WASHINGTON STATE UNIVERSITY
EXTENSION

Does a Liability Jury Decision Change the Toxicology of Roundup?

Allan Felsot

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AGRICULTURE | YOUTH & FAMILIES | HEALTH | ECONOMY | ENVIRONMENT | ENERGY | COMMUNITIES







Be Afraid, Be Very Afraid!

news from
UNDERGROUND

MAY
11

The planetary threat posed by Monsanto's herbicide (glyphosate)

Mystery Science: More Details on the Strange Organism That Could Destroy Monsanto
By Melanie Warner

Back in January, a noted plant scientist who spent much of his career at Purdue University sent a letter to theUSDA informing the agency that he'd discovered amysterious new disease-causing organism in Monsanto's (MON) genetically engineered Roundup Ready corn and soybeans. Now, that scientist — Don Huber — has written a follow-up letter to the USDA and appears in a videotaped interview where he presents an even scarier picture of the damage he claims Monsanto's herbicide chemical glyphosate (the main ingredient in Roundup) is doing to both plants and the animals who eat them.

In the 20-minute interview, which was conducted by Food Democracy Now's Dave Murphy, Huber makes a strong case for his own credibility, appearing as a droll, erudite Midwestern scientist with deep connections to corn and soybean growers and livestock farmers. Although Huber's findings have not yet been verified by outside scientists or published in a peer reviewed journal, the severity of his claims is such that the USDA ought to give them immediate attention.

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WHO Done It!

The New York Times

W.H.O. Report Links Ingredient in Roundup to Cancer

By REUTERS MARCH 20, 2015

The world's most widely-used weed killer can "probably" cause cancer, the World Health Organization said on Friday.

The organization's cancer arm, the International Agency for Research on Cancer, said glyphosate, the active ingredient in the Monsanto herbicide Roundup, was "classified as probably carcinogenic to humans." It also said there was "limited evidence" that glyphosate was carcinogenic in humans for non-Hodgkin lymphoma.

Monsanto, the world's largest seed company, said scientific data did not support the conclusions and called on the group to hold a meeting to explain the findings.

"We don't know how IARC could reach a conclusion that is such a dramatic departure from the conclusion reached by all regulatory agencies around the globe," Philip Miller, Monsanto's vice-president for global regulatory affairs, said in a statement.

The U.S. government says glyphosate is considered safe. It is mainly used on crops like corn and soybeans that are genetically modified to survive it.

WHO Broke the Flood Gates?

International Agency for Research on Cancer

World Health Organization

20 March 2015

IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides

Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate

In March, 2015, 17 experts from 11 countries met at the International Agency for Research on Cancer (IARC; Lyon, France) to assess the carcinogenicity of the organophosphate pesticides tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate (table). These assessments will be published as volume 112 of the IARC Monographs.[1]

to the bioactive metabolite paraoxon aggressive cancers after adjustment

Pending the release of the actual monograph, IARC announced in Lancet Oncology a summary of important studies that led to the conclusion, glyphosate is a probable a human carcinogen.

The insecticides malathion and females.[4] Malathion is rapidly absor

California Leads the Way

California Becomes First State to Label Monsanto's Roundup as a Carcinogen

Lorraine Chow | September 8, 2015 1:40 pm | Comments

In a first for the country, California's Environmental Protection Agency (Cal/EPA) has issued plans to list glyphosate—the toxic active ingredient in Monsanto's Roundup herbicide—as known to cause cancer.

Lawyers Licking their Lips??

Roundup's active ingredient facing wave of legal challenges as alleged carcinogen

ST. LOUIS POST-DISPATCH

By Bryce Gray St. Louis Post-Dispatch Mar 12, 2017

March 12, 2017

In this June 28, 2011 file photo, bottles of Roundup herbicide, a product of Monsanto, are displa on a store shelf, in St. Louis. (AP Photo/Jeff Roberson, File)

Glyphosate, the active ingredient in Monsanto's marquee product, Roundup, is coming under fire from hundreds of legal challenges across the U.S., with individuals alleging that the herbicide is carcinogenic and linked to cases of non-Hodgkin lymphoma.

The Lawsuit Heard Around the World

Landmark lawsuit claims Monsanto hid cancer danger of weedkiller for decades

In June, a California groundskeeper will make history by taking company to trial on claims it suppressed harm of Roundup

▲ Monsanto has been accused of hiding the dangers of its popular Roundup products for decades, a claim the company denies. Photograph: Benoit Tessier/Reuters

At the age of 46, DeWayne Johnson is not ready to die. But with cancer spread through most of his body, doctors say he probably has just months to live. Now Johnson, a husband and father of three in California, hopes to survive long enough to make Monsanto take the blame for his fate.

Definitely Not the End of the Beginning of Lawsuits

Roundup® ALERT

- Non-Hodgkin Lymphoma
- Leukemia (certain types)
- Other Cancers of the Blood

You may be entitled to significant compensation

Farmworkers, landscapers and homeowners

If You Don't File a Lawsuit, You're Not Patriotic!!

Good News???
(not if you own Bayer stock)

California Judge Cuts Award To $78.5 Million In Monsanto Weedkiller Case

October 23, 2018 · 1:27 PM ET

LAUREL WAMSLEY

A superior court judge slashed the punitive damages for Dewayne Johnson — a groundskeeper and pest-control manager at a Northern California school district who contracted cancer — by more than $200 million.

Josh Edelson/AP

A superior court judge in San Francisco has upheld a jury verdict against Bayer's Monsanto, maker of the weedkiller Roundup, but slashed the punitive damages by more than $200 million.

Brave New World?

REUTERS Mixed message on weed-killer reflects reality of scientific uncertainty

Mixed message on weed-killer reflects reality of scientific uncertainty

Monsanto's Roundup weedkiller atomizers are displayed for sale at a garden shop at Bonneuil-Sur-Marne near Paris, France, June 16, 2015. REUTERS/Charles Platiau

The First Challenge to the IARC Conclusions

European Food Safety Authority

EFSA Journal 2015;13(11):4302

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate[1]

European Food Safety Authority (EFSA)[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA), following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Germany, for the pesticide active substance glyphosate are reported. The context of the peer review was that required by Commission Regulation (EU) No 1141/2010 as amended by Commission Implementing Regulation (EU) No 380/2013. The conclusions were reached on the basis of the evaluation of the representative uses of glyphosate as a herbicide on emerged annual, perennial and biennial weeds in all crops [crops including but not restricted to root and tuber vegetables, bulb vegetables, stem vegetables, field vegetables (fruiting vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, potatoes, cereals, and sugar- and fodder beet; orchard crops and vine, before planting fruit crops, ornamentals, trees, nursery plants etc.] and foliar spraying for desiccation in cereals and oilseeds (pre-harvest). The reliable endpoints, concluded as being appropriate for use in regulatory risk assessment and derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified. Following a second mandate from the European Commission to consider the findings from the International Agency for Research on Cancer (IARC) regarding the potential carcinogenicity of glyphosate or glyphosate-containing plant protection products in the on-going peer review of the active substance, 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 according to Regulation (EC) No 1272/2008.

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The New News on Glyphosate: Same as the Old News

Glyphosate unlikely to pose risk to humans, UN/WHO study says

Chemical used in Monsanto's Roundup weedkiller 'unlikely to pose carcinogenic risk from exposure through diet'

Several EU states rebelled against an EU proposal to relicense glyphosate earlier this year. Photograph: Philippe Huguen/AFP/Getty Images

theguardian

Arthur Neslen

Monday 16 May 2016 18.53 BST

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Chemical used in Monsanto's Roundup weedkiller 'unlikely to pose carcinogenic risk from exposure through diet'

May 16, 2016

Glyphosate, the key ingredient in Monsanto's Roundup weedkiller brand, has been given a clean bill of health by the UN's joint meeting on pesticides residues (JMPR), two days before a crunch EU vote on whether to relicense it.

Several EU states rebelled against an EU proposal to relicense glyphosate earlier this year. Photograph: Philippe Huguen/AFP/Getty Images

Arthur Neslen

Monday 16 May 2016 18.53 BST

theguardian

The Most Current U.S. Version of the Story

ENVIRONMENT | Fri Sep 16, 2016 | 5:32pm EDT

EPA says glyphosate, used in Monsanto herbicide, likely not carcinogenic

REUTERS

By **P.J. Huffstutter** | CHICAGO

Glyphosate, the key ingredient in Monsanto Co's Roundup herbicide, is not likely carcinogenic to humans, the U.S. Environmental Protection Agency said on Friday as it outlined its current position on the controversial chemical.

The EPA has been involved in a decades-long process to assess human and animal health risks, as well as ecological risks, of glyphosate. Various agencies around the world have offered conflicting opinions on whether glyphosate causes cancer.

The EPA's "proposed" position on glyphosate was outlined in a 227-page paper it published on the regulations.gov website, which the EPA manages.

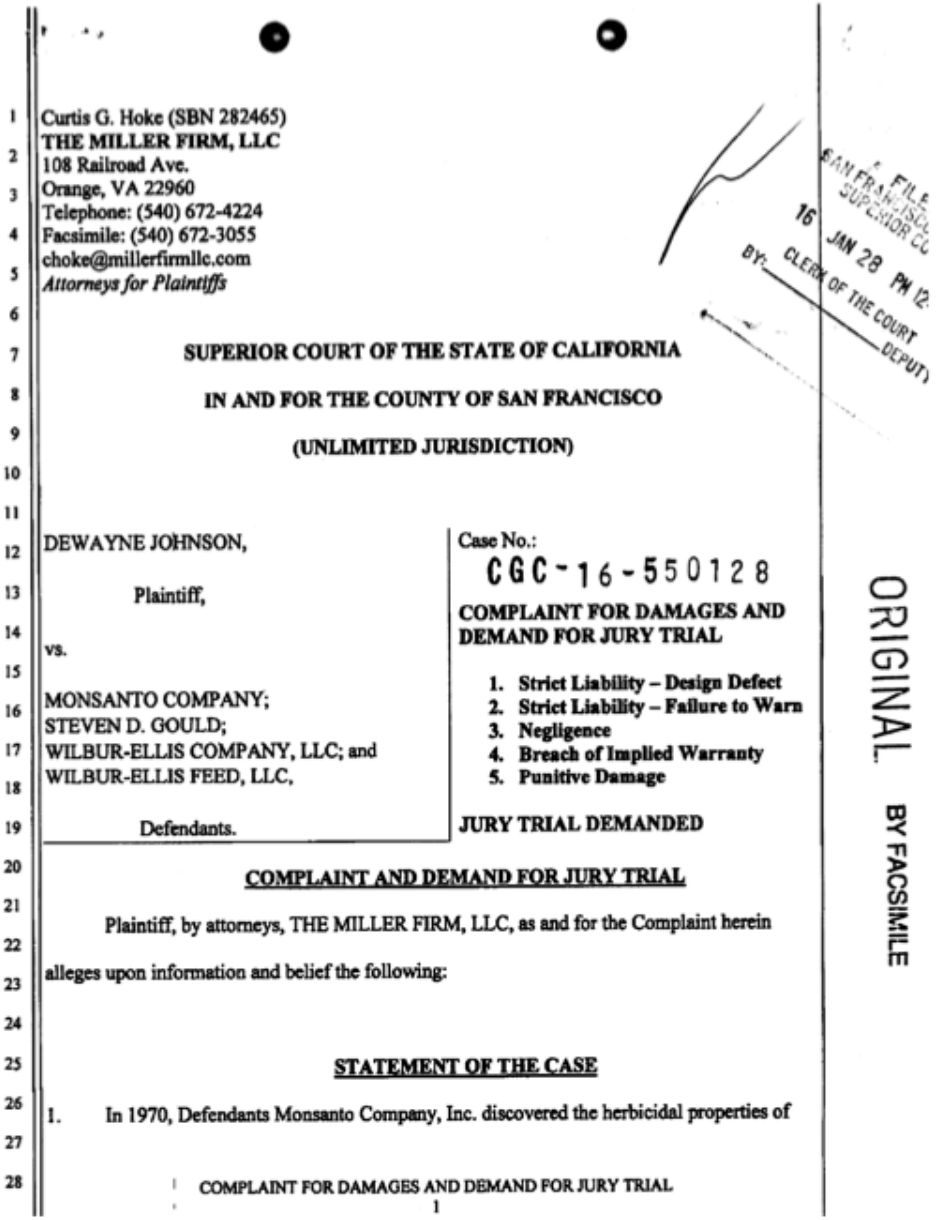
What Are the Issues?

- The UN funded agency, IARC (International Agency for Research on Cancer) declared glyphosate a probable human carcinogen
- The lawsuits (currently ~~>27,000~~ ~~>40,000~~ ~50,000) ballooned after IARC's conclusions made public and still the lawyers are sharpening their knives with television commercials across the U.S.
- EPA and other regulatory agencies worldwide have concluded that glyphosate does not pose a risk for cancer
  - ✓ Ironically, another UN funded agency, JMPR (Joint Meeting on Pesticide Residues) concluded evidence did not support a conclusion that glyphosate caused cancer
- A San Francisco jury ruled that glyphosate was responsible for one plaintiffs non-Hodgkin's lymphoma and thus should have warned users of Roundup hazards
  - ✓ Two other similar cases were tried in California & Bayer lost the third one with a $2 billion dollar judgement
- So, does a jury ruling change the science of glyphosate toxicology?

Lawsuit Premise: Claim One

- Strict Liability (Design Defect)

  ✓ At all times relevant to this litigation, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Roundup products, **which are defective and unreasonably dangerous to consumers**, including Plaintiff, thereby placing Roundup products into the stream of commerce



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Attorneys for Plaintiffs

FILED
SAN FRANCISCO
SUPERIOR COURT
16 JAN 28 PM 12
BY: CLERK OF THE COURT DEPUTY

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF SAN FRANCISCO

(UNLIMITED JURISDICTION)

DEWAYNE JOHNSON,

Plaintiff,

vs.

MONSANTO COMPANY;
STEVEN D. GOULD;
WILBUR-ELLIS COMPANY, LLC; and
WILBUR-ELLIS FEED, LLC,

Defendants.

Case No.:
CGC-16-550128

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

1. **Strict Liability – Design Defect**
2. **Strict Liability – Failure to Warn**
3. **Negligence**
4. **Breach of Implied Warranty**
5. **Punitive Damage**

JURY TRIAL DEMANDED

ORIGINAL

BY FACSIMILE

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, by attorneys, THE MILLER FIRM, LLC, as and for the Complaint herein alleges upon information and belief the following:

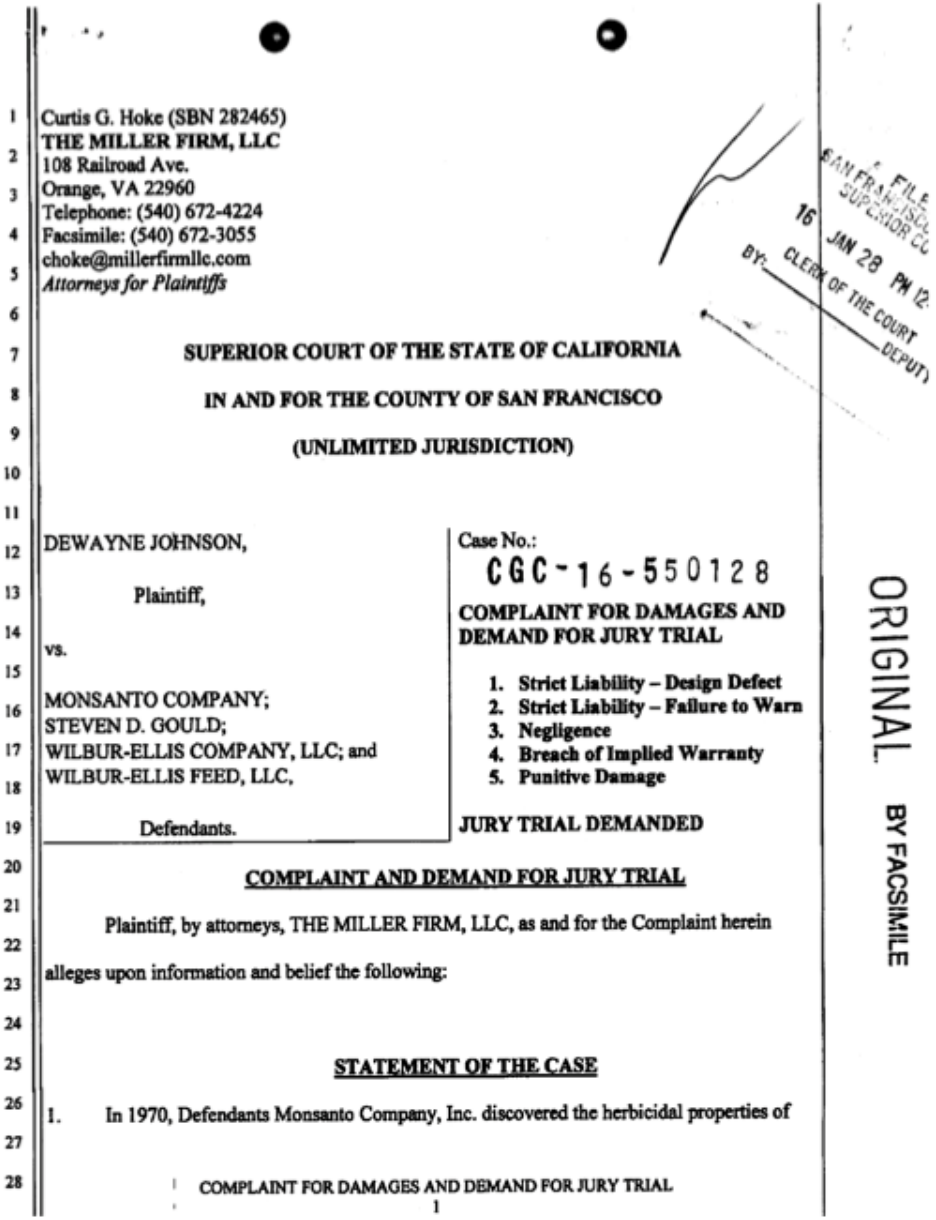
STATEMENT OF THE CASE

1. In 1970, Defendants Monsanto Company, Inc. discovered the herbicidal properties of

Lawsuit Premise: Claim Two

- Strict Liability (Failure to Warn)

✓ At all times relevant to this litigation, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, promoting and applying Roundup products, which are defective and unreasonably dangerous to consumers, including Plaintiff, **because they do not contain adequate warnings or instruction concerning the dangerous characteristics of Roundup and specifically, the active ingredient glyphosate**



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ORIGINAL BY FACSIMILE

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STATEMENT OF THE CASE

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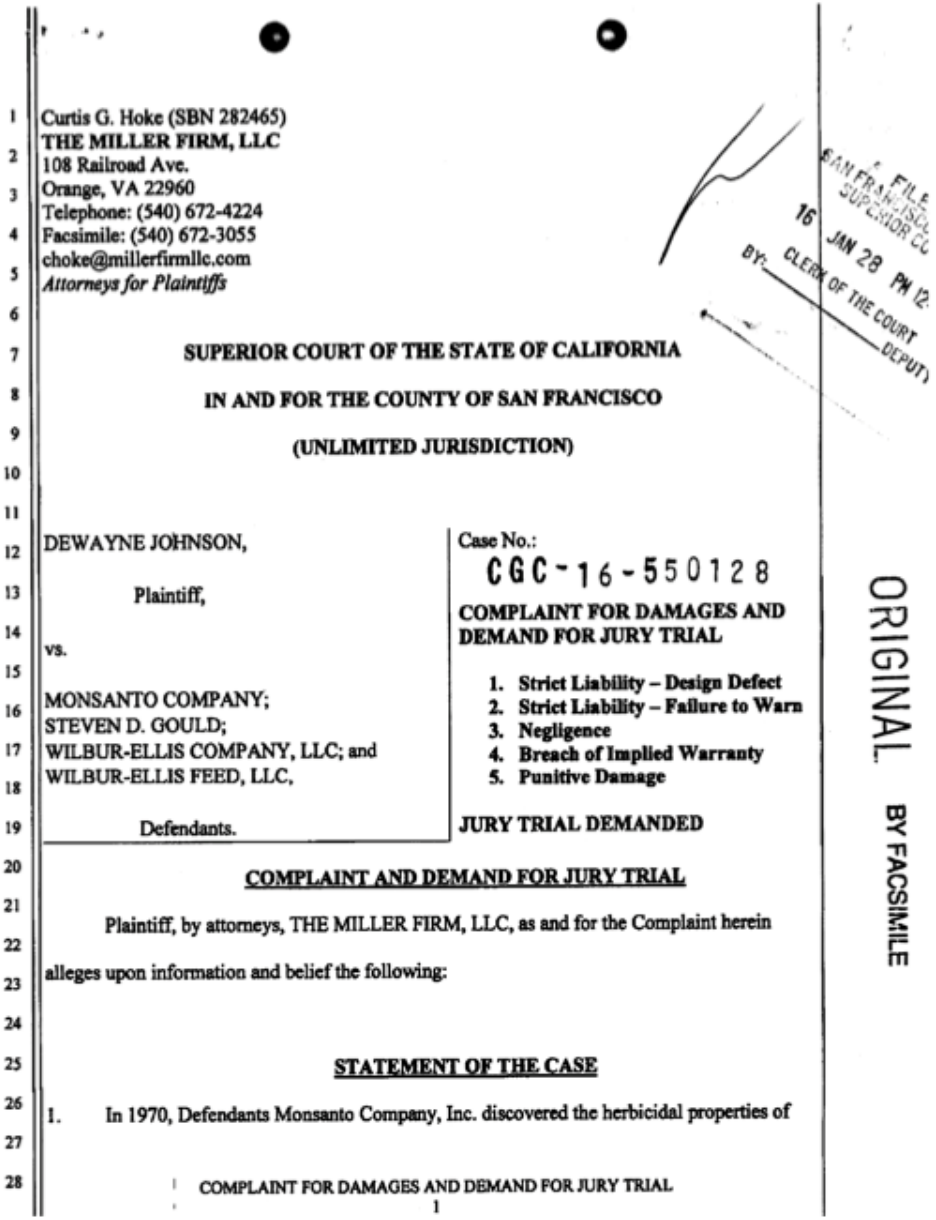
Lawsuit Premise: Claim Three

- Negligence

✓ At all times relevant to this litigation, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Roundup and specifically, **the carcinogenic properties of the chemical glyphosate**



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ORIGINAL

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COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL
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Glyphosate's Safety Endorsed

United States Environmental Protection Agency

- The EPA has considered glyphosate AI to be a reduced risk herbicide
  - ✓ Very low mammalian, bird, fish, crustacean, and honey bee toxicity
  - ✓ Endocrine Disruption Screening Program (EDSP) Tier 1 results:
    - ✳ "Based on weight of evidence considerations, mammalian or wildlife EDSP Tier 2 testing is not recommended for glyphosate since there was no convincing evidence of potential interaction with the estrogen, androgen or thyroid pathways." (EPA 2015)
  - ✓ 2015 Cancer Assessment Review
    - ✳ No evidence for carcinogenicity in experimental animals
    - ✳ No evidence for *in vitro* or *in vivo* genotoxicity
    - ✳ Epidemiological studies equivocal for non-Hodgkin's lymphoma

Existentialism of Pesticide Registration Decisions
"No Regulatory Agency Is an Island"

- If glyphosate products are so "defective and unreasonably dangerous to consumers", then why did six different regulatory & advisory agencies approve its use without concern before the IARC decision, declaring no evidence for a carcinogenic effect

  - ✓ Join Meeting on Pesticide Residues (2004, 2016)
  - ✓ WHO Core Assessment Group (2004)
  - ✓ Australian Pesticides & Veterinary Medicines Authority (APVMA)(2013)
  - ✓ EPA (1993, 2012, 2016)
  - ✓ German Federal Institute for Risk Assessment (2014)
  - ✓ Health Canada Pesticide Management Regulatory Agency (PMRA (2015)
  - ✓ European Food Safety Agency (EFSA, 2016)

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Government of Canada

World Health Organization

efsa
European Food Safety Authority

EPA United States Environmental Protection Agency

Roundup Original Product Label

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

WARNING! AVISO!

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

CAUSES SUBSTANTIAL BUT TEMPORARY EYE INJURY.

HARMFUL IF SWALLOWED OR INHALED.

Do not get in eyes or on clothing.

Avoid breathing vapor or spray mist.

FIRST AID: IF IN EYES, immediately hold eyelids open and flush with plenty of water for at least 15 minutes. Get medical attention.

IF INHALED, remove individual to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention. NEVER GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.

Roundup ORIGINAL™

HERBICIDE

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulations.

Roundup Original Product Label

Personal Protective Equipment (PPE)

Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, and protective eyewear. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If 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 Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations:

Users should:

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

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

Roundup ORIGINAL™

HERBICIDE

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulations.

But Was that Label in Existence ~15 Years Ago?

