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Is the amount of Roundup used on Roundup Ready crops safe for human consumption, particularly human gut flora?

## By: Kevin Folta, University of Florida

Plants are not "doused" in Roundup or, more precisely, its active ingredient glyphosate. Relatively small amounts of glyphosate are applied as weeds emerge. These die and do not compete against emerging glyphosate-resistant crops. Glyphosate is amazingly non-toxic to humans or any other animals. Acute effects are seen only at relatively high doses. The LD50 (the dose that kills half of the rats that consume the dose) is about 5,000 mg/kg of body weight. In other words, if you weigh 200 pounds, you'd have to drink about two pounds of the 41 percent commercial concentrate to have a 50 percent chance of dying. Of course, it is not recommended ask any of the hundreds of people that have tried to commit suicide by drinking it. It takes a good dose to cause problems. Look up "glyphosate" and "suicide" in PubMed.

The flora of the gut are hardly plant-like—they are microbes, the vast majority bacteria. The "Roundup resistance" gene comes from a bacterium.

The woman in the YouTube video you sent is Dr. Stephanie Seneff. She is a computer scientist in the Artificial Intelligence Laboratory at MIT. She is not a plant scientist, molecular biologist or expert in human disease. She uses the MIT affiliation and a Ph.D. to create arguments from authority without evidence. Her evidence is largely correlation. She claims that glyphosate causes autism. And obesity. And Parkinson's. And depression. And ADHD. And several other ailments.

She explains their effect being caused by "exogenous semiotic entropy," a phrase that, if Googled, gives you her paper in Entropy, a low-/no-impact physics journal that has a reputation of publishing anything for a fee. It claims peer review, but no biologist or medical researcher reviewed the work. The phrase "exogenous semiotic entropy" sounds fancy, but she's the first person to use it.

The big problem with glyphosate is not physiological; it is resistant weeds. Fortunately, new solutions are in the works. Glyphosate is a great tool for farmers; it keeps labor and fuels costs lower, and it allows for "no-till" farming, saving valuable topsoil.

## http://tiny.cc/my9qhx

# Should I be concerned about research showing that glyphosate has been found in human urine?

#### By: John Swarthout, Monsanto

Regarding glyphosate in the urine, the study you are referring to was conducted by a German non-government organization known as BUND (Association for Environment and Nature Protection German branch of Friends of the Earth) and is titled "Determination of Glyphosate residues in human urine samples from 18 European countries." The study looked for the presence of glyphosate in 182 urine samples collected from 18 different countries. Many of the samples collected were negative for glyphosate, and when glyphosate was found, it was far below what the European Union considers as its acceptable daily intake. While

there are no details on sample collection or possible dietary or operator exposure of the people from whom these samples were taken, I can safely say that there is nothing new or surprising to report from the results of the study, and that low levels of glyphosate are permitted in food and are considered safe. In fact, it is not surprising to find glyphosate in urine, should a person ingest food with low residues of glyphosate. Why? Well, because this is exactly where it should be. A fraction of glyphosate is absorbed after ingestion, and the remainder is excreted in feces. Absorbed glyphosate is not metabolized by the human body but excreted in urine. Furthermore, all independent health assessments conducted by public authorities in Europe and internationally over the past 40 years have consistently concluded that glyphosate does not pose any unacceptable risk to human health.

If you are still apprehensive about the possibility of glyphosate in your urine, perhaps taking a deeper dive into the details of the study will help. For example, look at the levels of glyphosate reported in the study. As stated above, many of the samples tested were negative, and of the ones that did contain glyphosate, the highest value observed was still less than two micrograms per liter (two parts per billion). This translates to an intake that is over 1,000 times lower than what the European Union considers as its acceptable daily intake (0.3 mg/kg body weight per day), and more than 3,500 times lower than the equivalent value from the World Health Organization (1.0 mg/kg body weight/day). These values are considered a safe oral exposure every day throughout a person's life, without incurring any appreciable health risk.

## (Calculation is below.)

Now let's discuss your statement that glyphosate causes male sterility. This is simply not true. Let's examine the source of your claim. I think the study you are referring to is by Clair et al., and it looks at the effect of glyphosate formulations on cells from the testis. These experiments from this study demonstrate what we already know: substances can injure unprotected cells in a test-tube.

Experiments performed in a petri dish in a laboratory often are not representative of exposures to a living animal and are not informative about real-world risks to humans. Furthermore, it should not be a surprise that a glyphosate-based formulation that contains surfactants (detergents), similar to detergents found in household and personal-care products (e.g., bath gels, hand soaps, shampoos and laundry and dishwashing detergents), would have an effect on cellular membranes. Cellular membranes contain lipids (grease, if you will), and detergents are designed to be tough on grease, so adding detergents directly to cells will disrupt them.

