The WHO sub-agency the International Agency for Research on Cancer classified glyphosate as "probably carcinogenic" in 2015 using what is called a hazard evaluation. IARC did no original research in preparing this classification; it considered about two dozen studies, eliminating all studies with what it considered as having financial links to industry or in which a researcher had professional associations with industry, regardless of the independence of the study. It also did not consider hundreds of independent studies with no links to industry. The panel concluded glyphosate posed no clear danger in food residues but was "probably carcinogenic" to agricultural workers, writing:

Limited evidence of carcinogenicity in humans for non-Hodgkin lymphoma. The evidence in humans is from studies of exposures, mostly agricultural, in the USA, Canada, and Sweden published since 2001. In addition, there is convincing evidence that glyphosate also can cause cancer in laboratory animals.

The claim of carcinogenicity, as limited and muddled as it was, generated global headlines, with Nature noting, "Widely used herbicide linked to cancer." IARC's declaratory statement was welcomed by GMO opponents, with blog headlines asking, "Why Monsanto's Glyphosate Herbicide Should be Banned." The IARC's review of glyphosate was distinct in two key ways. First, the WHO sub-agency assessed commercial formulations, such as Monsanto's Roundup, that include a mixture of chemicals including glyphosate while most other research groups evaluated the chemical alone. The additional chemicals are harmless scientists say, although glyphosate's critics claim the mixture could be a contributing factor to health issues that might not occur with glyphosate alone.

Second, IARC carried out a "hazard" assessment, which evaluates whether a substance might pose a danger; it does not examine the amount of exposure it would take to turn a potential hazard into a genuine risk. All the other agencies, on the other hand, performed a "risk" assessment. They looked at exposure and other factors to determine how significant the chance that someone could be harmed by the hazard—in other words, they performed a real-world assessment. IARC, in its own fine print, explains the difference between its hazard assessments and the risk assessments done by others:

... the Monographs Programme identifies cancer hazards even when risks are very low at current exposure levels, because new uses or unforeseen exposures could engender risks that are significantly higher.

Yet, the IARC's analysis was the central body of evidence cited by a California jury which found in August 2018 that there was sufficient evidence that glyphosate is carcinogenic and Monsanto tried to cover it up, awarding Johnson \$289 million in damages.

Judge Suzanne Ramos Bolanos, who presided over the trial, <u>doubted</u> that Johnson's lawyers proved their case, and later <u>reduced the damages</u> awarded to the plaintiff to \$78 million. Monsanto appealed the verdict on the same grounds. Many scientists questioned the validity of the jury's findings. Analyzing the trial, cancer epidemiologist Geoffrey Kabat <u>noted that there</u> are no additional studies scientists can do to

demonstrate that glyphosate is safe. He said::

....there are 8,700 cases and the number is certain to grow. And some scientists are only too willing to point to blips in the data that seem to indicate a risk, while ignoring the totality of the evidence and what are, by far, the strongest studies. In this modern-day "gold rush," the near unanimity of a large number of independent regulatory agencies that have found glyphosate to be safe should be taken seriously.

In March 2019, <u>a second jury decided</u> that exposure to the weed killer was a "substantial factor" in causing another California worker's cancer, awarding \$80.27 million in damages, later reduced to \$25.27 billion. Bayer announced it will appeal yet again. In May 2019, an Oakland jury concluded that the weed killer was to blame for an elderly couple's cancer and awarded them \$55 million in compensatory damages and \$2 billion in punitive damages. A judge reduced the damage award to "exceeded legal precedent." In May 2019, another California jury <u>awarded</u> \$2 billion to an applicator, with a judge reducing the award to \$86.7 million. Bayer will appeal that reduced award.

Jury awards in high profile tort cases are sometimes not reflective of the science. What is the consensus science say about the potential dangers of glyphosate?

Glyphosate is one of the most heavily studied chemicals in history. It is derived from an amino acid, glycine. It acts by suppressing an essential biochemical mechanism commonly found in plants, but not in animals. According to the <u>Extension Toxicology Network</u>, a joint university pesticide information project, glyphosate is non-volatile, minimizing exposure through inhalation and undergoes little metabolism in the human body. If accidentally consumed, glyphosate is excreted mostly unchanged in feces and urine, so it doesn't stay in the body and accumulate.