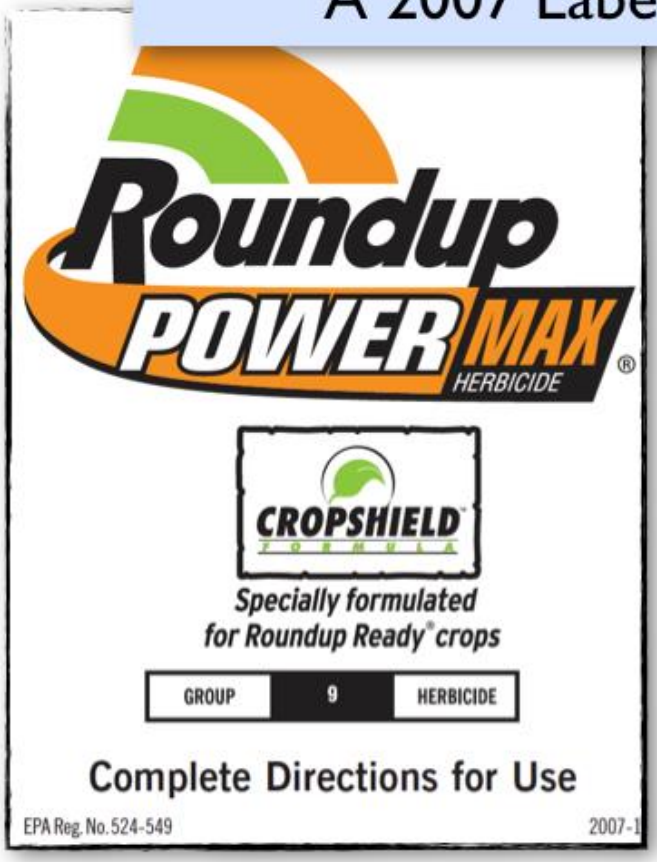
What you'll find on the last sheet of every label…copyright year

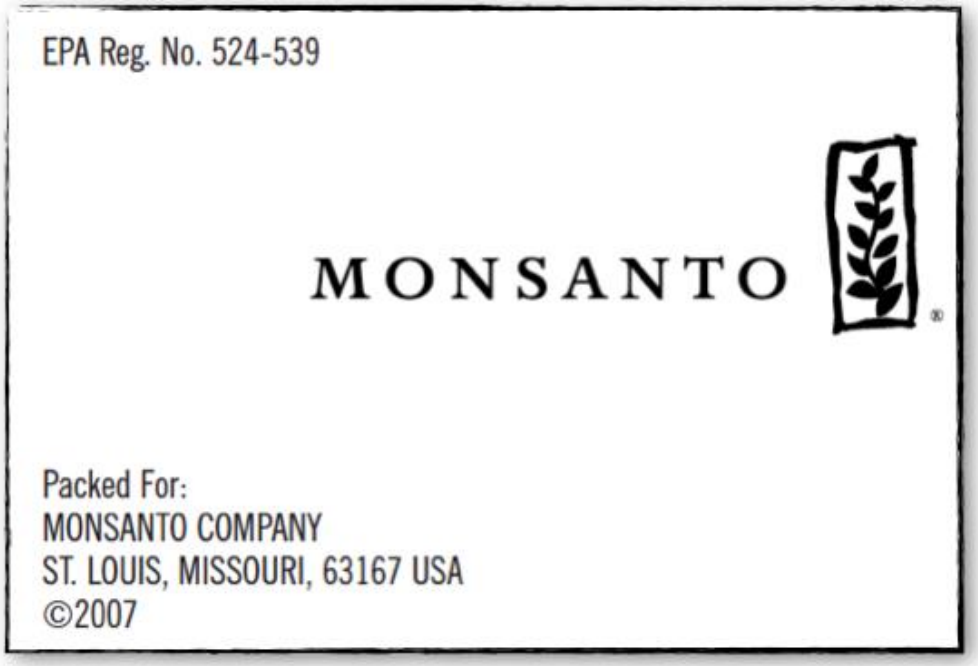
EPA Reg. No. 524-445 21154Z3-1/CG

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

MONSANTO ™

A 2007 Label: Note the Difference in PPE





Personal Protective Equipment (PPE)

Some of the materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for Category A on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves made of any waterproof material such as polyethylene or polyvinyl chloride.

Dazed & Confused: A 2018 "Modern" Label

Packed for:
MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ST. LOUIS, MISSOURI, 63167 USA
020316

Personal Protective Equipment (PPE)

Some of the materials that are chemical-resistant to this product are listed below.

Mixers, Loaders, Other Handlers and Applicators, when handling this concentrated product or its application solutions of 30 percent concentration or greater, must wear: long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material, such as polyethylene or polyvinyl chloride.

Applicators, when handling only spray solutions where concentration is 30 percent of this product or less, must wear: long-sleeved shirt and long pants, socks and shoes.

Follow manufacturer's instructions for cleaning/maintaining PPE (Personal Protective Equipment). If there are no 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.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

Worker Protection Standard: Some Confusion

- The Worker Protection Standard is placed in a box on every product label

  ✓ However, the WPS is meant for agricultural uses, defined as using the product to produce agricultural plants on farms, forests, nurseries or greenhouses

  ✓ Note that the older labels (pre 2001) did not specify gloves but the WPS stated that entry into treated fields required "chemical resistant gloves made of any waterproof material"

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. Supplemental labeling can be found on the Internet at www.cdms.net or www.greenbook.net or obtained from your Authorized Monsanto Retailer or Monsanto Company Representative.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulations.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: coveralls, shoes plus socks and chemical-resistant gloves made of any waterproof material.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep people and pets off treated areas until spray solution has dried.

Historical Assessment of Glyphosate Belies the Claims

United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-93-014
September 1993

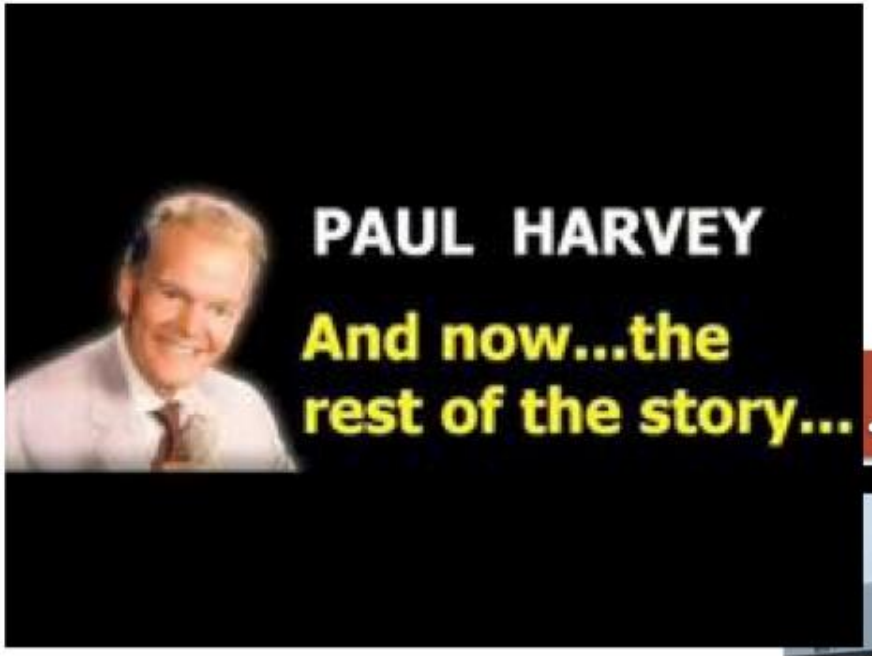
EPA

Reregistration Eligibility Decision (RED)

Glyphosate

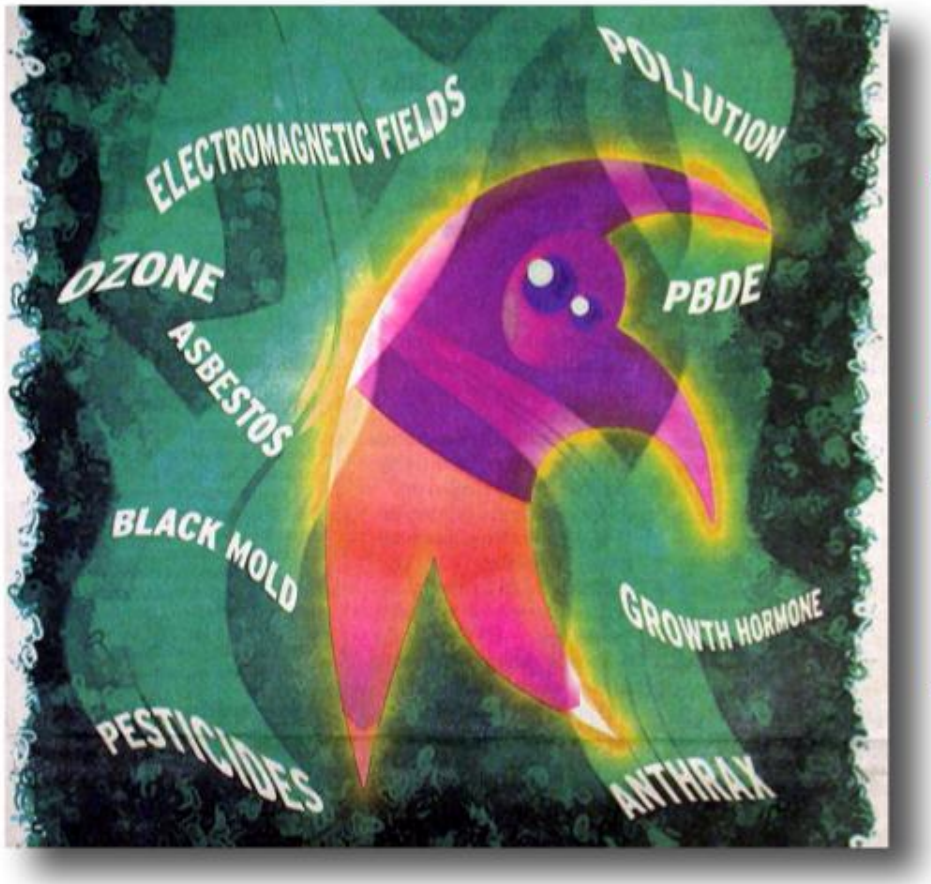
Exposure to workers and other applicators generally is not expected to pose undue risks, due to glyphosate's low acute toxicity. However, splashes during mixing and loading of some products can cause injury, primarily eye and skin irritation. EPA is continuing to recommend PPE, including protective eye wear, for workers using end-use products that are in Toxicity Categories I or II for eye and skin irritation. To mitigate potential risks associated with reentering treated agricultural areas, EPA is retaining the 12 hour REI set by the WPS.

Desperately Seeking the Truth



…and Current

How Do We Know When a Technology is Safe Enough?

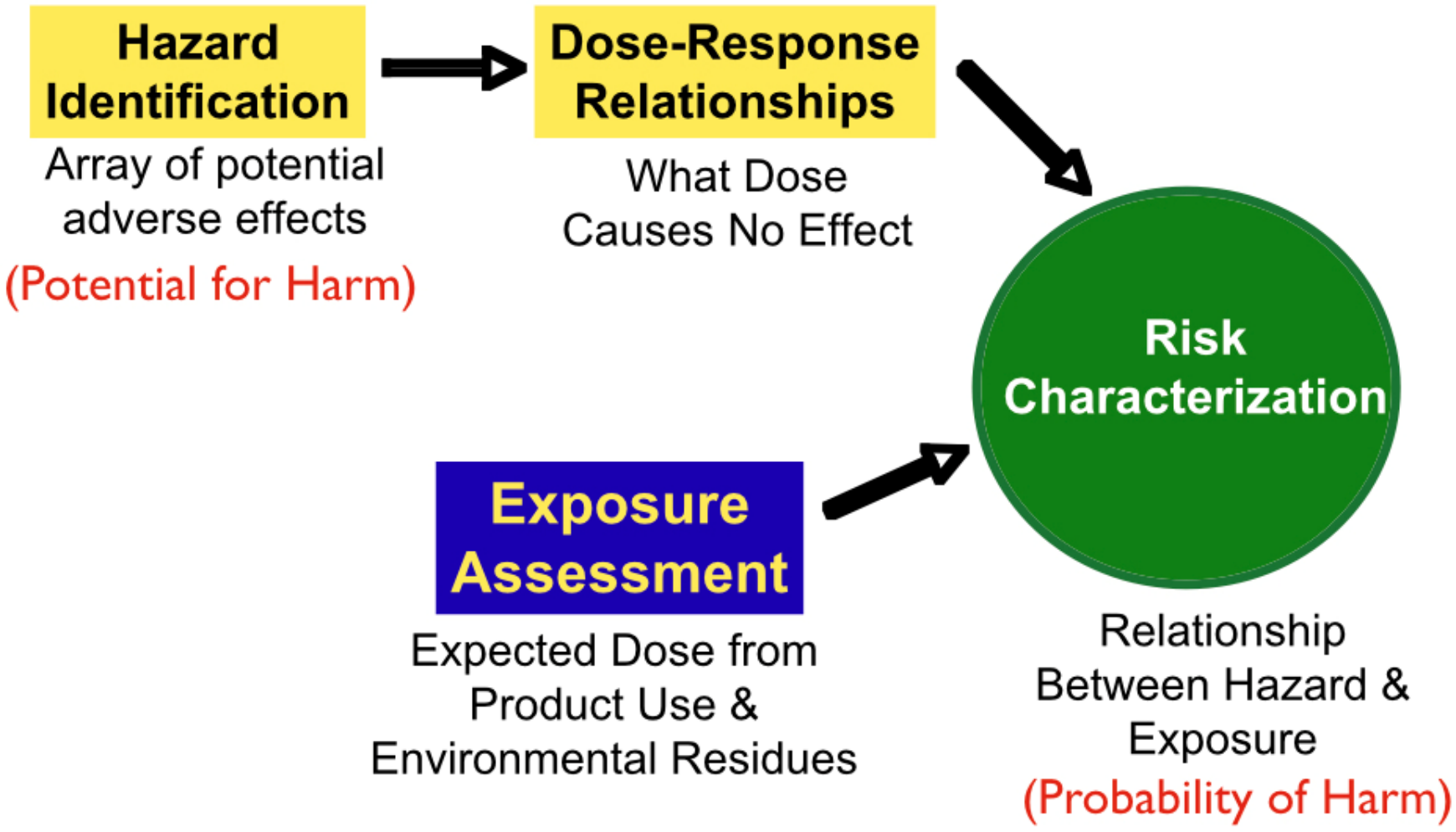


What is the risk (likelihood or probability) that something bad is going to happen?

Ideally, we should adopt a Life-Cycle perspective, including a quantitative analysis of benefits!

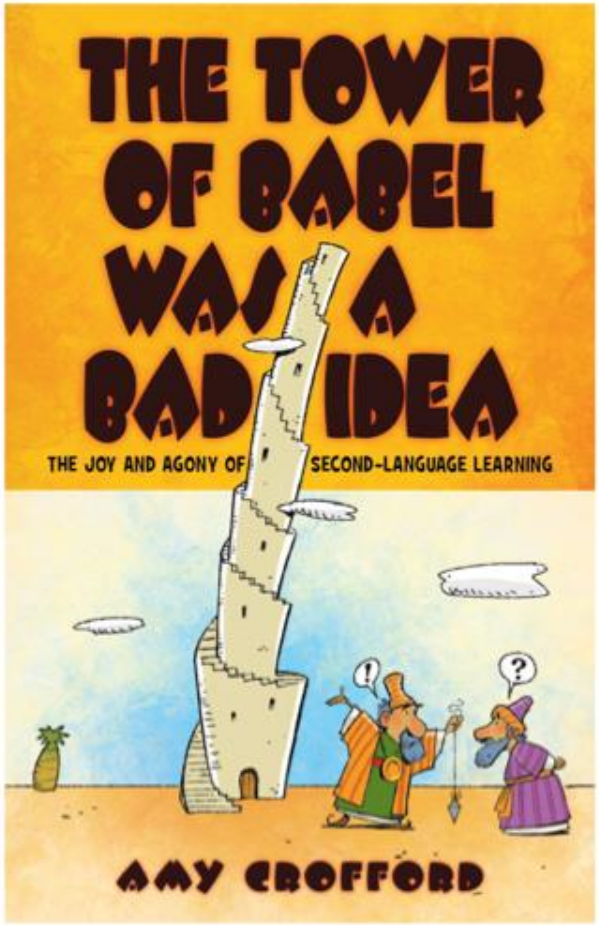
How Should We Manage the Technology to Ensure Safety

Risk Assessment
Estimating the Probability of Harm



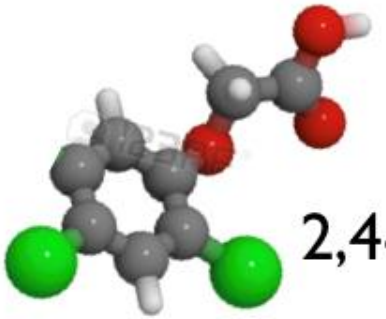
Speaking the Same Language--Toxicity Terms

- **Toxicity**: innate potential of a substance to cause injury (attribute of specifi c 3-D chemical structure & appropriate receptor in organism)
- **Hazard**: potential to cause injury under specifi c set of circumstances
- **Risk**: probability (likelihood) of harm; function of the magnitude of exposure (or contamination) integrated with hazard
- **Safety**: subjective term and therefore not defi nitive, but in the context of risk management it refers to the practical certainty that injury will not result from use of a substance under specifi ed conditions of



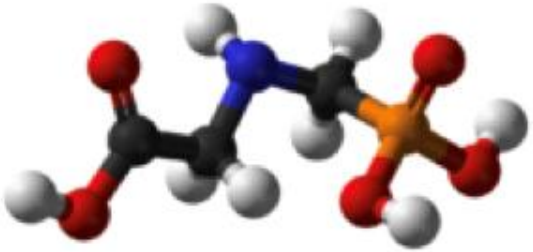
Do Not Confuse Toxicity, Hazard & Risk

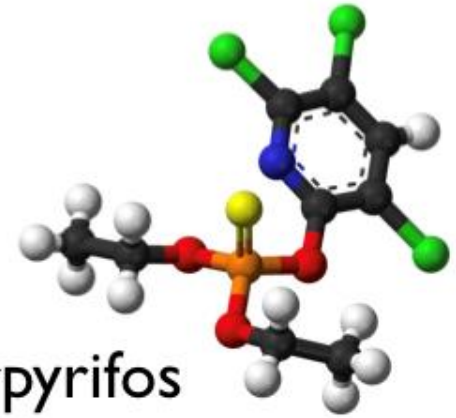
See the World of Chemistry in 3D



2,4-D

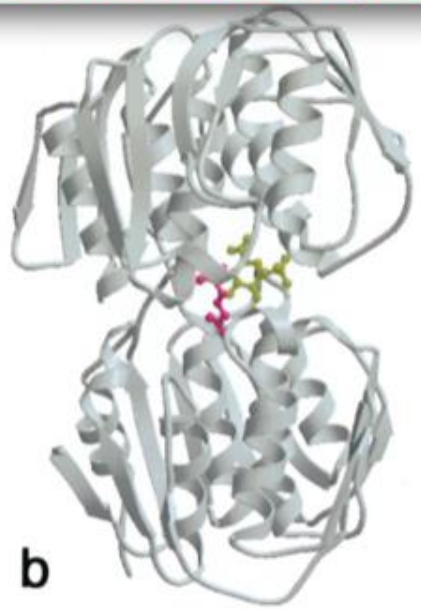
glyphosate



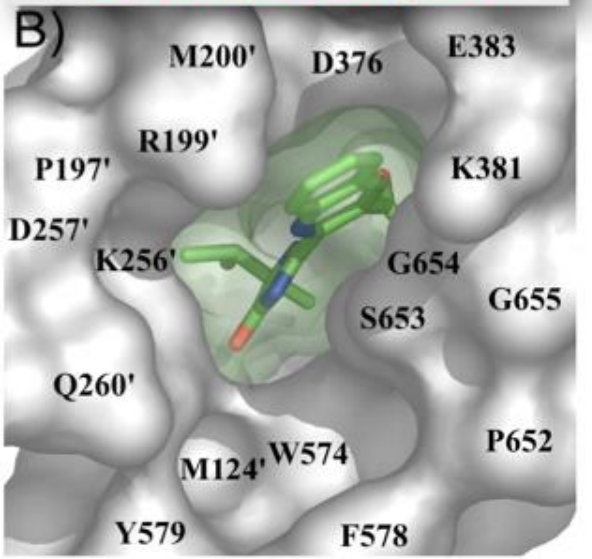


chlorpyrifos

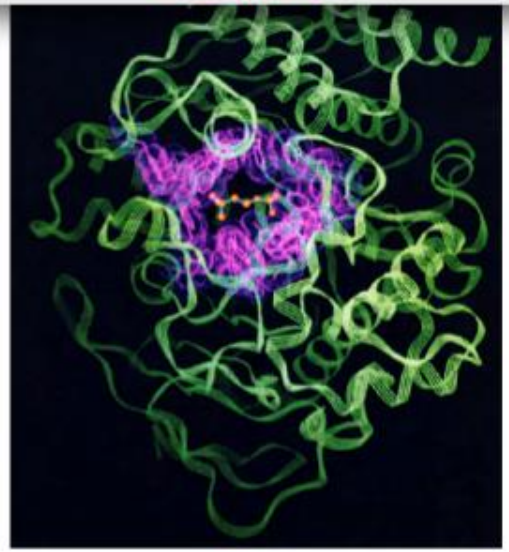
Glyphosate Blocks the Active Site of the Plant Enzyme EPSPS



Imazaquin herbicide Blocking the Active Site of the ALS Enzyme



Chlorpyrifos Blocks the Acetylcholinesterase Enzyme



Hazard Testing

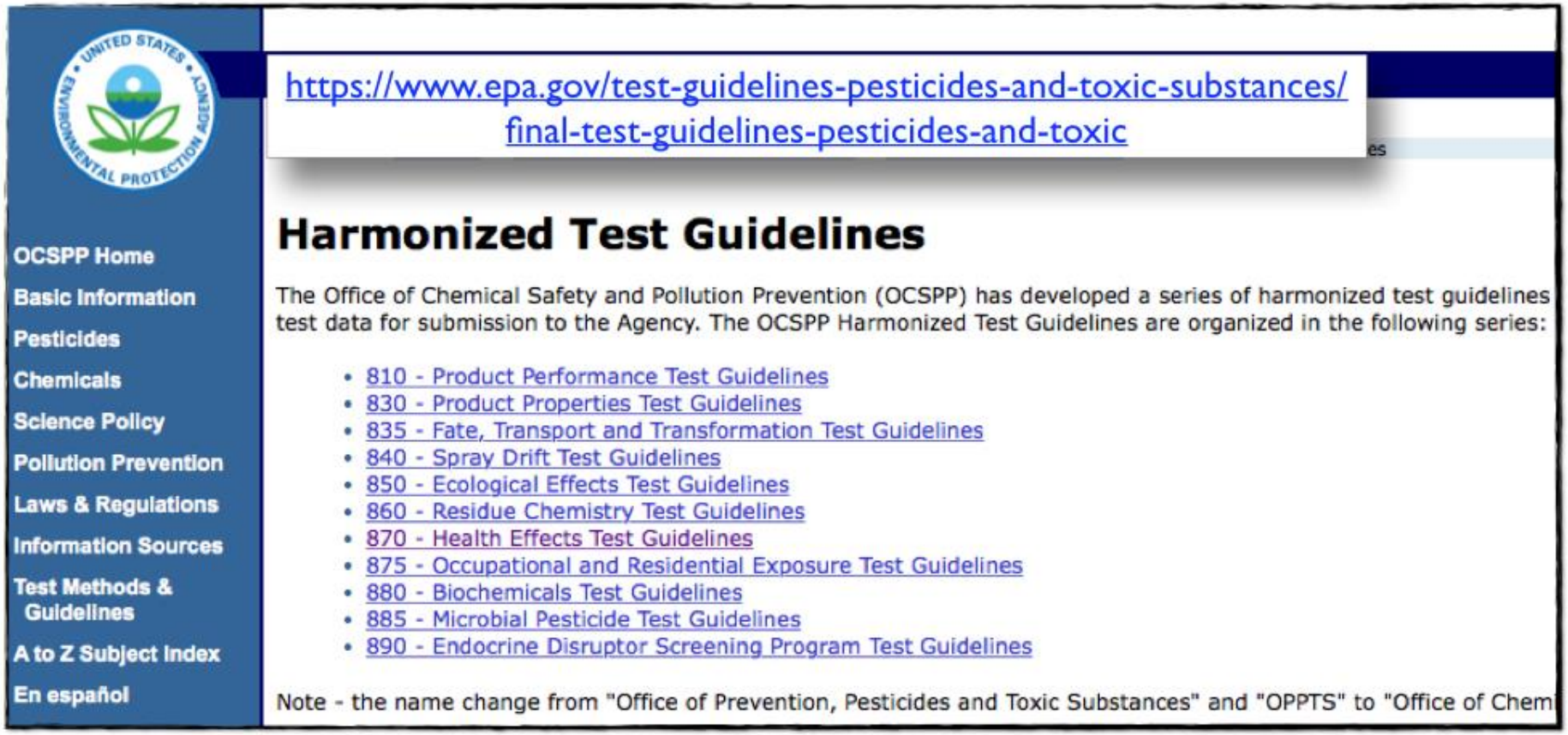
- Potential to do harm; manifestation is conditional
- Testing to characterize hazard
  - ✓ In vitro tests

** ✓ In vivo tests
  - ✳ 90-day exposure
  - ✳ 2-year exposure

  - ✓ Epidemiological studies

For risk assessment, the *in vitro* and *in vivo* experiments give us a NOAEL & LOAEL

EPA's Harmonized Test Guidelines



https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic

OCSPP Home
Basic Information
Pesticides
Chemicals
Science Policy
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Laws & Regulations
Information Sources
Test Methods & Guidelines
A to Z Subject Index
En español

Harmonized Test Guidelines

The Office of Chemical Safety and Pollution Prevention (OCSPP) has developed a series of harmonized test guidelines test data for submission to the Agency. The OCSPP Harmonized Test Guidelines are organized in the following series:

- 810 - Product Performance Test Guidelines
- 830 - Product Properties Test Guidelines
- 835 - Fate, Transport and Transformation Test Guidelines
- 840 - Spray Drift Test Guidelines
- 850 - Ecological Effects Test Guidelines
- 860 - Residue Chemistry Test Guidelines
- 870 - Health Effects Test Guidelines
- 875 - Occupational and Residential Exposure Test Guidelines
- 880 - Biochemicals Test Guidelines
- 885 - Microbial Pesticide Test Guidelines
- 890 - Endocrine Disruptor Screening Program Test Guidelines

Note - the name change from "Office of Prevention, Pesticides and Toxic Substances" and "OPPTS" to "Office of Chem

Harmonized test guidelines are developed by the EPA division called the Office of Chemical Safety and Pollution Prevention (OCSPP), formerly known as the Office of Prevention Pesticides and Toxic Substances (OPPTS)

The guidelines provide guidance for how tests should be conducted to meet data requirements that EPA has set for conducting risk assessments as required by FIFRA. The test guidelines provide standardized procedures but specific experimental protocols are developed using the guidelines.

