Glyphosate Environmental Chemistry & Exposure Assessment

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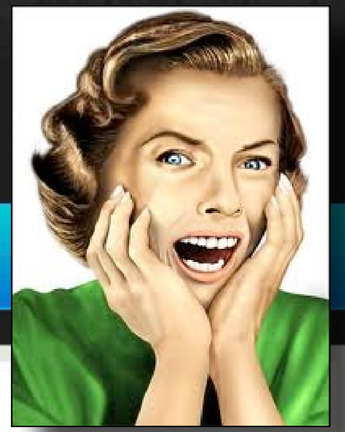
Be Afraid, Be Very Afraid!

news from
UNDERGROUND



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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.

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.

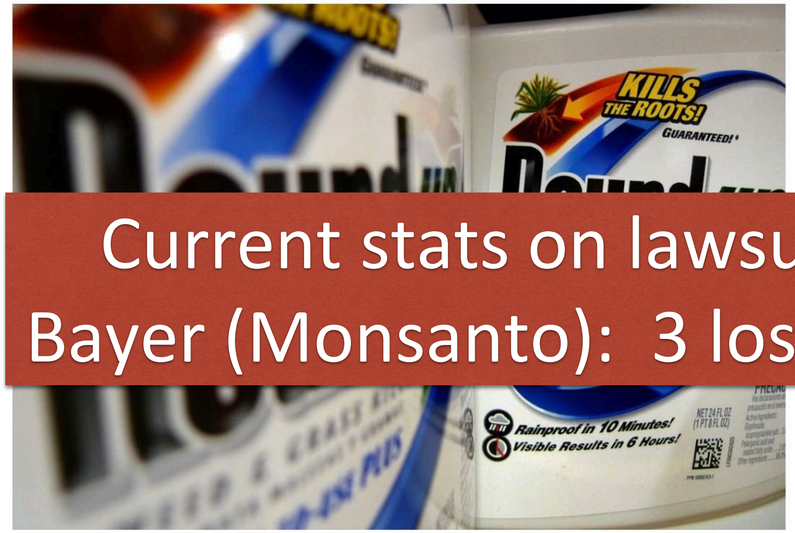
Lawyers Licking their Lips??

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)

Current stats on lawsuit cases:
Bayer (Monsanto): 3 losses, 6 wins

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.

Are You Pissed Yet?

‘Disturbing’: weedkiller ingredient tied to cancer found in 80% of US urine samples

Carey Gillam
Sat 9 Jul 2022 05.30 EDT

CDC study finds glyphosate, controversial ingredient found in weedkillers including popular Roundup brand, present in samples

The CDC has only recently started examining the extent of human exposure to glyphosate in the US. Photograph: Benoît Tessier/Reuters

More than 80% of urine samples drawn from children and adults in a US health study contained a weedkilling chemical linked to cancer, a finding scientists have called “disturbing” and “concerning”.

The report by a unit of the Centers for Disease Control and Prevention (CDC) found that out of 2,310 urine samples, taken from a group of Americans intended to be representative of the US population, 1,885 were laced with detectable traces of glyphosate. This is the active ingredient in herbicides sold around the world, including the widely used Roundup brand. Almost a third of the participants were children ranging from six to 18.

What the F**$*#@K…There's Glyphosate in My Body??

Agenda

- Risk Assessment for Human Health Protection Deconstructed
  - ✓ Why we need better characterization of exposure data
- Components of exposure data
  - ✓ For human health, risk cup factors (food, water, residential exposure)
- What we know about exposure from food, water, and residential use, worker use
  - ✓ EPA assessment
  - ✓ Literature assessment
- Use of exposure data for RA
  - ✓ EPA data
  - ✓ Dietary from the literature

Is There Glyphosate in My Food????

YES!!!!

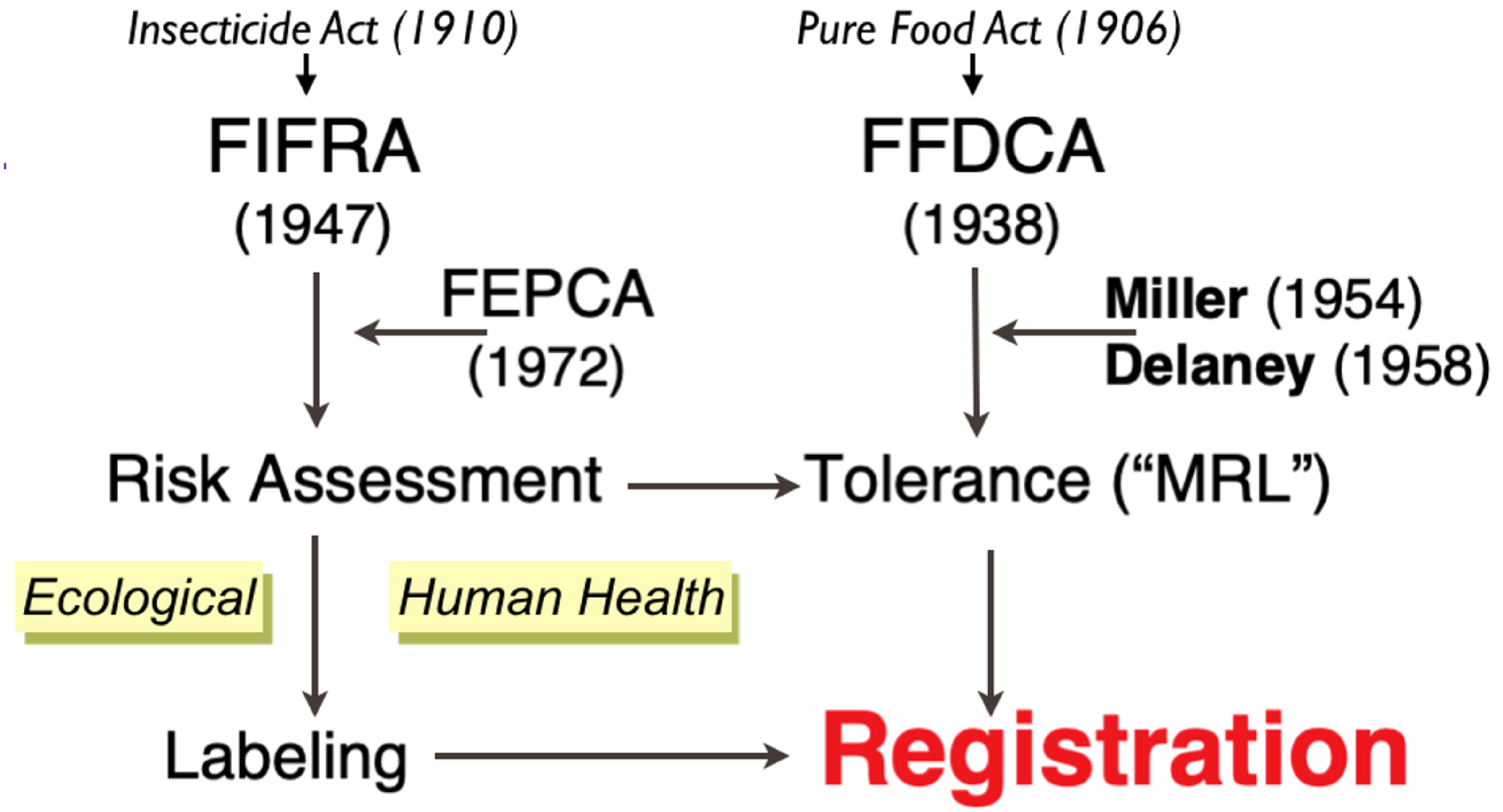
Why Is There Glyphosate in My Food????

Because It's Legal to Use Glyphosate on Nearly Every Crop!!!!!

But Is It Safe for My Health????

Yes, Under U.S. Law (i.e, FFDCA), the Residues Meet the Standard of "Safe", a Reasonable Certainty of No Harm

‘Pesticide Law’ Before the FQPA



The Label Is the Law
(The Prime Mechanism for Controlling Pesticide Use)

GROUP 9 HERBICIDE

Roundup PowerMAX® HERBICIDE

CROPSHIELD FORMULA

Specially formulated for Roundup Ready® crops

Complete Directions for Use

Herbicide for Roundup Ready® Crops

Selective broad-spectrum weed control in Roundup Ready® crops

Non-selective, broad-spectrum weed control for many agricultural systems and farmsteads

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product may only be used in accordance with the Directions for Use on this label or in separately published supplemental labeling. Supplemental labeling for this product can be obtained from your Authorized Bayer CropScience LP 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 regulation.

Legal Definition of Tolerance (via EPA)
(A Secondary Mechanism of Controlling Pesticide Use)

- Limits on the amount of pesticides that may remain in or on foods marketed in the USA

  ✓ The limits on pesticides left on foods are called "**tolerances**" in the U.S. (they are referred to as maximum residue limits, or **MRLs**, in many other countries)

  ✓ **EPA establishes tolerances for each pesticide based on the potential risks to human health posed by that pesticide**

    ❖ Some risk assessments are based on the assumption that residues will always be present in food at the maximum level permitted by the tolerance

    ❖ Other risk assessments use actual or anticipated residue data, to reflect real-world consumer exposure as closely as possible

- Tolerances are periodically reviewed
- Analytical method for residues must be validated

FFDCA: Authority for Establishment & Enforcement

- EPA sets the tolerance limits for each pesticide that may be found on foods...

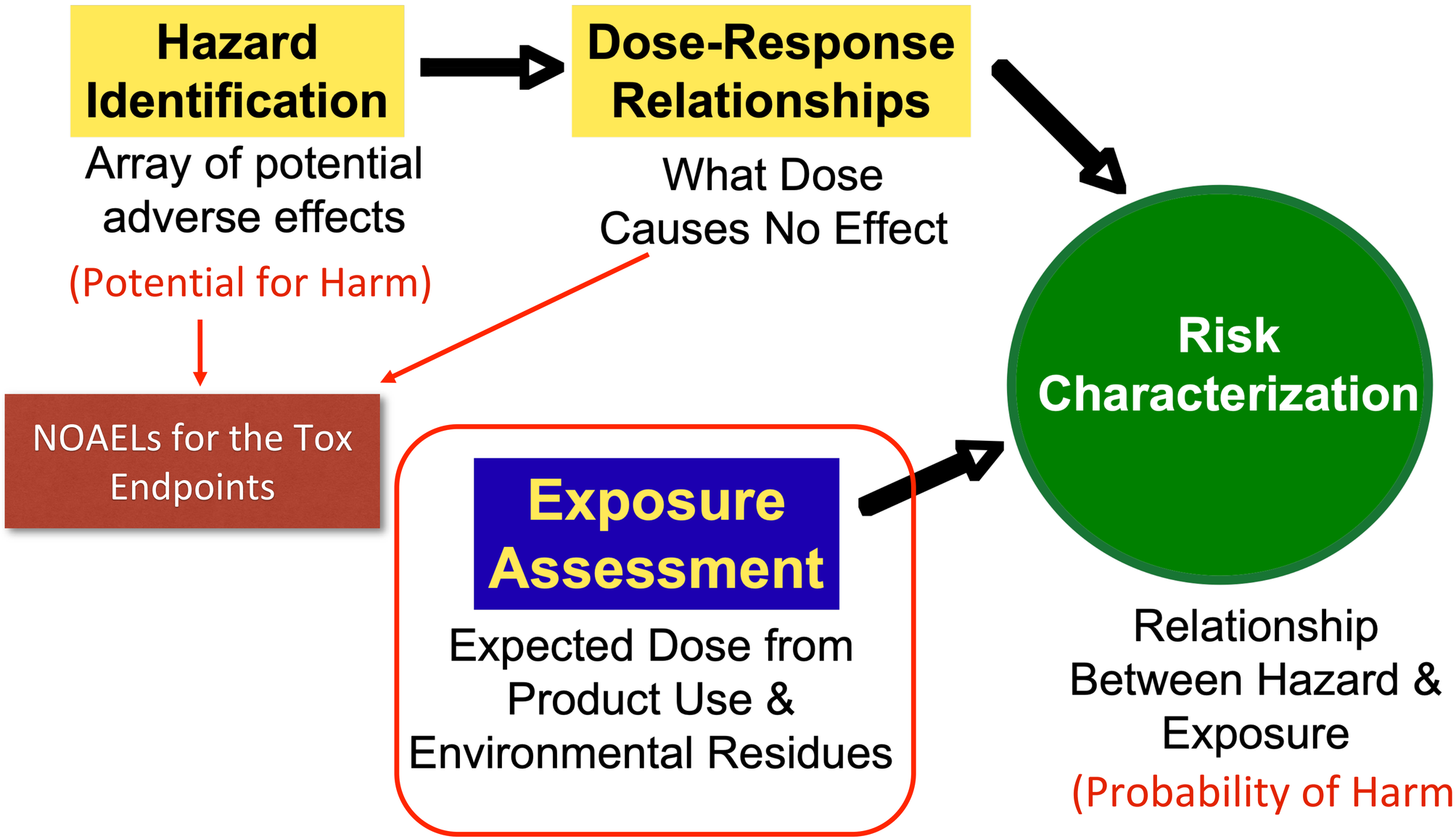
  ✓ But the US Department of Agriculture (USDA) **enforces** tolerances established for meat, poultry and some egg products...

  ✓ and the Food and Drug Administration (FDA) **enforces** tolerances established for other foods.

  ✓ "In this way, these federal agencies ensure that the nation's food supply is maintained safely at all times."

  - ❖ Under the FFDCA the EPA Administrator determines that the tolerance is **safe** and they can modify or revoke a tolerance if not safe."
  - ❖ A **"safe"** tolerance is one with a reasonable certainty that no harm will result from aggregate exposure (food, water, residential use) to the pesticide chemical residue

How Is “Safe” Determined: Enter the Risk Assessment Paradigm



How the FQPA Changed Pesticide Law

Insecticide Act (1910)

Pure Food Act (1906)

FIFRA (1947)

FFDCA (1938)

FEPCA (1972)

Miller (1954)

Delaney (1958)

Risk Assessment → Tolerance ("MRL")

Ecological

Human Health

Labeling → **Registration**

FQPA

(1996)

Mandates of the FQPA
EPA Creates New Science Policies for Risk Assessment

- Tolerances will be “safe,” i.e., “a reasonable certainty that no harm will result from aggregate exposure”

  ✓ Examine all sources of consumer exposure (dietary and residential pesticide use, i.e., aggregate exp.) and cumulate resides having the same biochemical mode of action

  ✓ Special consideration of whether a pesticide mimics hormones of the endocrine system (extra ‘safety factors’)

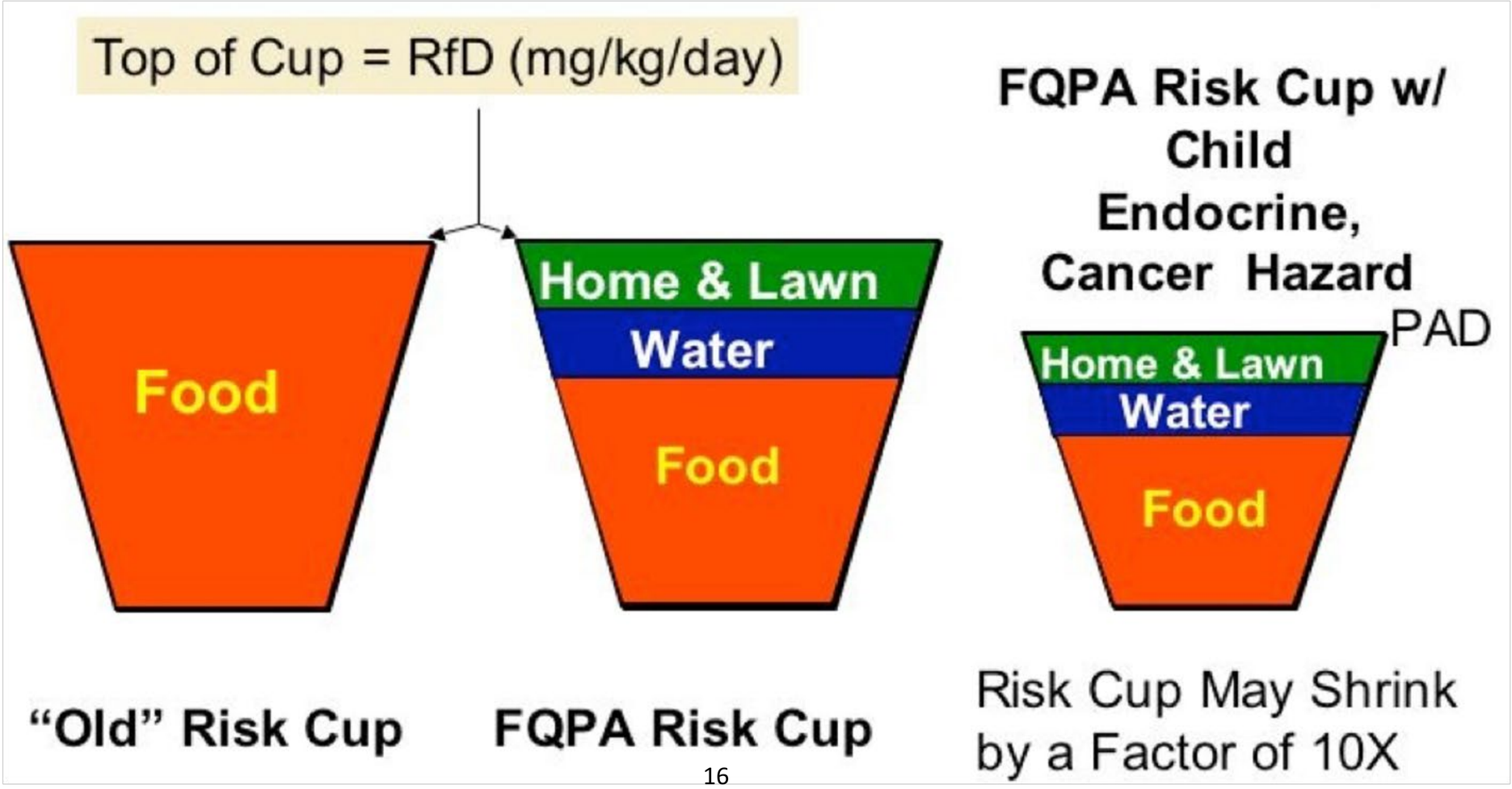
  ✓ Special consideration of whether children have a special sensitivity (extra ‘safety factors’)