To examine toxicity, one must look at a chemical's LD50 value—a standard measure of acute toxicity for chemicals, expressed in the amount of chemical (milligrams) per body weight (kg) that it took to kill fifty percent of a population of test animals. Caffeine is over ten times more toxic than glyphosate. Using scientific measures, glyphosate is less toxic than baking soda and salt.

But what about long-term exposure to glyphosate by agricultural workers or from residues in our food? The <u>EPA considered</u> exposure when it sets maximum safe levels of residues, called tolerances. EPA conducted a dietary risk assessment for glyphosate based on a worst-case risk scenario, that is, assuming that 100 percent of all possible acreage were treated, and that tolerance-level residues remained in/on all treated commodities. The agency concluded that there is no evidence of chronic dietary risk posed by glyphosate. A multi-university research project funded by the US Department of Agriculture <u>concluded</u> that glyphosate, if accidentally consumed, undergoes little metabolism, does not accumulate and is excreted mostly unchanged in feces and urine.

Following the 2018 glyphosate trial, the public health advocacy Environmental Working Group (EWG) released a <u>non-peer reviewed report</u> claiming that "[p]opular oat cereals, oatmeal, granola and snack bars come with a hefty dose of the weed-killing poison in Roundup." EWG toxicologist Alexis Temkin argued in the study that this "hefty dose" of glyphosate was potentially dangerous, especially to children. The report garnered dozens ofl headlines in the mainstream press and led to <u>a lawsuit against</u> General Mills, maker

of Cheerios.

Experts found EWG's report unconvincing. Trevor Charles, a microbiologist at the University of Waterloo in Ontario, <u>added</u>, "[g]lyphosate is rapidly degraded by microbes, and also absorbed to soil particles. It does not bioaccumulate [in the body]."

EWG also invented its own arbitrary standard for evaluating glyphosate exposure—"levels higher than what EWG scientists consider protective of children's health." The EPA maintains very strict tolerances for the amount of pesticide residues allowed on food, and when a product poses a risk to human health, it is <u>quickly pulled off</u> the market. EWG set its arbitrary glyphosate exposure limit <u>14,000 times lower</u> than the EPA's.

Other activist organizations have issued non-peer reviewed 'studies' claiming that dangerous residues of glyphosate have been found in one food or another. Friends of the Earth Europe and Mom's Across America claimed in 2014 that an informal test they funded found minute traces of glyphosate in breast milk and urine, causing a furor, with the story circulated even in such nominally mainstream blogs as Civil Eats. The results were challenged in a study led by Washington State University scientist and lactation expert, Michelle McGuire, who found no evidence that glyphosate accumulates in breast milk.

Activists criticized the study-three Monsanto employees were authors. But McGuire's team merely confirmed previous studies. And two subsequent German studies, including an <u>independent report</u> by scientists affiliated with the independent German Federal Institute for Risk Assessment (BfR)-which does risk assessments for the European Commission-published a separate study in 2016 found no traces of glyphosate.

In an attempt to get out their message that glyphosate is dangerous, scientists critical of GMOs have turned to <u>pay-for-play journals</u> (where authors pay to have their work published) to circulate studies that would never be accepted in mainstream science journals. In 2013 Stephanie Seneff, an MIT computer analyst with no expertise in toxicology, published a <u>data analysis</u> that correlated glyphosate use with all sorts of diseases, from depression to Parkinson's—claims that drew <u>sharp criticism</u> from scientists with expertise in genetics and healths. They pointed out that there was no original research and correlation is not causation. Just because two things are happening at the same time doesn't mean one of them caused the other—the rise in autism also correlates with the rise in organic food sales.