Chemical Safety and Pollution Prevention

Contact Us **Search:** ◯All EPA ◉This Area [ ] Go

You are here: EPA Home » Chemical Safety and Pollution Prevention » Test Methods and Guidelines » OCSPP Harmonized Test Guidelines » Series 870

https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-870-health-effects-test-guidelines

- OCSPP Home
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- Chemicals
- Science Policy
- Pollution Prevention
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- En español

For KIDS

The FINAL guidelines on this page are part of a series of test guidelines that have been developed by the Office of Chemical Safety and Pollution Prev and toxic substances, and the development of test data for submission to the Agency.

A Master List (PDF) (28 pp, 80K, About PDF) of the OCSPP Harmonized Test Guidelines is available | Microsoft Excel Version (84K) (Excel viewer EXIT Disclaime

More information about OCSPP Harmonized Test Guidelines.

You will need Adobe Reader to view some of the files on this page. See EPA's PDF page to learn more.

Supplemental Guidance

Test Guidelines/Acute Toxicity - Acute Oral Tox
Guidance for Waiving or Bridging of Mammalia
Guidance for Neurotoxicity Battery, Subchroni
Genetic Toxicology: Integration of in vivo Testi
Use of an Alternate Testing Framework for Classification of Eye Irritation Potential of EPA Pesticide Products
Update on the Use of the Local Lymph Node Assay for End Use Pesticide Pr ... col for LLNA (rLLNA)

Series 870 Health Effects Test Guidelines for Hazard Identification

Group A – Acute Toxicity Test Guidelines

870.1000 - Acute Toxicity Testing--Background (December 2002)
870.1100 - Acute Oral Toxicity (December 2002)
870.1200 - Acute Dermal Toxicity (August 1998)
870.1300 - Acute Inhalation Toxicity (August 1998)
870.2400 - Acute Eye Irritation (August 1998)
870.2500 - Acute Dermal Irritation (August 1998)
870.2600 - Skin Sensitization (March 2003) (PDF)

49 Health Effects Test Guidelines Currently Included

Group B – Subchronic Toxicity Test Guidelines

870.3050 - Repeated Dose 28-Day Oral Toxicity Study in Rodents (July
870.3100 - 90-Day Oral Toxicity in Rodents (August 1998)
870.3150 - 90-Day Oral Toxicity in Nonrodents (August 1998)
870.3200 - 21/28-Day Dermal Toxicity (August 1998)
870.3250 - 90-Day Dermal Toxicity (August 1998
870.3465 - 90-Day Inhalation Toxicity (August 1998)
870.3550 - Reproduction/Developmental Toxicity Screening Test (July 2000)
870.3650 - Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (July 2000)
870.3700 - Prenatal Developmental Toxicity Study (August 1998)
870.3800 - Reproduction and Fertility Effects (August 1998)

Note: An analogous battery of 26 tests is required to characterize ecological effects

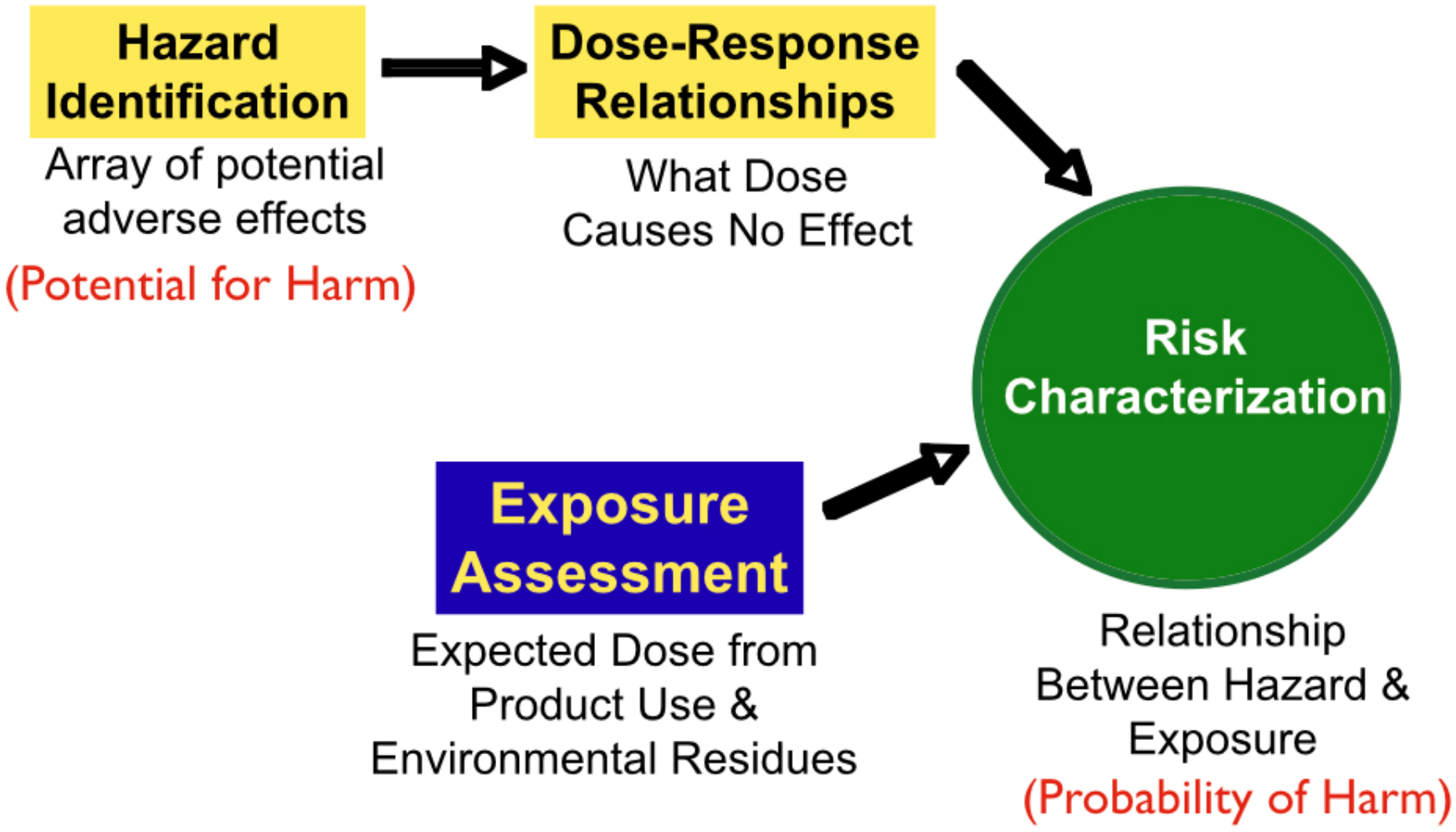
Toxicological Endpoints

- Sublethal Effects
  - ✓ Biochemical
  - ✓ Genetic
  - ✓ Cellular
  - ✓ Physiological
  - ✓ Morphological
  - ✓ Functional
  - ✓ Behavioral
- Lethal Effects
  - ✓ Death

Although these endpoint can be caused by a single dose exposure, often these endpoints are studied in association with repeated exposures

Sublethal effects following repeated "small dose" exposures is often called chronic toxicity, which includes cancer, developmental effects, neurological deficits

Risk Assessment
Estimating the Probability of Harm



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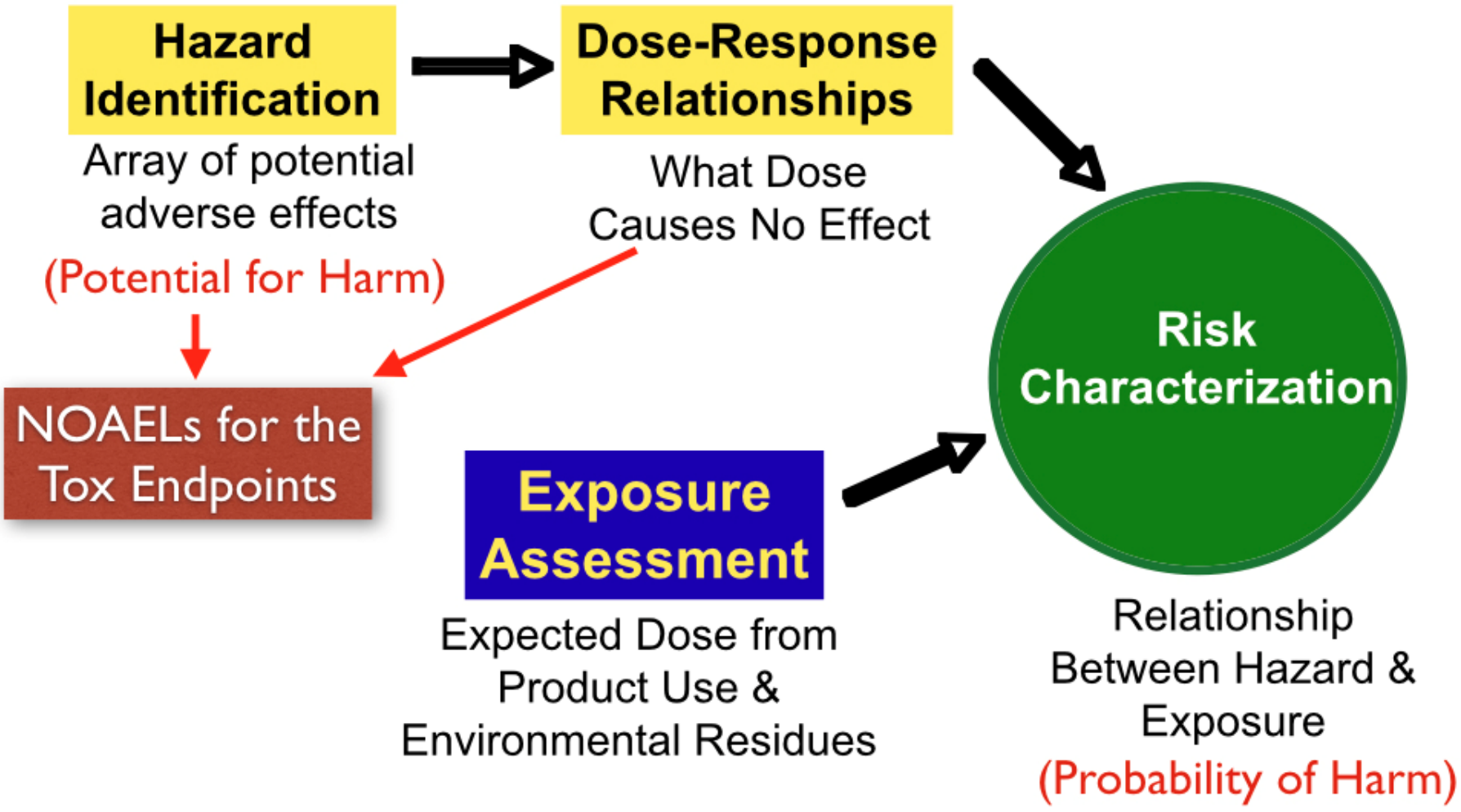
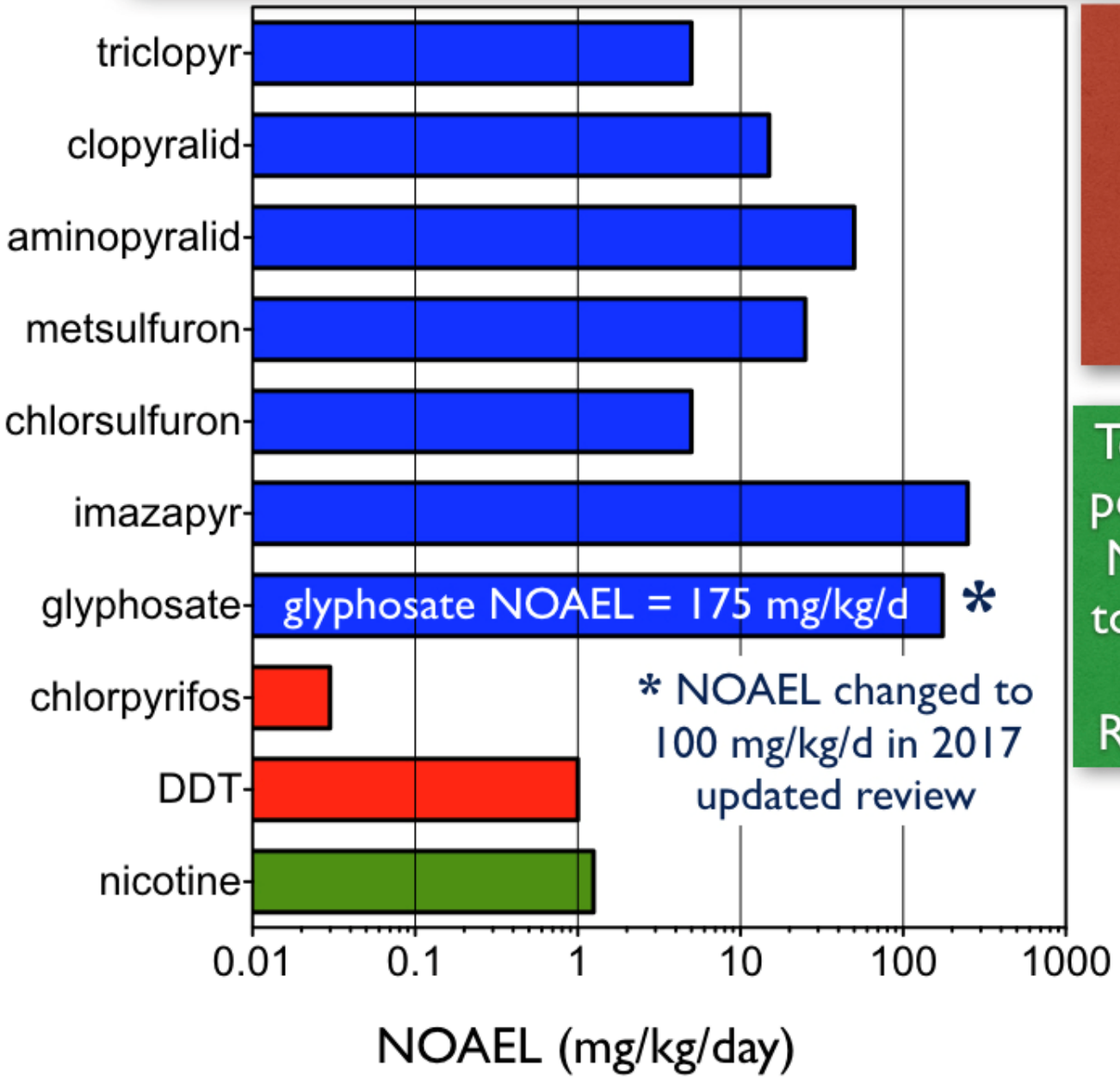


No Observable Effects Levels (Rodent NOAELs)



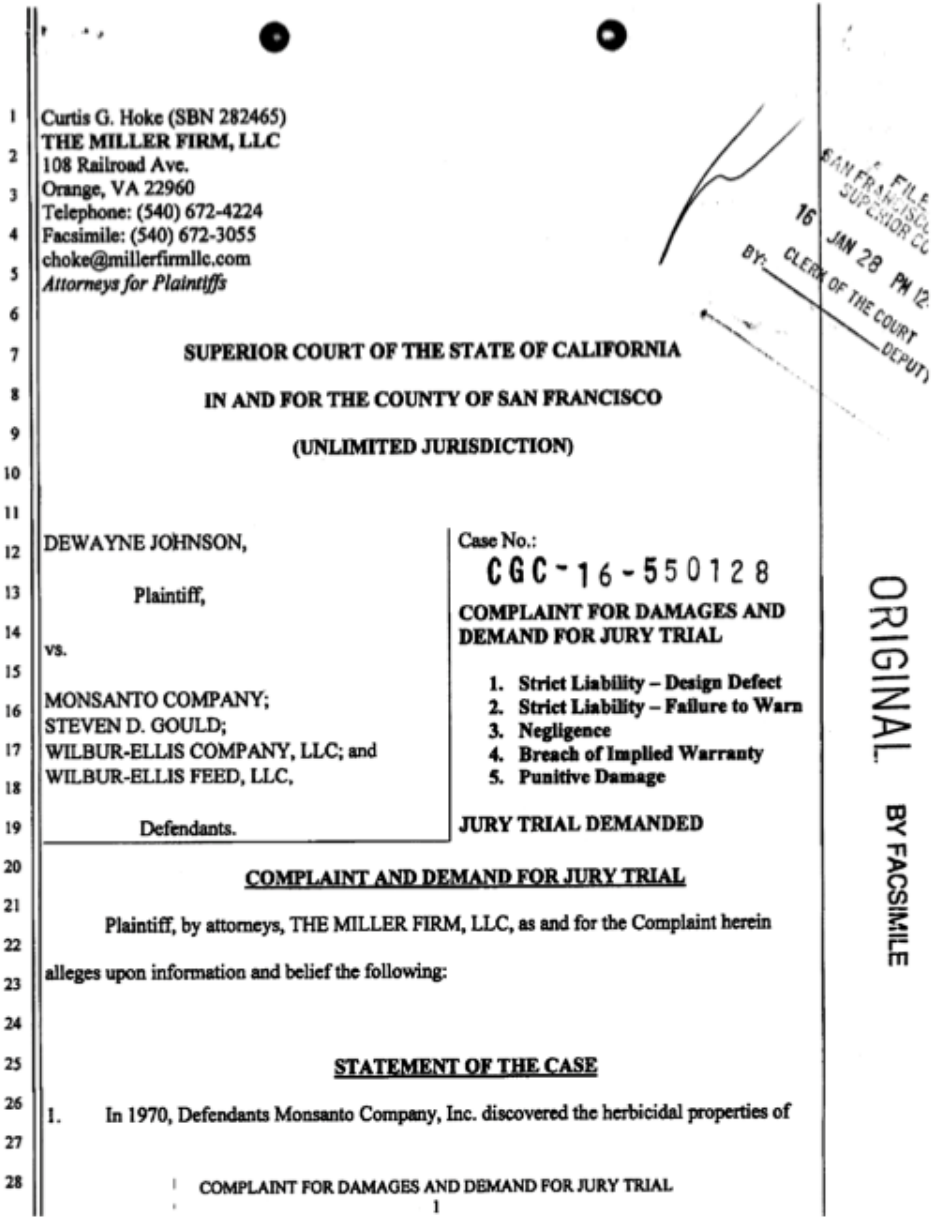
The NOAEL is the only toxicological endpoint for risk assessment and regulatory decisions for registration

To ensure safety for all people, EPA divides the NOAEL by a 100-fold to derive a "safe" dose, which is called the Reference Dose (RfD)

Glyphosate RfD = 1 mg/kg/d

Lawsuit Punitive Damages Rationale

- Defendant's misrepresentations included **knowingly withholding material information from the public**, including the Plaintiff herein, concerning the safety of the subject product



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Attorneys for Plaintiffs

FILED
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SUPERIOR COURT
16 JAN 28 PM 12
BY: CLERK OF THE COURT DEPUTY

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF SAN FRANCISCO

(UNLIMITED JURISDICTION)

DEWAYNE JOHNSON,

Plaintiff,

vs.

MONSANTO COMPANY;
STEVEN D. GOULD;
WILBUR-ELLIS COMPANY, LLC; and
WILBUR-ELLIS FEED, LLC,

Defendants.

Case No.:
CGC-16-550128

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

1. **Strict Liability – Design Defect**
2. **Strict Liability – Failure to Warn**
3. **Negligence**
4. **Breach of Implied Warranty**
5. **Punitive Damage**

JURY TRIAL DEMANDED

ORIGINAL BY FACSIMILE

COMPLAINT AND DEMAND FOR JURY TRIAL

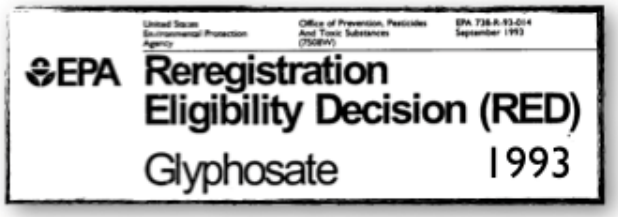
Plaintiff, by attorneys, THE MILLER FIRM, LLC, as and for the Complaint herein alleges upon information and belief the following:

STATEMENT OF THE CASE

1. In 1970, Defendants Monsanto Company, Inc. discovered the herbicidal properties of

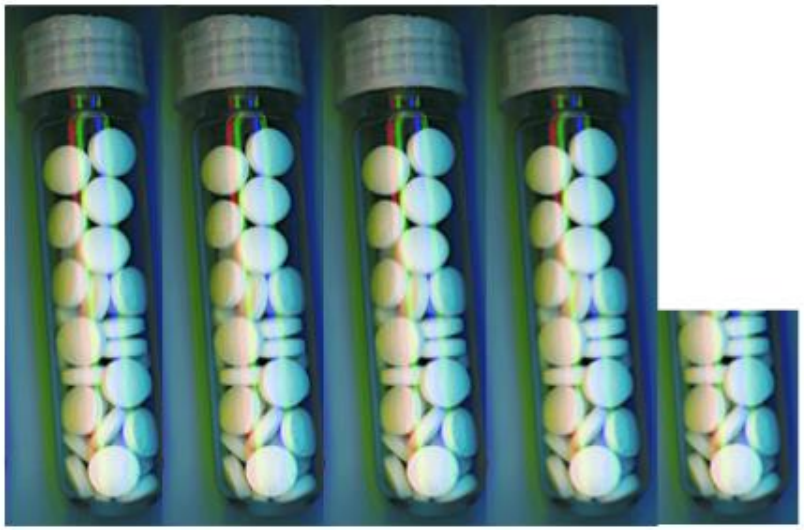
Glyphosate & Systemic Toxicity (Hazards Reported by Industry to EPA)

- Subchronic Studies--90 days continuous dietary exposure--Effects seen at highest dose, 1445 mg/kg/day
  - ✓ Decreased body weight
  - ✓ Pancreatic lesions (males only)
  - ✓ Salivary gland lesions
  - ✓ Increased urea nitrogen in blood
- Chronic studies--2 years continuous dietary; effects @ 1107 mg/kg/day
  - ✓ Decreased body weight
  - ✓ Increased incidence of cataracts, lens abnormalities
  - ✓ Decreased urine pH
  - ✓ Increased liver weight



Get Real!!

