Glyphosate
What’s Up With Roundup

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SELNA Trade Show
17th Annual
Jurors give $289 million to a man they say got cancer from Monsanto's Roundup weedkiller

(CNN) San Francisco jurors just ruled that Roundup, the most popular weedkiller in the world, gave a former school groundskeeper terminal cancer. So they awarded him $289 million in damages -- mostly to punish the agricultural company Monsanto.

Dewayne Johnson's victory Friday could set a massive precedent for thousands of other cases claiming Monsanto's famous herbicide causes non-Hodgkin's lymphoma.

The big questions at stake were whether Roundup can cause cancer and, if so, whether Monsanto failed to warn consumers about the product's cancer risk. The jury sided with Johnson on both.

While it was medically impossible to prove Roundup caused Johnson's terminal illness, it's also impossible for Monsanto to prove Roundup did not cause his cancer.

In this case, Monsanto was not required to prove anything. The burden of proof was on Johnson, the plaintiff.

But that doesn't mean Johnson's attorneys had to prove Roundup was the sole cause of his cancer. All they had to prove was whether Roundup was a "substantial contributing factor" to his illness.

"Under California law, that means Mr. Johnson's cancer would not have occurred but for his exposure to Roundup," Monsanto spokeswoman Lord said.

She noted that it's possible his cancer could have developed from something unrelated to Roundup. The majority of lymphoma cases are idiopathic -- meaning the cause is unknown, according to the American Cancer Society.

... August 11, 2018, CNN

Bayer stock plunges after jury awards man $289 million in Roundup cancer trial

Bayer's stock slumped more than 10 percent in trading Monday, three days after a California jury awarded $289 million to a former groundskeeper who said the popular weedkiller Roundup gave him terminal cancer.

The stock drop sent a cautionary signal to the company that acquired Monsanto, the maker of the weedkiller, in June for $63 billion. The merger created the world's largest seed and agrochemical company, marrying Monsanto's dominance in genetically modified crops with Bayer's pesticide business. Bayer's portfolio also includes pharmaceuticals with such household brands as Aleve to Alka-Seltzer.

... August 13, 2018, The Washington Post

Groundskeeper Accepts Reduced $78 Million Award In Monsanto Cancer Suit

The groundskeeper who won a massive civil suit against Bayer's Monsanto claiming that the weedkiller Roundup caused his cancer has agreed to accept $78 million, after a judge substantially reduced the jury's original $289 million award. According to Reuters, Bayer faces about 8,000 more lawsuits on the herbicide.

... November 1, 2018, NPR

Glyphosate Use and Cancer Incidence in the Agricultural Health Study

Among 54 251 applicators, 44 932 (82.8%) used glyphosate, including 5779 incident cancer cases (79.3% of all cases). In this large, prospective cohort study, no association was apparent between glyphosate and any solid tumors or lymphoid malignancies overall, including NHL (non-Hodgkin lymphoma) and its subtypes. There was some evidence of increased risk of AML (acute myeloid leukemia) among the highest exposed group that requires confirmation.

History of Glyphosate

1950 – First synthesized by Swiss chemist Henry Martin but never published.
1964 – Patented by Stauffer Chemical as a chelator for binding and removing Ca, Mg, Mn, Cu, Zn (pipes, etc.)
1970 – Independently discovered at Monsanto and synthesized by chemist John Franz as an herbicide
1974 – Brought to the market as Roundup under patent
1991 – Initial patent expires but Monsanto retained exclusive US rights until auxiliary patent expired in 2000
1996-1997 – First Roundup Ready transgenic crops were introduced.
What Is Glyphosate and How Does It Work?

Glyphosate is an aminophosphonic analogue of the natural amino acid glycine. The name is taken as a contraction of the compounds used in its synthesis - viz. glycine and a phosphonate.
The **shikimic acid pathway** is a seven-step metabolic route used by bacteria, fungi, algae, and plants for the biosynthesis of aromatic amino acids (phenylalanine, tyrosine, and tryptophan).

Where Does It Work?

How Does It Work?