For some additional perspective, the exposure of people to surfactants is common, and adults and children consume residues of detergents from utensils, dishes and glasses washed with dish-washing detergents that have the same ability to disrupt membranes. Yet you eat and drink every day with no appreciable harm. So while you can take shampoo and put it on some cells in a petri dish in the lab and the cells will die, washing your hair every day with that same shampoo will not make you sterile.

#### Here is the calculation:

The highest value found in the study was less than 2 micrograms per liter (two parts per billion). A simple calculation shows that, as people typically produce about 2.5 liters per day, then this

highest value indicates the maximum systemic dose was 5 micrograms. Oral intake to reach a systemic dose of 5 micrograms (30 percent gastrointestinal absorption) would be 16.7 micrograms ingested glyphosate; for a 60-kilogram person, this would be a dose of 0.28 micrograms glyphosate per kilogram of body weight (or 280 nanograms of glyphosate per kilogram), over 1,000 times lower than the EU acceptable daily human exposure level (considered a safe oral exposure every day throughout person's life without that person incurring any appreciable health risk).

This is unlikely to be of any significance to health because it is more than 1,000 times lower than the acceptable daily intake established by the European Union, and more than 3,500 times lower than the equivalent value from the World Health Organization. The acceptable daily intake is the amount that can be consumed without cause for concern, even for the most vulnerable groups, and includes significant safety factors.

- •The EU acceptable daily intake (ADI) is 0.3 mg/kg/day, or 300 ug/kg/day.
- •The 5 ug number from the BUND study gives a daily systemic dose of 0.083 ug/kg/day for a 60 kg person (5/60), which equates to  $0.083 \times 100 / 30 = 0.280 \text{ ug/kg/day}$  ingested glyphosate.
- $\bullet 300$  divided by 0.280 is 1,000 times lower that the ADI for a 60 kg individual.
- $\bullet \text{Even}$  if you do the math for a 10 kg child, you get  $\sim 176$  times lower than the ADI.

## http://tiny.cc/kyarhx

Are Glyphosate tolerant GM crops lower in plant compounds such as auxin than their organic counterparts?

## By: Angela Hendrickson Culler, Monsanto

Thank you for your question, and I have to admit, I am a little excited that someone is asking about auxin! As a graduate student, I studied how auxin (a plant growth regulator, also called a phytohormone) is made in sweet corn, so I am happy that the knowledge I gained might be of some help here.

As you seem well aware, there is an enzyme in plants and bacteria (called EPSPS) that catalyzes a reaction necessary for the synthesis of some amino acids, specifically the amino acids that have a chemical structure known as an "aromatic ring." These "aromatic amino acids" are precursors to other important plant compounds, including the ones you list in your question (auxin, phytoalexins, folic acid, lignin, plastoquinones). Glyphosate works by binding to the EPSPS enzyme and prevents it from catalyzing the reaction, thus affecting the synthesis of the aromatic amino acids and potentially the downstream plant compounds. In glyphosate-tolerant crops, a version (from naturally occurring bacteria) of this enzyme is expressed that has a slightly different shape. This slightly different shape prevents glyphosate from binding, rendering the plant resistant to glyphosate's effects, and allows normal rates of amino acid synthesis.

There are a lot of data published in peer-reviewed journals that show that the chemical makeup, or composition, of glyphosate-tolerant crops is equivalent to that of conventional counterparts. A good example of how aromatic amino acid (tyrosine, tryptophan and phenylalanine) amounts are not affected in gly-

phosate-tolerant crops, compared to a conventional comparator, can be found in Lundry et al. (2013). The data show that tyrosine amounts were 0.31 and 0.30 percent dwt, tryptophan amounts were 0.65 and 0.63 percent dwt and phenylalanine amounts were both 0.49 percent dwt in glyphosate-tolerant and conventional corn, respectively. We can see from this data that glyphosate tolerance does not decrease aromatic amino acid amounts, and that aromatic amino acid amounts, like all compounds, can vary due to natural causes like environment or background genetics. There is less information on comparisons of conventionally grown crops with organically grown crops, likely because these are no requirements for regulatory studies or approvals of crops based on input systems. One study available in corn (Rohlig and Engel, 2010) showed that input system (conventional vs. organic) had little effect on composition, but, as expected, environment and variety largely influenced the nutrient content. So, based on the data that show compositional equivalence between glyphosate-tolerant crops and conventional counterparts, and the data that show little effect of input system on composition, it stands to reason that GM crops would not have lower levels of aromatic amino acids and the other compounds that you mention, compared with organic counterparts.