- A 1445 mg/kg/day dose, if pelleted as a regular strength aspirin, would be equivalent to >200 tablet per day



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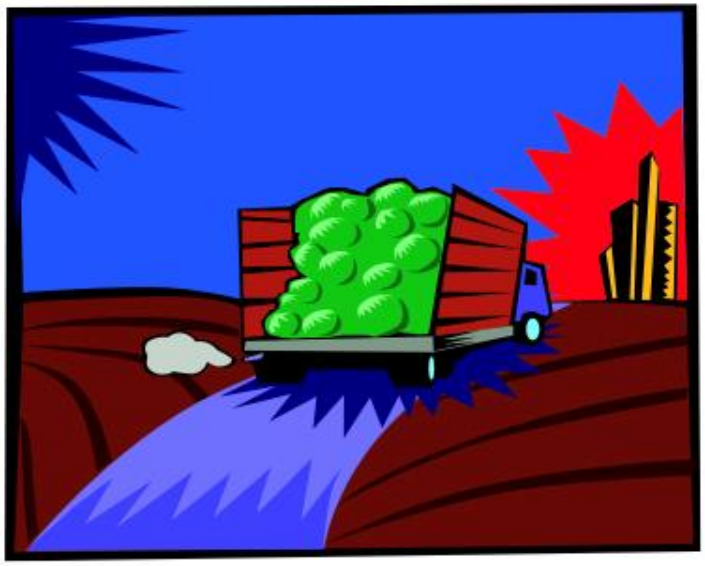
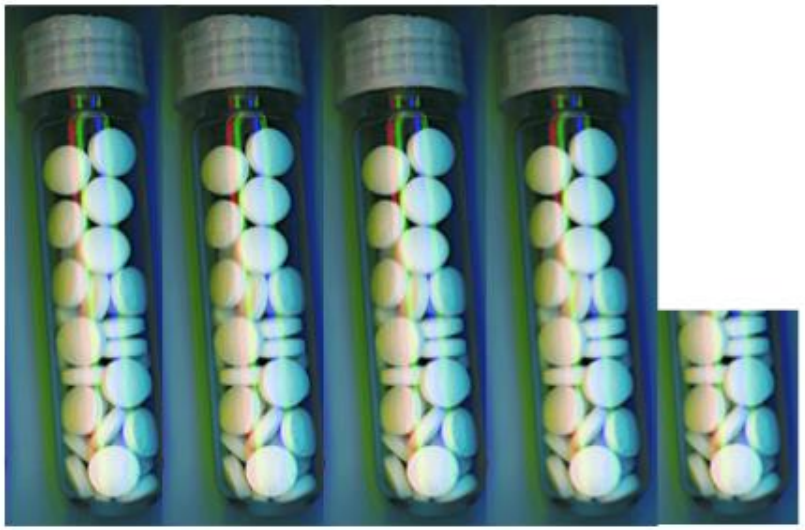




'A real truck load'

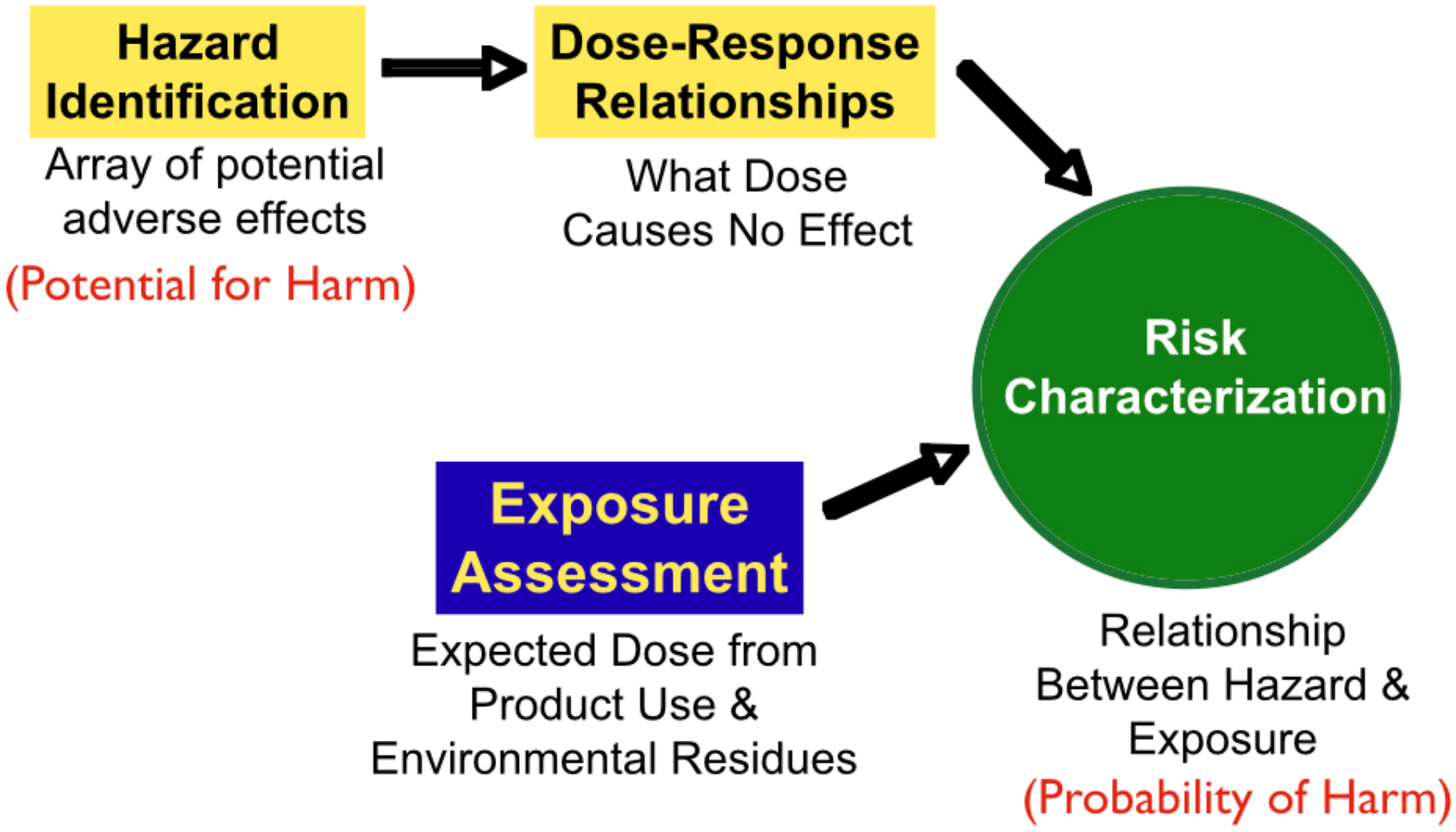
What We Know about the Mammalian Toxicology of POEA (courtesy of analysis by the European Food Safety Agency, EFSA 2015)

Endpoint	Glyphosate	POEA Tallowamine
Acute Toxicity		
Oral LD50	>5000 mg/kg bw	>864 mg/kg bw
Dermal LD50	>2000 mg/kg bw	>907 mg/kg bw
Skin irritation	non irritant	irritant
Skin sensitizing	non sensitizing	sensitizing
Eye irritation	moderate to severe	severe
Mutagenicity		
Gene mutations	negative	negative
Chromosome aberrations	negative	negative
DNA damage	negative	@ high & toxic doses

What We Know about the Mammalian Toxicology of POEA (courtesy of analysis by the European Food Safety Agency, EFSA 2015)

Endpoint	Glyphosate NOAEL (mg/kg bw)	POEA Tallowamine NOAEL (mg/kg bw)
Short term toxicity		
Rat, oral 90-day	150	20
Dog, oral ~90-day	300	21
2-Generation Reproduction Toxicity		
Parental toxicity	700	38
Reproductive toxicity	2000	12
Offspring toxicity	700	12
Developmental Toxicity		
Maternal Toxicity	300	10.8
Developmental Toxicity	300	72

Risk Assessment
Estimating the Probability of Harm



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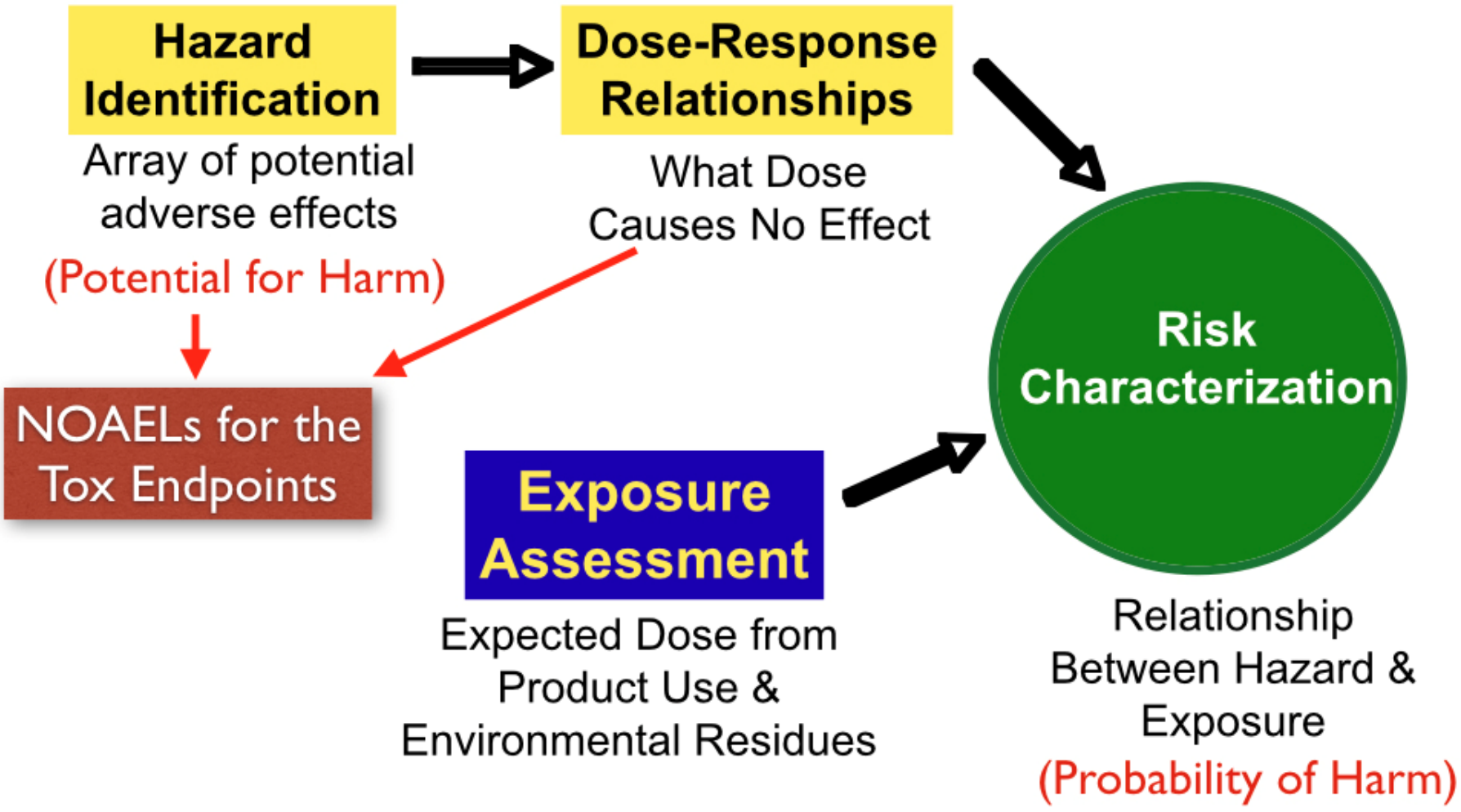
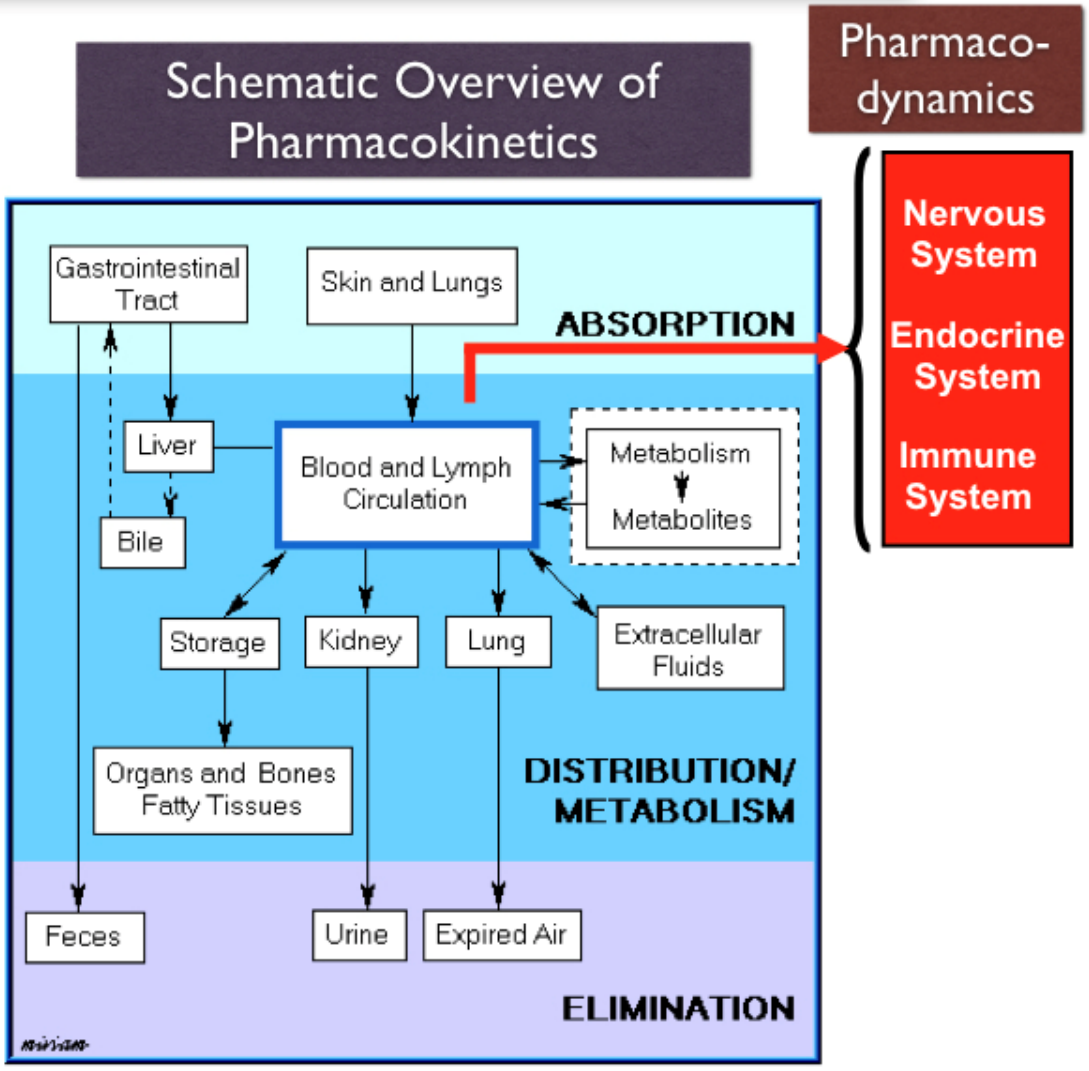


"Enquiring" Minds Want to Know

- How can modern pesticides be toxic to pests but when used as prescribed by the label, be pretty safe for everything else?

Why Are "Toxins" Selective

- Pharmacodynamics
  - ✓ **Interaction with target macromolecule (enzyme or cell receptor) is low in nontarget organism compared to pest**
- Pharmacokinetics
  - ✓ **Aggregated processes of absorption, distribution, metabolism, & excretion (ADME)**



Why Are "Toxins" Selective

- Pharmacodynamics
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    - ✳ **No biochemical pathway in non-target organisms**
    - ✳ Unfavorable binding kinetics at most likely environmental exposures
- Pharmacokinetics
  - ✓ **Aggregated processes of absorption, distribution, metabolism, & excretion (ADME)**
    - ✳ Low dermal penetration potential in nontarget organisms
    - ✳ High detoxification & excretion rate in nontarget organism compared to pest

Why is Glyphosate (and Many Other Herbicides) of Such Low Toxicity to Animals?
Answer: Pharmacodynamics

Known Toxic Mechanisms at Environmental Levels of Exposure

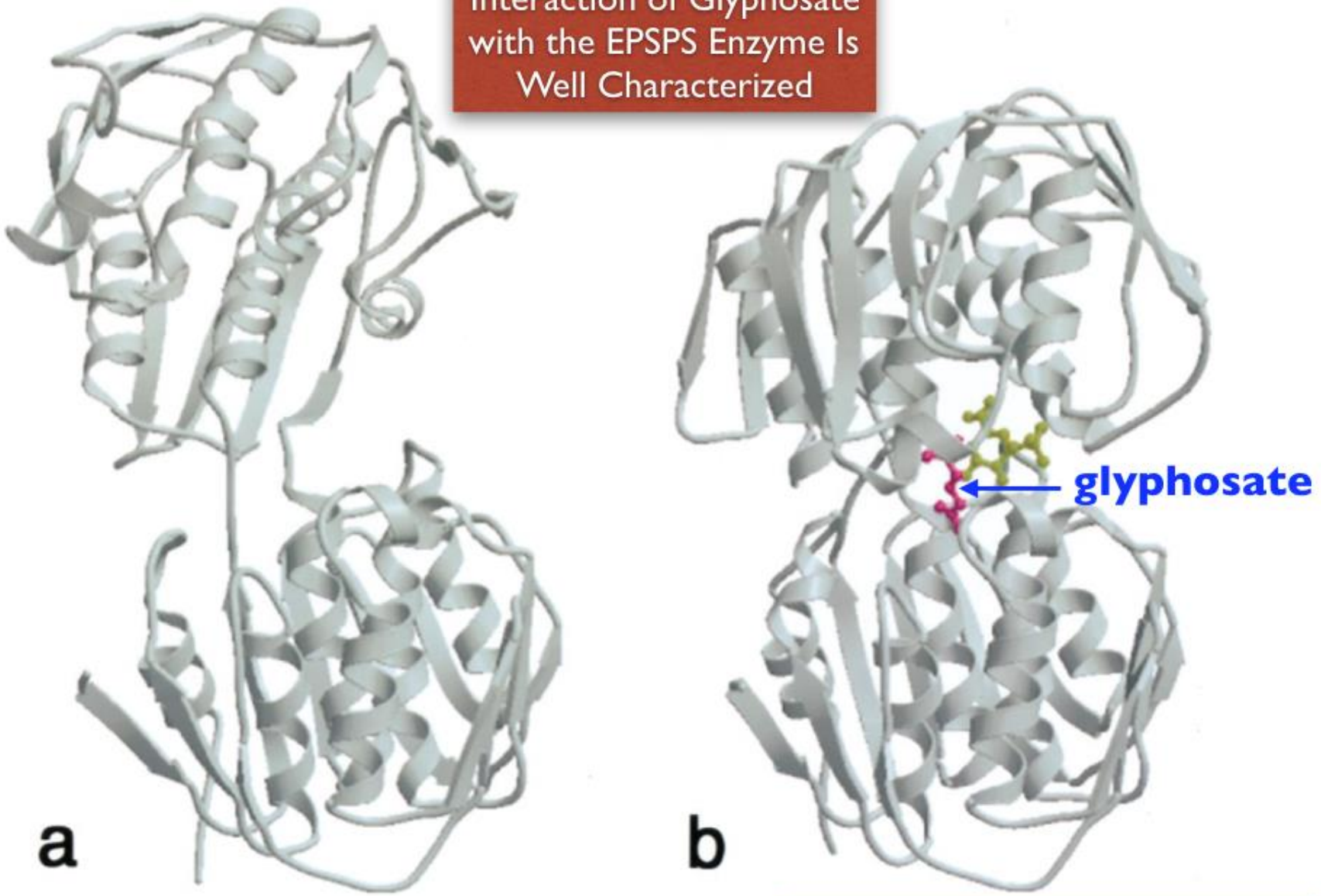
Active Ingredient	Formulated Product	Mechanism of Action
glyphosate *	Roundup	Inhibits EPSPS enzyme & thus aromatic amino acid synthesis
imazapyr	Arsenal	Inhibits ALS enzyme & thus branched chain amino acid synthesis
chlorsulfuron metsulfuron-methyl	Telar Escort	Inhibits ALS enzyme & thus branched chain amino acid synthesis
aminopyralid, clorpyralid, triclopyr	Milestone, Transline, Garlon	Mimic the hormonal action of auxin, the "plant growth hormone"

These biochemical targets are lacking in animals

EPSPS Enzyme in Open Conformation
(No Ligand)

Closed Conformation
(Ligand w/ Glyphosate & S3P)

Interaction of Glyphosate with the EPSPS Enzyme Is Well Characterized



Schonbrunn et al. (2001) PNAS 98:1376

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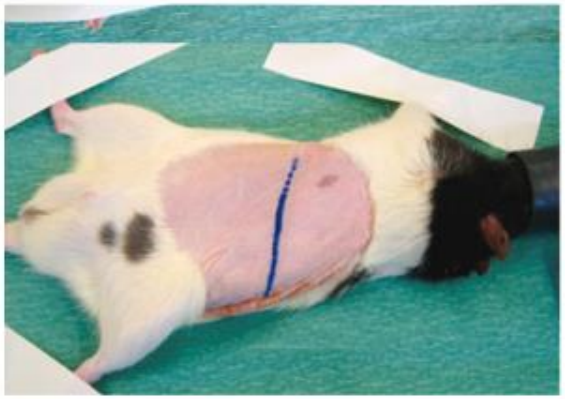
Comparison of Dermal Toxicity Relative to Dermal Penetration



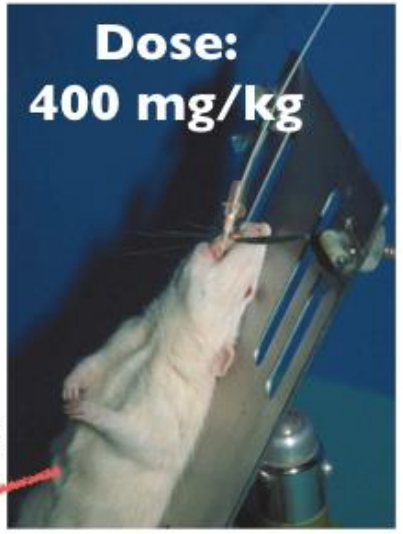
	24-h Dermal Penetration
nicotine	~32 - 100%
2,4-D	~6%
fluazifop-P-butyl	~2 - 9%
glyphosate	~2 %

0 1000 2000 3000 4000 5000 6000

LD50 (rat, mg/kg)

Metabolism of Glyphosate in Rodents after Oral & IV Exposure

Anadon (2009)



Oral Bioavailability: 23%

Plasma concentration (µg ml^{-1})

1000
100
10
1
0,1
0,01

$T_{1/2}$ = 14.4 h — Glyph Oral

$T_{1/2}$ = 10.0 h — Glyph IV

$T_{1/2}$ = 15.8 h — AMPA

>99% of IV dose eliminated after 24 h

0 5 10 15 20 25

Time (h)

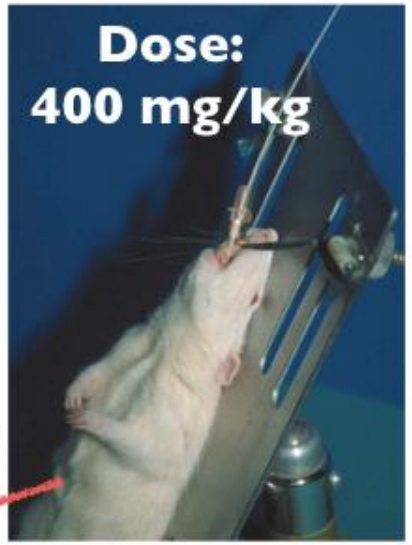
Elimination Half Life = $T_{1/2}$

Maximum Plasma Concentration = 4.62 µg/mL

Metabolism of Glyphosate in Rodents after Oral & IV Exposure

Anadon (2009)

The highest applicator exposure to glyphosate is ~ 0.004 mg/kg



Oral Bioavailability: 23%

Elimination Half Life = $T_{1/2}$

Maximum Plasma Concentration = 4.62 µg/mL

What Else Is New?

Formulations of glyphosate-based weedkillers are toxic, tests show

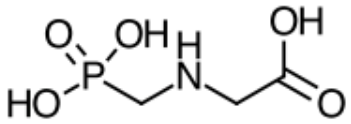
Government scientists say danger lies with added ingredients in the products not glyphosate

▲ One of the world's best-known glyphosate-based products is Monsanto's Roundup weedkiller. Photograph: Mike Blake/Reuters

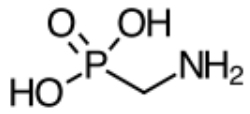
Tests by a US government agency on common weedkilling products made with the chemical glyphosate have found some formulations sold to the public to be genotoxic, meaning they are damaging to human DNA.