- Disrupts the shikimic acid pathway by inhibiting EPSP synthase
- Plants cannot produce all the proteins they need to live
- Plants starve in 4-20 days

EPSP Synthase is not present in animals, but is present in plants and some microorganisms.

Glyphosate acts as a competitive inhibitor of PEP and binds more tightly to the EPSP synthase-S3P complex than does the normal substrate PEP; however, like PEP, glyphosate has no affinity for the enzyme alone. A major difference between glyphosate and PEP is that the dissociation rate for glyphosate is 2,300 times slower than PEP. Therefore, once glyphosate binds the enzyme-substrate complex (EPSP synthase-S3P) the enzyme is essentially inactivated.
Effects of a glyphosate-based herbicide on soil animal trophic groups and associated ecosystem functioning in a northern agricultural field

- Study was done on fields in Finland. Theorized that the short active period of decomposers in northern climes may restrict glyphosate degradation.
- Non-treated plots, Hoed plots, Roundup + hoed plots.
- Hoeing (and in like manner plowing) had drastic effects on soil fauna and functioning.
- Effects of Roundup on soil fauna and functioning was minor and transient and no glyphosate remains were found in the soil at the end of the experiment.
- Disturbance of ground by hoeing or plowing is more damaging to soil biota than glyphosate.
Glyphosate – Some Important Properties

• Glyphosate binds very tightly to most soils and sediments in the environment – it’s a dirt lover
• Glyphosate residues are not likely to leach into groundwater and only limited amounts of glyphosate are found in surface water as a result of runoff (Adsorption)
• Glyphosate that reaches surface water is rapidly adsorbed to sediment and degraded to aminomethylphosphonic acid (AMPA) by microorganisms
• AMPA is further degraded to naturally-occurring substances such as carbon dioxide and phosphate by microorganisms
• Glyphosate does not volatilize (become vaporous)
In all the organisms tested, including earthworms, birds, mammals and arthropods, glyphosate exhibited only low toxicity at typical application rates.

Honeybees were not affected by a glyphosate based-formulation even when they were fed high concentrations or exposed in semi-field studies when vegetation adjacent to beehives was over-sprayed.

These results are also supported by a recently completed bee brood study conducted to meet current EU testing requirements for the ongoing glyphosate renewal process.

Potential risks for most aquatic organisms are mild or negligible if glyphosate is used according to label instructions - fish, frogs and aquatic invertebrates are not affected by typical glyphosate usage.

Glyphosate does not bioaccumulate in fish or other animals (doesn’t accumulate over time).

Because of this relatively favorable safety profile, glyphosate products have even been used in protected habitats such as the Galapagos Islands and the Florida Everglades to protect the native flora from invasive weed species with no reported deleterious effects.

Based on laboratory and field research the exposure risk from glyphosate and the primary soil metabolite aminomethylphosphonic acid (AMPA) on representative species of earthworms, springtails, and predatory soil mites and the effects on nitrogen-transformation processes by soil microorganisms with worst-case soil concentrations expected for glyphosate and AMPA for annual applications at the highest annual rate indicate very low likelihood of adverse effects on soil biota.
Glyphosate Entry Routes to the Body?

About 2% of glyphosate by dermal exposure is absorbed through the skin.

Glyphosate is non-volatile. Absorption from inhalation exposure is not expected to be significant.

About 1/3 of ingested glyphosate is absorbed through the digestive tract, the remainder is excreted.

Krüger et al., J Environ Anal Toxicol 2013, 3:5
Fundam Appl Toxicol, 1991 May;16(4):725-32.
Low to Very Low Toxicity by all routes of exposure