  ✓ No distinction between raw and processed commodities with regard to risk assessment (including carcinogenicity potential)

- All tolerances had to be reassessed by 2006

FQPA Objective: Protect Consumers
Premise: Most Exposures from Diet

The Risk Cup Metaphor



How a Tolerance Is Developed

- Tolerances are residues (typically expressed as ppm or mg/kg)
- Manufacturer proposes tolerance
  - ✓ Based on field studies of residues on a commodity in major growing regions of the country
    - ❖ A tolerance is always a little higher than the highest residues to hedge bets against exceeding it
      - ▪ Thus, a tolerance is not really a safety standard, however...
- EPA validates tolerances using risk assessment and applies a concept known as TMRC (Total Maximum Residue Contribution) to judge whether a tolerance meets the standard of "safe" (i.e., reasonable certainty of no harm)
  - ✓ Thus, the EPA must determine a reference dose (RfD), as well as estimate the residues likely to be found, and the amount of each commodity typically consumed

TMRC
(Theoretical Maximum Residue Contribution)

- The sum of all exposures to residues at the tolerance level cannot exceed the Reference Dose (RfD), the "safe" level by policy design

  ✓ **The RfD is 100X less exposure than the NOAEL (No Observable Adverse Effect Level) from required tox studies**

  ✓ Pre-FQPA: considered food residues only

  ✓ Post-FQPA: tolerance would have to account for aggregate exposures

- Because the benchmark of safety is whether exposure exceeds the RfD, risk assessment is necessarily part of the process on the road to tolerance validation

  ✓ Thus, tolerances are tied to, but not synonymous with, a benchmark of safety

- The EPA has determined that any exposure to glyphosate over a lifetime is "safe" if the body dose is < 1 mg/kg; in the EU, the safe dose is 0.5 mg/kg

Field Residue Studies

- Recommended application rates and one or two levels higher
- Harvest at the recommended or desired Pre-Harvest Interval (PHI)
- Normally samples are composited

✓ But for many fresh fruits, a single unit (single serving) contributes to acute exposure

TMRC--Basic Procedure

- Applicable to new registrations
  - ✓ Screening tool when tolerances are used as the exposure residue
  - ✓ Can use field residues (higher tier or refined analysis)
  - ✓ Modify residues by % Crop Treated
- Need food consumption information
  - ✓ USDA Continuing Survey of Food Intake by Individuals
- Multiply residue tolerance by food consumption of that food to give exposure
- Sum all exposure possibilities
- Total exposure cannot exceed RfD (for glyphosate, RfD = 1 mg/kg/day)

History of Glyphosate Use

- Roundup, the original formulation of glyphosate, registered in 1974

- EPA issues final Re-registration Eligibility Decision (RED) document in 1993

  ✓ Glyphosate largely restricted to pre-plant “burn down” uses

  ✓ Rights-of-way & Aquatic uses

- USDA approves non-regulated status of RR crops, allowing Monsanto to commercialize soybean seed lines resistant to glyphosate toxicity (~1995-1996)

- The birth of the transgenic crop era

Roundup ORIGINAL™ HERBICIDE

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Roundup POWERMAX® HERBICIDE

CROPSHIELD FORMULA

Specially formulated for Roundup Ready® crops

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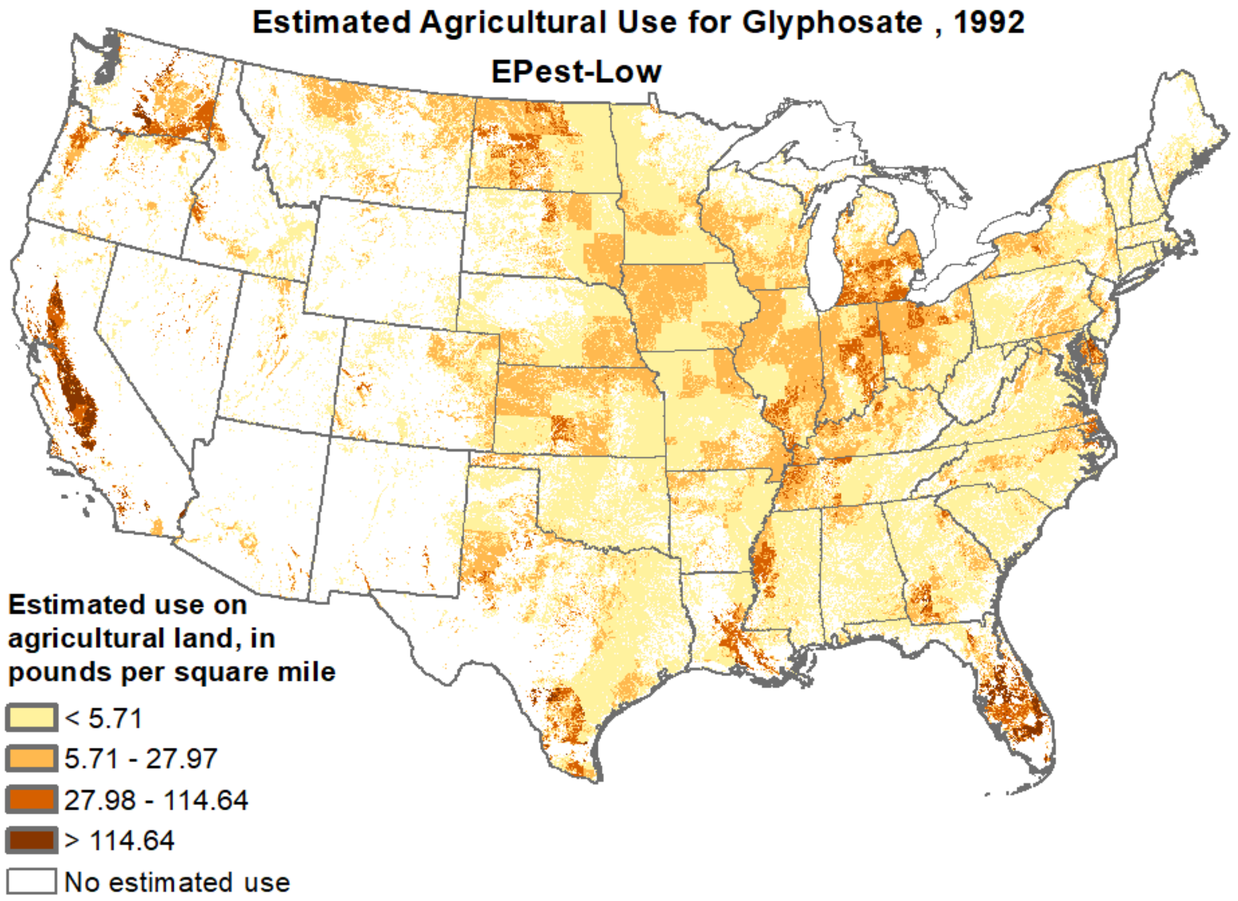
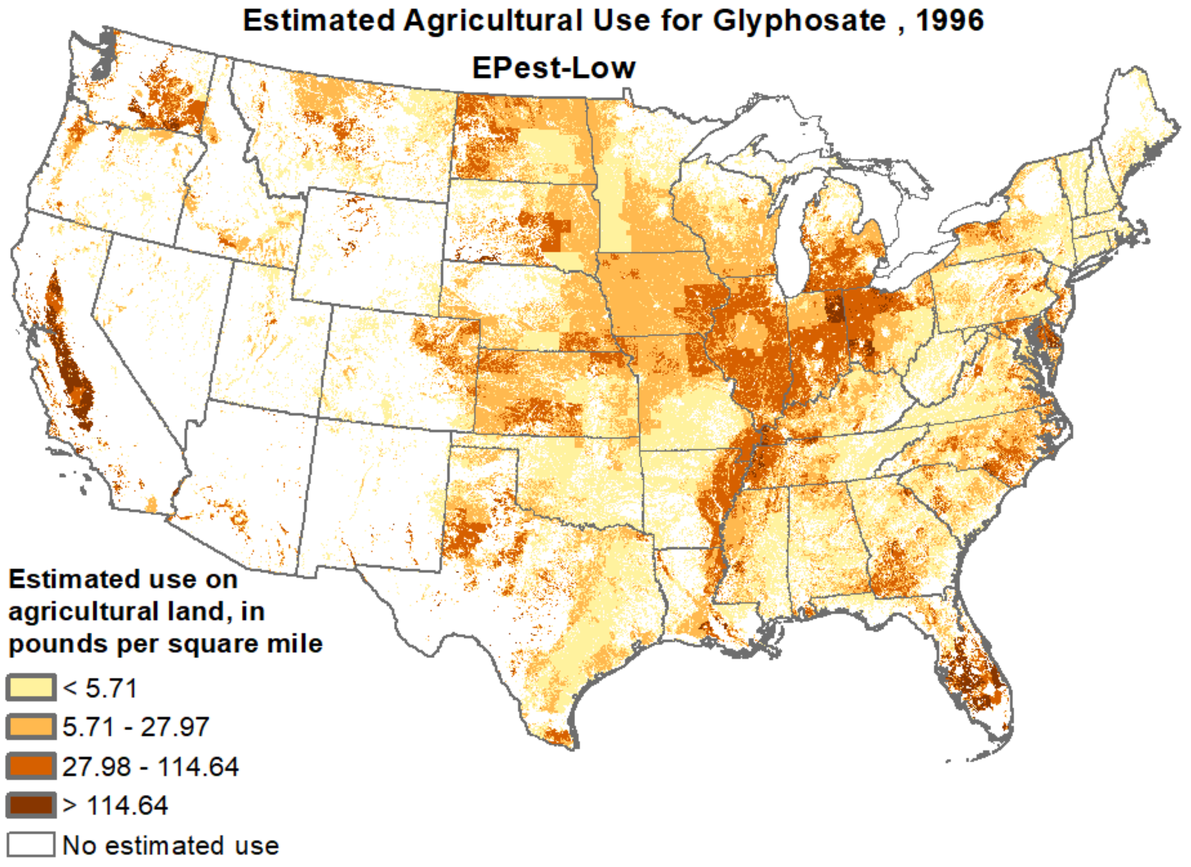
Historical Trends in Glyphosate Use in the USA

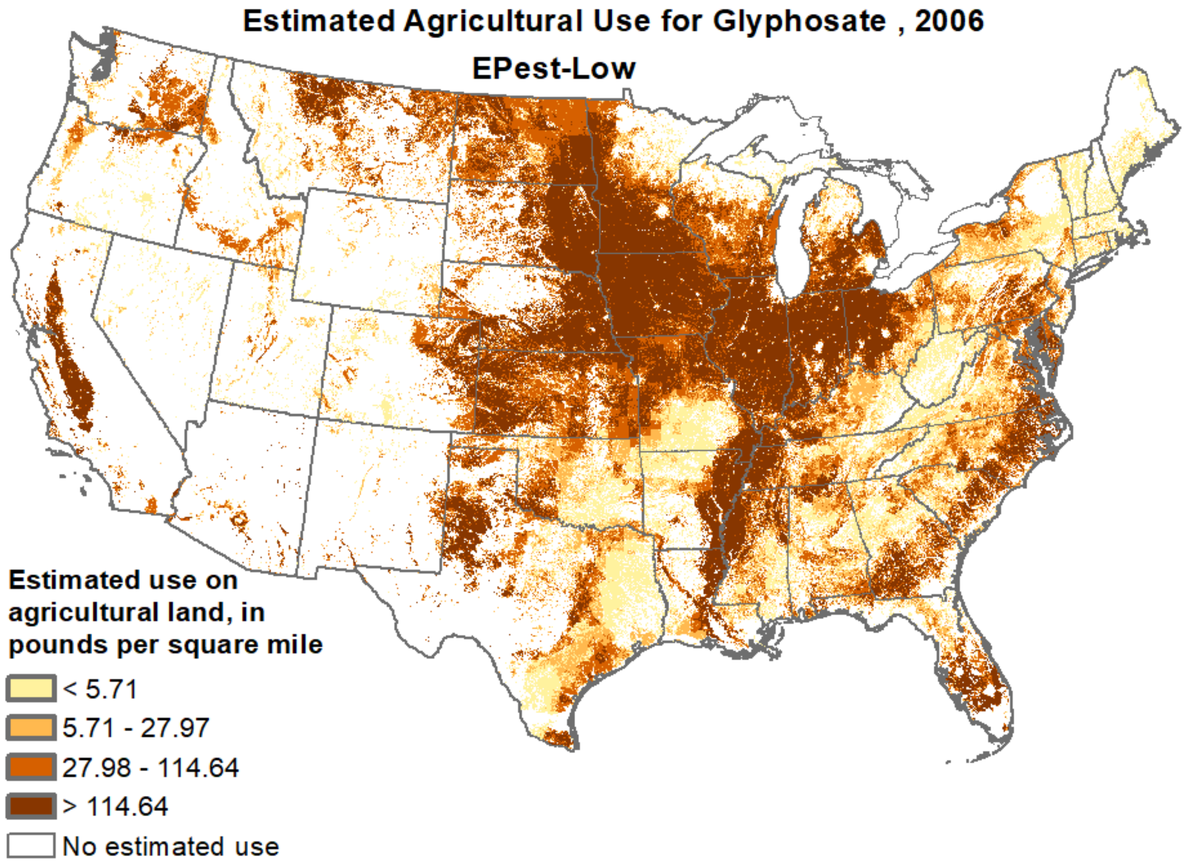


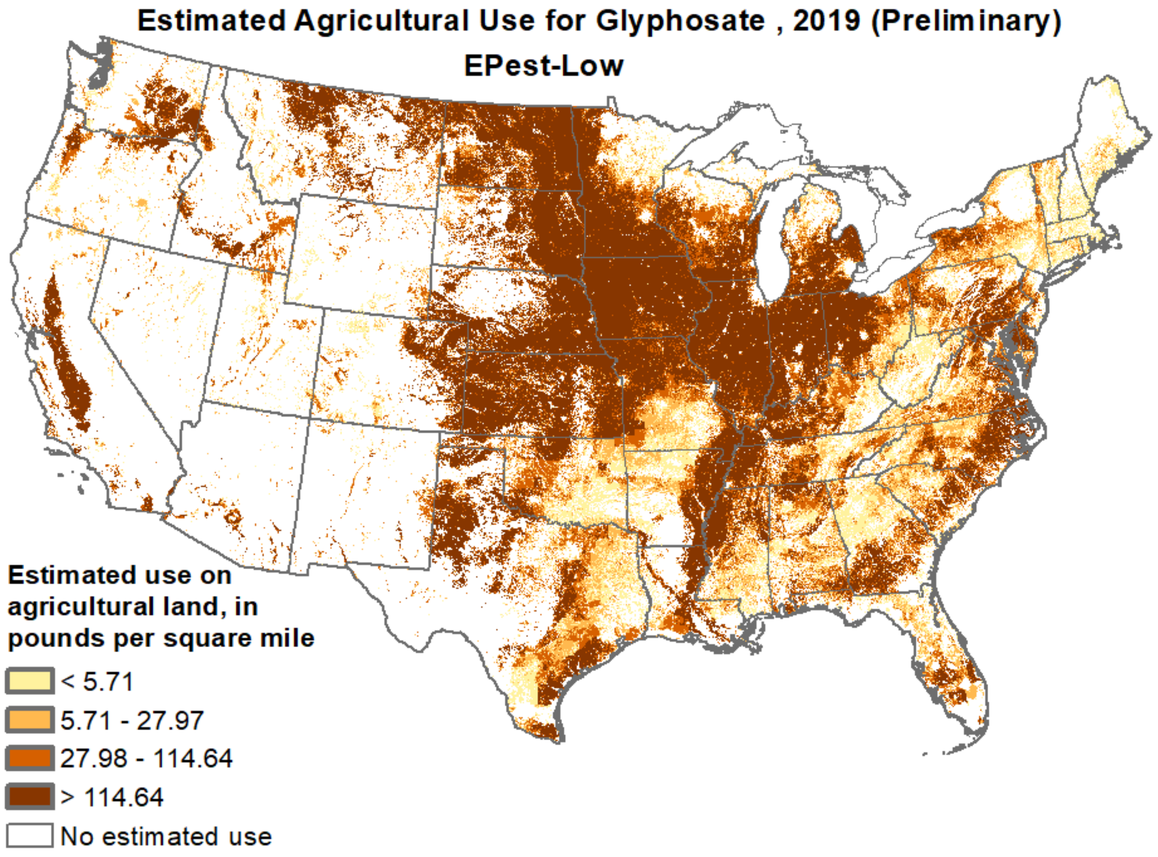


Data from the USGS NAWQA Program Pesticide National Synthesis Project

https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2019&map=GLYPHOSATE&hilo=L&disp=Glyphosate