Glyphosate vs Formulation: Effect on Cell Viability

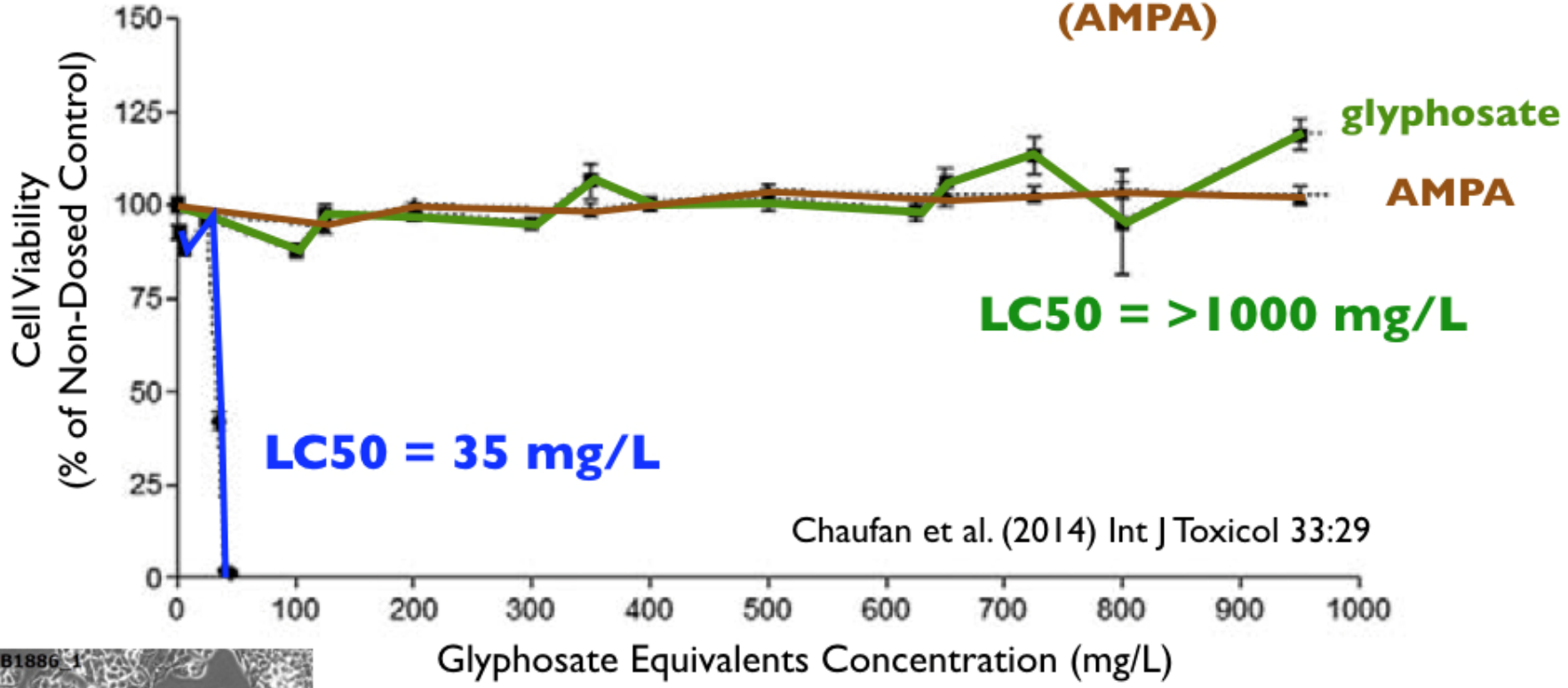
72 Hour Exposure

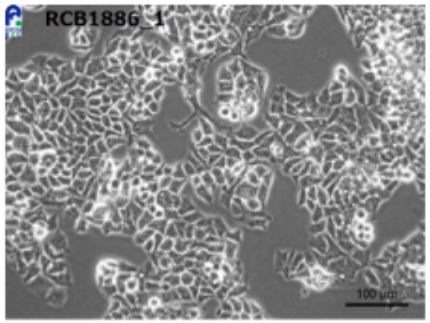


glyphosate



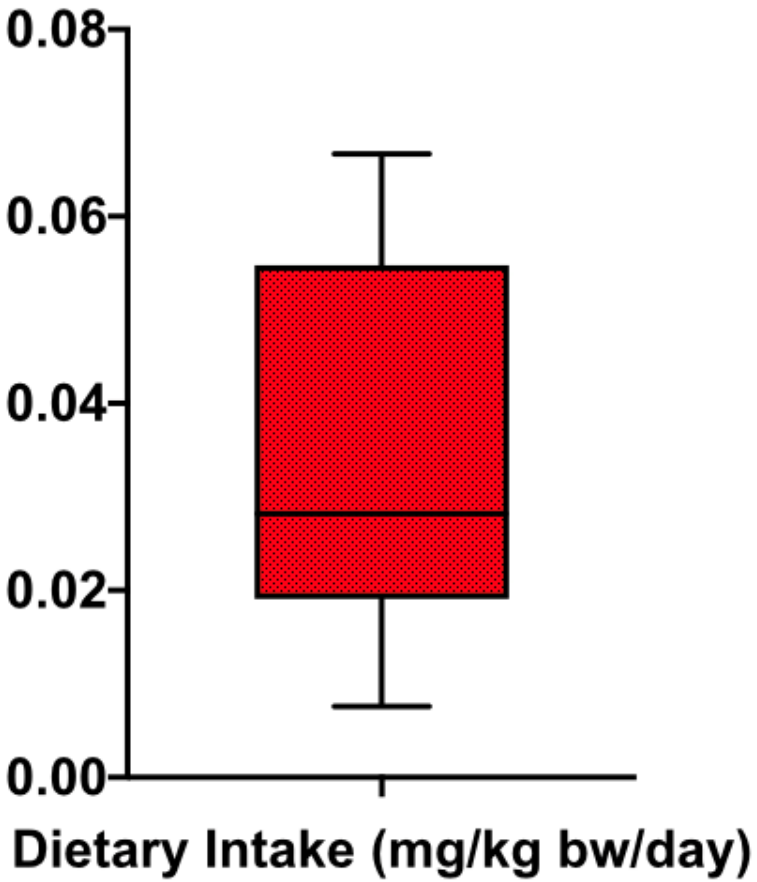
aminomethylphosphonic acid (AMPA)





HepG2 cells (human liver tumor cells) were exposed in culture to different concentrations of glyphosate technical, AMPA (the metabolite), and a glyphosate formulation

Estimated Dietary Intake Distributions for POEA Based on Glyphosate Residues in Food



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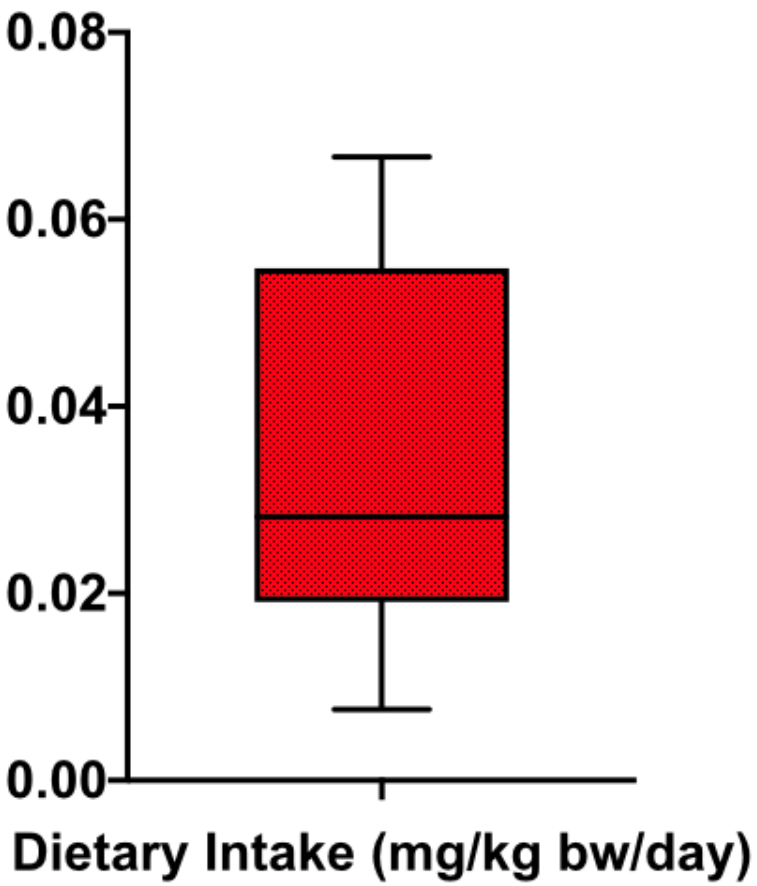
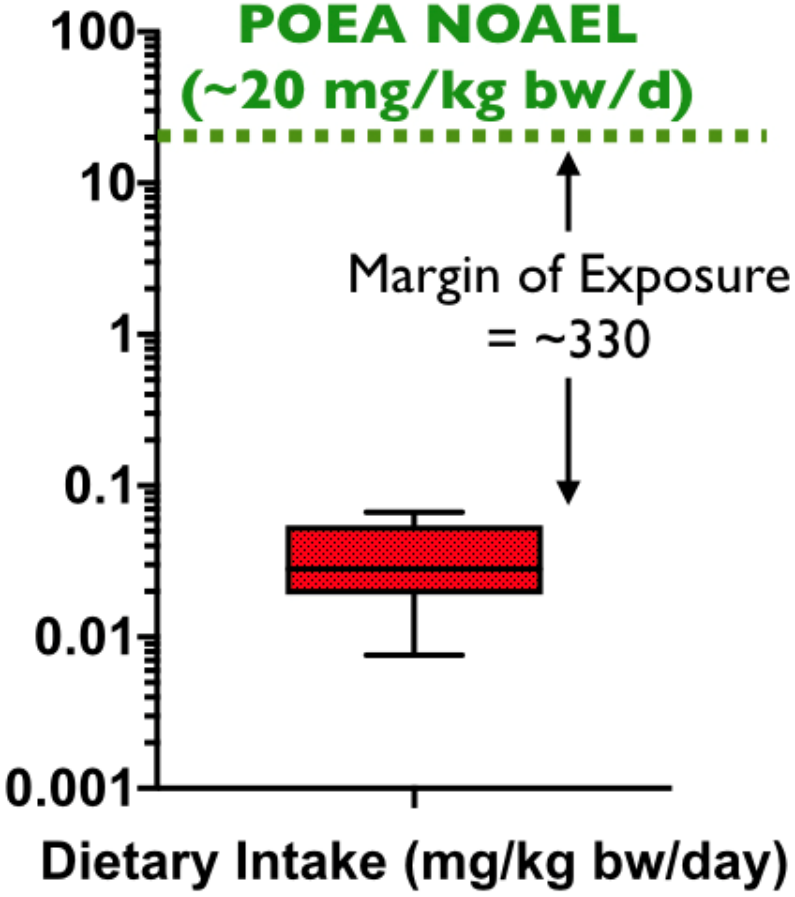




Environmental Chemistry Determines Inerts Exposure Potential

- Direct exposure potential for consumers is to a highly diluted sprayed product (i.e., mostly water), thereby reducing risk substantially, or to residues in the diet

  ✓ Dietary exposures are at least 100s to 1000s of times **lower** than the doses of glyphosate or POEA surfactant known to cause **NO adverse effects** in repeated exposures toxicology tests

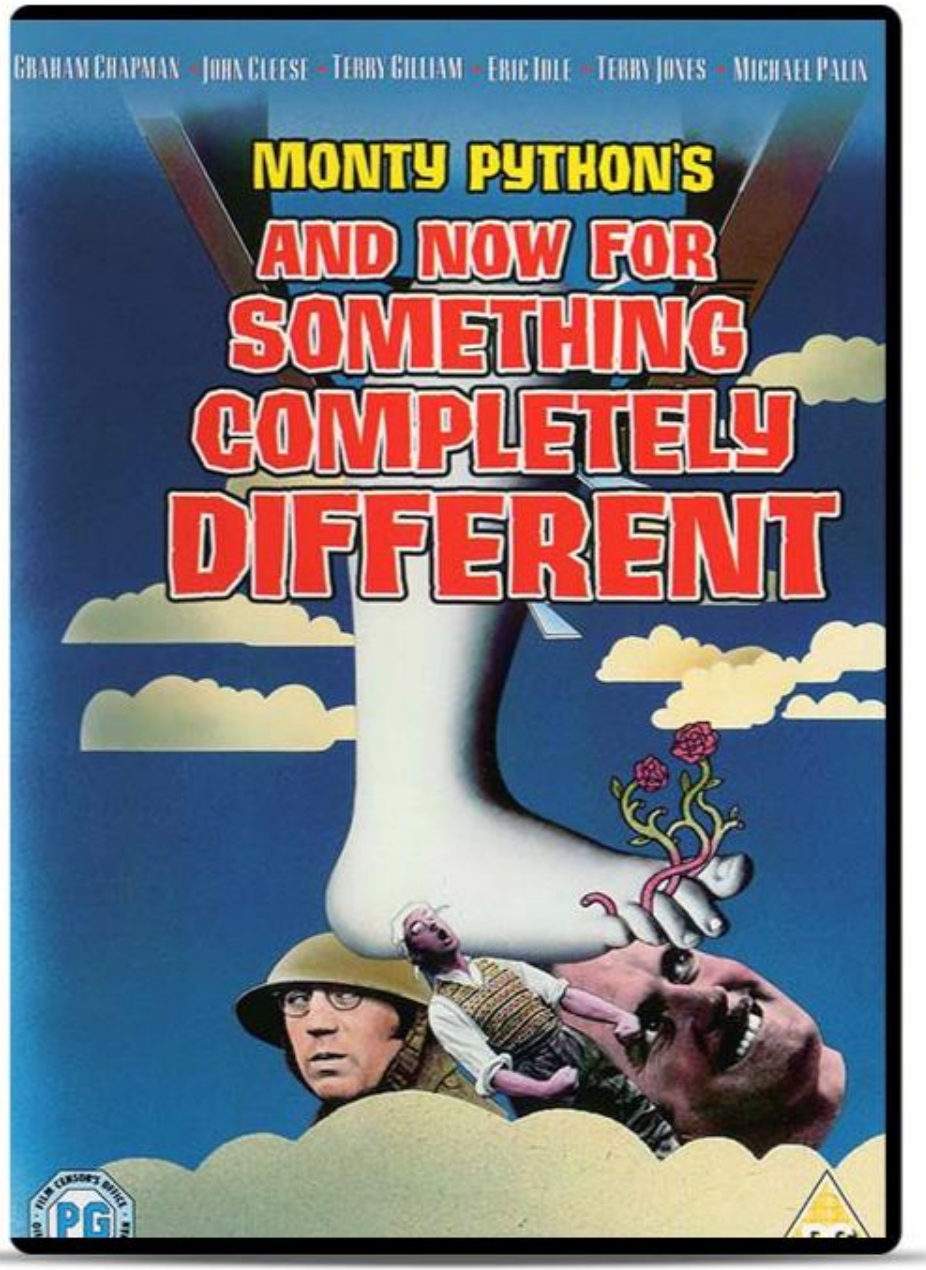
- Post spray exposures to skin are to residues of active ingredient or residues of inerts that are mostly the functional equivalent of soaps (surfactants)

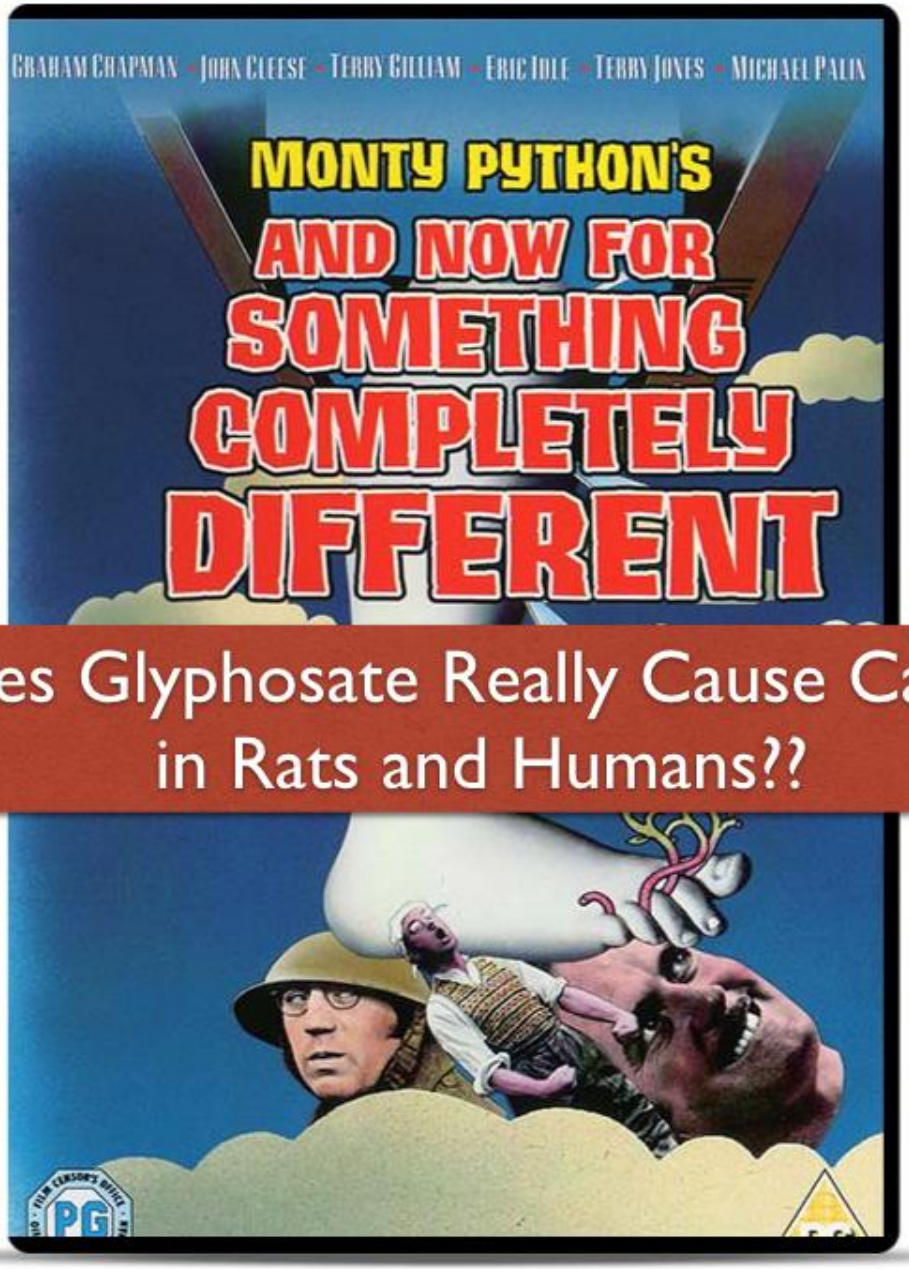
  ✓ The molecular weight of many agricultural surfactant ingredients are too large for efficient skin penetration, however, they can increase flux of active ingredients (AIs) across the epidermis

  ✓ Many modern pesticide AIs themselves do not penetrate skin efficiently

    ✴ AIs in formulations penetrate slower than AIs in diluted sprays!

- The inert chemicals and active ingredients behave **independently** of one another


GRAHAM CHAPMAN • JOHN CLEESE • TERRY GILLIAM • ERIC IDLE • TERRY JONES • MICHAEL PALIN
MONTY PYTHON'S
AND NOW FOR
SOMETHING
COMPLETELY
DIFFERENT
PG



Does Glyphosate Really Cause Cancer in Rats and Humans??

Why Did IARC Conclude Glyphosate is a Probable Carcinogen?

- IARC is all about describing hazards, not risks
- Risk cannot be known unless exposure is characterized
- However, IARC claims to use a weight of evidence approach, but for glyphosate, the agency seemed to ignore the significance of "negative" studies and the meaning of confidence intervals

Weed Killer, Long Cleared, Is Doubted

The New York Times

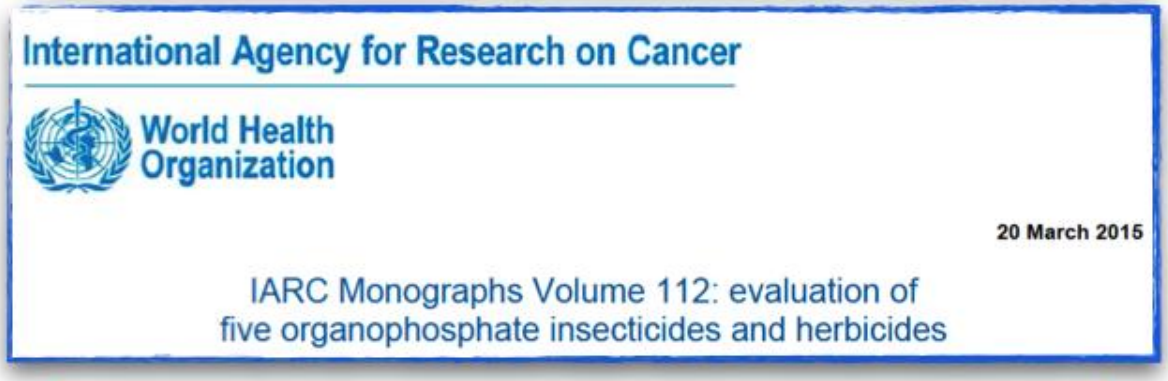
By ANDREW POLLACK MARCH 27, 2015

Thirty years ago, an Environmental Protection Agency committee determined that the popular weed killer Roundup might cause cancer. Six years later, in 1991, the agency reversed itself after re-evaluating the mouse study that had been the basis for the original conclusion.

Now the issue is back again, in an even bigger way. An agency of the World Health Organization has declared that glyphosate, the active ingredient in Roundup, "probably" causes cancer in people. One piece of evidence the agency cites is that same mouse study.

The declaration drew an angry response from Monsanto, the maker of Roundup, which has accused the agency of having an "agenda" and "cherry picking" the data to support its case.

Glyphosate being sprayed on a field in Suffolk, England. Introduced in the 1970s, it is the most widely used herbicide in the world. Universal Images Group, via Getty Images



International Agency for Research on Cancer

World Health Organization

20 March 2015

IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides

IARC reviewed epidemiological studies, concluding evidence supported association with non-Hodgkin's lymphoma (NHL). Conclusion backed up by review of genotoxicity studies.

Glyphosate & Cancer: A Hypothesis Generating Study?

Data taken from the paper by Hardell & Erikkson (1999), claiming they "saw" an increased association of NHL cancer with glyphosate exposure

Agent	Exposed Cases	Exposed Controls	Odds Ratio	95% Confidence Interval
All Herbicides	61	81	1.6	1.0 - 2.5
Phenoxys	51	71	1.5	0.9 - 2.4
Glyphosate	4	3	2.3	0.4 - 13
Insecticides	90	139	1.2	0.8 - 1.7

Curiously, no mention of glyphosate in the abstract. But in the results, this statement: "Both exposure to glyphosate and other herbicides yielded increased risks for NHL." Finally, "For these reasons, glyphosate deserves further epidemiologic studies."

And Now…Definitions

$$\text{Odds Ratio (OR)} = \frac{\text{Odds of Exposure in Diseased Group}}{\text{Odds of Exposure in Non-diseased Group}}$$

An OR > 1.0 is interpreted as a positive association (correlation) between a disease and the hypothetical cause of that disease.

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Thus, every OR estimation has a 95% CI associated with it, showing the upper and lower bound of the estimated OR. When the lower bound of the OR is less than 1.0, then no conclusion can be made about the association.