<table>
<thead>
<tr>
<th>Toxicity Classification - Glyphosate</th>
<th>High Toxicity</th>
<th>Moderate Toxicity</th>
<th>Low Toxicity</th>
<th>Very Low Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute Oral LD₅₀</strong></td>
<td>Up to and including 50 mg/kg ((\leq 50 \text{ mg/kg}))</td>
<td>Greater than 50 through 500 mg/kg ( (&gt;50-500 \text{ mg/kg}))</td>
<td>Greater than 500 through 5000 mg/kg ( (&gt;500-5000 \text{ mg/kg}))</td>
<td>Greater than 5000 mg/kg ( (&gt;5000 \text{ mg/kg}))</td>
</tr>
<tr>
<td><strong>Inhalation LC₅₀</strong></td>
<td>Up to and including (0.05 \text{ mg/L}) ((\leq 0.05 \text{ mg/L}))</td>
<td>Greater than (0.05 \text{ mg/L}) through 2.0 ( (&gt;0.05-2.0 \text{ mg/L}))</td>
<td>Greater than 2.0 ( (&gt;2.0 \text{ mg/L}))</td>
<td>(2.0 \text{ mg/L})</td>
</tr>
<tr>
<td><strong>Dermal LD₅₀</strong></td>
<td>Up to and including (200 \text{ mg/kg}) ((\leq 200 \text{ mg/kg}))</td>
<td>Greater than 200 through 2000 ( (&gt;200-2000 \text{ mg/kg}))</td>
<td>Greater than 2000 through 5000 ( (&gt;2000-5000 \text{ mg/kg}))</td>
<td>Greater than 5000 ( (&gt;5000 \text{ mg/kg}))</td>
</tr>
<tr>
<td><strong>Primary Eye Irritation</strong></td>
<td>Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days</td>
<td>Corneal involvement or other eye irritation clearing in 8 - 21 days</td>
<td>Corneal involvement or other eye irritation clearing in 7 days or less</td>
<td>Minimal effects clearing in less than 24 hours</td>
</tr>
<tr>
<td><strong>Primary Skin Irritation</strong></td>
<td>Corrosive (tissue destruction into the dermis and/or scarring)</td>
<td>Severe irritation at 72 hours (severe erythema or edema)</td>
<td>Moderate irritation at 72 hours (moderate erythema)</td>
<td>Mild or slight irritation at 72 hours (no irritation or erythema)</td>
</tr>
</tbody>
</table>


What About Cancer?

• Animal studies have mixed results, but mostly negative.
• A long-term study with over 50,000 applicators found no association with overall cancer rates or most subtypes.
• Epidemiological data show a suggested association with Non-Hodgkin Lymphoma (NHL)

• IARC classification: “Probable carcinogen”  March 2015
• EPA Classification: “Evidence of non-carcinogenicity”  September 2016

Why such a difference of classification between the Environmental Protection Agency (EPA) and the International Agency for Research on Cancer (IARC)?
Alcohol, Tobacco Smoke, Arsenic, Plutonium, Mineral Oils, Nitrates, Air Pollution, Painter, Soot, Wood Dust, Asbestos, PCBs

Glyphosate, Shift Work (Circadian Rhythm Disruption), Hot beverages, Indoor Wood Fires, Frying, Barber, Malathion, Diazinon

There is no category for “Does not cause cancer” because you can’t prove a negative.

You will not find warning labels about cancer on packages of processed meats.

The IARC Monographs Programme seeks to classify cancer hazards, meaning the potential of any substance to cause cancer based on current knowledge. The classification does not indicate what level of risk exists to people’s health associated with exposure to a classified hazard.
Why the Classification Difference?

IARC asks, “Can it cause cancer?”

EPA asks, “Is it likely to cause cancer?”

Can it cause cancer + What level of exposure is expected = Is that exposure level likely to result in cancer

“IARC defers risk assessment and risk management to national and international bodies, restricting itself to provision of hazard identification as a scientific foundation to those subsequent steps.” IARC response to criticisms of the Monographs and the glyphosate evaluation - Prepared by the IARC Director, January 2018
For cancer descriptors, the available data and weight-of-evidence clearly do not support the descriptors “carcinogenic to humans”, “likely to be carcinogenic to humans”, or “inadequate information to assess carcinogenic potential”. For the “suggestive evidence of carcinogenic potential” descriptor, considerations could be looked at in isolation; however, following a thorough integrative weight-of-evidence evaluation of the available data, the database would not support this cancer descriptor. The strongest support is for “not likely to be carcinogenic to humans” at doses relevant to human health risk assessment.
Glyphosate Use and Cancer Incidence in the Agricultural Health Study