Historical Trends in Glyphosate Use in the USA





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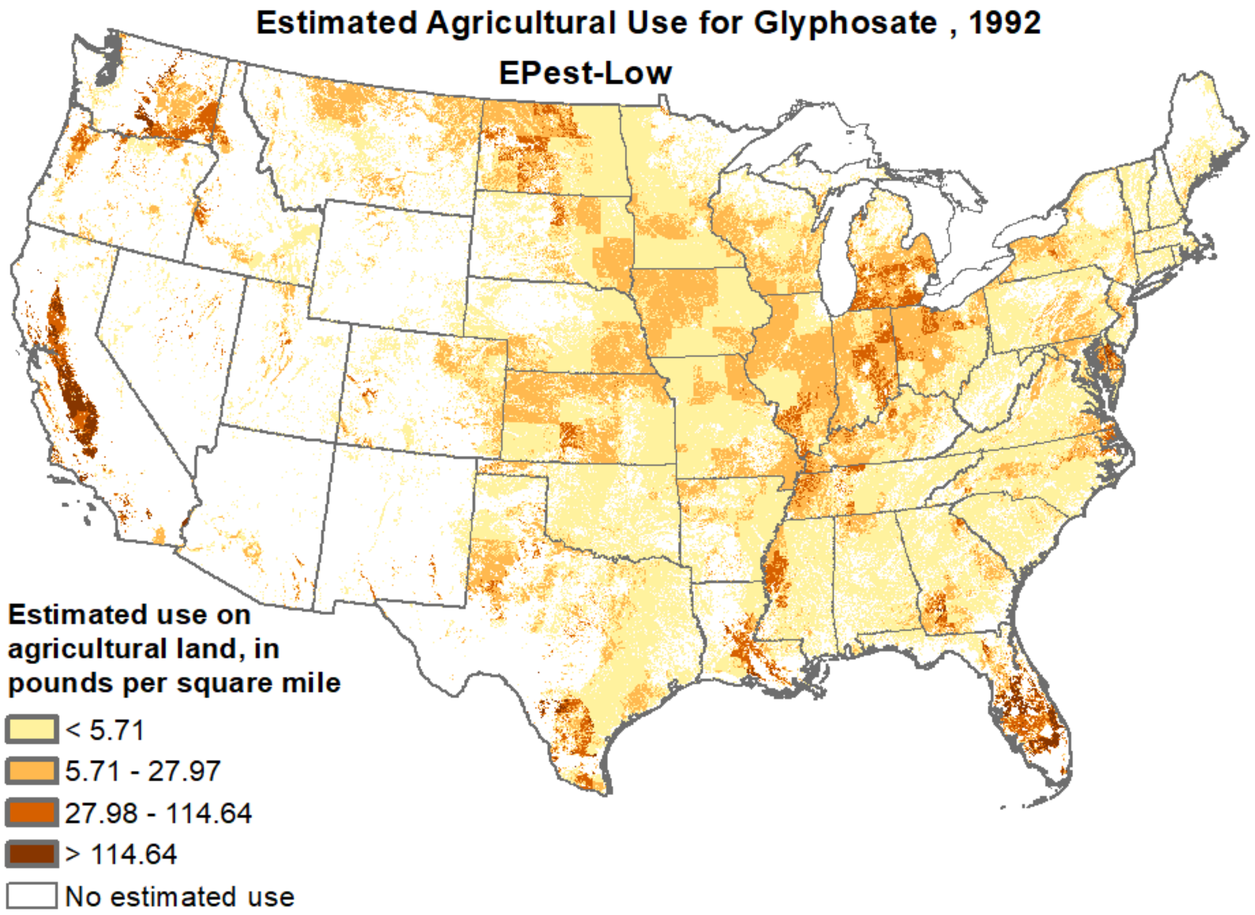
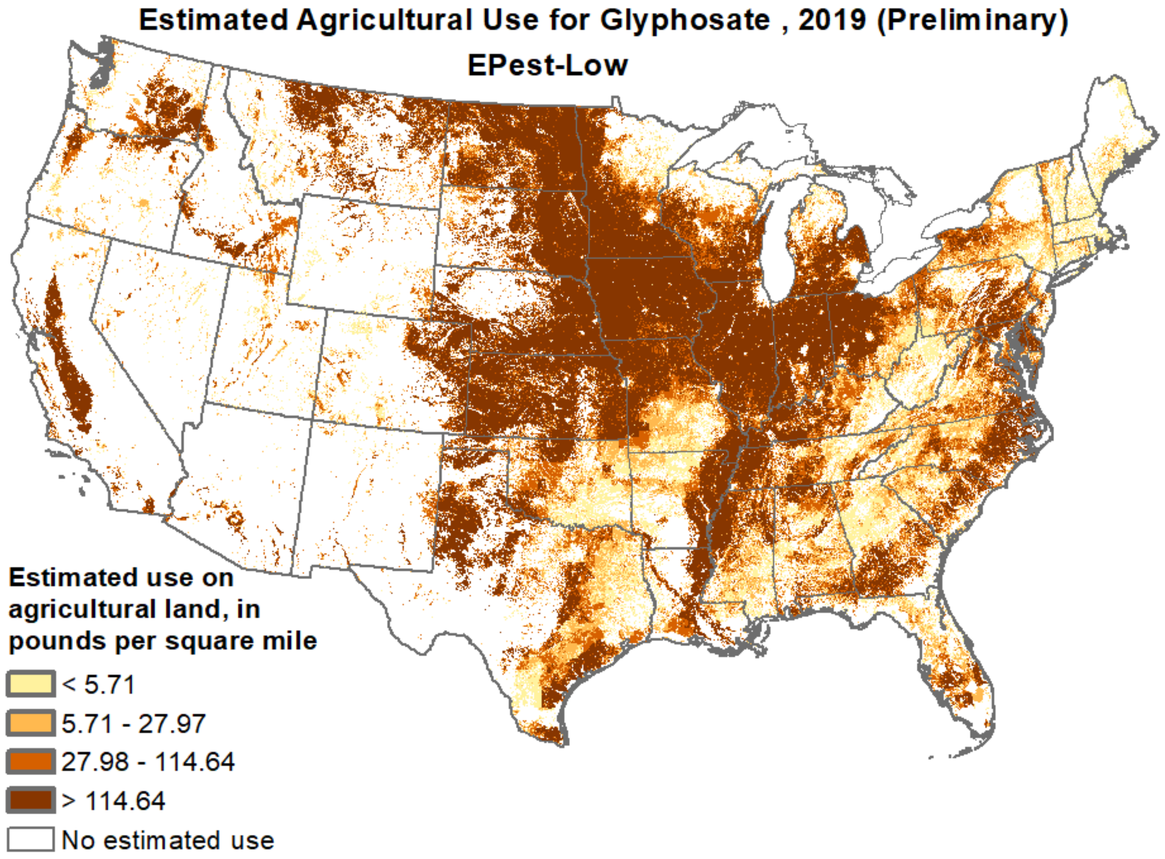
The 29 Year Trend in Glyphosate Use in the USA





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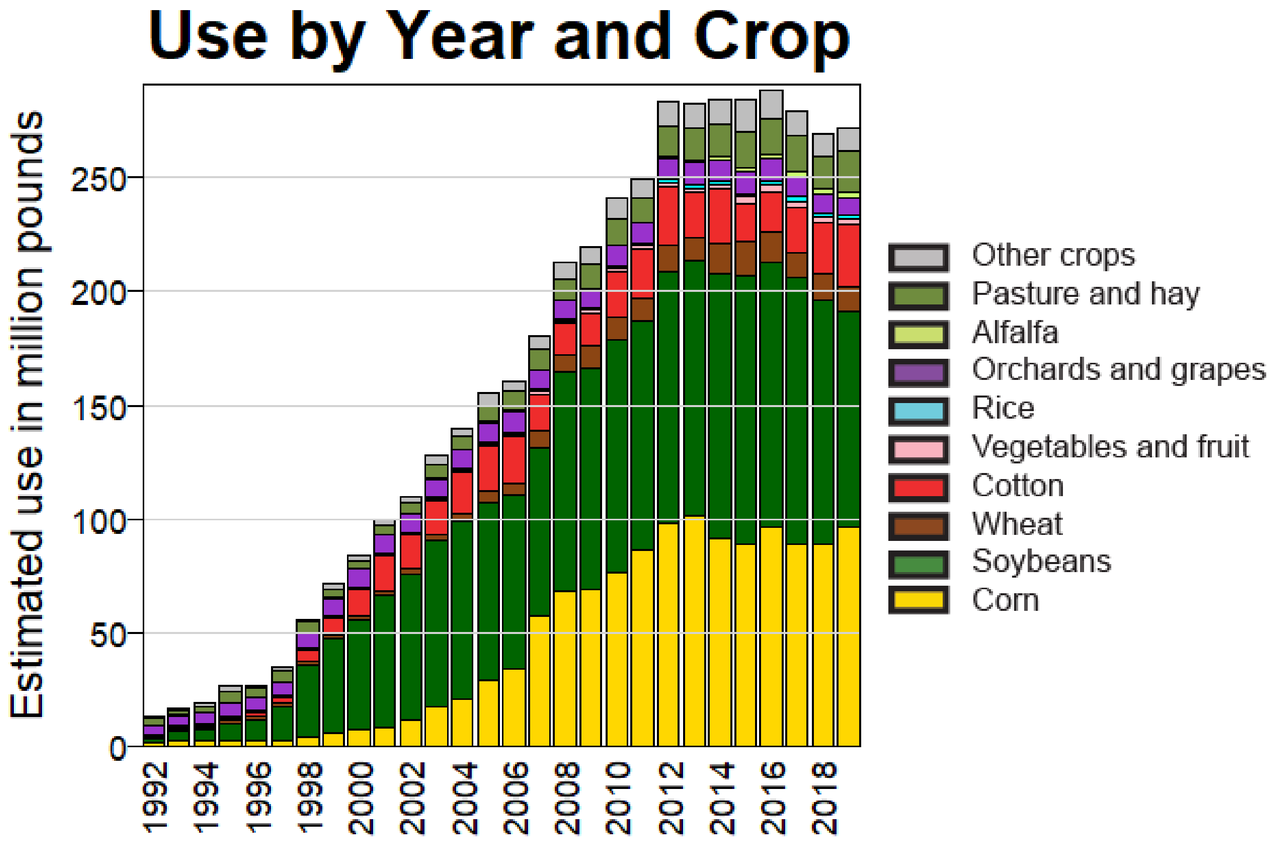
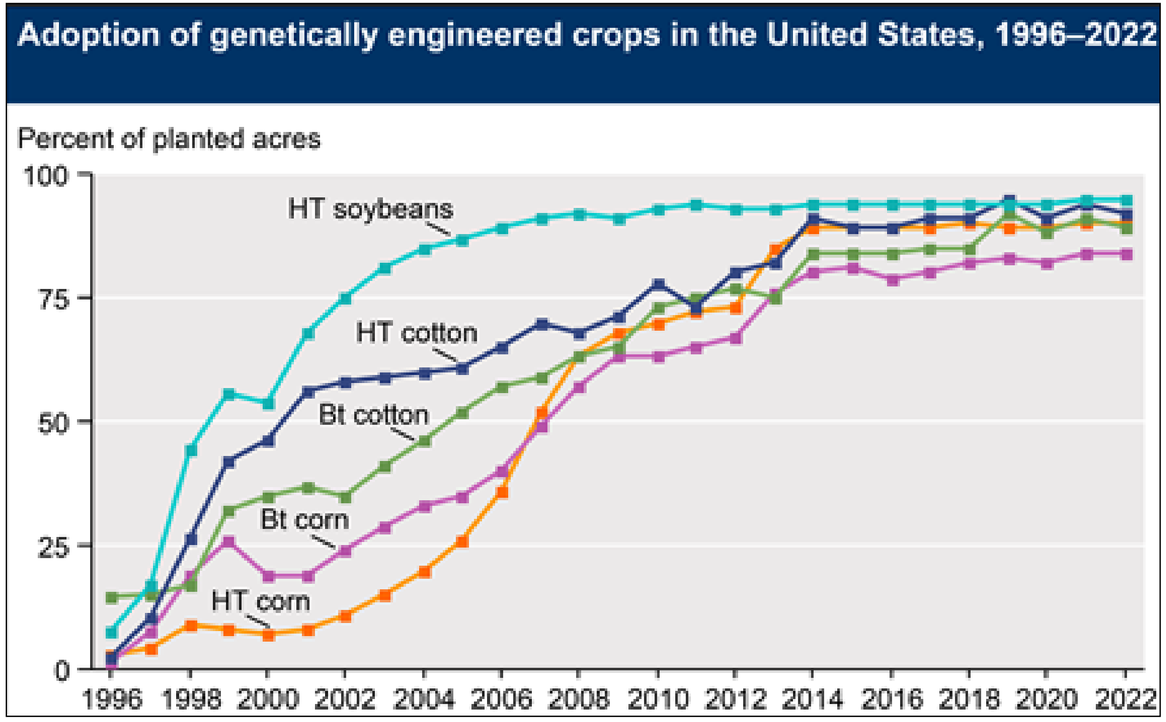
Historical Trend in Glyphosate Use Intensity
Tracks with Roundup Ready Crop Production



USGS NAWQA Program Pesticide National Synthesis Project



USDA Economic Research Service

https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-u-s/recent-trends-in-ge-adoption/

Tolerances, Tolerances Everywhere…
And It's All Legal and Validated under FFDCA as "Safe"