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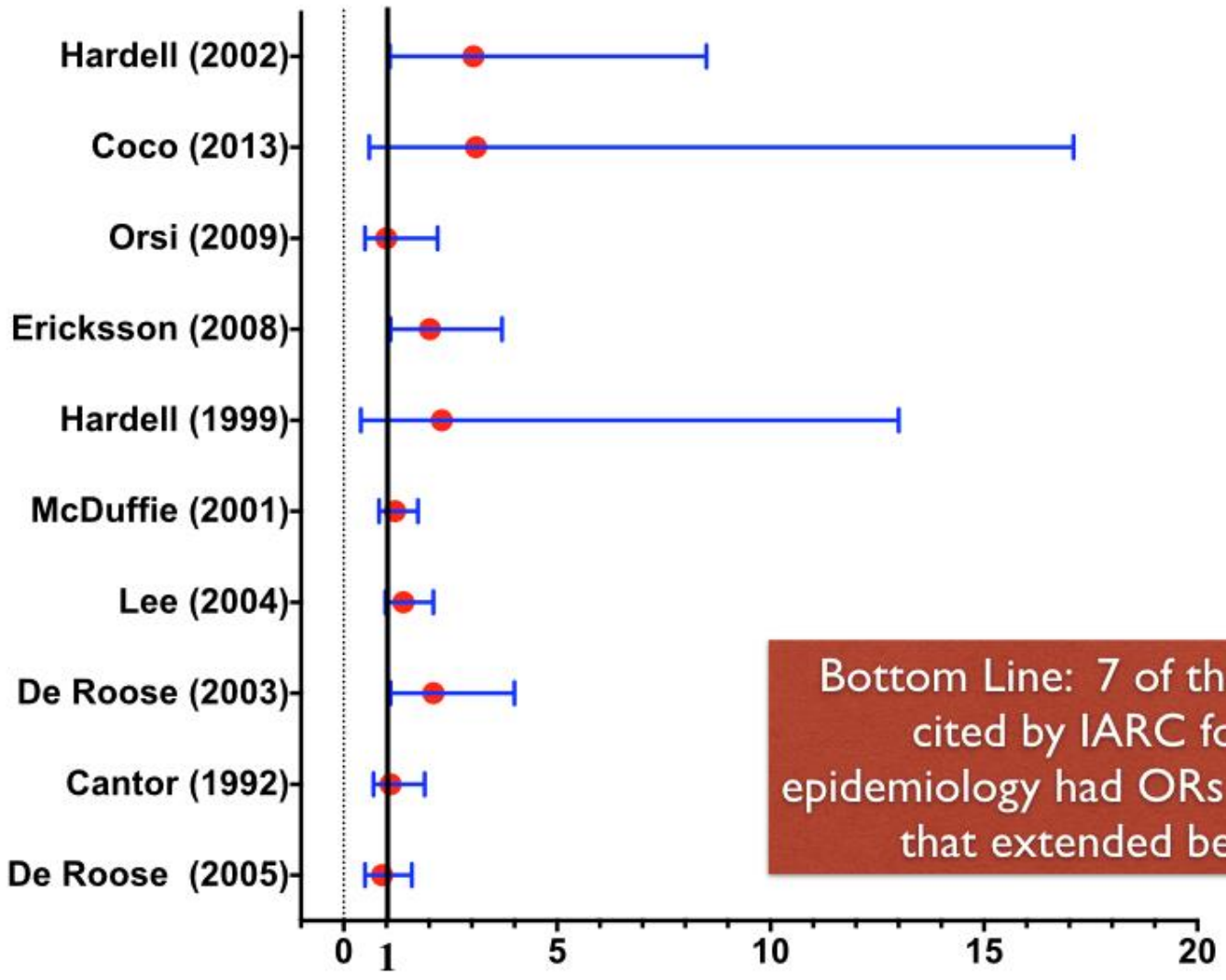
Overview of Odds Ratios for NHL Reviewed by IARC



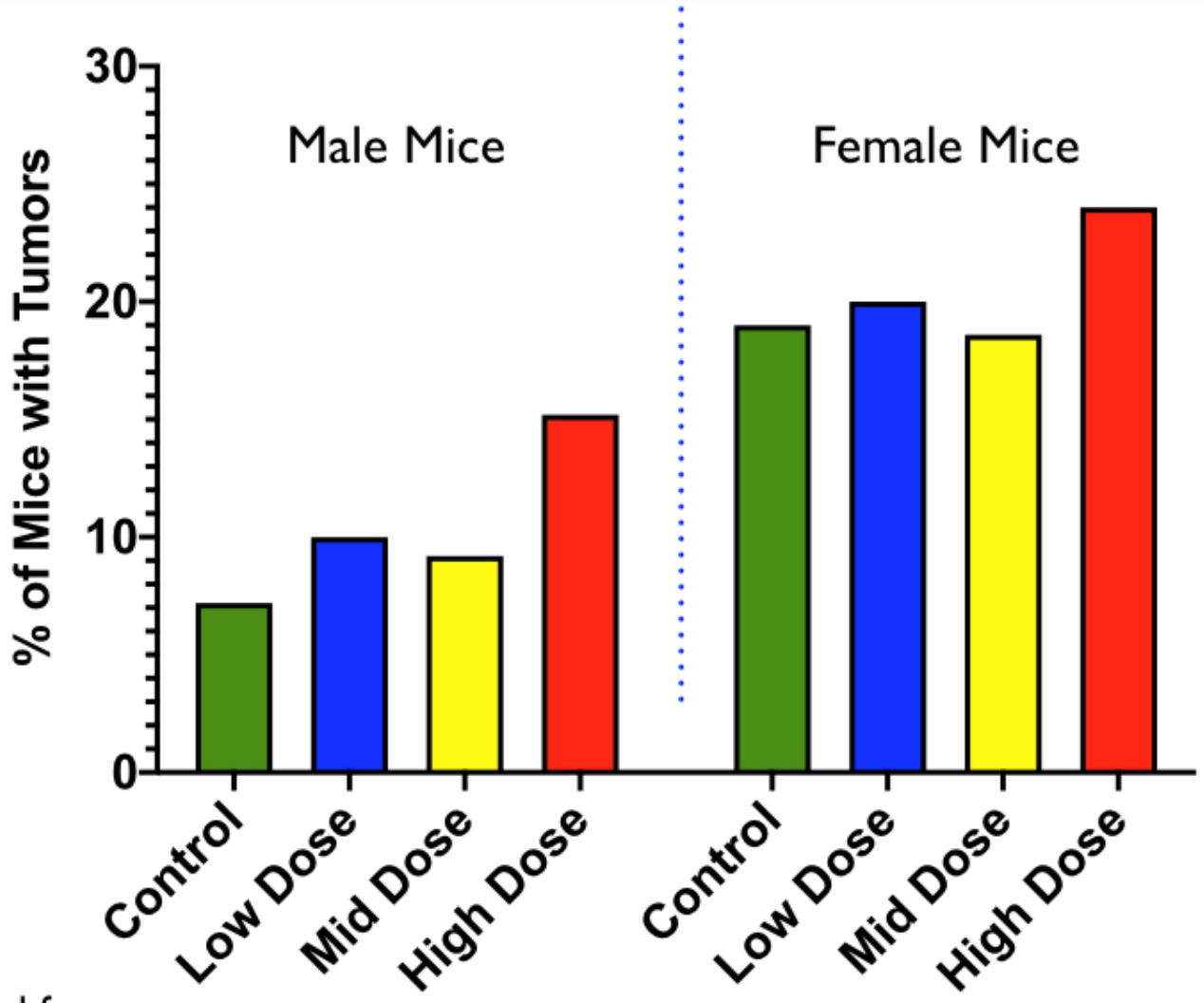
Bottom Line: 7 of the 10 studies cited by IARC for NHL epidemiology had ORs with 95% CIs that extended below 1.0

Desperately Seeking a Mechanism
Aggregation of IARC Cited Studies for In Vivo Genotoxicity Tests with Rodents

Parameter	Glyphosate Tech.	Formulated Product	Dose Range (mg/kg bw)
Number of Studies or Cell Types Measured	12	13	
Dose Administration	Single Intraperitoneal	Single Intraperitoneal or Drinking Water	
# Positive (for any genotoxic effect)	6	8	200 - 2000
# Negative	6	5	25 - 1080

Highest estimated systemic dose of pesticide applicators: 0.004 mg/kg bw
(Aquavella et al. 2004, Environ Health Perspectives 112:321-326)

Dose Response Graphs for Malignant Lymphoma in Five Mouse Carcinogenicity Studies (18 - 24 month Dietary Exposure)



High dose ranged from 810-7470 mg/kg bw/day

(Based on Portier 2020)

EPA Weighs In

- 7 of the 9 animal feeding studies (2-yrs of exposure) showed **no evidence of excess tumors**, even at doses of 1000 mg/kg bw/day

Glyphosate Issue Paper:
Evaluation of Carcinogenic Potential

EPA's Office of Pesticide Programs
September 12, 2016

- Glyphosate is **not mutagenic** nor does it cause chromosomal breakage

Potential for Dietary Exposure:
How Many Pounds of Soybeans Is Equivalent to a Dose of 1000 mg/kg BW

The tolerance for glyphosate residues on soybeans = 20 ppm

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x 1000 bags!!!!!!!!

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x 1000 bags!!!!!!!!

That's a lot of tofu!!

EPA Weighs In

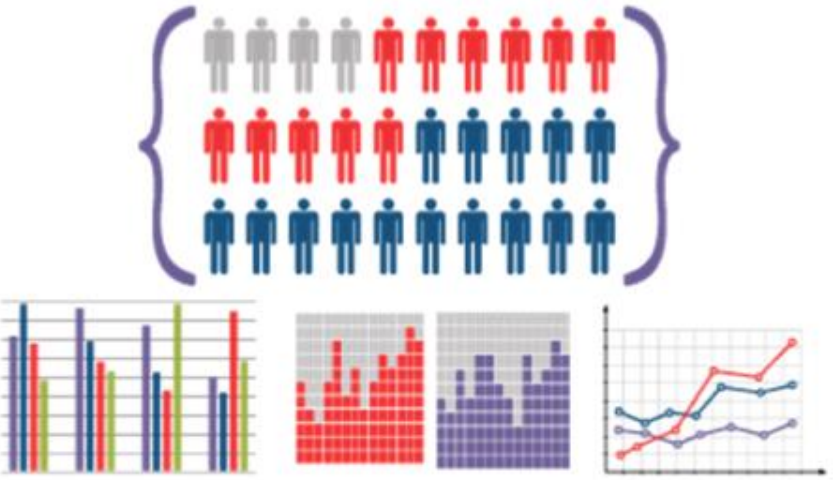
- EPA reviewed all the epidemiological studies cited by IARC and those IARC chose to 'ignore'

✓ EPA concluded, "…due to conflicting results and various limitations identified in studies investigating NHL, a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data"

Glyphosate Issue Paper:
Evaluation of Carcinogenic Potential

EPA's Office of Pesticide Programs
September 12, 2016

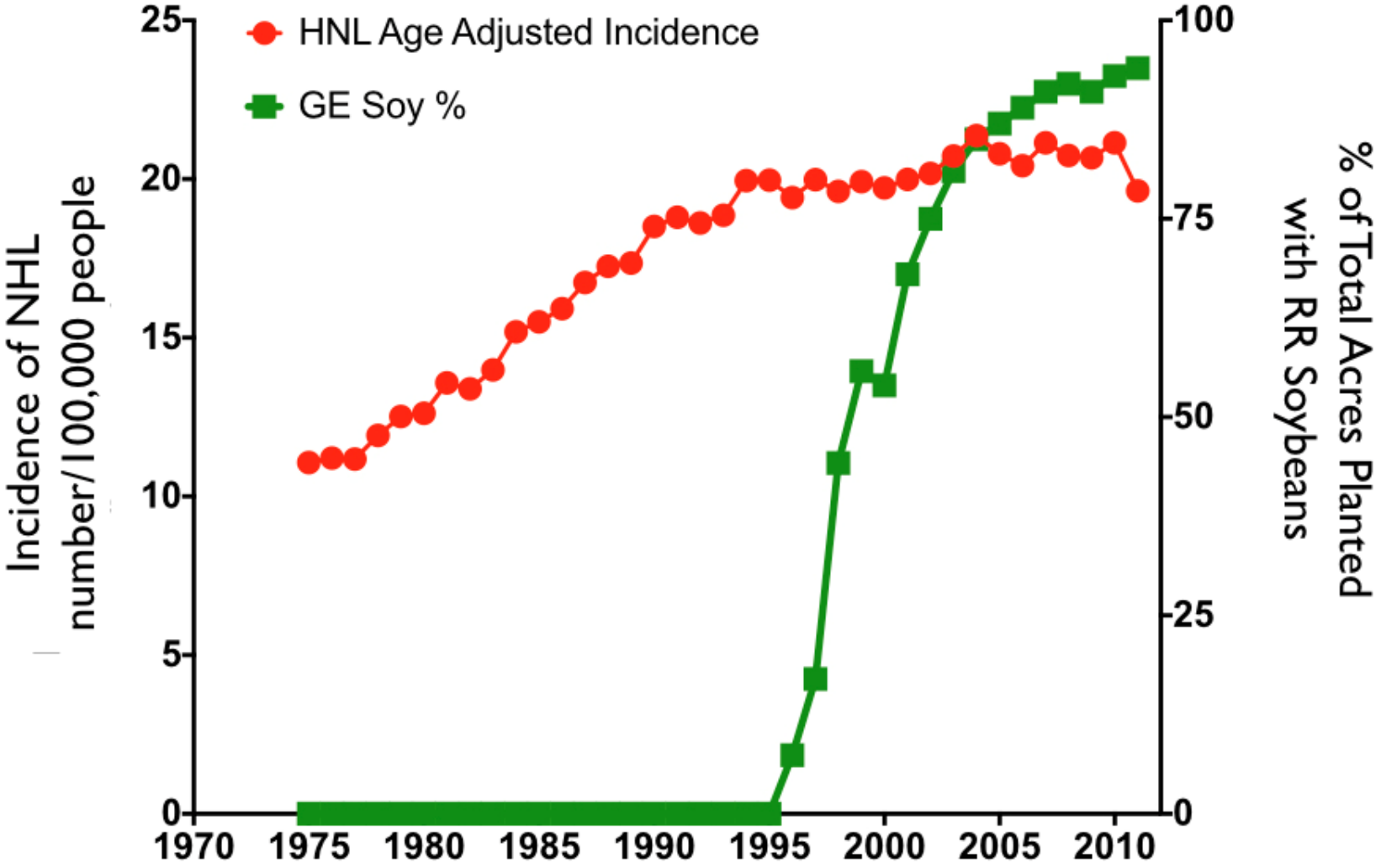
Epidemiology:
Study of disease incidence and its association with pathogens, chemicals, and lifestyle factors



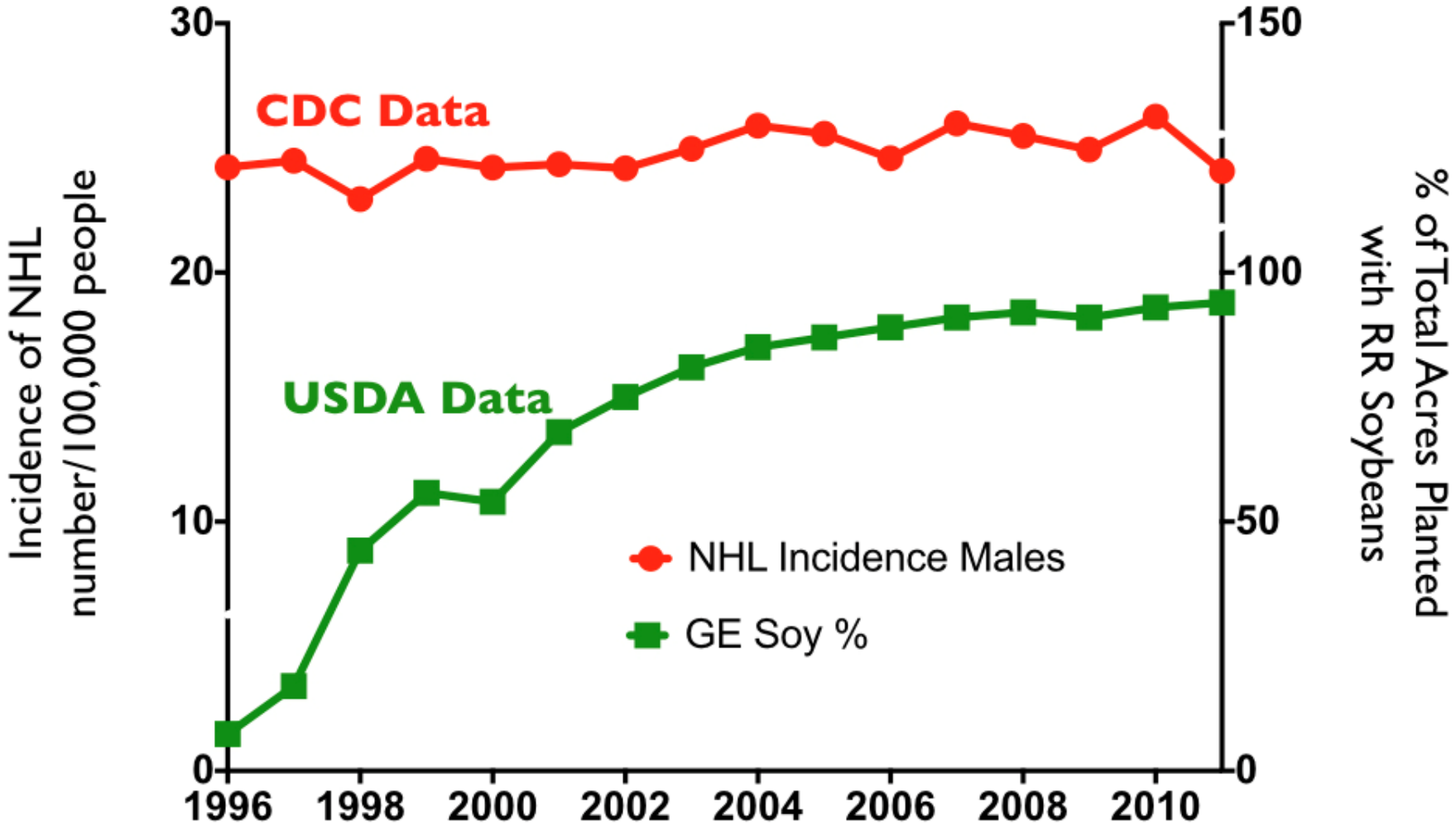
Is Declaration of Glyphosate as a Probable Human Carcinogen Amenable to Hypothesis Testing?

- Hypothesis: Glyphosate is a probable human carcinogen as evidenced by trend in rate of incidence of non-Hodgkin's Lymphoma (NHL)
- Prediction: Trend in rate of incidence of NHL should be rising coincidentally with trend in rate of use of glyphosate products (e.g., Roundup)
- Test:
  - ✓ Use rate of NHL incidence trends from statistical database of the NCI SEER (U.S. National Cancer Institute Surveillance, Epidemiology, and End Results Program)
  - ✓ Use trends in Roundup Ready crop plantings available from the USDA Economic Research Service and the National Agricultural Statistics Service

Trends in NHL Incidence Do Not Reflect Trends in US Plantings of RR Soybeans



A Closer Perspective:
Trends in NHL Among Males & Use of RR Soybeans



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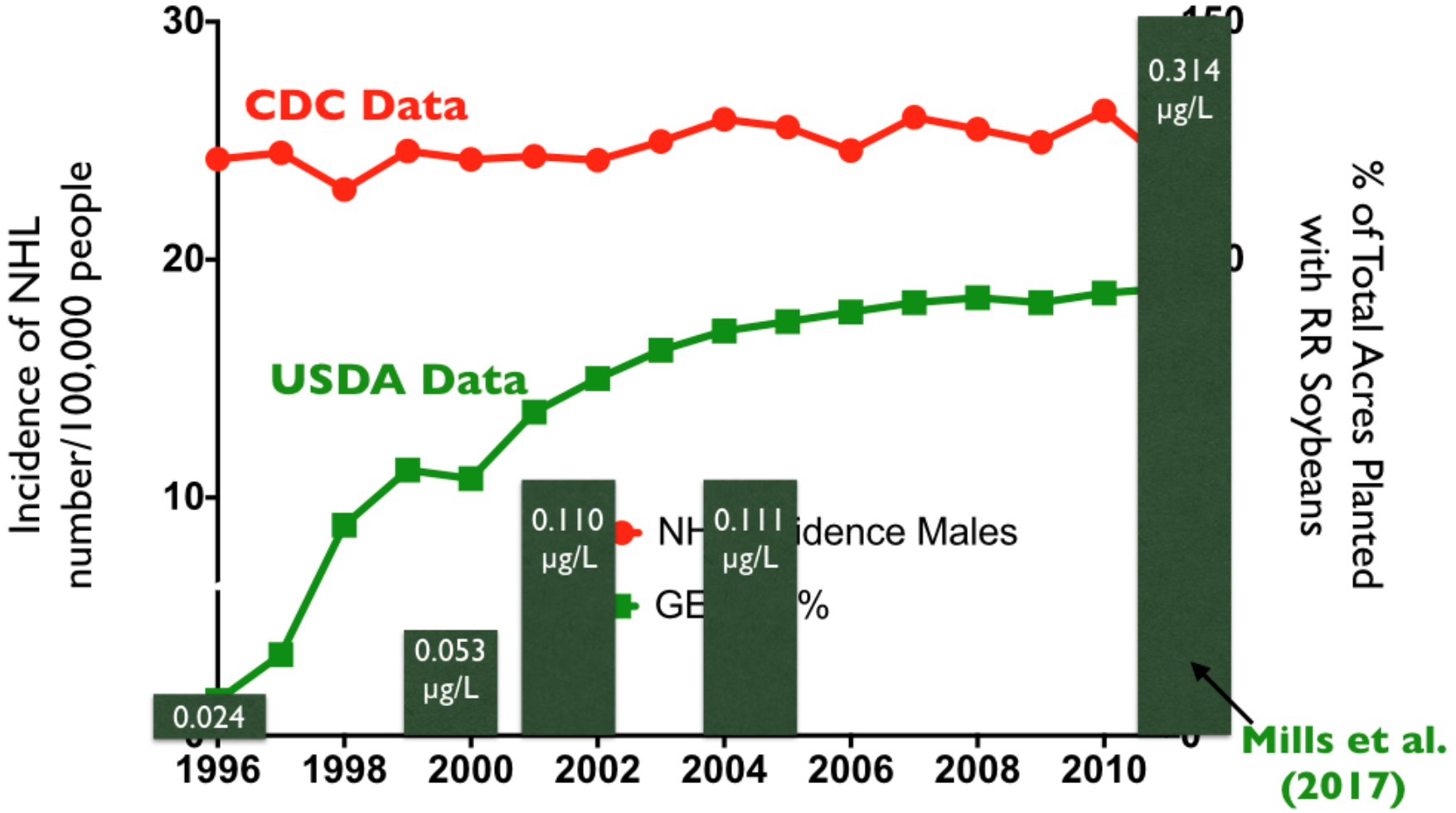