## glyphsate and autism rev x

Image not found or type unknown

autism organic x

Image not found or type unknown

Seneff and other GMO critics, including <u>Jeffrey Smith</u>, a former yogic instructor who heads the one-man Institute for Responsible Technology, also <u>allege</u> that glyphosate disrupts gut microbes—a problem they relate to what has popularly become known as 'leaky gut," a syndrome that affects the intestinal walls and allows pathogenic contents of the intestines including E. coli, salmonella and botulism to enter the bloodstream. According to Smith:

The way glyphosate works is that it interrupts the <u>shikimate pathway</u>, a metabolic function in plants that allows them to create essential amino acids. When this path is interrupted, the plants die. Human cells don't have a shikimate pathway so scientists and researchers believed that exposure to glyphosate would be harmless. The problem is that bacteria DO have a shikimate pathway and we have millions of good bacteria in our guts – our "<u>gut flora</u>." These bacteria are essential to our health. Our gut isn't just responsible for digestion, but also for our <u>immune system</u>. When glyphosate gets in our systems, it wrecks our gut and as a result our immune system.

The three studies often cited by Seneff, Smith and other well known anti-GMO opponents to support these claims provide no empirical evidence of microbial disruption in animals let alone humans.

Safety concerns were also raised by an oft-cited <u>2013 study</u> by French geneticist Gilles-Eric Séralini, which featured pictures of rats with bodies twisted by cancer allegedly caused by exposure to glyphosate or GMO corn. The controversial study was <u>retracted</u> and then republished the following year without peer

review. The study's methodology was criticized by <u>scientists</u> and <u>independent oversight agencies</u> around the world, and was reviewed and dismissed by the European Food Safety Authority and the National Academies its May 2016 report on genetically engineered crops.

What have respected, independent international regulatory and research organizations concluded about the potential dangers of glyphosate both before and in the wake of the IARC hazard conclusion that glyphosate might pose a danger to workers? Many scientists and the regulatory community have



conclusions and in some cases the integrity of the organization. <u>Conflict of interest</u> raised because one of the scientists on the IARC committee was an advisor to a nich is supposedly forbidden under IARC guidelines.

IARC's conclusion that glyphosate could lead to some cancers in workers who handled

the herbicide is at odds with the findings of every major regulatory and oversight body that has reviewed the evidence or studied it directly. No major international regulatory advisory agency has agree with IARCC's conclusion that glyphosate is a likely carcinogen. [See infographic: <u>What do global regulatory</u> and research agencies conclude about the health impact of glyphosate]

In the wake of the IARC finding, the World Health Organization again reviewed and dismissed IARC's findings. The toxicity was so low, the committee wrote, it was not necessary to establish a ARfD– an acute toxicity reference dose often used to regulate risk. It also reviewed its impact on workers, noting that the only "high quality" study found no evidence of a cancer link.

In a separate review, a joint panel from WHO and the Food and Agriculture Organization of the United Nations issued a <u>review of glyphosate</u> in May 2016, concluding it poses no cancer risks as encountered in food and does not impact our genes.

WHO has <u>posted</u> an online Q&A to address confusion over apparently conflicting evaluations, as four WHO agencies have concluded that glyphosate poses no significant risks while its sub-agency, IARC, has

raised hazard concerns.

The German BfR issued an FAQ on glyphosate in March 2016 <u>again concluding</u>: "based on current scientific knowledge, no carcinogenic risk to humans is to be expected from glyphosate if it is used in the proper manner for the intended purpose."

The original BfR's study, which was relied upon by the EFSA in issuing its regulatory recommendations, has come under sharp attack from critics of glyphosate. An <u>alliance of Green European Parliamentary</u> <u>members alleged</u> in January 2019 that a key European Commission study that found the glyphosate-based herbicide was safe to use may have been plagiarized in part from Monsanto-funded studies.

One of the EU Parliament members behind the report on BfR plagiarism maintained that <u>industry</u> <u>influence was to blame</u> for the discrepancy. "This [report] helps explain why the [IARC] assessment on glyphosate as a probable human carcinogen was so at odds with EU assessors, who awarded this toxic pesticide a clean bill of health, brushing off warnings of its dangers."