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Risk =

Toxicity \times Exposure

- Toxicology of the active ingredient
- Product signal word
- Dose estimate
- Effects reported in the literature
- Onset, duration and resolution of symptoms

- Distance to application site
- Route of potential exposure
- Physical/chemical properties of active ingredient
- Duration/frequency of exposure
- Bioavailability by the route in question

Risk Benefit Analysis - Are the benefits worth the risk?
Benefits of Glyphosate Usage

What are the benefits for farmers of glyphosate herbicide use?
• Glyphosate herbicides provide simple, flexible and cost-effective weed control
• Glyphosate helps to remove perennial weeds for several years
• Glyphosate is effective on all weeds, providing broad spectrum control
• Pre-plant application of glyphosate has the potential to increase yields 30%-60% for many major crops
• Glyphosate reduces disease and insect incidence by removing weeds that might otherwise act as an intermediate host for parasites and disease vectors
• Its effectiveness as a broad-spectrum herbicide has reduced the use of plowing as a means of controlling weeds. Plowing exposes fertile topsoil to water and wind erosion, twice as costly and time consuming.

http://www.glyphosate.eu/
Benefits of Glyphosate Usage

Why is glyphosate so important for worldwide agriculture?

• Recent case studies conducted by researchers in Germany and the UK predict that losing glyphosate would have a considerable effect on crop production costs and would also have an impact on international trade.
• Food prices would increase if glyphosate use was restricted.
• It is estimated that crop yields for farmers would be reduced by 5% to 40%, depending on the region and the crops if glyphosate was no longer available.
• By using glyphosate for weed control, farmers have been able to forgo or significantly reduce traditional plowing methods.
• Conventional plow tillage is an energy-intensive process that releases tons of carbon dioxide into the atmosphere from the soil. If farmers are forced to return to these weed-control methods, CO$_2$ emissions and fossil fuel consumption are predicted to more than double, while soil erosion could increase six times (6X).
Benefits of Glyphosate Usage

Are there ecological benefits to use glyphosate?
• By chemically controlling a broad spectrum of weeds and their entire root systems, glyphosate has eliminated or reduced the need for plowing. These reduced tillage practices allow farmers to plant crop seeds directly into stubble fields.
• A large proportion of cultivated land is prone to soil erosion, and minimal soil disturbance practices are sustainable alternatives that help to protect the soil from degradation and reduce greenhouse gas emissions and energy consumption.
• Several important crops worldwide, including corn and sugar beet, are predominantly managed with these tillage practices in combination with glyphosate. This makes glyphosate a vital tool for many farmers that decide to pursue these soil conservation practices.

http://www.glyphosate.eu/
Based on currently available research-based data, use of glyphosate according to label directions and allowed use presents a very low risk of environmental, ecological, and human health injury.
“Little evidence of toxicity, and there was no evidence of glyphosate causing damage to DNA”

“Available data on occupational exposure for workers applying Roundup indicate exposure levels far below the NOAELs [no observed adverse effect levels] from the relevant animal experiments”

“Under usual conditions, the presence of glyphosate and AMPA [aminomethylphosphonic acid, glyphosate’s primary metabolite] in drinking-water does not represent a hazard to human health”

“Limited evidence in humans for the carcinogenicity of glyphosate... Evidence in humans is from studies of exposures, mostly agricultural [e.g. not from dietary exposure]... A positive association has been observed for non-Hodgkin lymphoma... There is ‘strong’ evidence that exposure to glyphosate or glyphosate-based formulations is genotoxic”

IARC placed glyphosate in its hazard category “Group 2A: probably carcinogenic to humans” along with red meat, hot beverages, and working as a barber. The evidence on carcinogenicity was less robust than for agents such as bacon, salted fish, oral contraceptives and wine.