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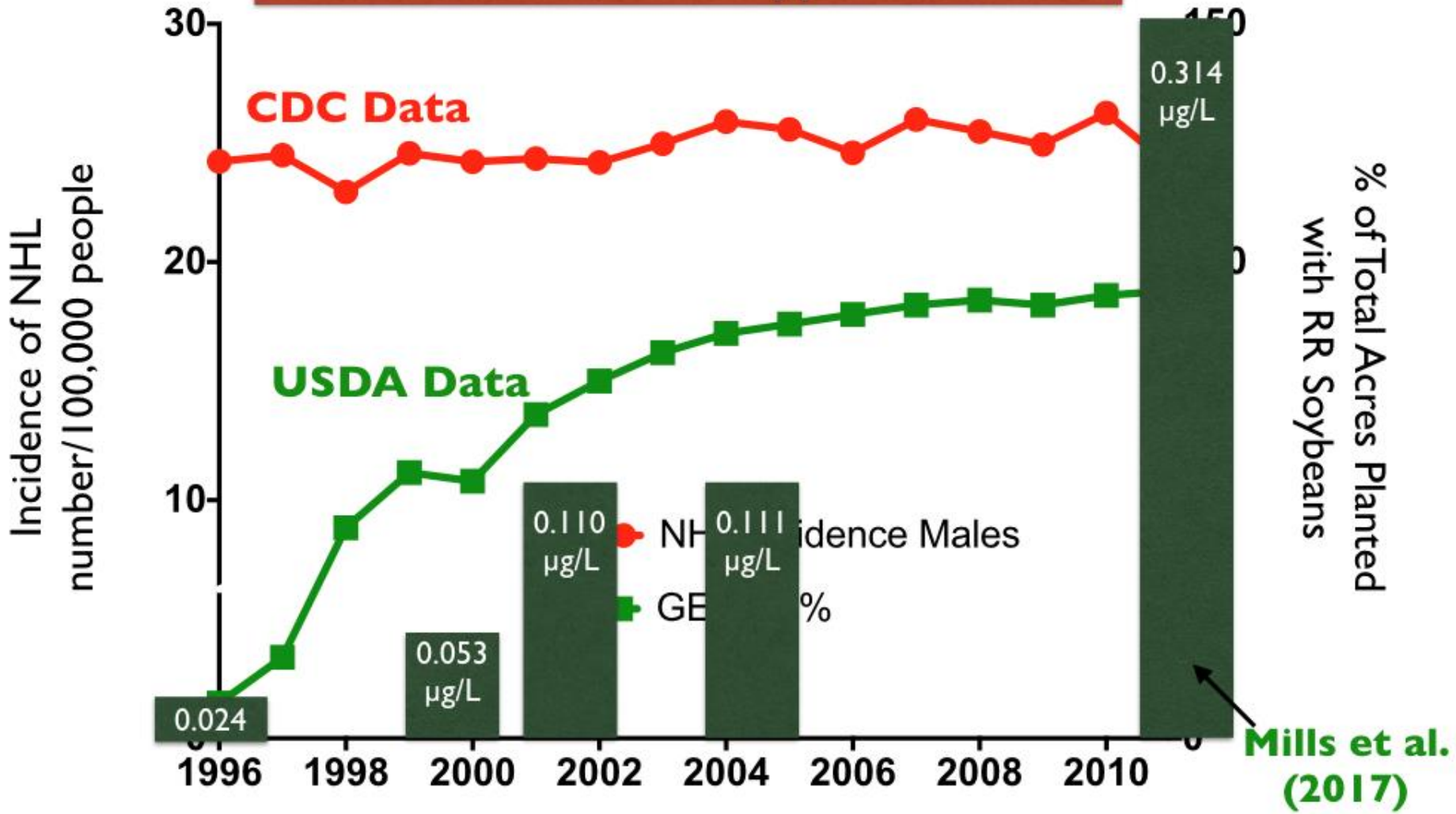
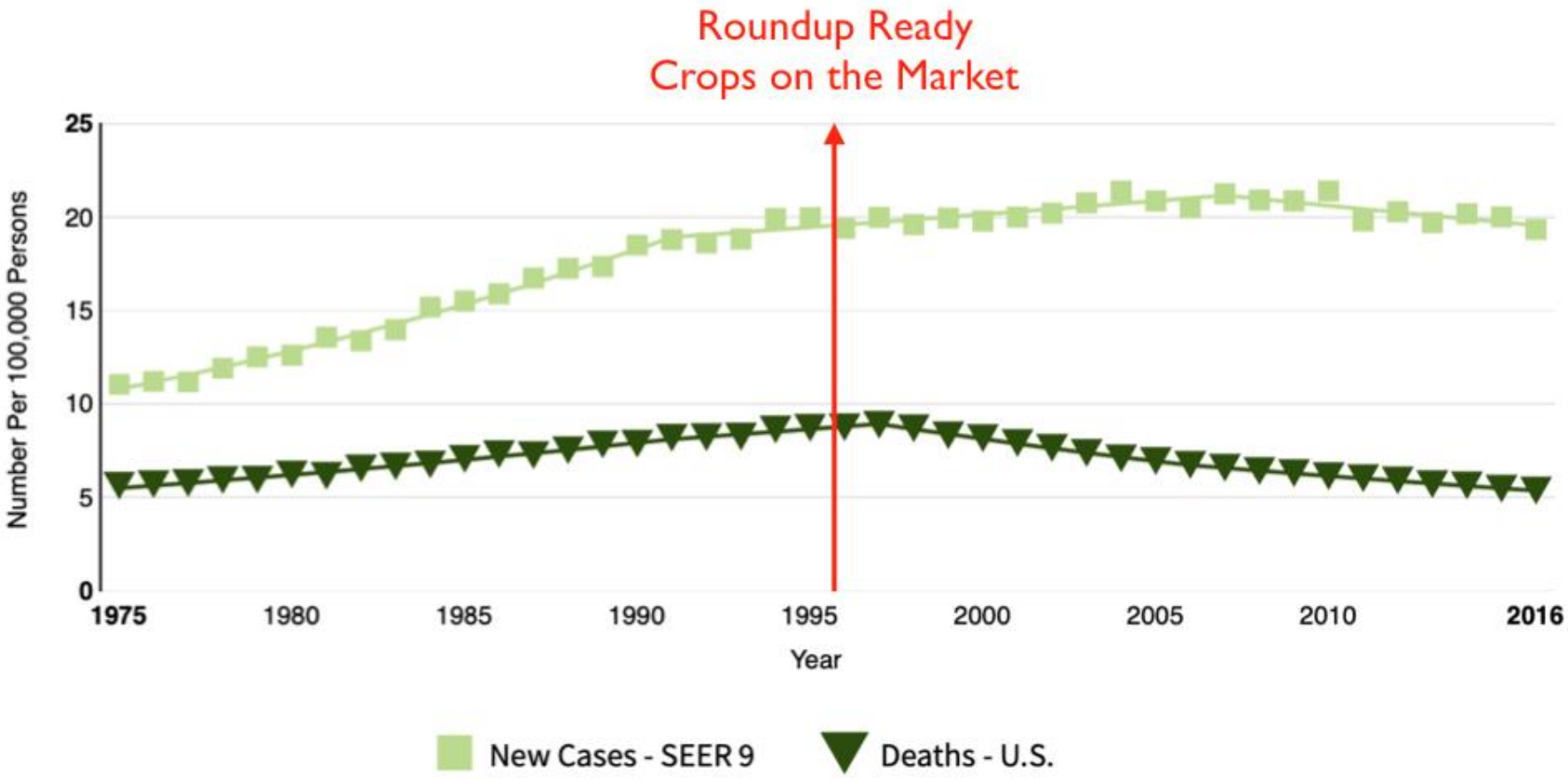
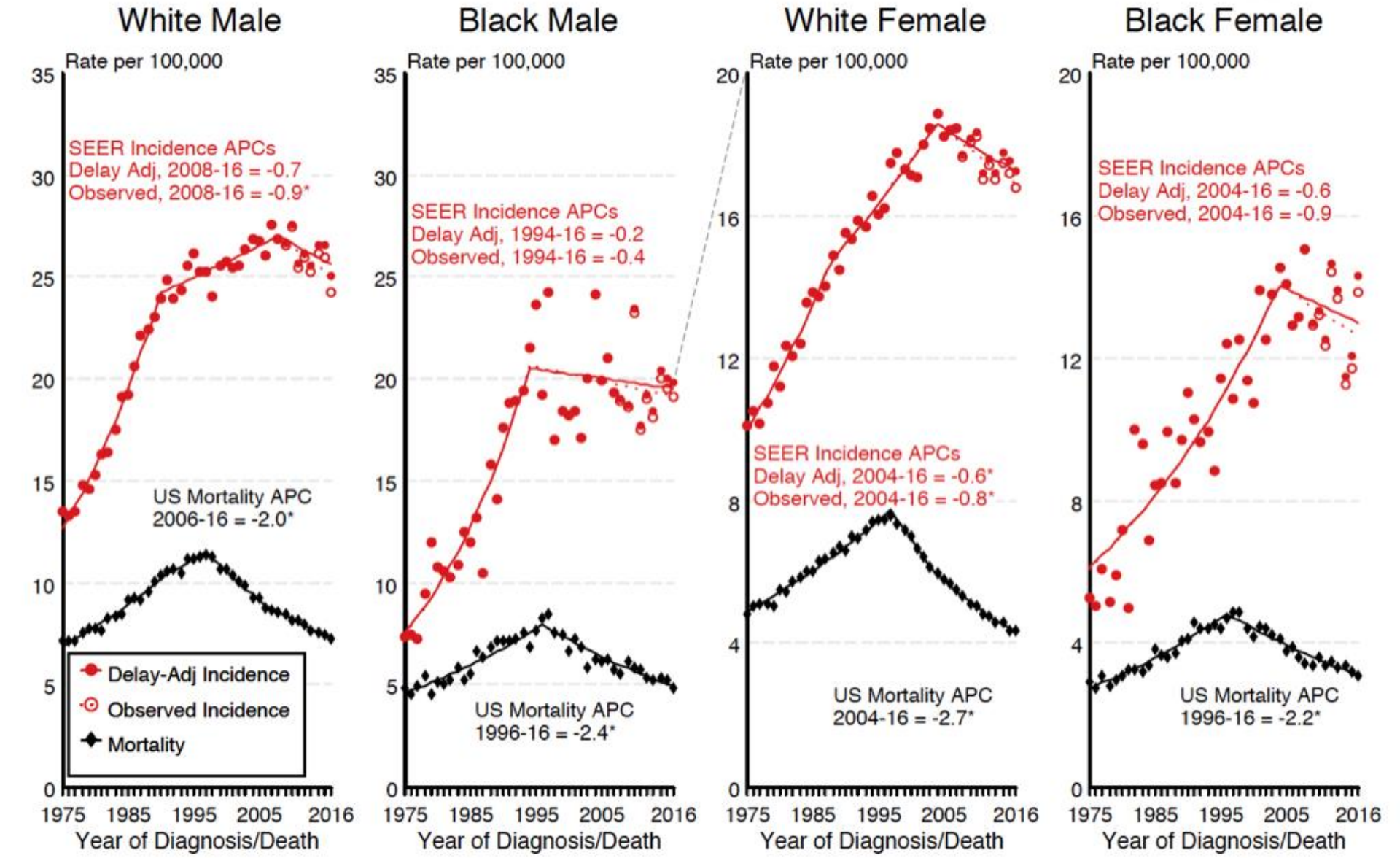
The Bottom Line: Hypothesis Fails



Most Recent Trend Data in NHL Incidence



Update on the NHL Cancer Trends: Adjusted Delayed Incidence Trend for White Males Down ~0.7%



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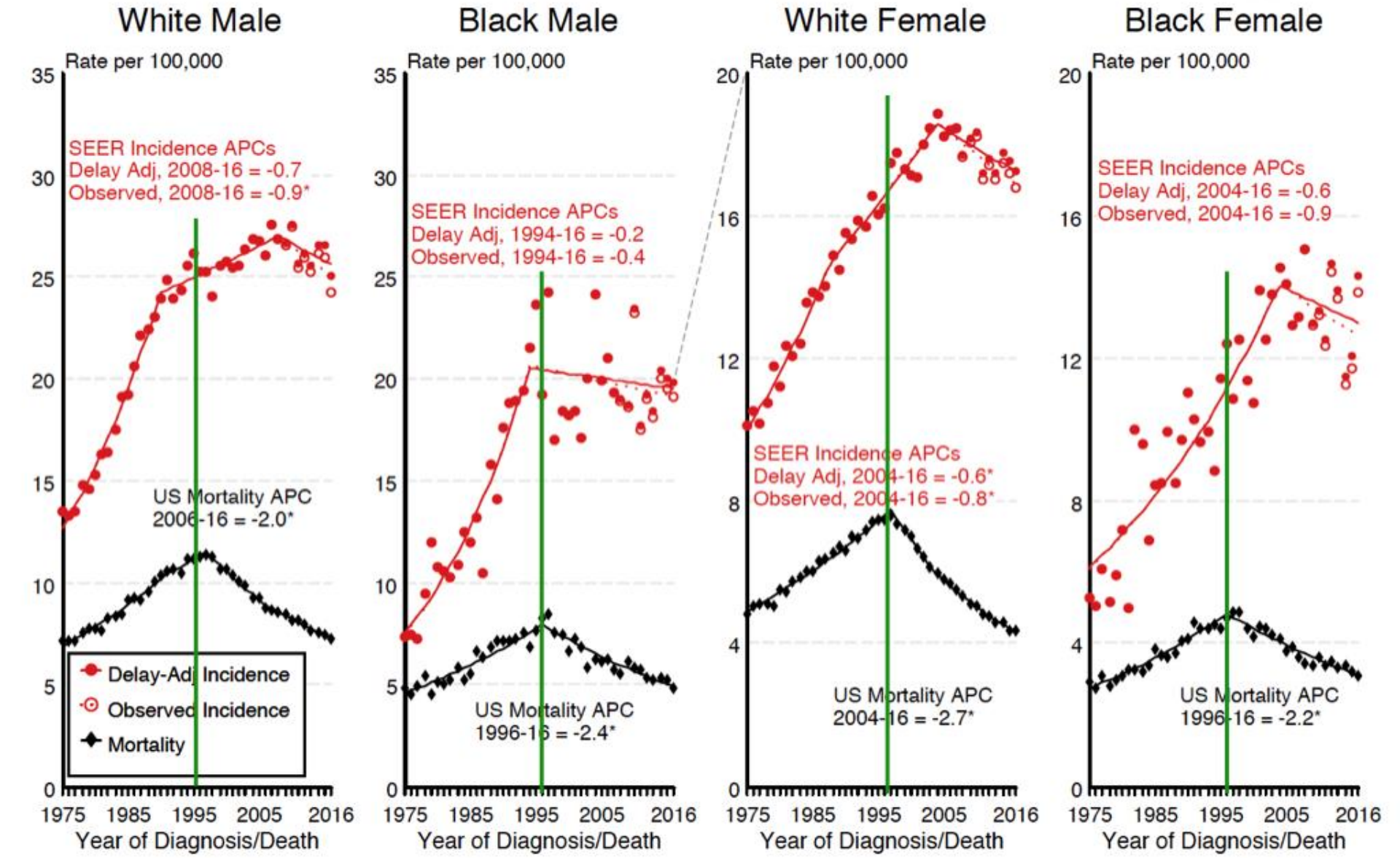
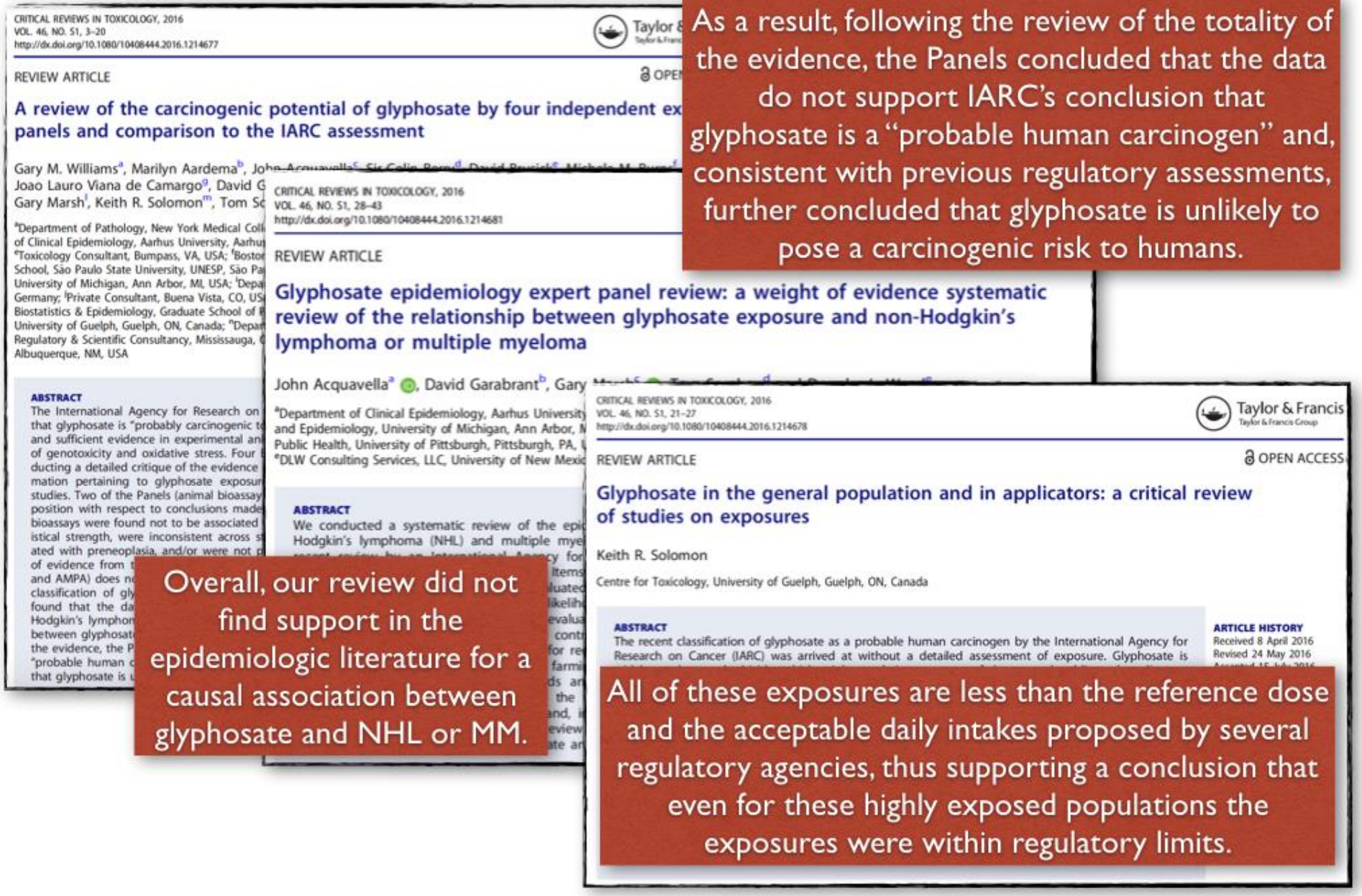


Don't Take My Word for It: The Latest from a High Impact Factor Journal



CRITICAL REVIEWS IN TOXICOLOGY, 2016
VOL. 46, NO. 51, 3–20
http://dx.doi.org/10.1080/10408444.2016.1214677

REVIEW ARTICLE

A review of the carcinogenic potential of glyphosate by four independent ex
panels and comparison to the IARC assessment

Gary M. Williams[a], Marilyn Aardema[b], John Acquavella[c], Sir Colin Berry[d], David Bruwick[e], Michele M. Burns[f], Joao Lauro Viana de Camargo[g], David G
Gary Marsh[l], Keith R. Solomon[m], Tom Sc

[a]Department of Pathology, New York Medical Coll
of Clinical Epidemiology, Aarhus University, Aarhu
[e]Toxicology Consultant, Bumpass, VA, USA; [f]Bosto
School, São Paulo State University, UNESP, São Pa
University of Michigan, Ann Arbor, MI, USA; [l]Depa
Germany; [l]Private Consultant, Buena Vista, CO, US
Biostatistics & Epidemiology, Graduate School of P
University of Guelph, Guelph, ON, Canada; [q]Depar
Regulatory & Scientific Consultancy, Mississauga,
Albuquerque, NM, USA

ABSTRACT

The International Agency for Research on
that glyphosate is "probably carcinogenic t
and sufficient evidence in experimental an
of genotoxicity and oxidative stress. Four
ducting a detailed critique of the evidence
mation pertaining to glyphosate exposur
studies. Two of the Panels (animal bioassay
position with respect to conclusions made
bioassays were found not to be associated
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As a result, following the review of the totality of the evidence, the Panels concluded that the data do not support IARC's conclusion that glyphosate is a "probable human carcinogen" and, consistent with previous regulatory assessments, further concluded that glyphosate is unlikely to pose a carcinogenic risk to humans.

CRITICAL REVIEWS IN TOXICOLOGY, 2016
VOL. 46, NO. 51, 28–43
http://dx.doi.org/10.1080/10408444.2016.1214681

REVIEW ARTICLE

Glyphosate epidemiology expert panel review: a weight of evidence systematic review of the relationship between glyphosate exposure and non-Hodgkin's lymphoma or multiple myeloma

John Acquavella[a], David Garabrant[b], Gary

[a]Department of Clinical Epidemiology, Aarhus University
and Epidemiology, University of Michigan, Ann Arbor, M
Public Health, University of Pittsburgh, Pittsburgh, PA,
[e]DLW Consulting Services, LLC, University of New Mexic

ABSTRACT

We conducted a systematic review of the epi
Hodgkin's lymphoma (NHL) and multiple mye
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Overall, our review did not find support in the epidemiologic literature for a causal association between glyphosate and NHL or MM.

CRITICAL REVIEWS IN TOXICOLOGY, 2016
VOL. 46, NO. 51, 21–27
http://dx.doi.org/10.1080/10408444.2016.1214678

Taylor & Francis
Taylor & Francis Group

REVIEW ARTICLE

OPEN ACCESS

Glyphosate in the general population and in applicators: a critical review of studies on exposures

Keith R. Solomon

Centre for Toxicology, University of Guelph, Guelph, ON, Canada

ABSTRACT

The recent classification of glyphosate as a probable human carcinogen by the International Agency for Research on Cancer (IARC) was arrived at without a detailed assessment of exposure. Glyphosate is

ARTICLE HISTORY
Received 8 April 2016
Revised 24 May 2016

All of these exposures are less than the reference dose and the acceptable daily intakes proposed by several regulatory agencies, thus supporting a conclusion that even for these highly exposed populations the exposures were within regulatory limits.

Warm Off the Presses

Large U.S. farm study finds no cancer link to Monsanto weedkiller

By Kate Kelland

Reuters November 18, 2017

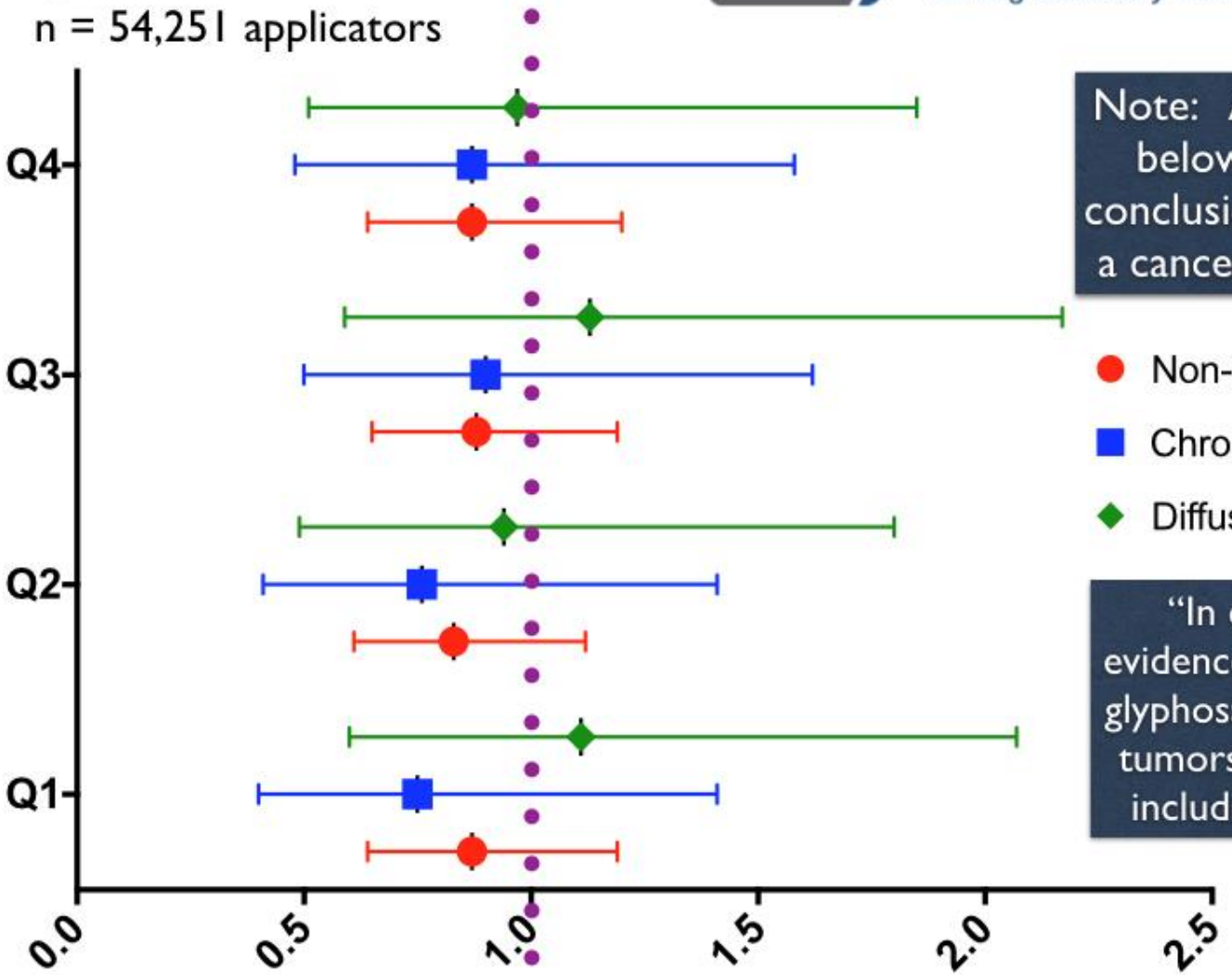
LONDON (Reuters) - A large long-term study on the use of the big-selling weedkiller glyphosate by agricultural workers in the United States has found no firm link between exposure to the pesticide and cancer, scientists said on Thursday.

Published in the Journal of the National Cancer Institute (JNCI), the study found there was no association between glyphosate, the main ingredient in Monsanto's popular herbicide RoundUp, "and any solid tumors or lymphoid malignancies overall, including non-Hogkin Lymphoma (NHL) and its subtypes".