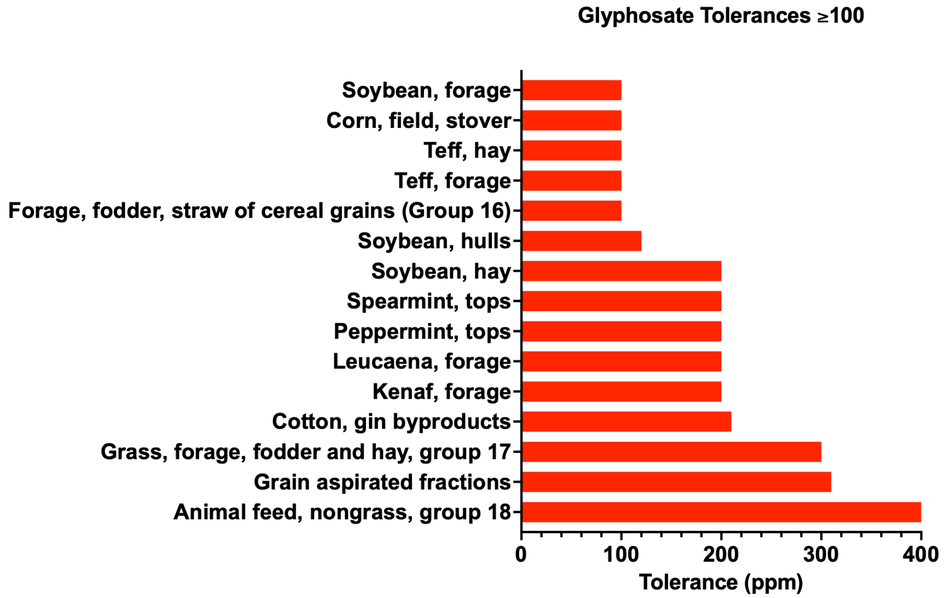


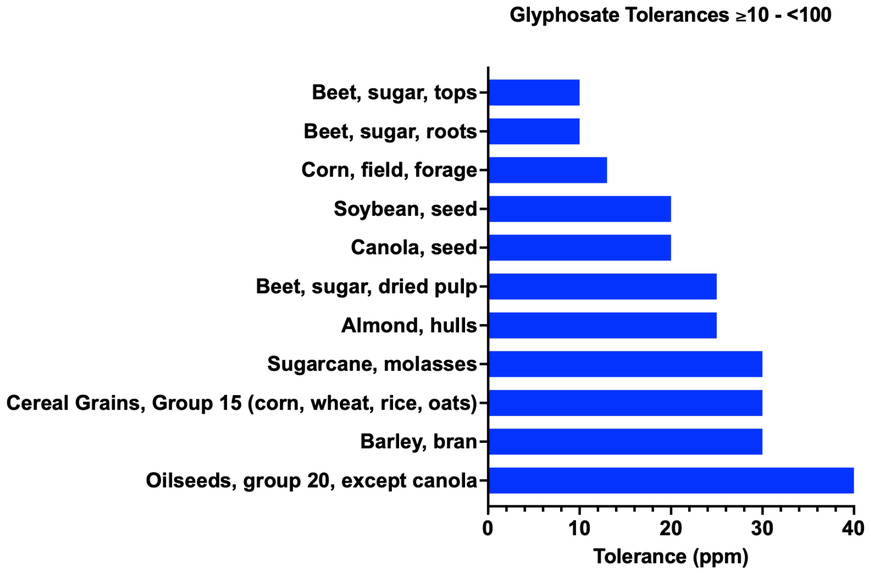


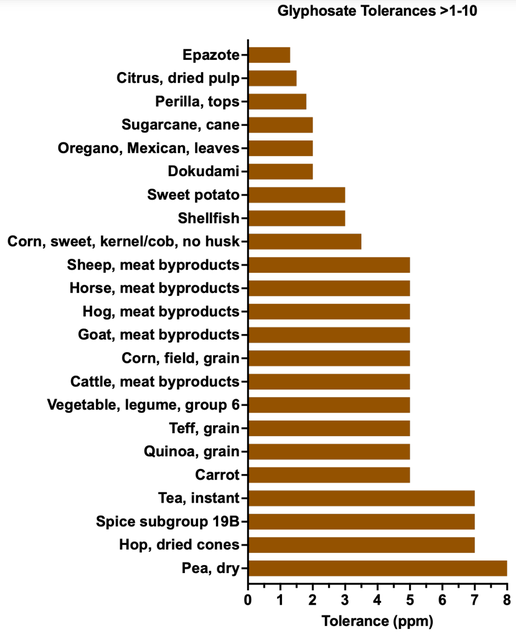


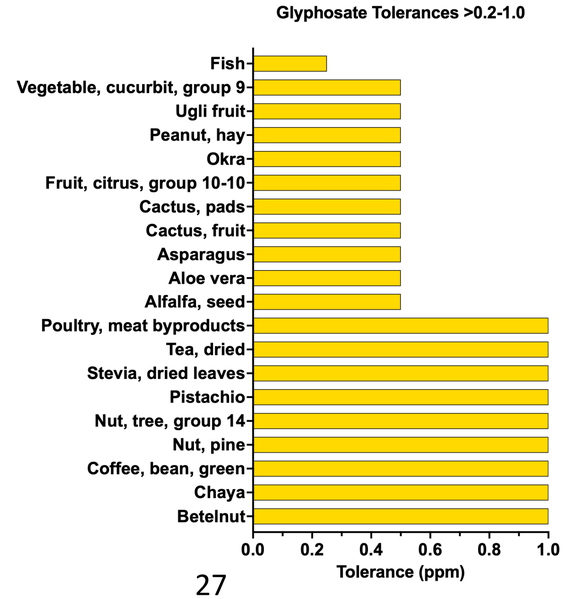


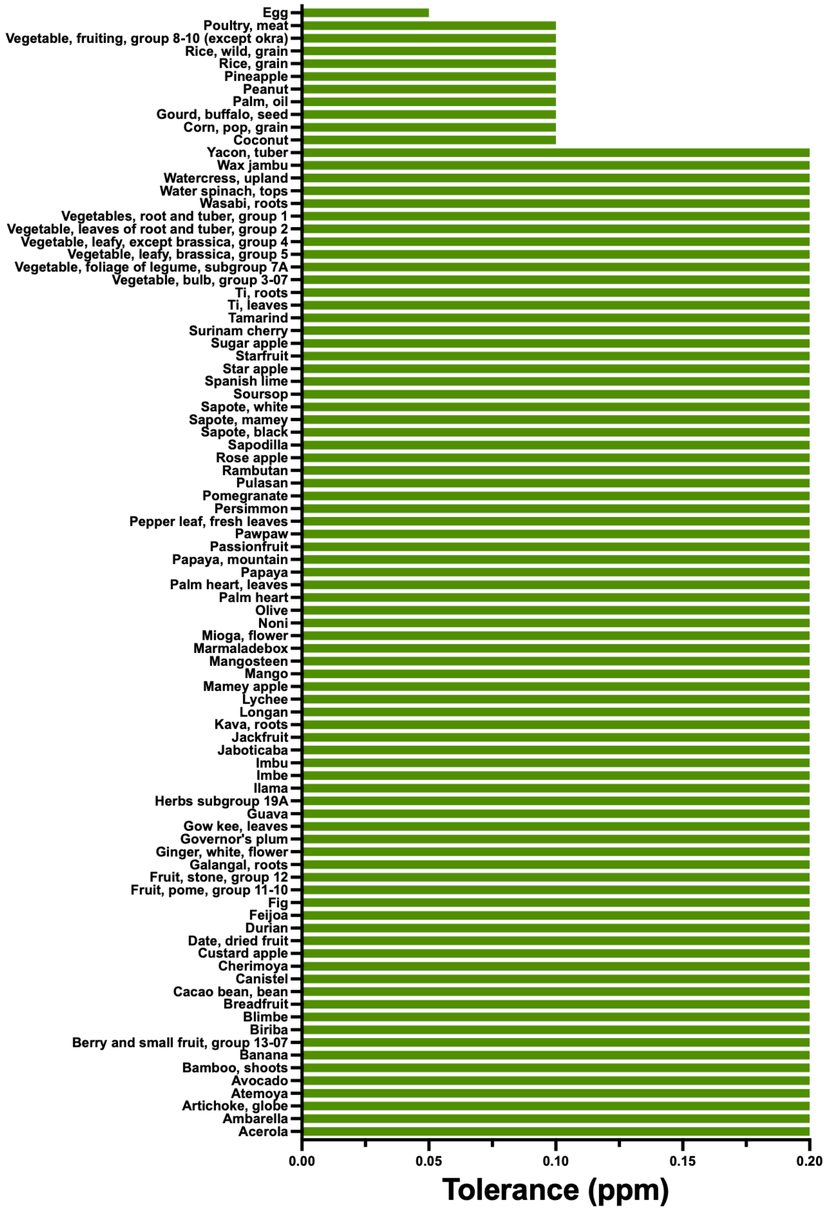

Tolerances, Tolerances Everywhere…And It's All Perfectly Legal & "Safe"



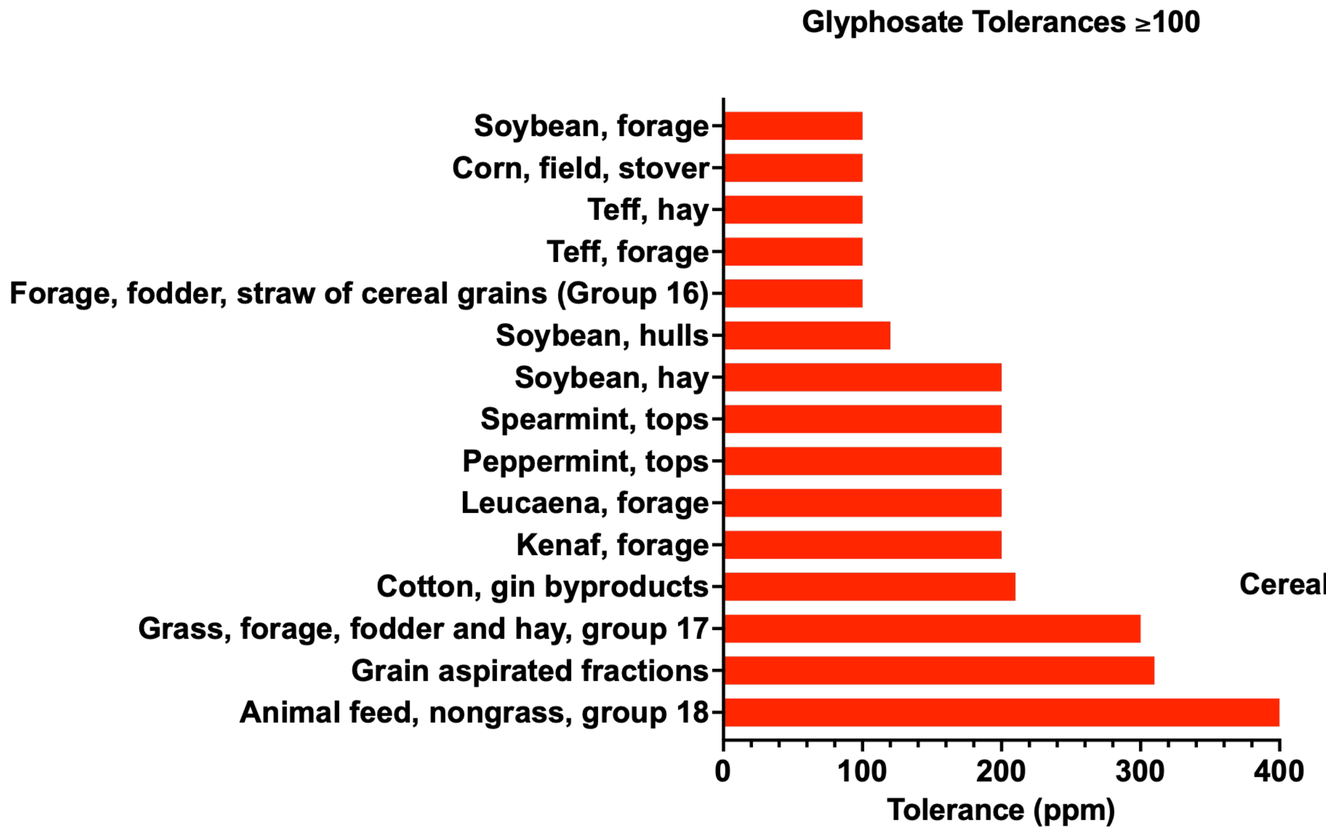


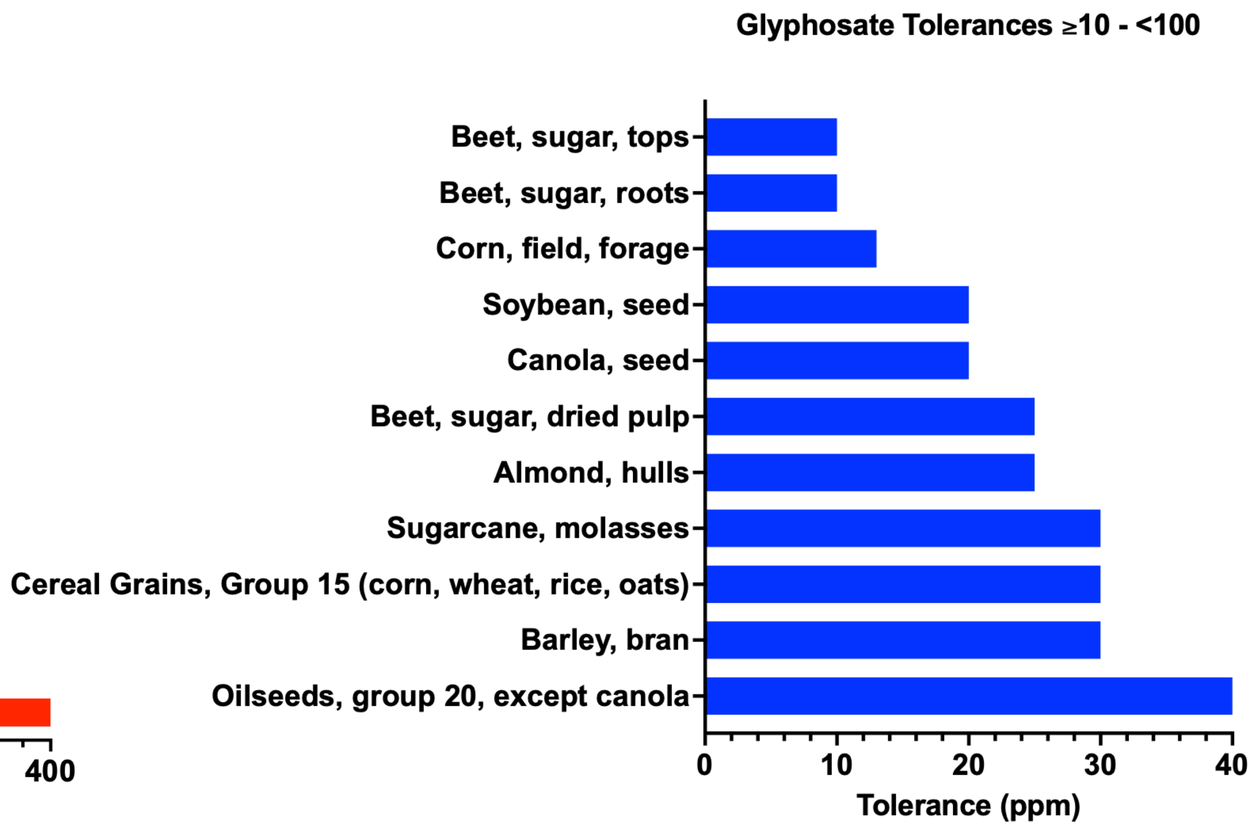






Glyphosate Tolerances (ppm) Authorized under FIFRA





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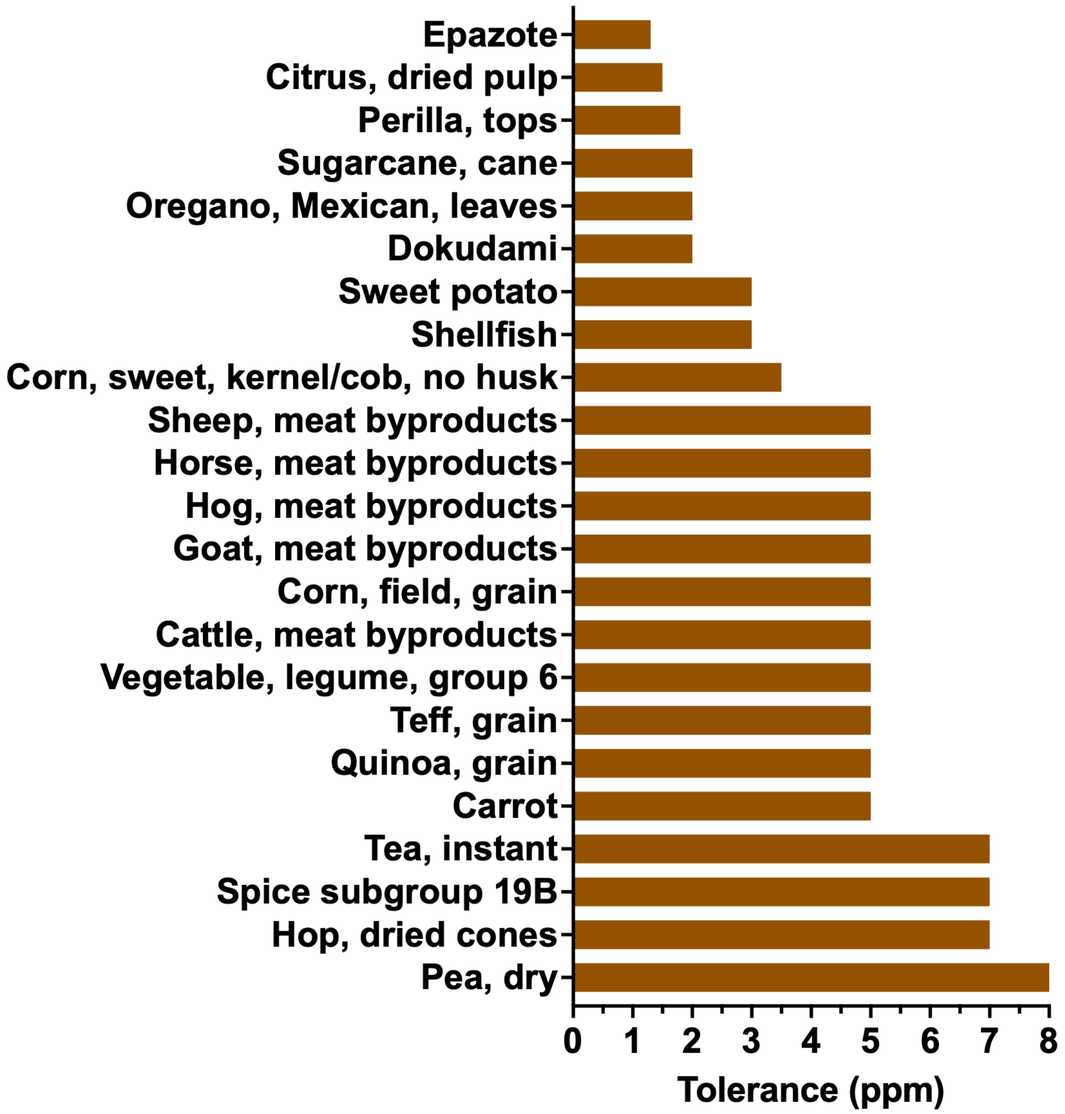