BfR rejected the assertion:

In Europe, it was customary and recognized in evaluation procedures for plant protection products that, following critical evaluation, assessment authorities would also integrate relevant passages of documents submitted by [industry] applicants into their assessment reports as long as these were up to standard....The BfR did not in any way adopt the applicant's conclusions without first assessing their validity....The sole criterion for the consideration of study results is the scientific quality and evidence of the studies themselves. Possible interests of the applicants, politics or other interest groups cannot and must not play any role in a scientific assessment.

The EFSA also dismissed the charge of plagiarism and questions about its independent review.

The [Green's] report does not provide any new scientific information that calls into question the assessment and conclusions of glyphosate. EFSA stands firmly behind the integrity of its risk assessment processes and its conclusions on glyphosate.

In September 2016, the US Environmental Protection Agency issued what is considered the one of the most comprehensive reviews of the pertinent studies on glyphosate ever undertaken, authored by 13 prominent independent scientists, <u>concluding</u>:

...there is not strong support for the "suggestive evidence of carcinogenic potential" cancer classification descriptor based on the weight-of-evidence, which includes the fact that even small, non-statistically significant changes observed in animal carcinogenicity and epidemiological studies were contradicted by studies of equal or higher quality. The strongest support is for "not likely to be carcinogenic to humans" at the doses relevant to human health risk assessment for glyphosate.

The EPA's Carcinogenicity Peer Review Committee specifically rejected IARC's claims that epidemiological studies raise questions of a likely cancer link, <u>concluding</u>:

The epidemiological evidence at this time does not support a causal relationship between glyphosate exposure and solid tumors. There is also no evidence to support a causal relationship between glyphosate exposure and the following non-solid tumors: leukemia, multiple myeloma, or Hodgkin lymphoma. The epidemiological evidence at this time is inconclusive for a causal or clear associative relationship between glyphosate and NHL.

Health Canada has evaluated glyphosate four times. Its June 2015 re-review of glyphosate concluded:

An evaluation of available scientific information found that products containing glyphosate do not present unacceptable risks to human health or the environment when used according to the proposed label directions.

Its April 2017 evaluation <u>concluded</u>, "[g]lyphosate is not genotoxic [unable to damage DNA] and is unlikely to pose a human cancer risk." Following the release of this evaluation, the <u>agency received</u> eight "notices of objection" to its conclusion. Like their European counterparts, Canadian environmental activists also alleged that Monsanto had ghostwritten some of the research Health Canada relied on, biasing the results and thus invalidating the agency's review.

Health Canada investigated these concerns in January 2019 and issued yet another determination on glyphosate, <u>writing</u>:

After a thorough scientific review, we have concluded that the concerns raised by the objectors could not be scientifically supported when considering the entire body of relevant data. The objections raised did not create doubt or concern regarding the scientific basis for the 2017 re-evaluation decision for glyphosate. Therefore, the Department's final decision will stand....**No pesticide regulatory authority in the world currently considers glyphosate to be a cancer risk to humans at the levels at which humans are currently exposed.** 

In the time since the IARC report was released, a groundbreaking, longitudinal epidemiological study– <u>Glyphosate Use and Cancer Incidence in the Agricultural Health Study (2017)</u>–was published in the Journal of the National Cancer Institute based on data collected by the Agricultural Health Study since 1993. The AHS gathered data on 54,251 pesticide applicators, including 44,932 who had handled glyphosate, concluding:

In this large, prospective cohort study, no association was apparent between glyphosate and any solid tumors or lymphoid malignancies overall, including NHL [non-Hodgkins lymphoma] and its subtypes. There was some evidence of increased risk of AML among the highest exposed group that requires confirmation.

The conclusions of the AHS study have been challenged by critics of the weed killer. According to a recent review by a group of scientists from UC Berkeley, Mount Sinai School of Medicine, and the University of Washington, workers exposed to glyphosate at high levels continuously over decades could suffer an increase in incidences of non-Hodgkin's lymphoma of 41%. The review included no new

research.

Prominent cancer researchers who reviewed the study (here and here) found serious flaws, what they say was manipulation of the data. The headlined 41% increase, even if true, represents represents relative risk and distorts its real world impact. Because of the few number of people who contract NHL, the actual risk increases by approximately 8 additional cases each year in the US. Prominent Johns Hopkins biostatistics Engineer Steven Salzberg concluded, "this new study should not cause much concern, but for agricultural workers, it does raise a warning flag."