New Results from the NIH Sponsored Ag Health Study

Andreotti et al. (2018)
J Natl Cancer Inst
n = 54,251 applicators

National Institutes of Health
Turning Discovery Into Health

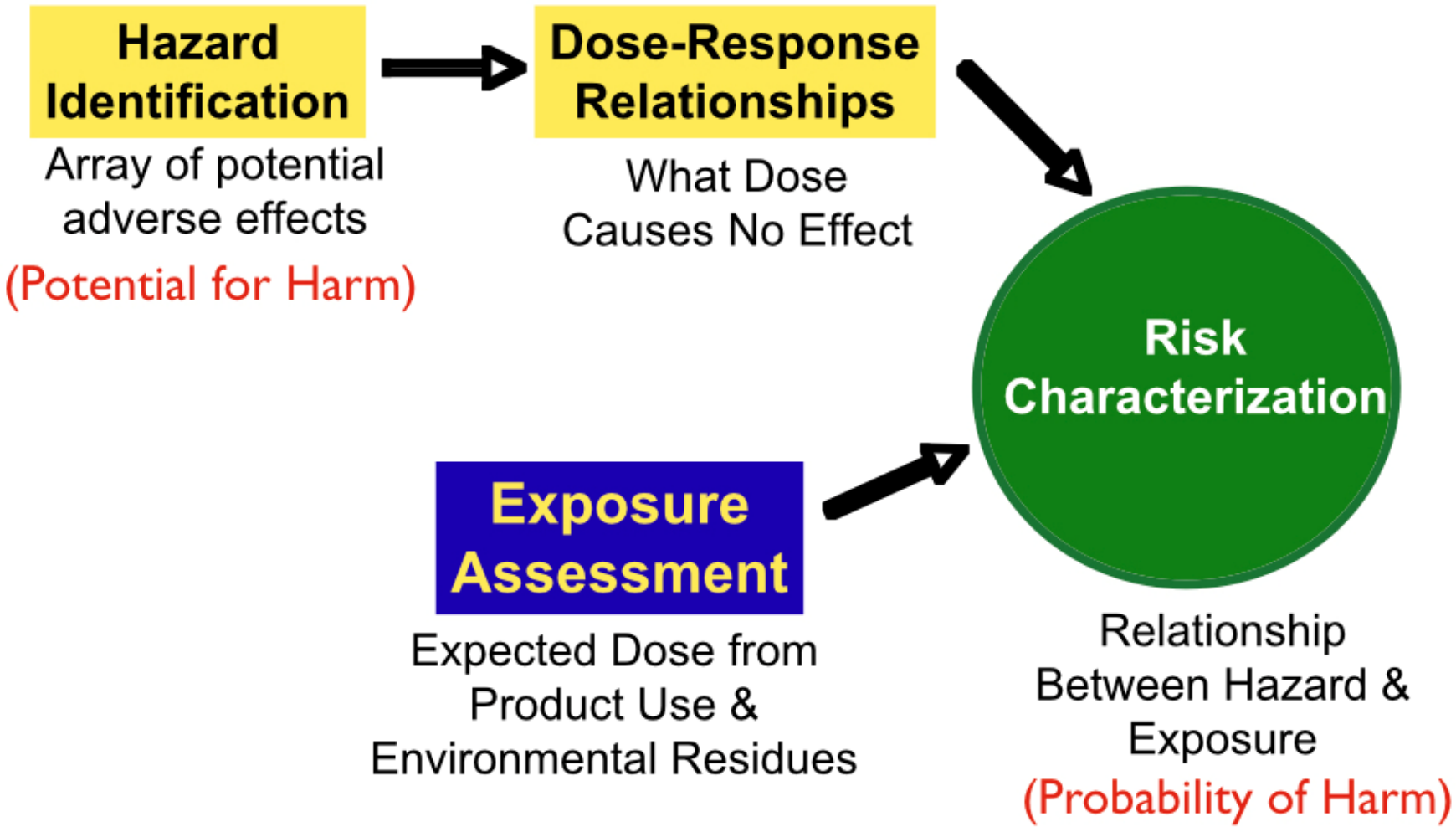


Note: All lower 95% CI extend below 1.0, necessitating the conclusion that the hypothesis of a cancer association is not valid

- Non-Hodgkin's Lymphoma
- Chronic Lymphocytic Lymphoma
- Diffuse Large B Cell Lymphoma

"In conclusion, we found no evidence of an association between glyphosate use and risk of any solid tumors or lymphoid malignancies, including NHL and its subtypes"

Risk Assessment
Estimating the Probability of Harm



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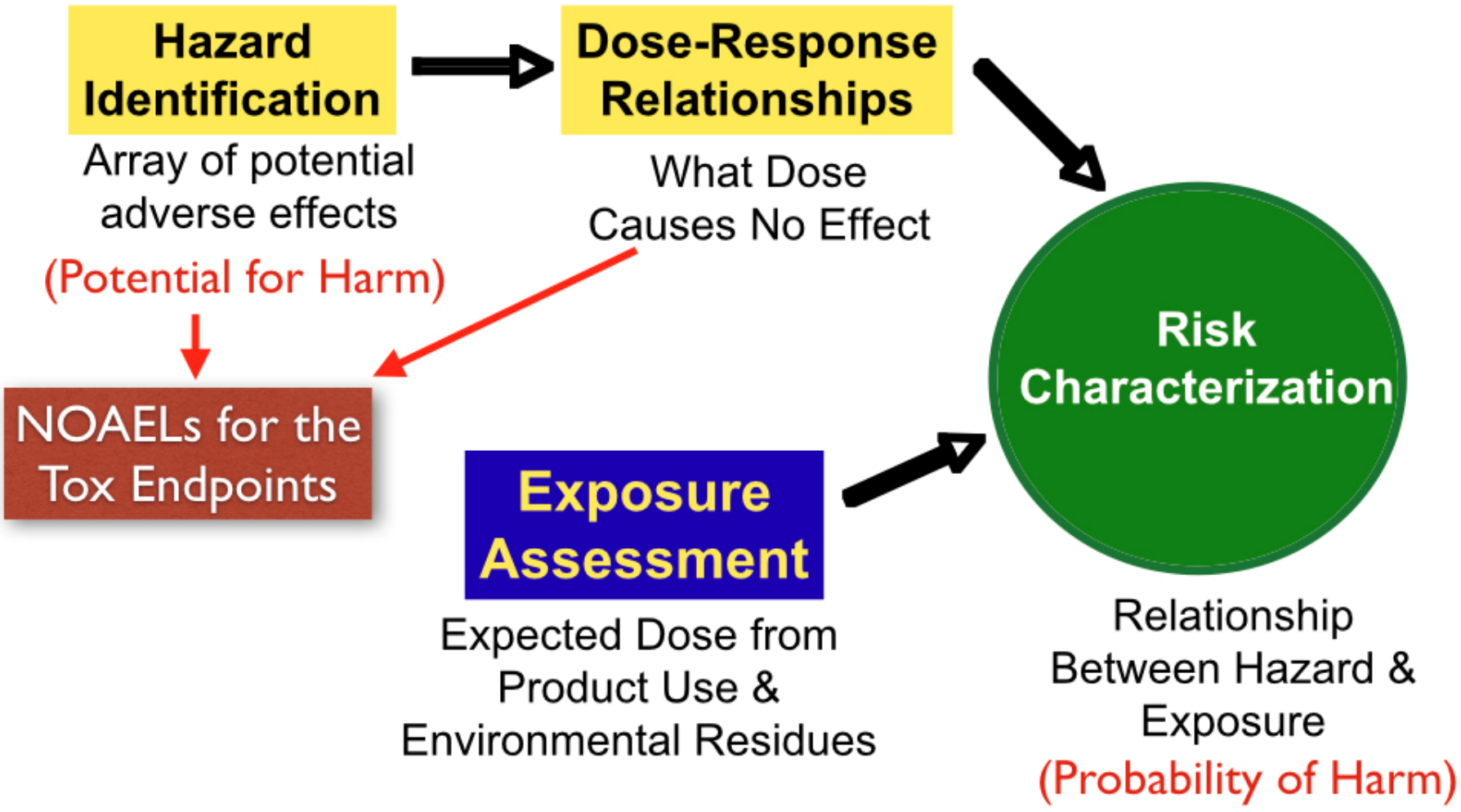
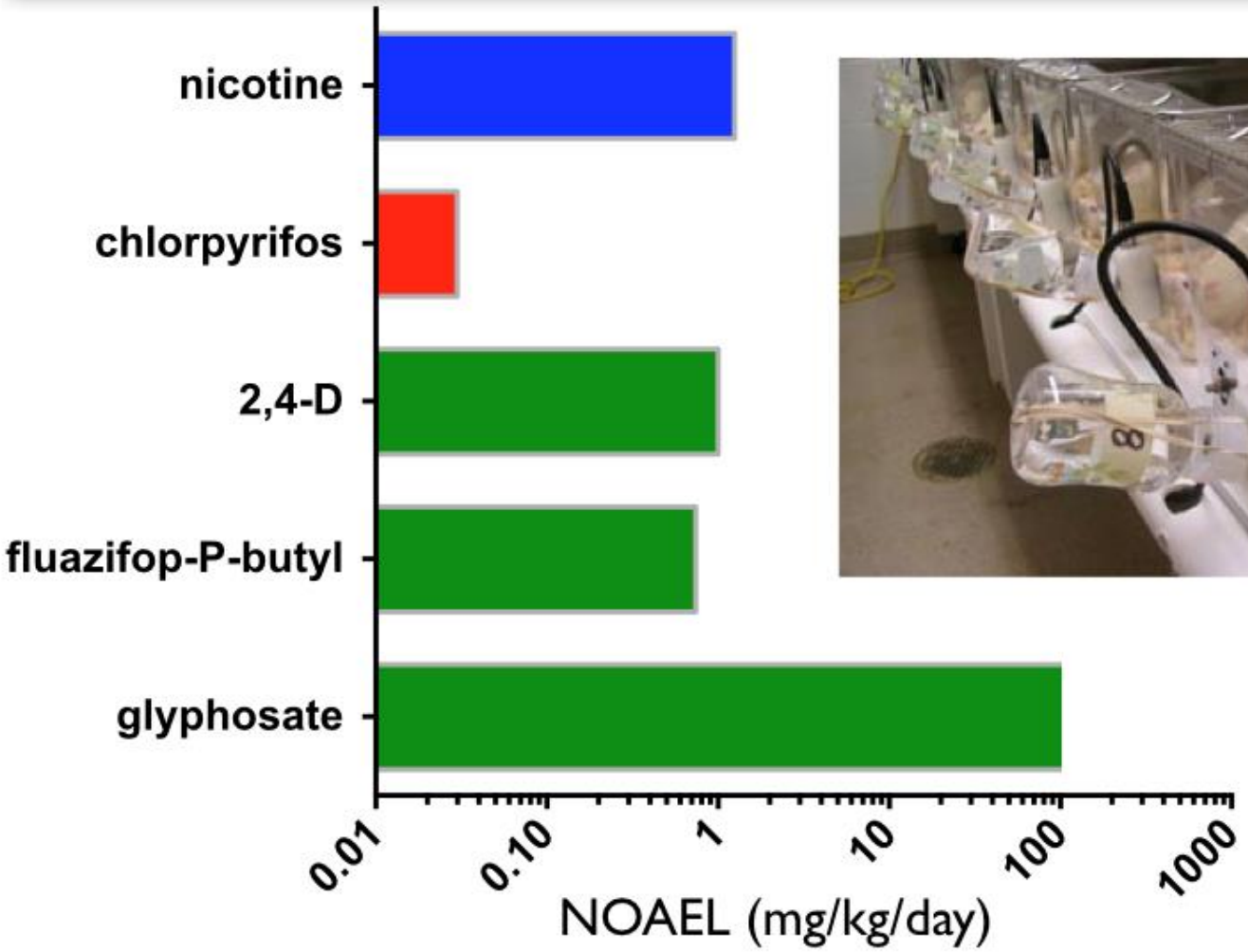


No Observable Adverse Effect Level (NOAEL)

Endpoint based on 2-year continuous dietary exposure



These are the toxicological endpoint data (hazards) that EPA uses to estimate risk (likelihood of adverse effects)

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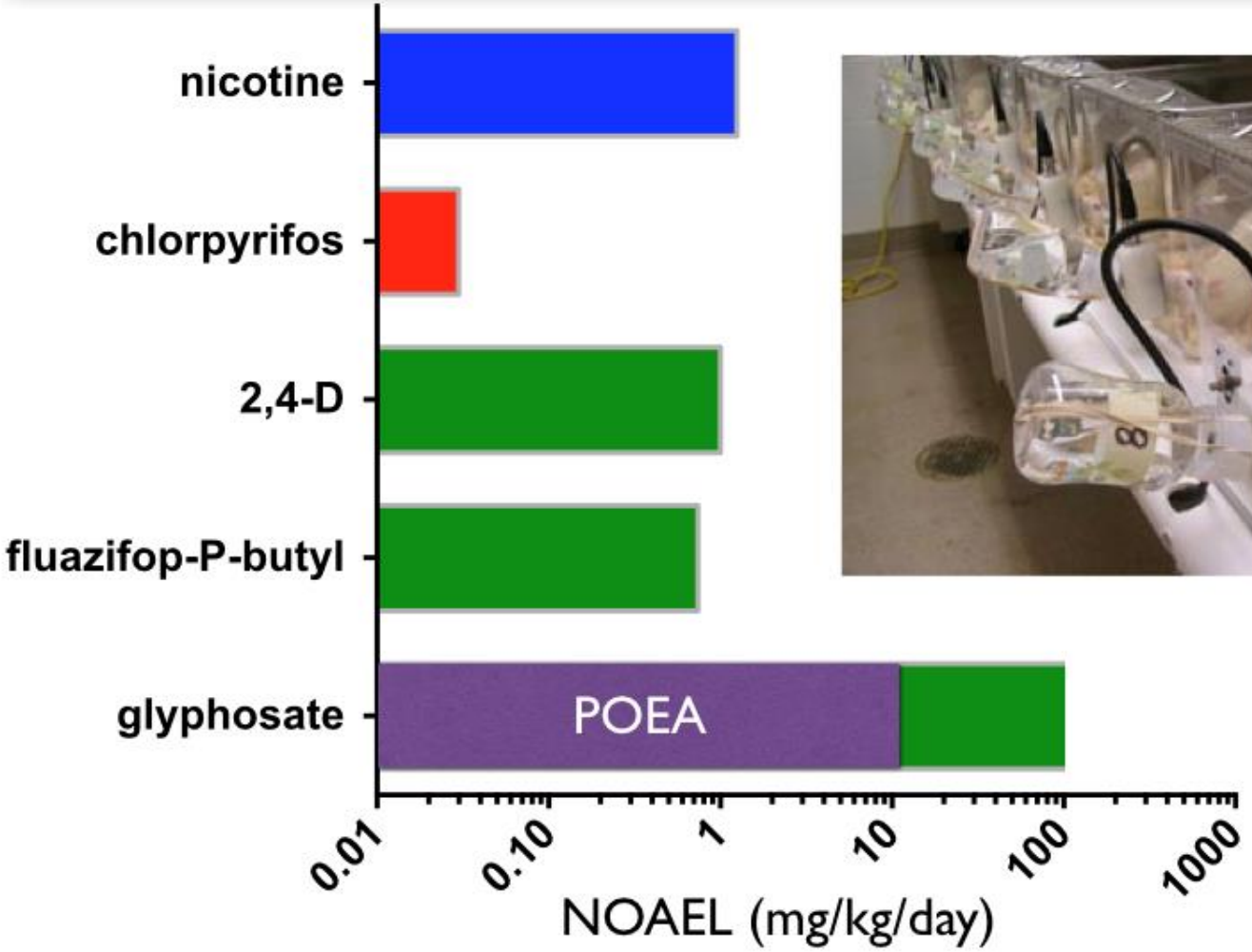

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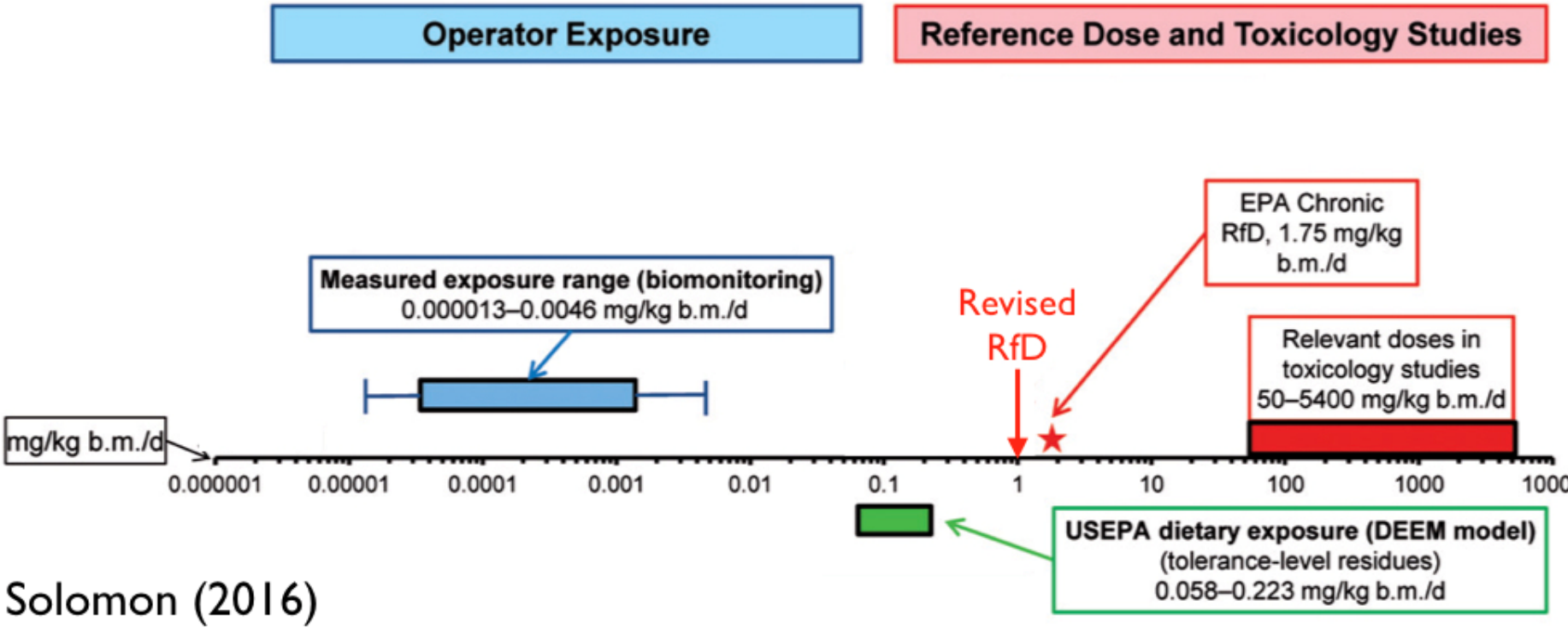
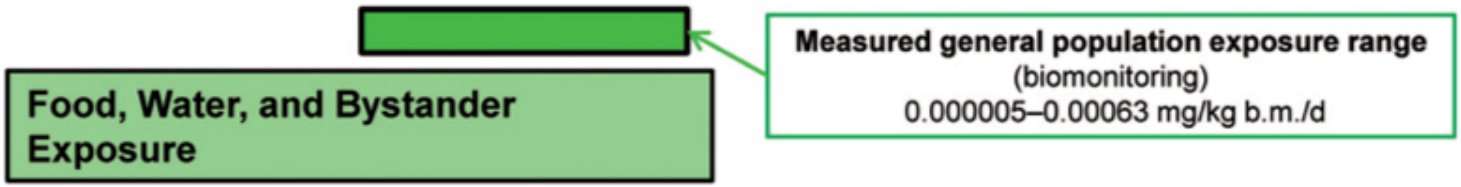
What Is the Relationship Between Exposure & Relevant Toxicological Endpoints?



Solomon (2016)



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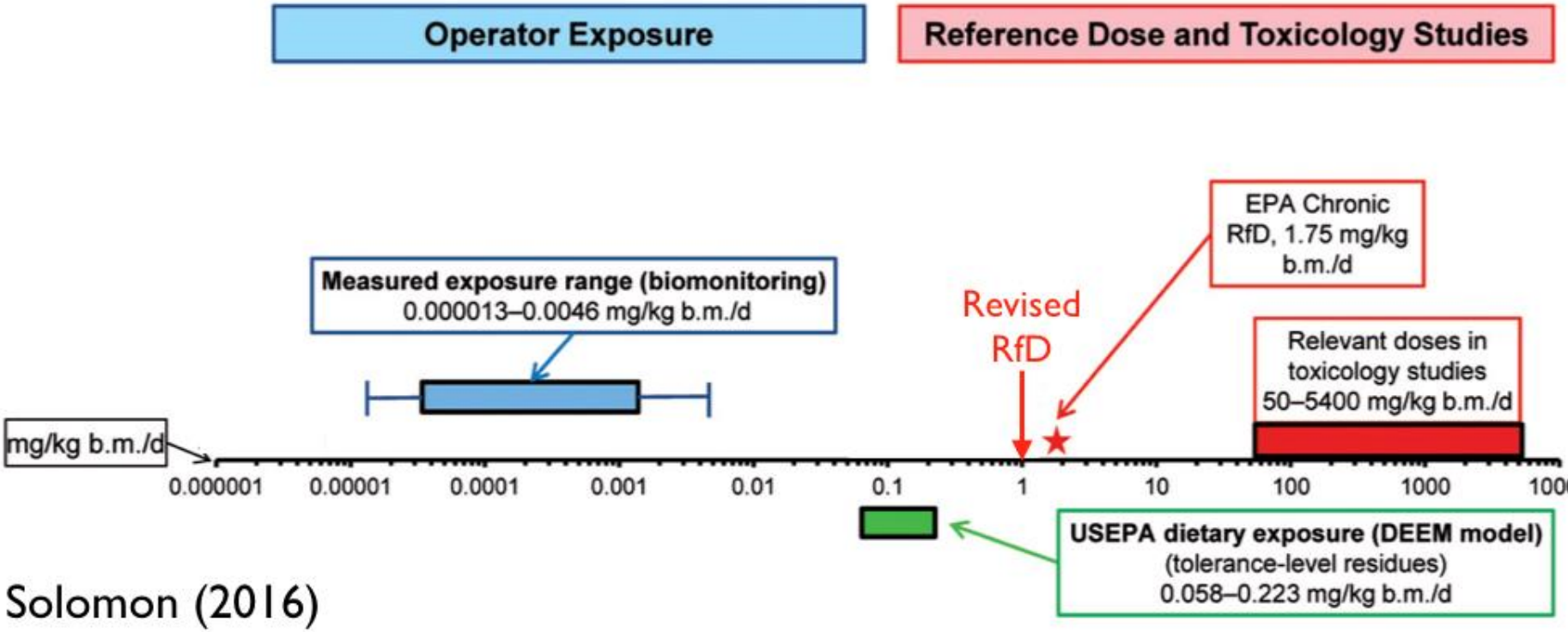
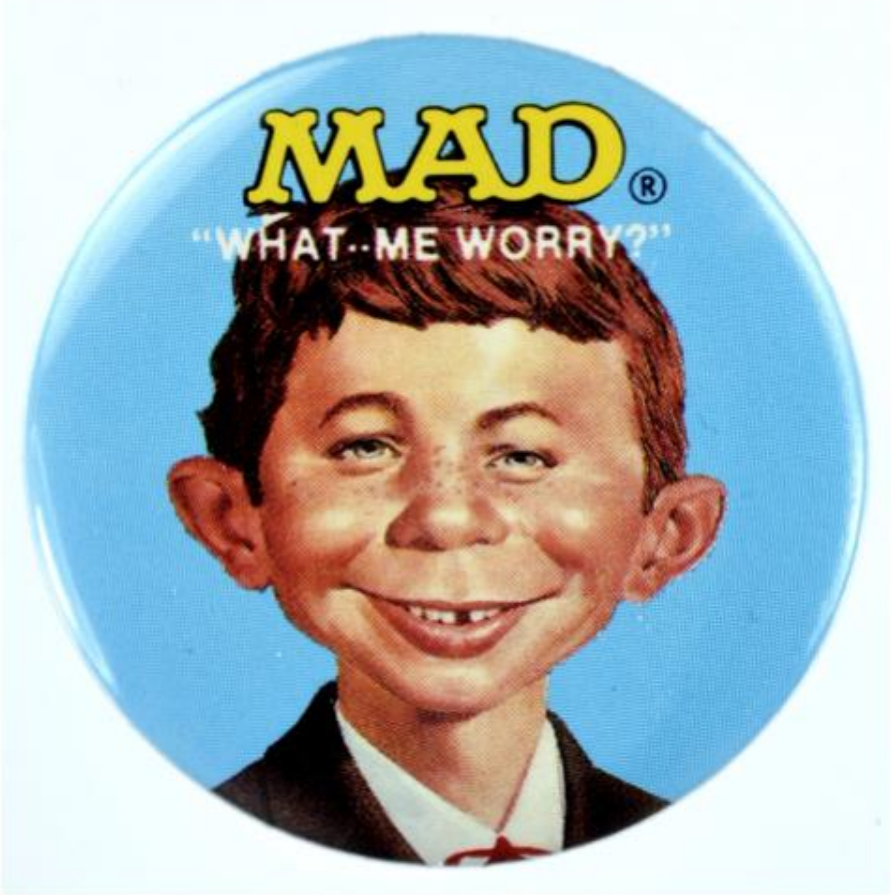


Solomon (2016)

Conclusion: Toxicology study doses are ~100,000 times higher than the level of exposure to both workers and the general population based on actual measurements from bodily fluids. Actual exposures are at least 1000 time lower than the RfD.

Overall Conclusions

EPA was right!!
Glyphosate (& products) are reduced risk pesticides.



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Questions?