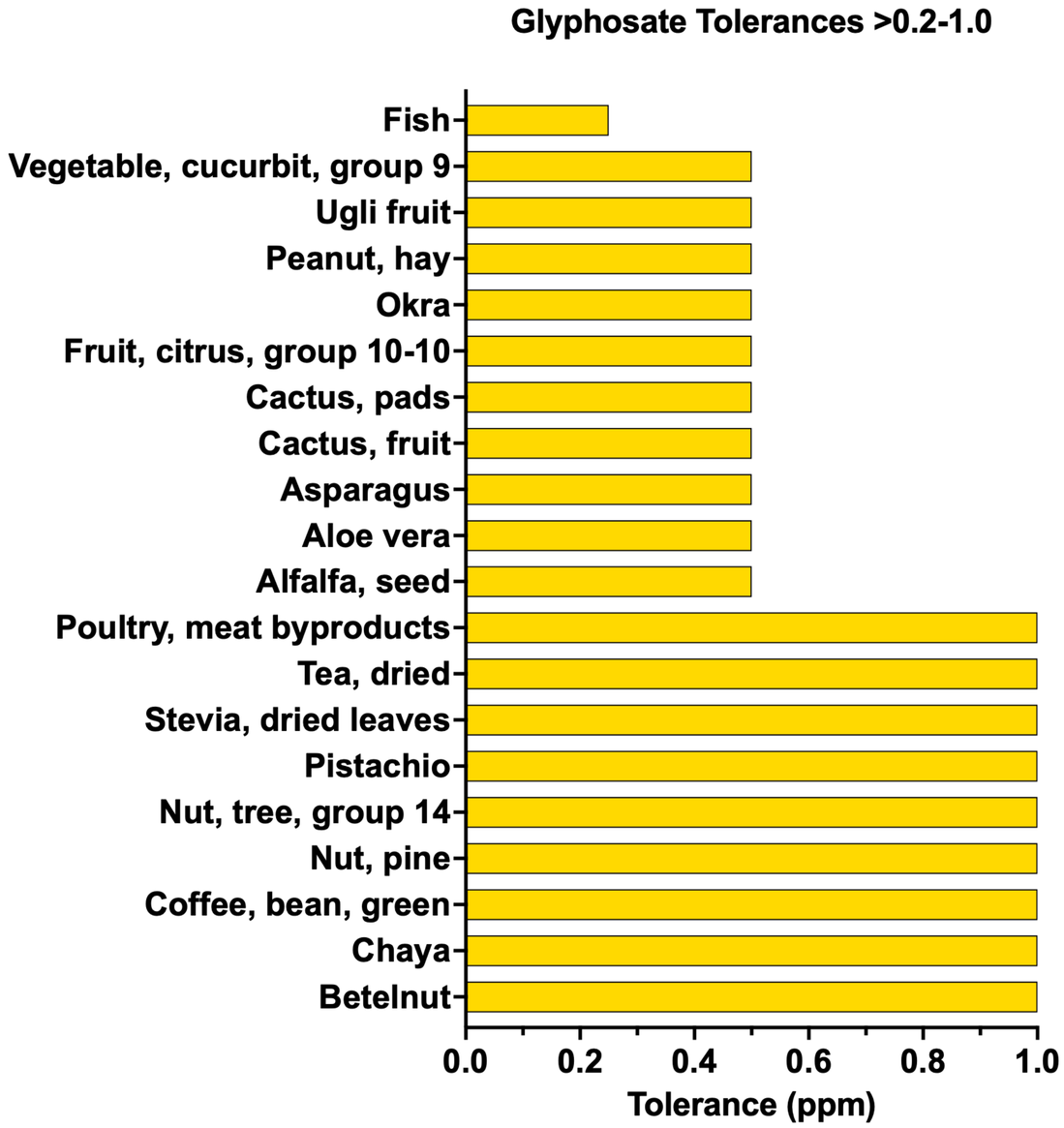

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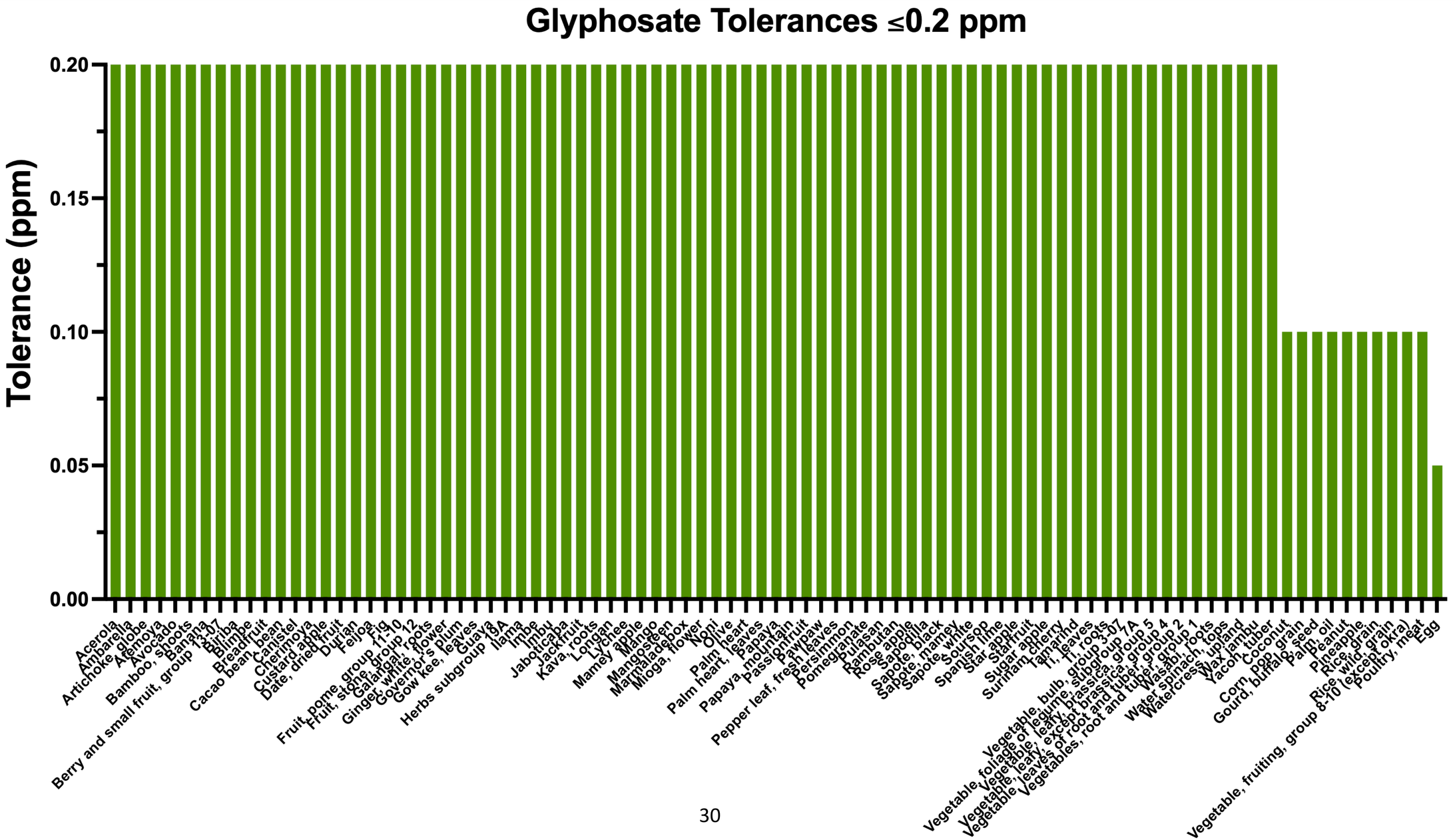
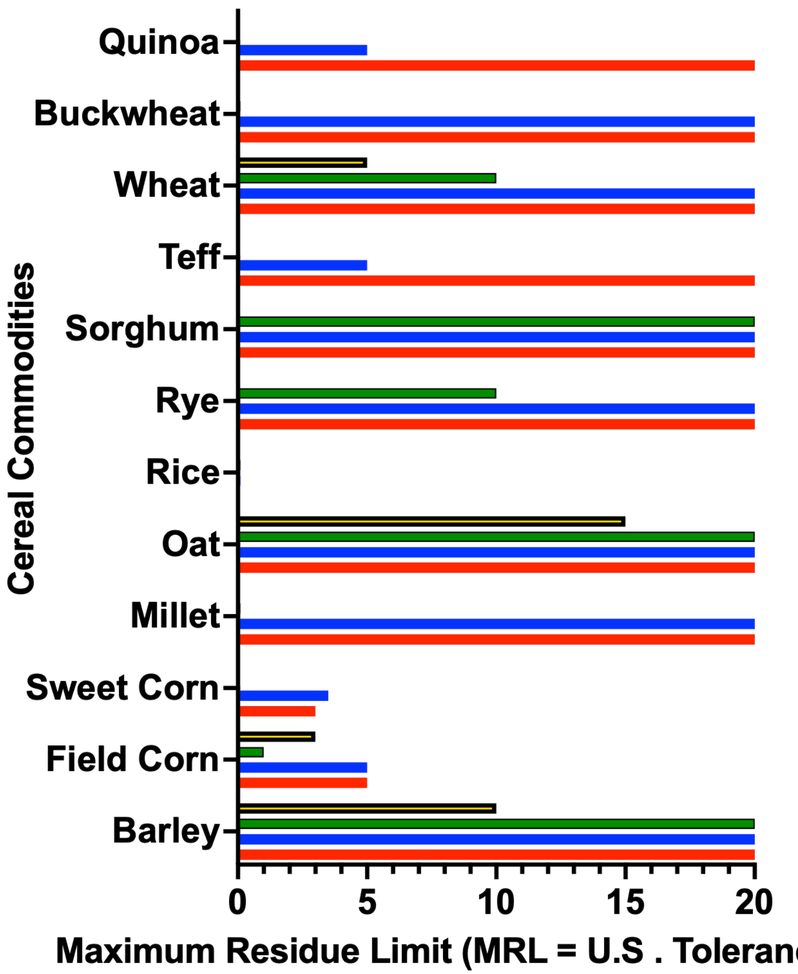
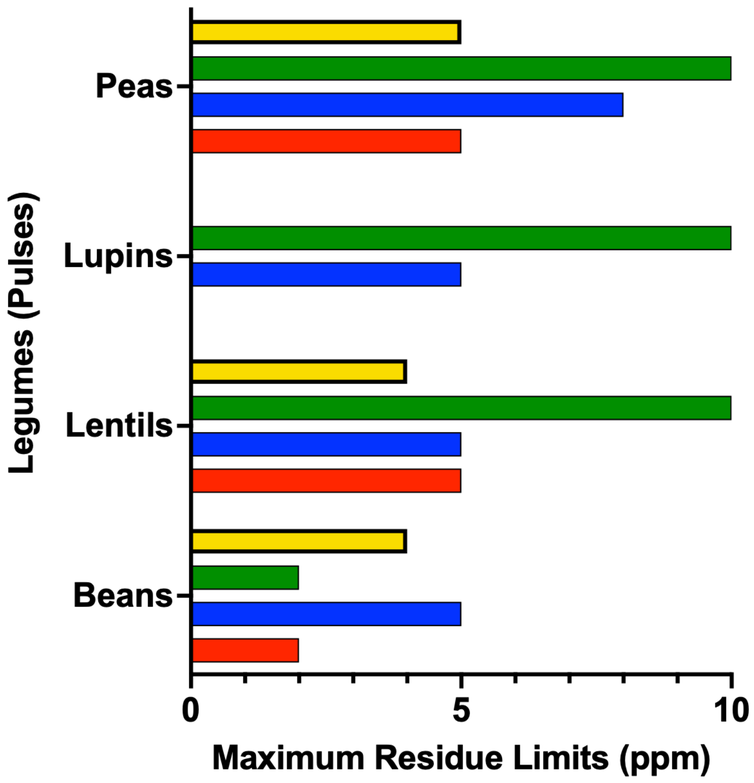
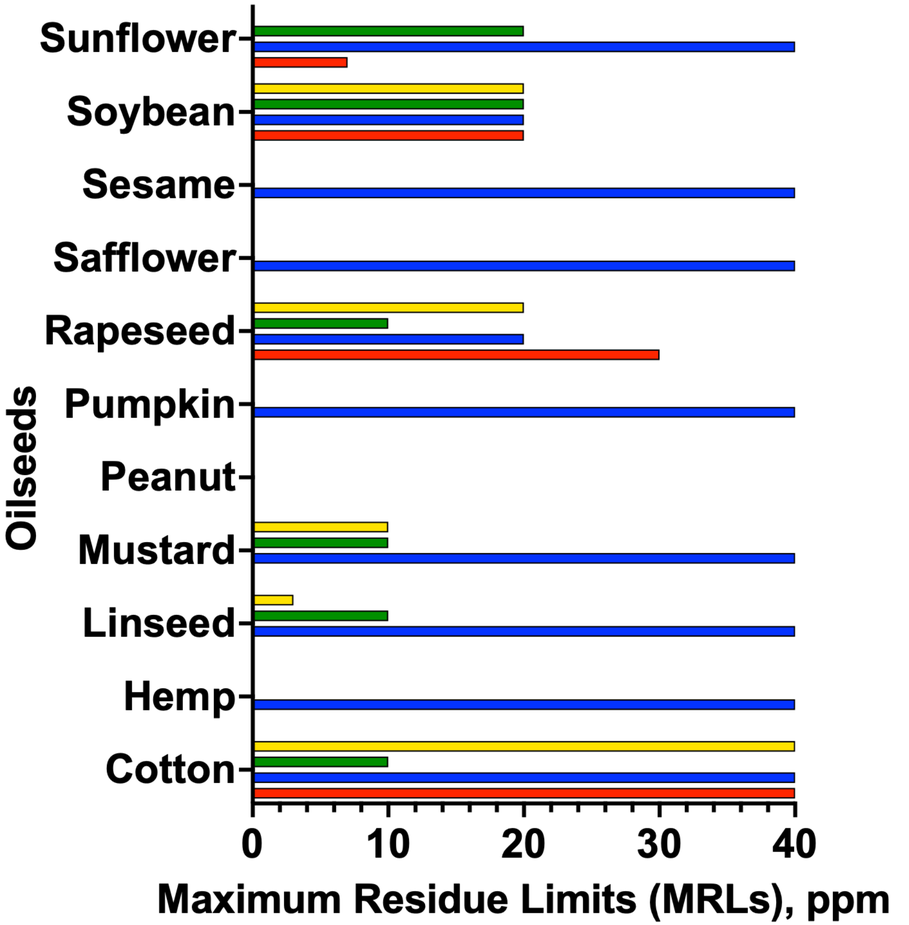
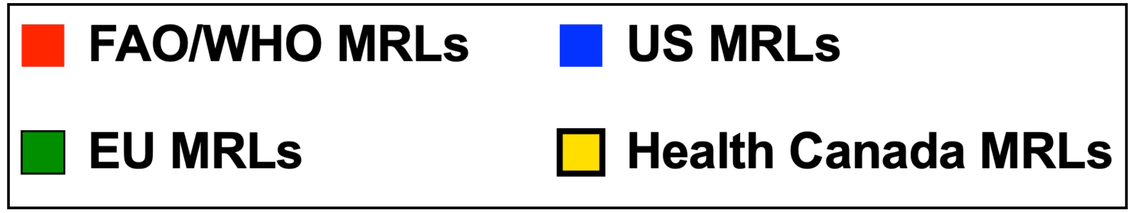


Comparison of Tolerances (=MRLs, Maximum Residue Limits) Among OECD Countries









Global Harmonization

- So as not to impede global commerce, all countries engaged in importing and exporting food commodities have agreed to worldwide standards for MRLs
- However, in the U.S., our tolerances may differ somewhat from global MRLs
- Thus, we are constantly in negotiation with other countries to harmonize our tolerances and MRLs

So, What Are the Residues Found on Food

- In the U.S., Two basic government routine monitoring programs
  - ✓ FDA Monitoring Programs
    - ❖ Enforces tolerances under the FFDCA
      - ▪ Regulatory & Compliance Monitoring
      - ▪ Incident/Level Monitoring
      - ▪ Total Diet Study
  - ✓ USDA Pesticide Data Program (PDP)
    - ❖ Cooperative with 10 State laboratories
- Academic studies:
  - ✓ Periodic depending on funding; more snapshot than trend over time

Glyphosate Residues in Cereal Commodities (Based on 6 Published Academic Studies)

Cereals	Maximum Residues (ppm)	US Tolearnce	% of Tolerance
Wheat	11.1	30	37.0
Wheat bran	<0.7	30	2.3
Barley	<0.45	30	1.5
Durum wheat	0.421	30	1.4
Breakfast cereal	0.291	30	1.0
Flour & baking mixtures	0.133	30	0.4
Corn syrup	<0.015	5	0.3
Oat	<0.08	30	0.3
Bread	0.0458	30	0.2
Rye	<0.04	30	0.1
Wheat Flour	0.02	30	0.1
Wheat pastry snacks	0.0179	30	0.1

Xu et al (2019)

Glyphosate Residues in Legume Commodities (Based on 6 Published Studies)

Legumes (Pulses)	Maximum Residues (ppm)	US Tolerance	% of Tolerance
RR Soybean	8.8	20	44.0
Soy sauce	0.6	20	2.8
Pea	0.1	5	1.2
Soy milk, tofu	<0.075	20	0.4

Xu et al (2019)

Glyphosate Residues in U.S. Soybean, Corn, Milk, Eggs: USDA & FDA Studies (2018-2020)

Vicini et al. (2021)

	Agency	# Samples Analyzed	% Detections	Maximum ppm Detected	% of US Tolerance
Soybean grains	USDA	300	90	18.5	93
Soybean grains	FDA	337	61	10.0	50
Corn	FDA	313	58	4.5	90
Milk	FDA	121	0	0	-
Eggs	FDA	108	0	0	-

U.S. Tolerance for Soybeans = 20 ppm
U.S. Tolerance for Corn = 5 ppm

U.S. Tolerance for Eggs = 0.05 ppm
No US Tolerance for Milk

Canadian Food Inspection Agency
Studies of Glyphosate Residues in Diverse Foods

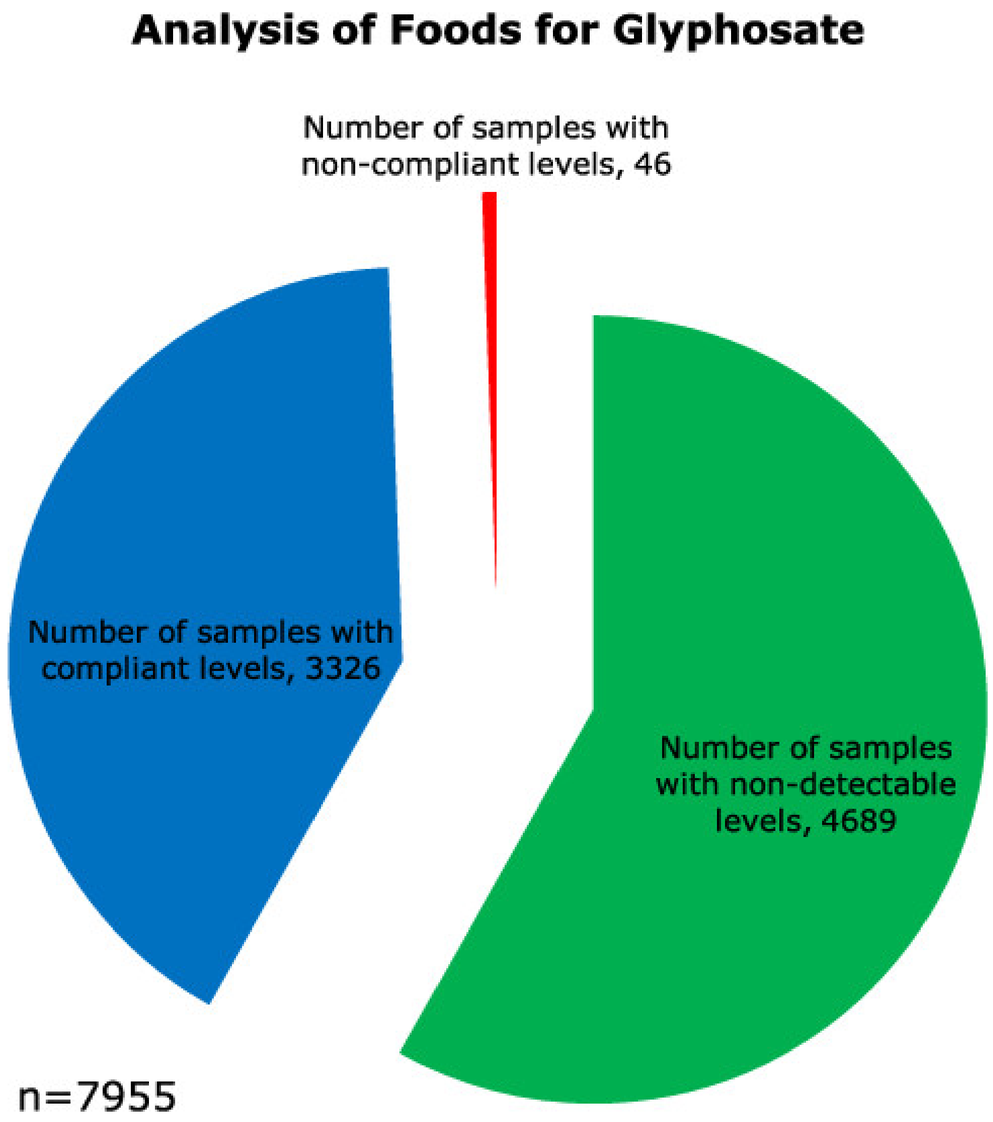
Food Category	# Samples	% Detections	Max	% of MRL
Dairy/Meet	22	0	0	0
Fresh/Processed Fruit & Vegetables	1473	12	0.15	150 *
Other Grains (e.g., rice, buckwheat, rye)	626	31	5.9	5900 *
Corn & Products	501	23	0.45	15
Legumes (Beans/Peas)	770	42	13	325 *
Wheat & Products	807	76	8.5	57
Barley & Products	103	50	2.1	21
Oats & Products	310	75	3.1	21
Soybean & Products	204	10	6.0	30
Infant Foods	927	31	2.5	7
Processed Foods (e.g, cookies, pizzas)	2212	61	1.9	5

Kolakowski et al (2020)

Significance of Canadian Findings

- Out of 7955 samples analyzed, only 46 in total (i.e., 0.5%) were found to be violative of the MRL

Food Category	# Samples	% Detections	Max	% of MRL
Fresh/Processed Fruit & Vegetables	1473	12	0.15	150 *
Other Grains (e.g., rice, buckwheat, rye)	626	31	5.9	5900 *
Legumes (Beans/Peas)	770	42	13	325 *



Kolakowski et al. (2020)

Why Is There Glyphosate In Our Piss???