Epidemiologist Geoffrey Kabat was critical of the study:

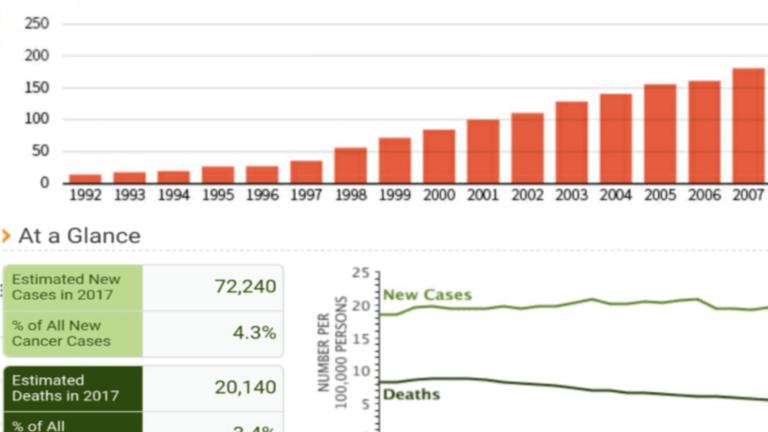
One can't escape the impression that the authors deliberately included a selected and unrepresentative result from the highly-respected AHS in their meta-analysis and use the far inferior case-control studies to jack up the summary of relative risk to obtain a statistically-significant finding. The authors appear to have judged that few lay people including journalists, and even many scientists, were likely [to] notice the sleight of hand amidst the large number of secondary analyses and lengthy obfuscatory discussions.

Real world data also raises doubts of a glyphosate-non-Hodgkin's lymphoma link. Data on rates of glyphosate use from its registration in 1974 through the year 2000 show the total usage of glyphosate increased more than 70-fold while the incidence of NHL nationwide actually peaked then declined. Allowing for a 10-year latency period, this is the opposite of the expected result if glyphosate increased the risk of developing NHL. Crunching data for the years 1992 to 2014—a period when Roundup use soared because it was paired with glyphosate-resistant crops, the number of new NHL cases overall remained steady while the number of deaths declined.

## NATIONWIDE GLYPHOSATE USE



Cancer Deaths



**Number of New Cases and Deaths per 100,000:** The number of new cases of non-Hodgkin lymphome women per year. The number of deaths was 5.9 per 100,000 men and women per year. These rates as 2010-2014 cases and deaths.

1992

1995

1998

2001

2004

YEAR

2007

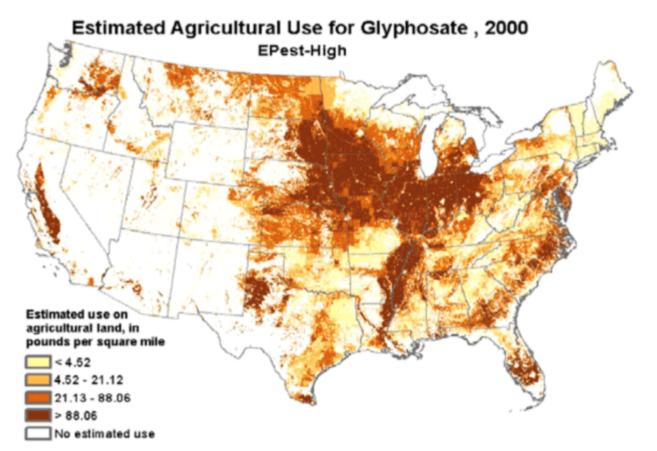
2010

20

3.4%

Lifetime Risk of Developing Cancer: Approximately 2.1 percent of men and women will be diagnosed some point during their lifetime, based on 2012-2014 data.

Is there a link between people living in areas where glyphosate was used most? Regional differences in the usage of glyphosate in the US counties can vary by more than 20-fold, yet many of the counties with the highest usage of glyphosate have a relatively low incidence of NHL. This data further argues against a relationship between glyphosate exposure and an increased risk of developing NHL.