“Glyphosate is unlikely to be genotoxic or to pose a carcinogenic threat to humans... Neither the epidemiological data nor the evidence from animal studies demonstrated causality between exposure to glyphosate and the development of cancer in humans”

“Available data do not show carcinogenic or mutagenic properties of glyphosate nor that glyphosate is toxic to fertility, reproduction or embryonal/fetal development in laboratory animals”
“Level of evidence of carcinogenicity in animals and humans is considered to be relatively limited and does not allow for a 1A or 1B classification (known or suspected carcinogen for humans)”

2016

“Glyphosate does not pose a carcinogenic risk to humans... Products containing glyphosate are safe to use as per the label instructions”

2016

“No neurotoxicity, carcinogenicity, reproductive toxicity, teratogenicity, and genotoxicity”

2016

“Unlikely to be carcinogenic to humans or genotoxic (damaging to genetic material or DNA) and should not be classified as a mutagen or carcinogen”

2016

“Glyphosate is unlikely to be genotoxic at anticipated dietary exposures. Glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet”

2016

“Human health risk assessment concludes that glyphosate is not likely to be carcinogenic to humans... [and] no other meaningful risks to human health when the product is used according to the pesticide label”

2017

“Not strong support for... ‘suggestive evidence of carcinogenic potential...’ based on the weight-of-evidence... Even small, non-statistically significant changes... were contradicted by studies of equal or higher quality. The strongest support is for ‘not likely to be carcinogenic to humans’”

2017
"Products containing glyphosate do not present unacceptable risks to human health or the environment when used according to the revised product label directions... Risks to [occupational] handlers are not of concern for all scenarios."

2017

"Based on the epidemiological data as well as on data from long-term studies in rats and mice, taking a weight of evidence approach, no hazard classification for carcinogenicity is warranted."

2017

"Epidemiological studies on glyphosate... found no cancer link."

2017

"Residues of glyphosate in the foods investigated do not represent a risk of cancer."

2018

"No association was apparent between glyphosate and any solid tumors or lymphoid malignancies overall, including non-Hodgkin’s lymphoma and its subtypes... some evidence of increased risk of AML [acute myeloid leukemia] among the highest exposed group that requires confirmation."

2018

"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."

2019

"No evidence to indicate that the herbicide glyphosate is carcinogenic."

2019
Human Health

EPA scientists performed an independent evaluation of available data for glyphosate and found:

❖ No risk to human health from current uses of glyphosate. Glyphosate products can be safely used by following label directions. There are no risks to children or adults from currently registered uses.

❖ No indication that children are more sensitive to glyphosate. After evaluating numerous studies from a variety of sources, the Agency found no indication that children are more sensitive to glyphosate from in utero or post-natal exposure. As part of the human health risk assessment, the Agency evaluated all populations, including infants, children and women of child-bearing age, and found no risks of concern from ingesting food with glyphosate residues. EPA also found no risks of concern for children entering or playing on residential areas treated with glyphosate.

❖ No evidence that glyphosate causes cancer. The Agency concluded that glyphosate is not likely to be carcinogenic to humans. EPA considered a significantly more extensive and relevant dataset than the International Agency on the Research for Cancer (IARC). EPA’s database includes studies submitted to support registration of glyphosate and studies EPA identified in the open literature.

❖ EPA’s cancer classification is consistent with other international expert panels and regulatory authorities, including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan. For more information, read the Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential.

❖ No indication that glyphosate is an endocrine disruptor. Glyphosate has undergone Tier I screening under EPA’s Endocrine Disruptor Screening Program. Based on all available information, EPA concluded, using a weight-of-evidence approach, that the existing data do not indicate that glyphosate has the potential to interact with the estrogen, androgen or thyroid signaling pathways. The screening program did not indicate the need for additional testing for glyphosate. **April 2019**
Food Safety

- Residues of glyphosate on any food or feed item are safe for consumers if they comply with the established tolerances. Before allowing the use of a pesticide on food crops, EPA sets a tolerance or limit on how much pesticide residue can legally remain on food and feed products, or commodities. The complete listing of tolerances for glyphosate can be found in 40 CFR § 180.364. If residues are found above the established tolerance level, the commodity will be subject to seizure by the government. The presence of a detectible pesticide residue does not mean the residue is at an unsafe level.