Why Has Glyphosate Been Detected in Numerous Water Bodies?

No water body is an ‘island’; everything is connected to everything else. Environmental chemodynamic theory tells us that if you use it, glyphosate molecules will become dispersed in the environment.

Water Treatment Plants Clean Nearly 99.9% of Contaminants for Drinking Water Use

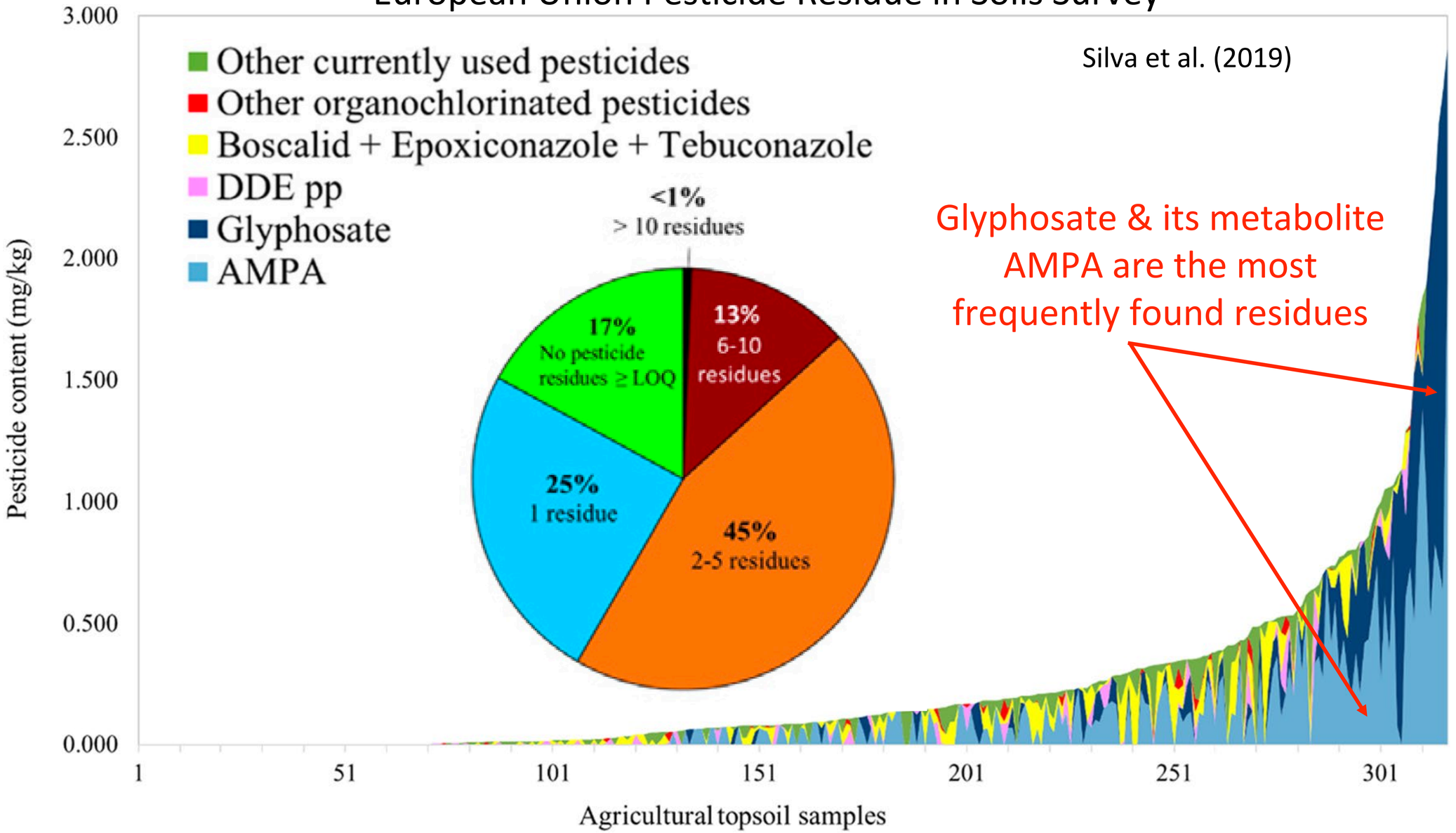
…But,

- 99.9% clean means there are 0.1% of contaminants left
- If 1% is 10,000 ppm, than 0.1% is 1000 ppm
- Thus, after diluting 1000X in the system of water distribution, there could still be 1 ppm of contaminants

Glyphosate Is Found Frequently in Soil Samples

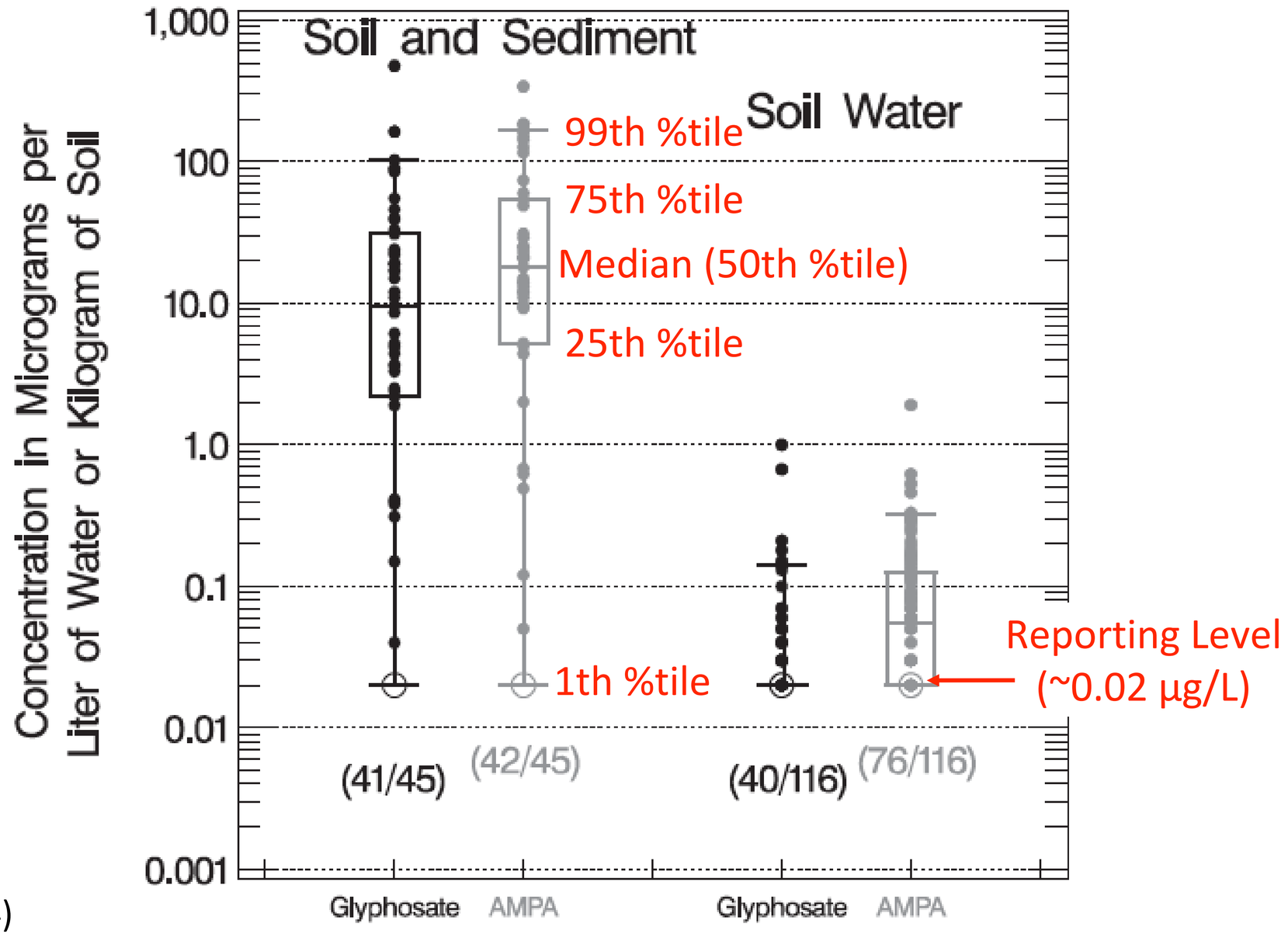
European Union Pesticide Residue in Soils Survey

Silva et al. (2019)



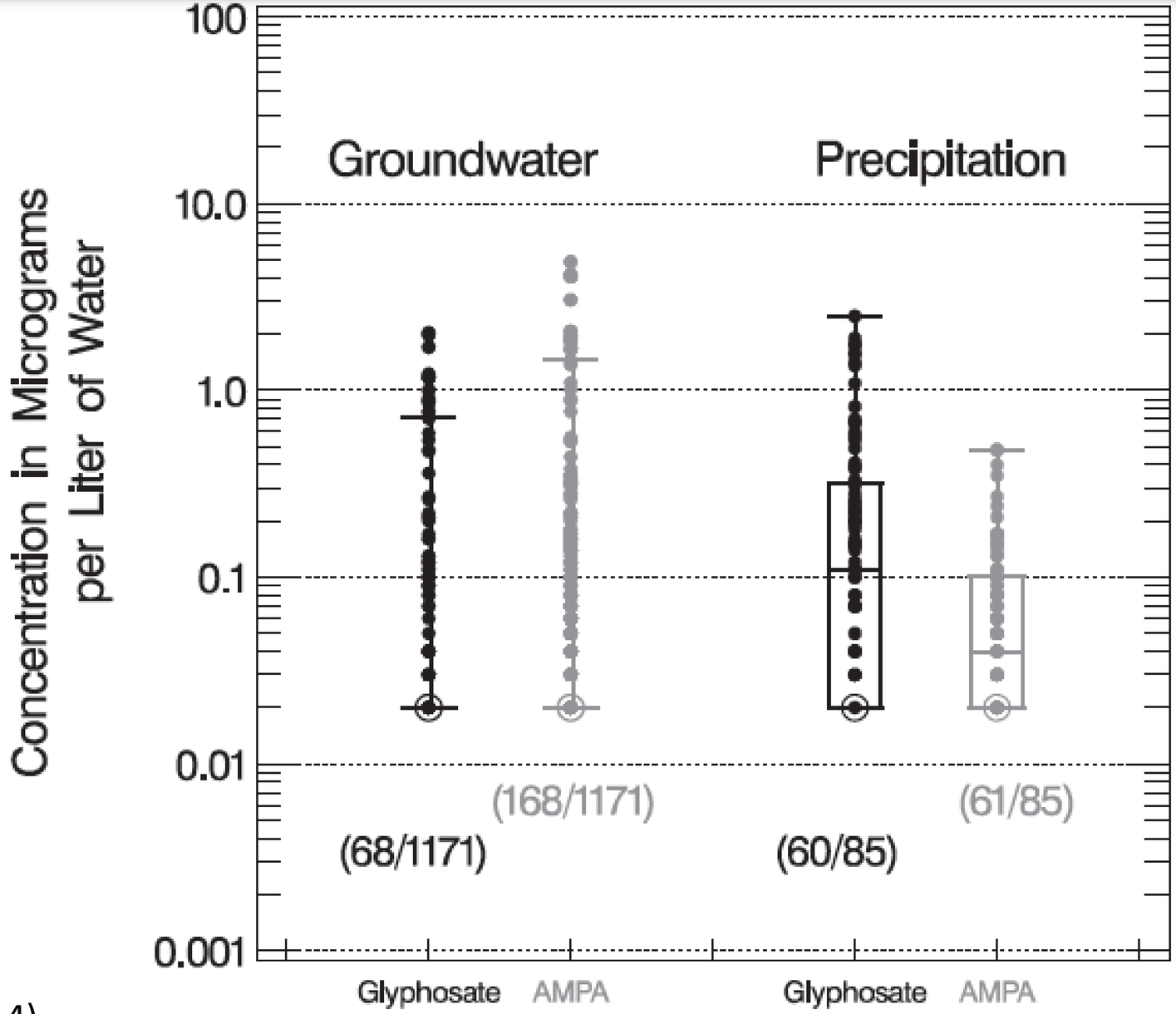
Glyphosate & its metabolite AMPA are the most frequently found residues

Concentrations of Glyphosate and AMPA for Soil and Sediment and Soil Water Samples



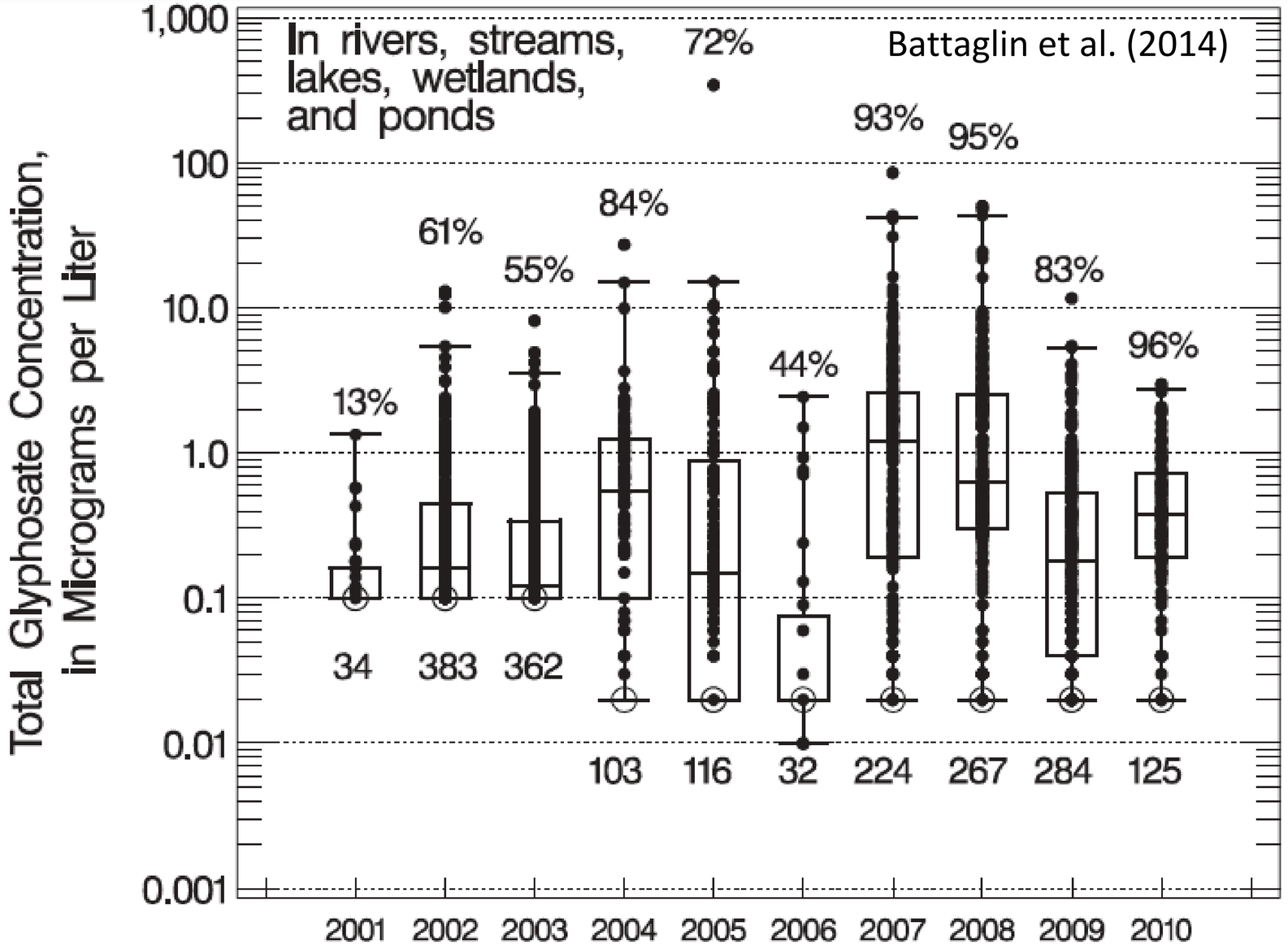
Battaglin et al. (2014)