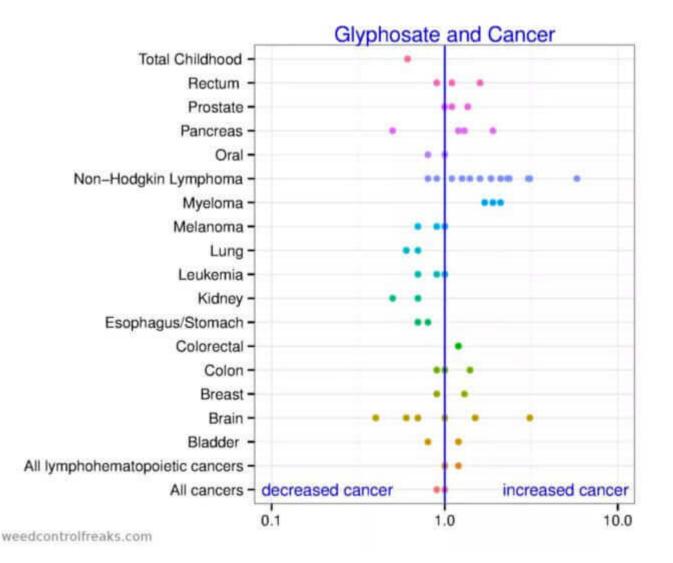


## Figure 4: Glyphosate Use in the U.S. (2000)

All Races, Non-Hodgkin Lymphoma (Both Sexes) Rate per 100,000 7.4 - 16.3 16.4 - 18.3 18.4 - 19.9 20.0

Age-Adjusted Incidence Rates by County (2008 to 2012)

University of Wyoming weed scientist Andrew Kniss <u>assembled a graphic</u> summarizing what the major studies on glyphosate have found found as to its potential for causing cancer. The chart is an oversimplification, as Kniss has noted, but it illustrates that more than 20 studies have shown that glyphosate exposure *reduces* the cancer risk in some instances—which underscores why scientists look at "weight of evidence" to make carcinogenic calculations rather than depending on a small sample of studies, as IARC did. Regulatory scientists, reviewing this contradictory evidence, have concluded that glyphosate has no predictive impact as to whether human exposure at normal levels would result in cancer.



In the essay that accompanies the graphic, Kniss notes that the small data set of case controlled studies that underpinned the IARC's determination:

An additional limitation of the case control studies I read is that a *very* small fraction of non-Hodgkin lymphoma cases were actually exposed to glyphosate. For example, only 97 people (3.8% of the study

population) had been exposed to glyphosate in the DeRoos (2003) study. Only 47 people (2.4% of the study population) had been exposed to glyphosate in the Eriksson (2008) study. These are very small numbers. To look at it another way, only about 3% of the non-Hodgkin lymphoma cases in most of the case control studies had actually been exposed to glyphosate, and therefore around 97% of non-Hodgkin lymphoma cases in these studies had nothing to do with glyphosate. So even if glyphosate does increase the risk for cancer, it seems to not be a major contributor to this type of cancer in the general population.

In a 2017 study published in <u>Nature Communications</u>, Kniss further observed that glyphosate has a lower chronic toxicity than 90 percent of the 118 herbicide active ingredients he evaluated. Therefore, instead of protecting the health of individuals who face the highest levels of glyphosate exposure, eliminating the weed killer from agriculture would force farmers to revert to other, more toxic herbicides—increasing their risk of developing serious diseases, including cancer:

In the final year for which data were available (2014 or 2015), glyphosate accounted for 26% of maize, 43% of soybean and 45% of cotton herbicide applications. However, due to relatively low chronic toxicity, glyphosate contributed only 0.1, 0.3 and 3.5% of the chronic toxicity hazard in those crops, respectively .... [I]f glyphosate use were discontinued (as was recently proposed in the EU) the resulting displacement of glyphosate by other herbicides is likely to have a negative impact on chronic health risks faced by pesticide applicators.