture of:

- Correlation (Which is NOT causation)
- Not supported by laboratory data – no mechanism



Confusing Correlation with Causation

Rate of illness in the US vs Glyphosate use





Implications of Ban





Major crisis in Sri Lankan plantations due to ban on weedicides

View(s): 7

The Planters Association of Ceylon (PA), faced with devastating crop losses in excess of Rs. 15 billion in 2016, is urging the Government to immediately provide a rational and effective solution to the management

http://www.sundaytimes.lk/170108/business-times/majorcrisis-in-sri-lankan-plantations-due-to-ban-on-weedicides-222776.html















Pesticides are Critical for Human Health





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http://www.scielo.edu.uy/scielo.php?pid=S1688-12492003000200009&script=sci_arttext www.Wikipedia.org





Human Health

- // Pesticides are some of the most important advances in the control of infectious disease
- // >1 million insect borne deaths/year
- // > ½ the world's population at risk of insect borne diseases
 - // Dengue
 - // Yellow Fever
 - // Filariasis
 - // Onchocerciasis
 - // Zika

Malaria & other infectious diseases were wiped out in the USA and Europe by draining swamps and using pesticides

Pesticides are more regulated than antibiotics

Major contribution to public health

Bans put food supply and children's health at risk