Concentrations of Glyphosate and AMPA in Groundwater and Precipitation

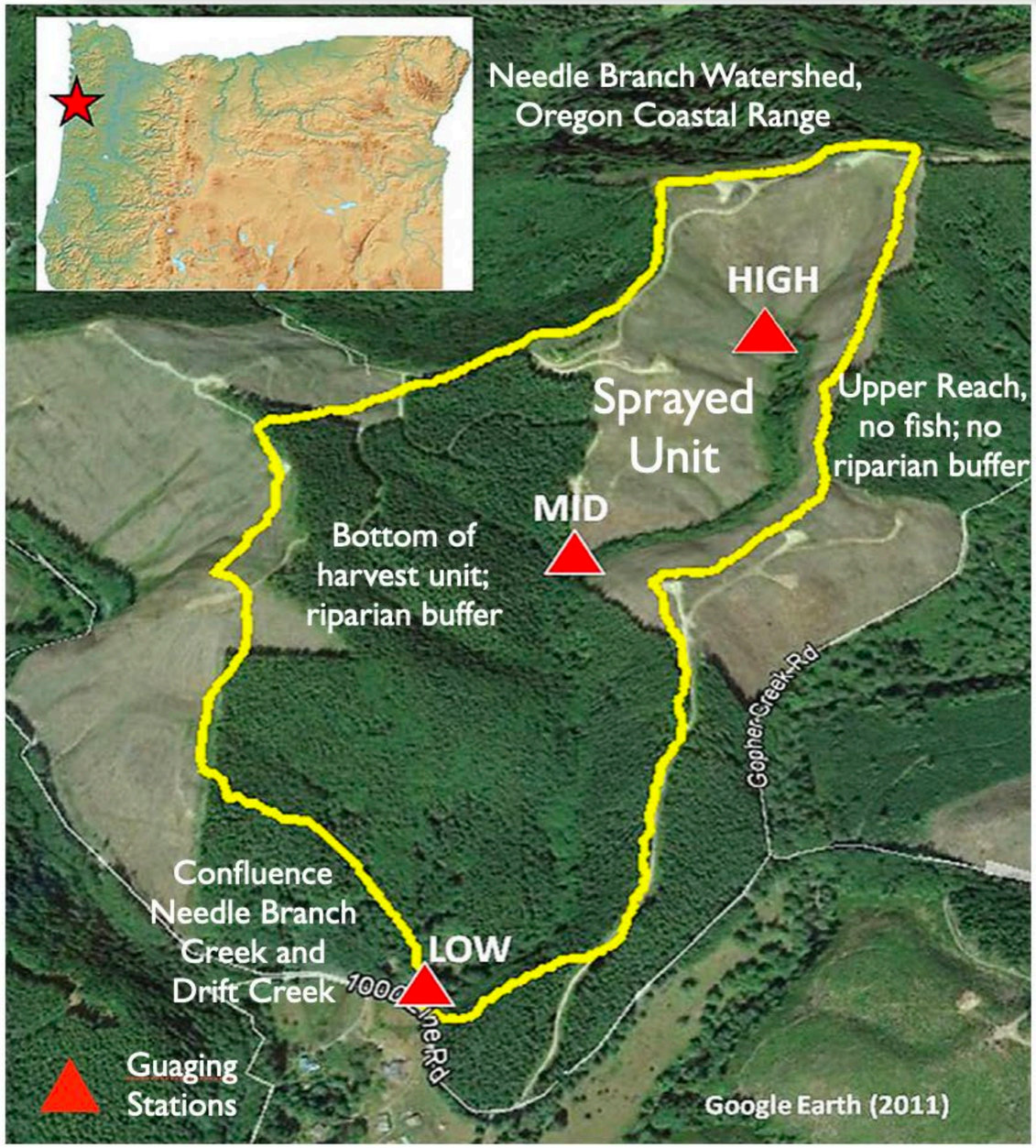


Battaglin et al. (2014)

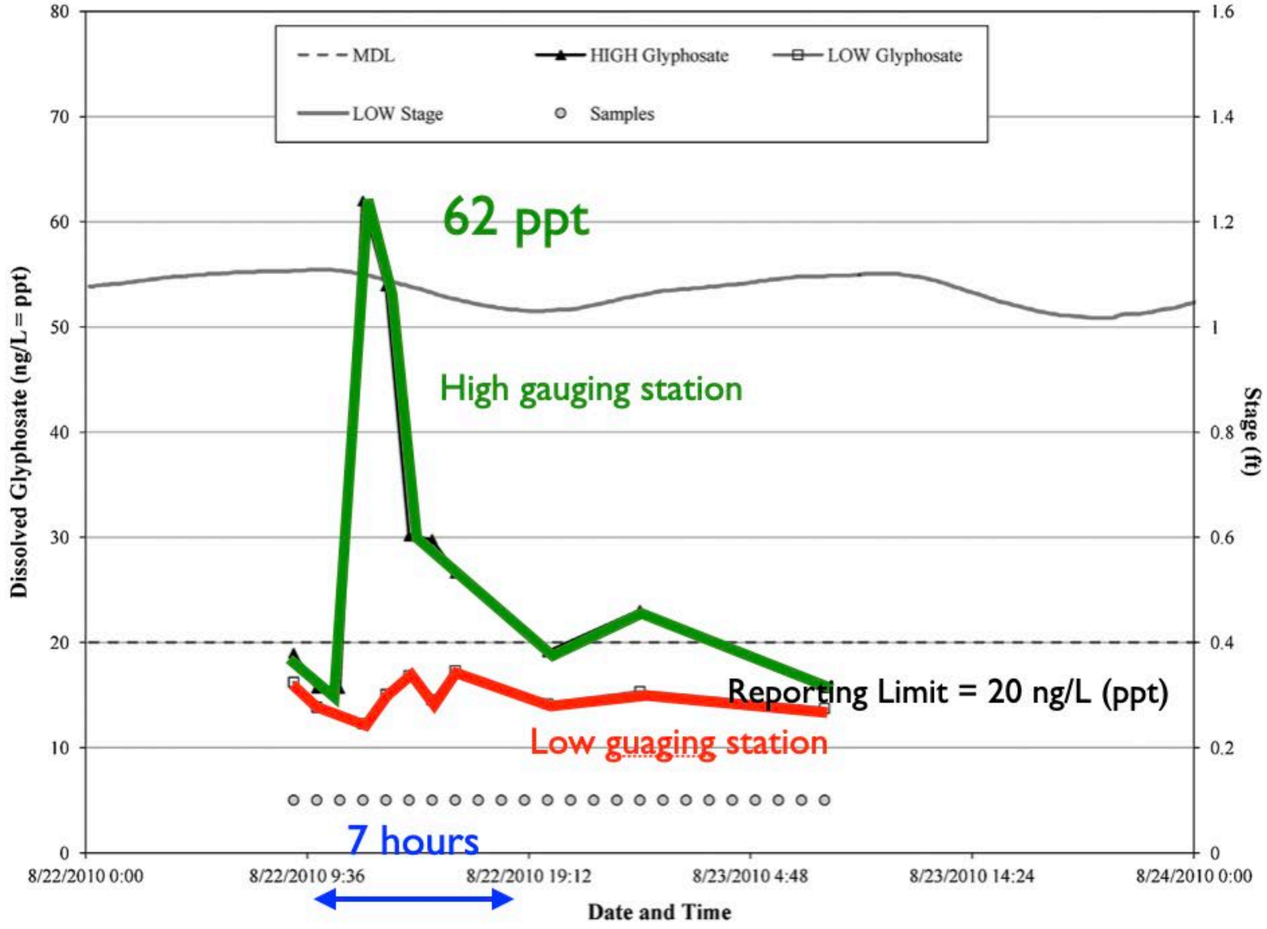
Percentage Detections and Total Glyphosate Concentrations (2001-2010) for Surface Water Samples from Rivers, Streams, Lakes, Wetlands, and Ponds



Glyphosate Residues in Water: Empirical Study from Oregon Forest Watershed



Dissolved glyphosate in streamwater (baseflow) during and immediately following application of herbicides



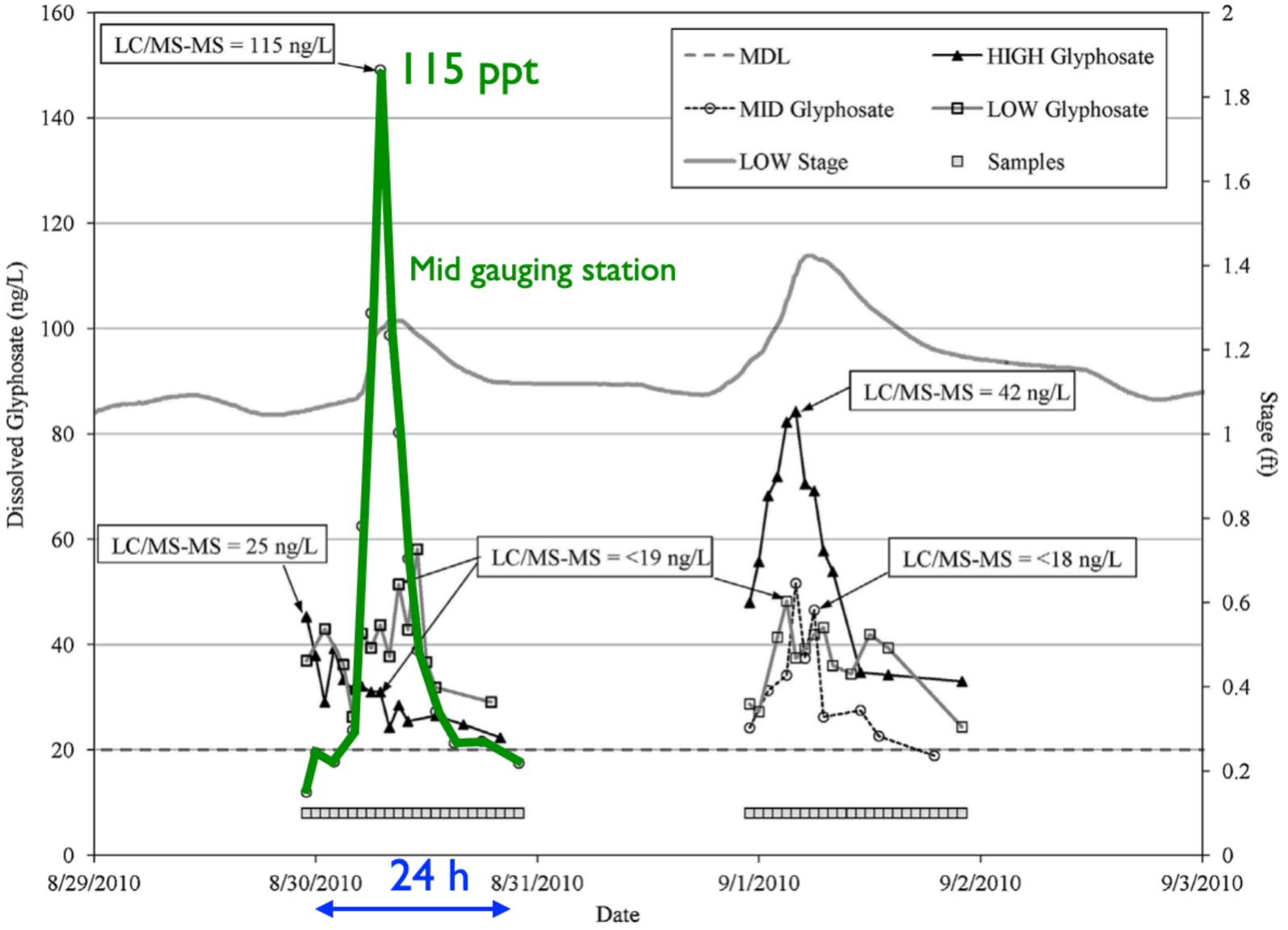
Louch et al. (2017) Potential risks to freshwater aquatic organisms following a silvicultural application of herbicides in Oregon's Coast Range. Integrated Environmental Assessment and Management, 13(2), 396-409.

Dissolved glyphosate in streamwater during first 2 post application storm events at the Needle Branch watershed with results from LC/MS-MS confirmations

- In the USGS study, the maximum concentration of glyphosate in water bodies was 20-40 ppb

- Thus, forestry use in one study shows residues of glyphosate in a gauged stream near the sprayed site were at least 10x lower than residues in watersheds dominated by row crop agriculture

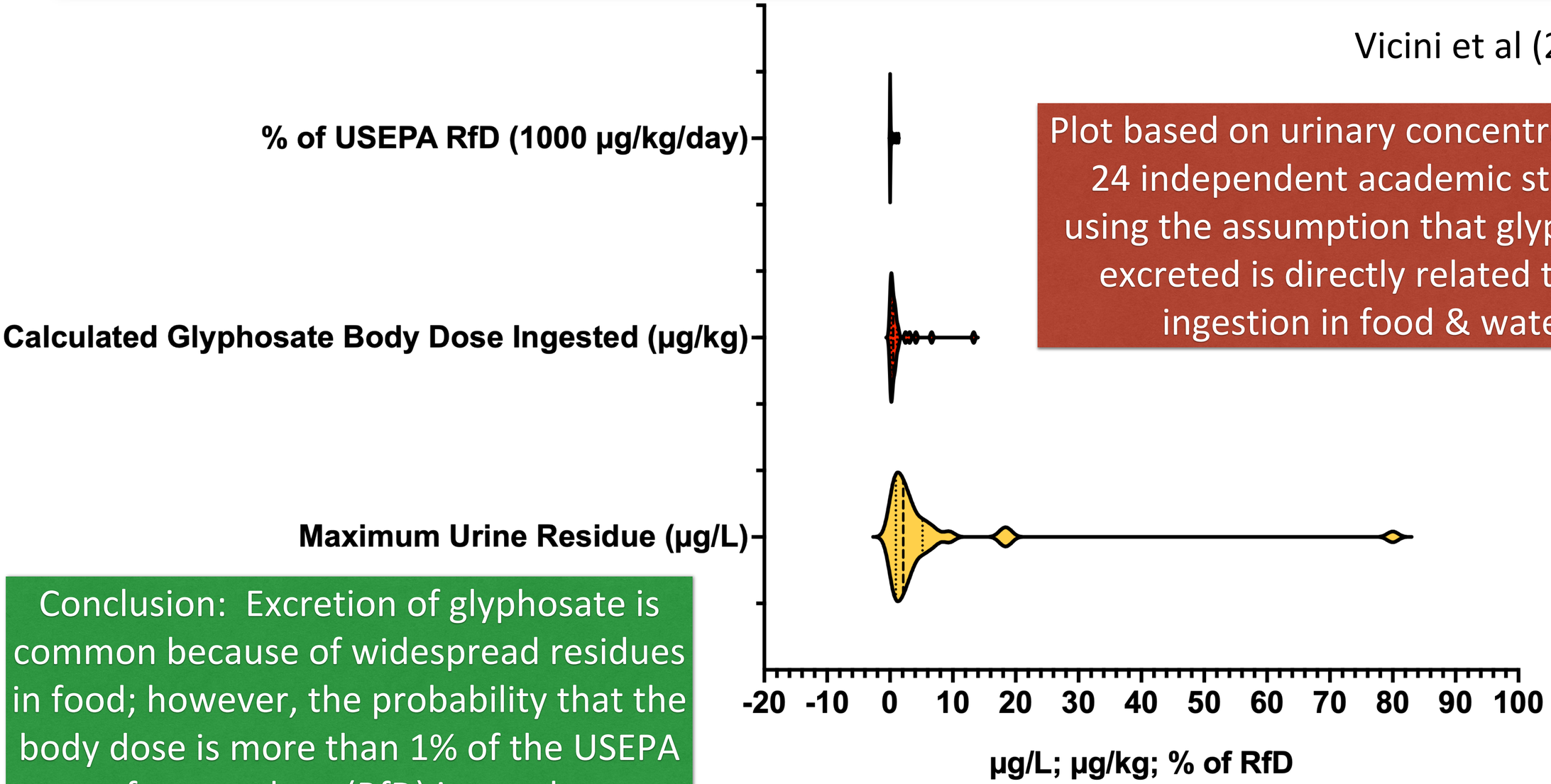
Louch et al. (2016)



Residential & Worker Use of Glyphosate

Combined Probability Distribution of Glyphosate Exposure Based on Residue Excretion in Urine

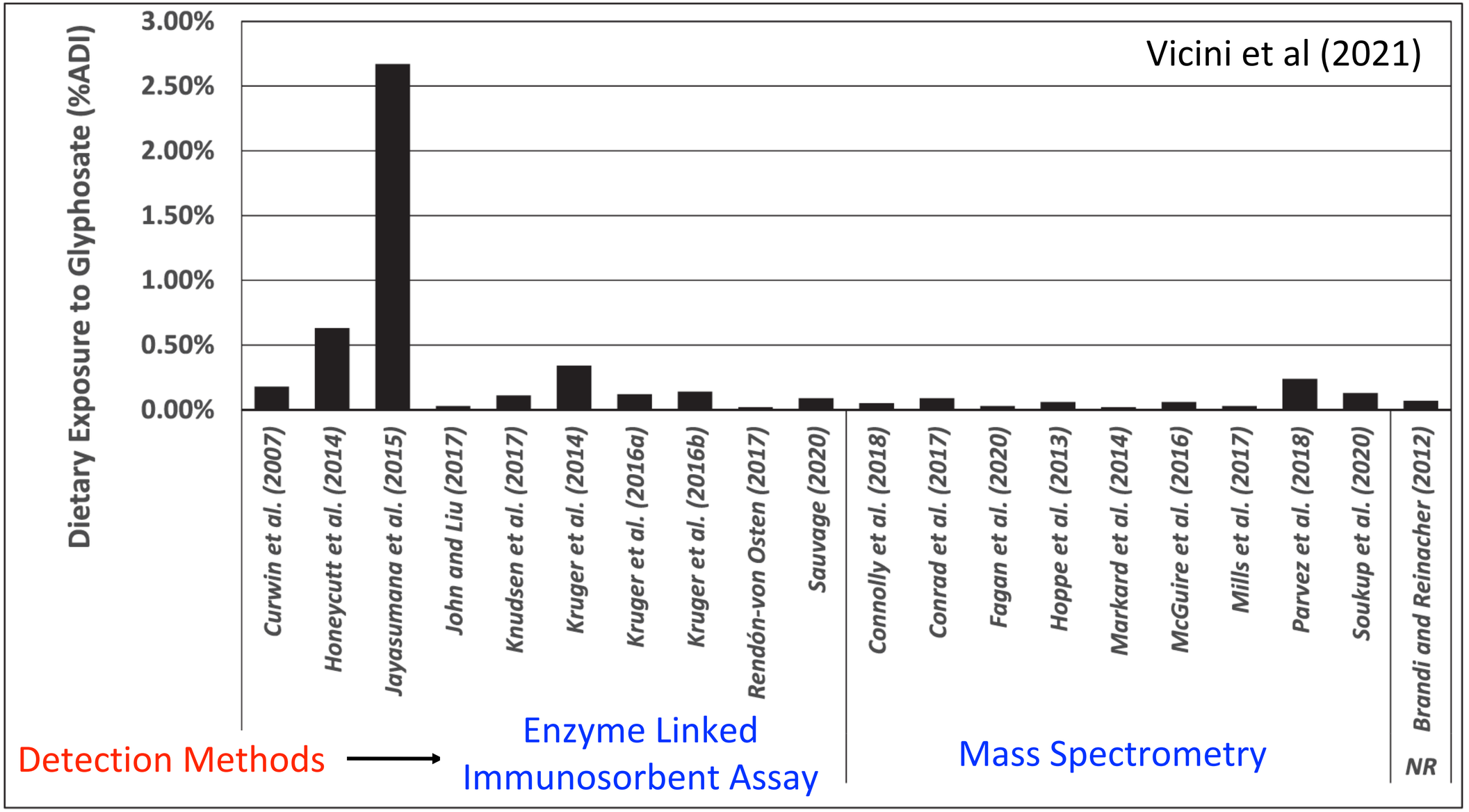
Vicini et al (2021)