For some of the compounds that you mention, if there were significantly lower amounts in glyphosate-tolerant plants, the plants would not look physiologically normal. You would be able to see these abnormalities just by looking out into a field. Auxin, for example, helps plants grow and develop normally (similar to hormones in other species, which is why it is called a phyto, or plant, hormone). It helps enable plants to respond to light (which is why plants grow up toward the sun), as well as plant responses to gravity (why roots grow down into the ground), as well as individual cell growth and multiplication. If there were lower levels of auxin in glyphosate-tolerant corn, you would be able to look out into the field and see corn that didn't grow upright, might be very stunted in growth and might have multiple stems growing (instead of just one). One example of what you might see can be found here.

## http://tiny.cc/r7arhx

How can eating a plant sprayed with Roundup be healthy for humans?

## By: Rashmi S. Nair, Monsanto

Good question, and let me explain to you why a genetically modified plant that does not die when sprayed with glyphosate (the active ingredient in Roundup) is as safe as a non-modified plant. There are actually several reasons.

First, conventional plants naturally contain a protein/enzyme, EPSPS, that produces the aromatic amino acids that are essential for plant growth. Glyphosate works to block this enzyme. That is how glyphosate-based herbicides can kill most non-modified plants. Plants modified to withstand glyphosate contain a gene that produces a similar EPSPS from bacteria called Agrobacterium strain CP4, and this EPSPS is tolerant to glyphosate. In other words, plants to which this variant of EPSPS is introduced can continue to produce the normal essential amino acids and survive. It was the discovery of the variant of the EPSPS from the bacteria that allowed scientists to introduce this variant of EPSPS into the conventional plants to make them tolerant to glyphosate.

Next, after establishing that the plants modified with the CP4 EP-SPS enzyme were able to withstand the spray of glyphosate, these plants were grown and treated with glyphosate in multiple regions all across the United States. All edible plant parts produced from these plants were extensively analyzed to show that the composition of the modified plants was compositionally equivalent to conventional plants grown at the same locations.

Lastly, there are limits on how much herbicide can be used and the intervals at which the herbicide can be sprayed on the plants. These limits are established by the U.S. EPA and other agencies across the world and are based on scientific data that determine the breakdown of the herbicide on the plant material itself, as well as degradation rates in the soil. Also, early in the development of these technologies, developers of such plants are required to actually measure the residue of glyphosate—in this case, on the plant at various stages of plant development and at the end of the season. It is on the basis of these data that levels of glyphosate that can be sprayed early in the season were established. (Note: this has been described in more detail here.)

Thus, use of innovative technologies allows scientists to safely introduce a gene that in turn becomes part of the plant's genome and produces food as safe as conventional crops. This technology allows for an effective weed-control system that improves yields. In addition, please note that weeds are the most persistent pests that cause extensive yield losses in agriculture. In addition, it is also important to point out that farmers have been using various herbicides in U.S. agriculture to control weeds for over 50 years and the use of herbicide-tolerant crops for the last 18 years has allowed farmers to improve yields and prevent extensive soil loss through use of low-till farming.

## http://tiny.cc/5ebrhx

How does the industry respond to the independent research that is showing connections between Glyphosate residue and damage to our environment and health including an increase in Autism prevalence?

## By: Andrew Kniss, University of Wyoming

There is simply no reason to believe that there is any link between increased use of glyphosate and increased prevalence of Autism Spectrum Disorder (ASD). Certainly, glyphosate use has increased due to widespread use of glyphosate-resistant crops. And there also appears to be an increase in the prevalence in ASD over the same time period. But just because two things happen at the same time, does not mean there is a causal relationship (or any relationship, for that matter). For example, between 1997 and 2007, deaths from cardiovascular disease declined 28 percent; but there is no reason to believe increased use of glyphosate was responsible for that change, either. There is no credible hypothesis for how glyphosate exposure might cause ASD. Emily Willingham, a research scientist who often writes about autism, points out that the balance of evidence indicates that "diagnostic substitution and enhanced awareness and recognition are the main drivers" of the increase in ASD prevalence. She also says there is "little published evidence" to support the idea that pesticide exposure is associated with ASD diagnoses.

## http://tiny.cc/ulbrhx

There does not appear to be more than anecdotal evidence available to prove Glyphosate safety, how do I know a GMO is safe to eat in this case?

## By: Steve Savage, Consultant, Savage & Associates

First of all, no organisms have ever been modified to produce Roundup (glyphosate). Several crops have been modified with a minimally altered version of one of their existing enzymes (EP-SPS) which makes them tolerant to that herbicide, but they don't make it. Second, regulatory agencies around the world don't base their decisions on "anecdotal evidence," no matter how much is available. They stick to solid science.

The consensus among regulators is quite clear that glyphosate has no real health or environmental issues. I'm sorry that so many people think that agencies like the EPA are somehow "bought off." All I can say is that if you are in an industry such agencies regulate, it certainly never feels like that. I also know independent academic toxicologists who serve on EPA committees, so I get some window on that source of objectivity that is involved in the process. I also have a lot of respect for all the EPA folks I've had occasion to meet, and I don't think they deserve the criticism they get from either the Right or the Left of the political spectrum. I'm really glad that the EPA has been around for 44 years, refining their risk assessment capabilities and regulatory processes. I wish more people could have that confidence.