- Due to its widespread use, trace amounts of glyphosate residues may be found in various fresh fruits, vegetables, cereals, and other food and beverage commodities. However, these trace amounts are not of concern for the consumer.

- EPA conducted a highly conservative dietary risk assessment for glyphosate that evaluated all populations, including infants, children, and women of child-bearing age. EPA assumed that 100 percent of all registered crops were treated with glyphosate, that residues were at the tolerance level for each crop, and that residues in drinking water were from direct application of glyphosate to water. These assumptions would lead to much higher estimated levels of exposure than would be expected to occur with actual use. The resulting conservative estimates of dietary exposure were not of concern.
EPA Takes Action to Provide Accurate Risk Information to Consumers, Stop False Labeling on Products

- EPA is issuing guidance to registrants of glyphosate to ensure clarity on labeling of the chemical on their products. EPA will no longer approve product labels claiming glyphosate is known to cause cancer – a false claim that does not meet the labeling requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The State of California’s much criticized Proposition 65 has led to misleading labeling requirements for products, like glyphosate, because it misinforms the public about the risks they are facing. This action will ensure consumers have correct information, and is based on EPA’s comprehensive evaluation of glyphosate.
- In April, EPA took the next step in the review process for glyphosate. EPA found – as it has before – that glyphosate is not a carcinogen, and there are no risks to public health when glyphosate is used in accordance with its current label. These scientific findings are consistent with the conclusions of science reviews by many other countries and other federal agencies.
- On Feb. 26, 2018, the United States District Court for the Eastern District of California issued a preliminary injunction stopping California from enforcing the state warning requirements involving glyphosate’s carcinogenicity, in part on the basis that the required warning statement is false or misleading. The preliminary injunction has not been appealed and remains in place.

8/8/2019
Questions?
10 Things You Should Know About Glyphosate

1) Glyphosate, patented in 1971, is the most popular pesticide in the world. Almost 300 million pounds are used annually worldwide. Glyphosate, as Monsanto’s Roundup, was approved for use as a registered non-selective herbicide in 1974. It has been used and researched for almost 50 years.

2) Glyphosate acts as a competitive inhibitor of EPSP synthase in the shikimic acid pathway. This biochemical pathway is found in plants and some microorganisms. Glyphosate prevents the production of phenylalanine, tyrosine and tryptophan. This causes plants to starve in 4-20 days.

3) Glyphosate is quickly and tightly bound by clay and organic matter in soil. There is little surface water glyphosate runoff and what does occur is quickly bound by organic matter in the water.

4) Excess glyphosate in soil and water is degraded by naturally occurring microorganisms to glycine, phosphate and carbon dioxide (CO₂).

5) Exposure to pesticides can occur through inhalation, ingestion, and dermal. Glyphosate is non-volatile which significantly reduces the exposure potential through inhalation. Ingestion is the primary route of entry into humans. One-third of ingested glyphosate is absorbed through the digestive tract and the rest is excreted immediately. With dermal exposure only about 2% of glyphosate is absorbed.

6) No scientific studies to date have shown a direct causation between glyphosate and any types of cancer.

7) The International Agency for Research on Cancer (IARC) gave a 2A categorization of glyphosate as “probably carcinogenic to humans” (2015). Other material and activities classified as 2A “probable carcinogen” are indoor wood-burning fireplaces, drinking hot beverages, high-temperature frying, occupation as a barber, and working third shift.

8) Subsequent to IARC’s 2015 categorization, additional research and data analysis results are that 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.

9) Glyphosate residue levels detected in food are far below the tolerance levels established by the Environmental Protection Agency (EPA). The EPA are several orders of magnitude below the lowest level at which research has been able to show any detectable effect.

10) The EPA will no longer approve product labels claiming glyphosate is known to cause cancer. This is considered a false claim that does not meet the labeling requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In April 2019, the EPA found – as it has before – that glyphosate is not a carcinogen, and there are no risks to public health when glyphosate is used in accordance with its current label.