Plot based on urinary concentrations in 24 independent academic studies, using the assumption that glyphosate excreted is directly related to the ingestion in food & water

Conclusion: Excretion of glyphosate is common because of widespread residues in food; however, the probability that the body dose is more than 1% of the USEPA reference dose (RfD) is very low

Deterministic Risk Assessment Based on Maximum Residues Excreted in Urine

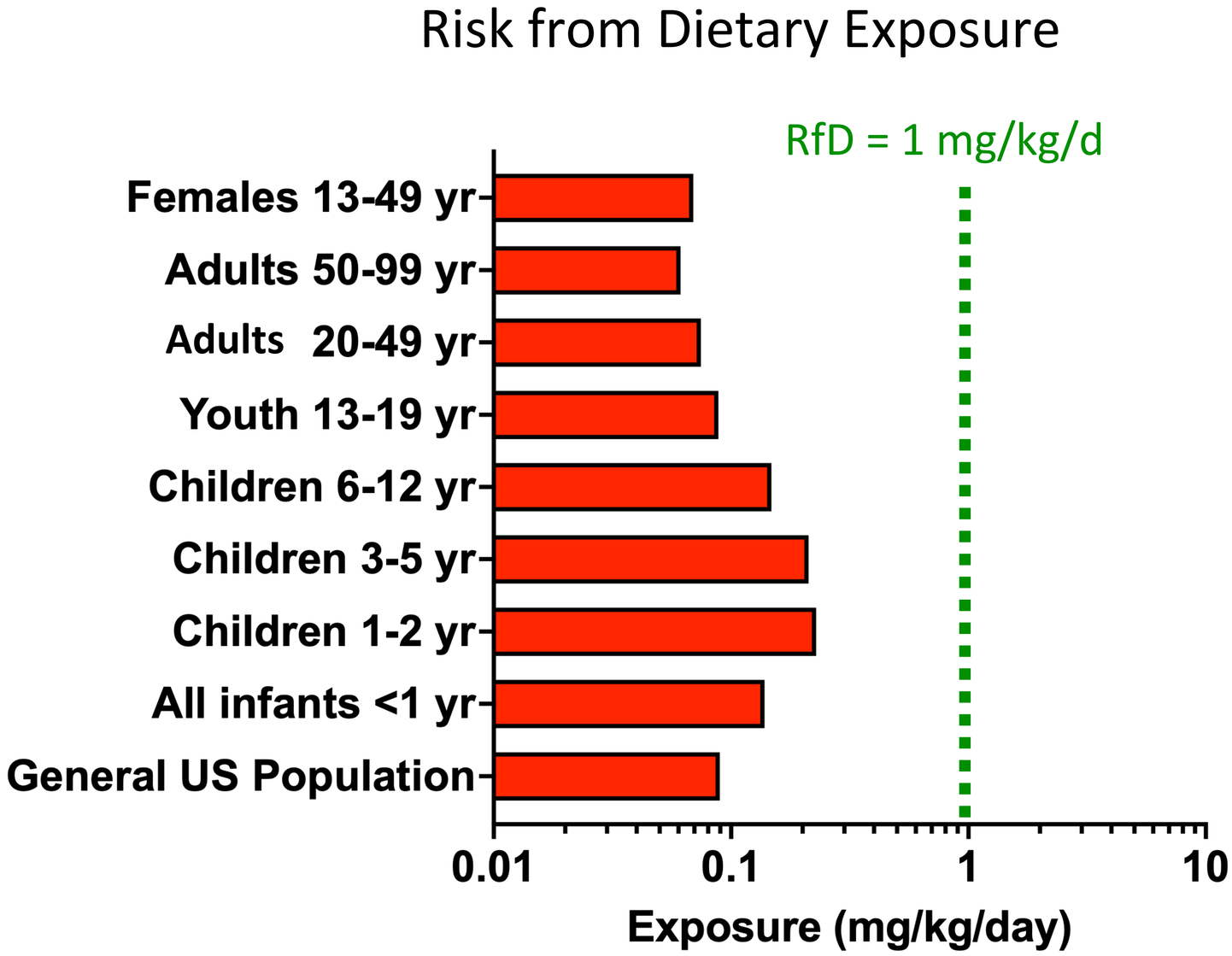


And Finally, What Does the EPA Think About Glyphosate Risk?

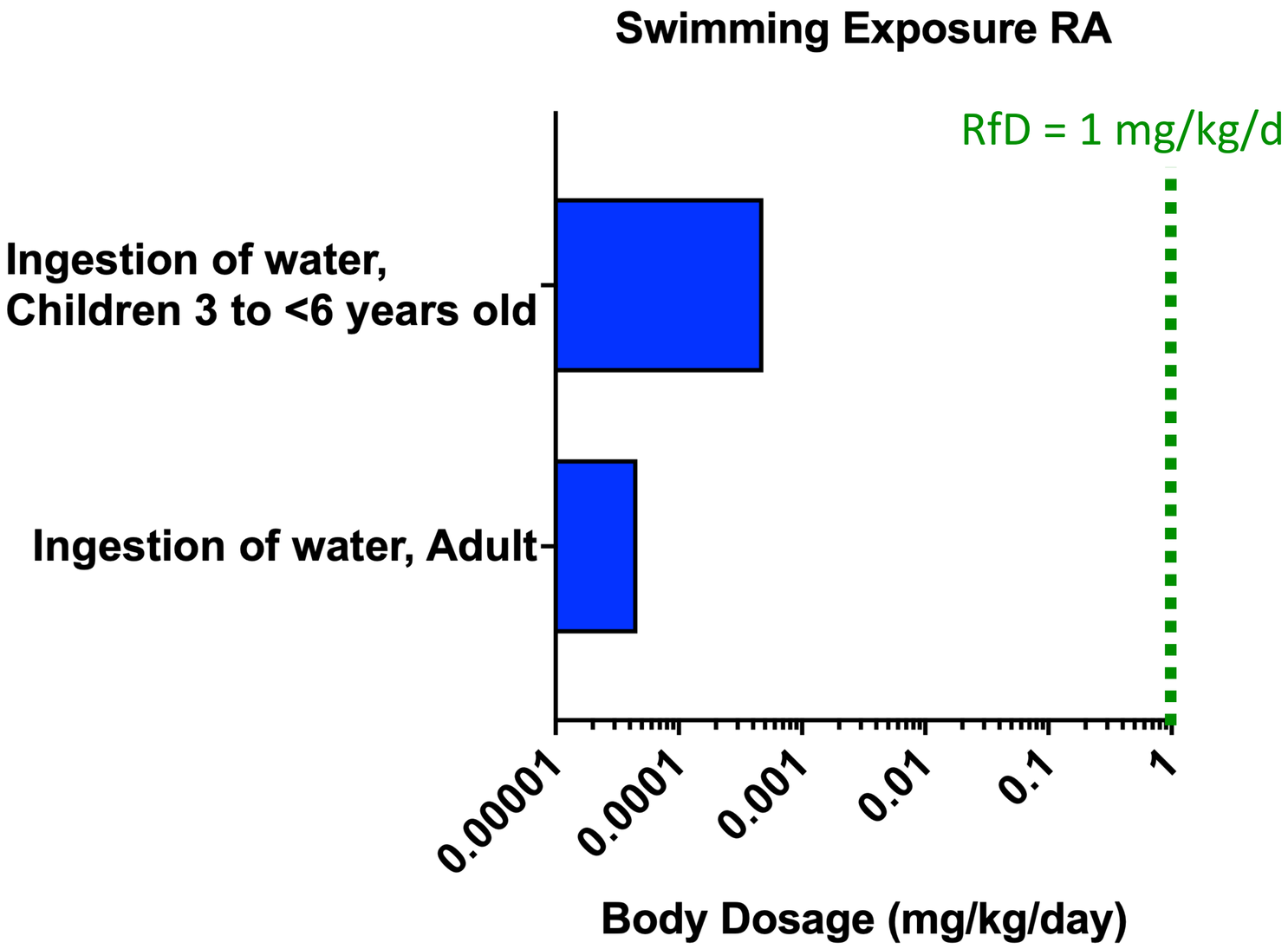
- EPA only estimated risk from chronic (lifetime) glyphosate exposure because the tox database did not indicate any short term adverse effects from glyphosate exposure

- EPA assumed that all glyphosate residues were were at the tolerance level, a very conservative assumption and all registered commodities were sprayed

- The outcome of the analysis showed nil risk because the estimated exposure was at least 5-10 times less than the RfD

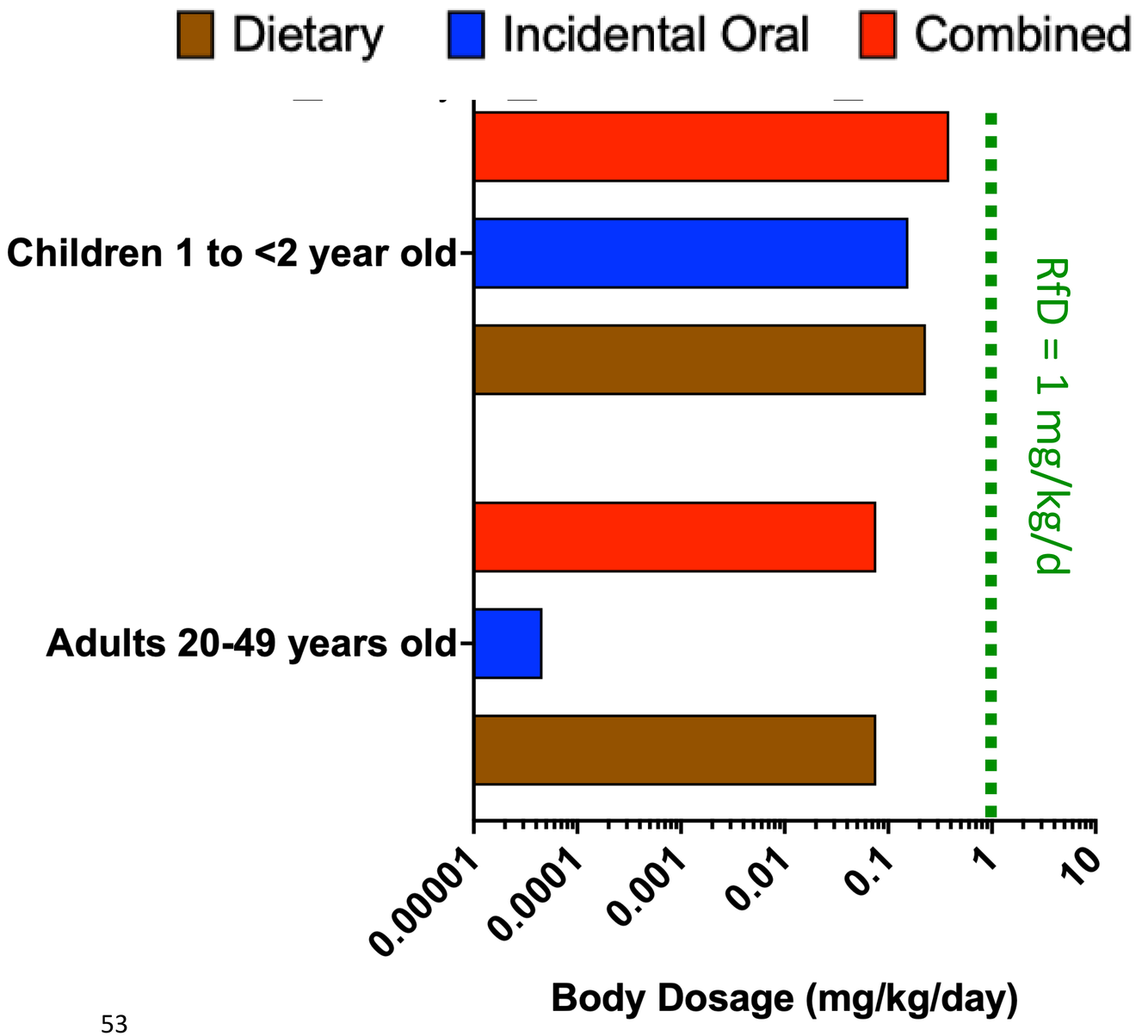


EPA Takes a Swim

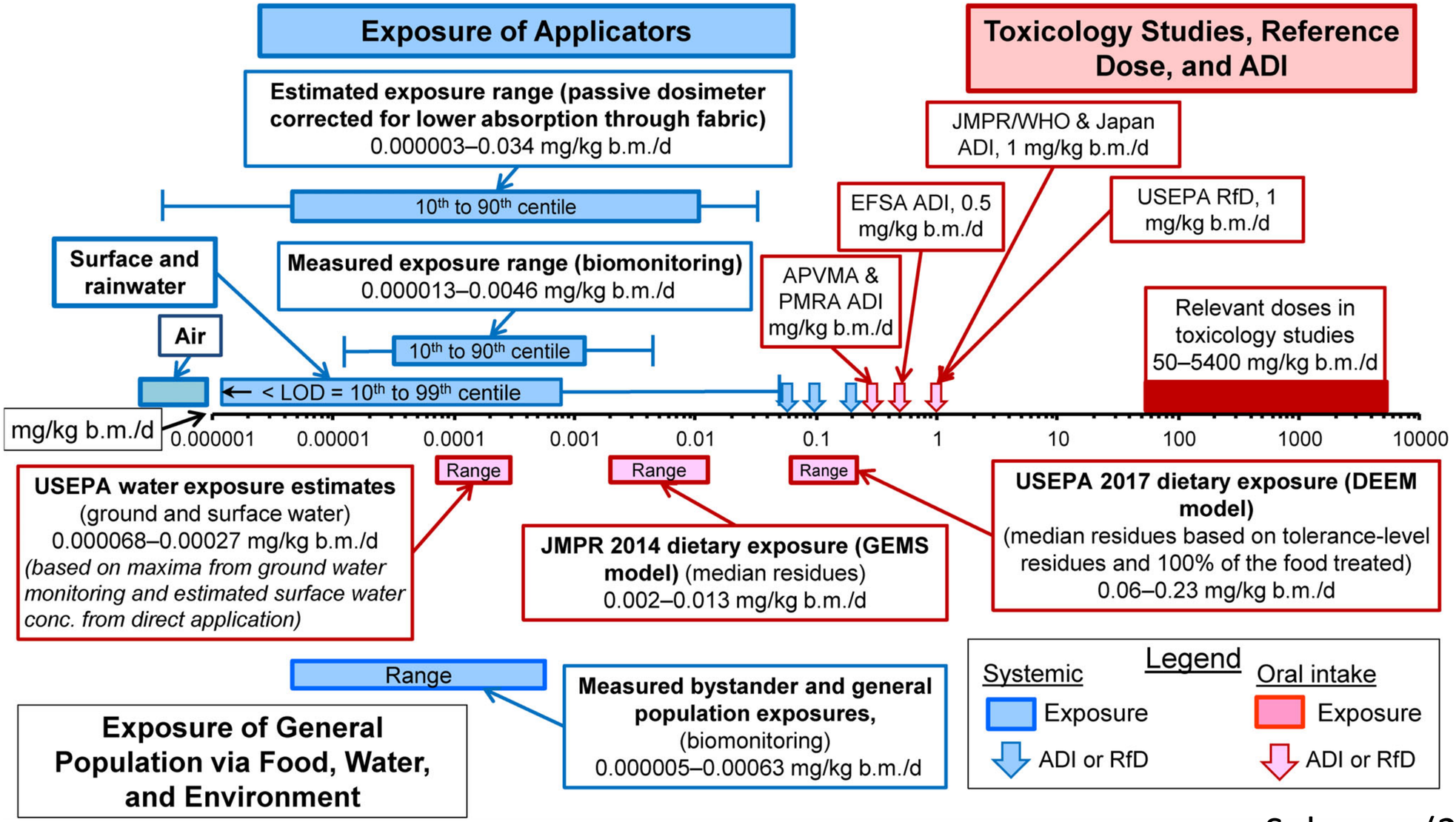


EPA the Aggregator (of Risk)

- Under the mandate of the FQPA, EPA determines risk of aggregate exposure
- For glyphosate, EPA considered residential exposure such as treating a lawn
- Drinking water was combined with dietary exposure
- Incidental oral exposure is mostly the hand-to-mouth behavior of infants and toddlers
- The bottom line: even under worst case assumptions, aggregate exposure to glyphosate is well below the RfD



A Nice Summary of Exposure Relative to Toxicological Benchmarks



Solomon (2019)

Rounding Up Glyphosate Exposure Data

- Glyphosate's very low non-target organism toxicity at environmentally relevant application rates has allowed the compound to be registered for many uses
- Glyphosate use, however, increased at least 10 fold by the early 2000's owing to approval of RR corn, beans, cotton, and canola in 1995
- Owing to the widespread use of glyphosate, residues are found everywhere (soil, water, air, food, bodies)
- However, presence of residues is not the same as risk, but does inform exposure analysis
- Exposure analysis by EPA and other regulatory agencies along with close analysis of academic research papers shows levels of exposure are accurately characterized as "safe"

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- The bottom line: exposure to glyphosate in comparison to toxicological endpoints deemed by EPA to be the most conservative for protecting health could be characterized as meeting the standard of reasonable certainty of no harm