Finally, the ultimate responsibility for the tragic health issues with Agent Orange is not something that is easily assigned. It was a repugnant military strategy in the first place—to drive the peasants off their farmland so that they could not provide food for the insurgents, and also to defoliate the jungles to make it easier to find the Viet Cong. The military also required several U.S. chemical manufacturers to quickly provide large quantities of the active ingredients: 2,4-D and 2,4,5-T. This was a long time ago (40—50 years), and at the time, no one realized that there was a trace process contaminant in the 2,4,5-T—a dioxin. The effects of that unintended component were horrible but it does no service to the Vietnamese and American people and families who suffered to casually assign blame. Hopefully, we have learned a great deal from that collective mistake.

## http://tiny.cc/qqbrhx

There is research that links glyphosate and breast cancer, due to its chelating nature and other characteristics, how are these GM foods safe and nutritionally identical to their non-GM food counterparts?

## By: Marian Bleeke, Monsanto

Your first question involves breast cancer, and I'd recommend you review a response that my colleague John Swarthout provided to a similar question posed on this site.

Regarding your other question, it is true that glyphosate is a chelating agent, but that does not imply that it makes nutrients "unavailable in the soil." Let me explain why. First, chelation is a natural and important process in soil. Metals are mostly present in soil as solids and need to be dissolved to be taken up by

a plant. Chelation increases the solubility of metal ions, reduces their toxicity, and makes them available for uptake by plants. Organic acids and amino acids, such as citric acid and glycine, are naturally occurring chelators that are present in soil and play an important role in micronutrient uptake. Plants also exude strong chelators that bind to micronutrients and make them available for update. It all makes for a complex mixture in soil of metals and chelators, of which glyphosate is just one small component.

The degree to which metals and chelators bind depends on the relative strength of their interaction and their concentrations, and it adjusts as the mixture changes. In other words, binding does occur but it is not permanent and each molecule can bind only a specific number of ions at any one time. For instance, one glyphosate molecule will bind no more than one manganese ion. So amounts of glyphosate and metal ions are important parts of the equation. Glyphosate primarily stays in the top 6-12 inches of soil, with maximum concentrations in that zone of several parts per million (ppm), and declines over time, with a typical half-life of about a month. In contrast, the concentrations of micronutrient metal ions in soil are much higher. Metals such as iron and aluminum are in the range of 7,000-300,000 ppm or higher; others, such as manganese (20-3,000 ppm) and zinc (10-300 ppm), are present in lower concentrations but still significantly higher than those of glyphosate. Because metal ion concentrations are so much higher than glyphosate's, with much of it in insoluble soil particles, glyphosate binds tightly to soil and shows very little uptake into plants or movement through soil.

There is not any indication that these low levels of glyphosate are having an impact on the uptake of metal ion micronutrients into crops. All studies comparing GM crops to their non-GM counterparts to date have shown no biologically relevant differences in micronutrient levels. One excellent review publication from multiple public-sector scientists can be found here. The authors concluded most of the literature available indicates that mineral nutrition in glyphosate-resistant crops is not affected either by the glyphosate-resistance trait or by application of glyphosate, and that yield data on glyphosate-resistant crops do not support the hypotheses that there are substantive mineral nutrition or disease problems that are specific to glyphosate-resistant crops.

I realize that this accusation about nutrient deficiencies with GM crops is readily found on the Internet. These allegations are not, however, backed by a credible data set. (See a response from Kevin Folta here.)

There are many environmental studies related to glyphosate, and there is no indication of harm to microbial structure of the soil. Remember that microbes are ubiquitous, and each type responds to changes in the environment. For instance, they would undoubtedly be different between a location with loamy soil that is irrigated and in a higher average daily temperature than one with clay soil not being irrigated and with a lower average temperature. So be careful when you hear about changes in microbes. Furthermore, if plants were weakened, then high yields would not be sustainable. But we also have data. All plants are evaluated for germination characteristics, crop growth and development from emergence to maturity, including vegetative and reproductive stages, crop yield and crop response to abiotic stressors, diseases and arthropods.

Finally, a comprehensive paper was published in 2012 by Dr. Duke (USDA) on these glyphosate topics; it can be found at J. Agric. Food Chem 60 (2012): 10375–97.

## http://tiny.cc/bwbrhx

Glyphosate seems to be linked to many health issues including cancer, how can I believe the claims that GMO foods are safe and "comparable" to non-GMO foods after having been sprayed with Glyphosate?

## By: Dan Goldstein, Monsanto

This is a multifaceted question with the understanding that you don't trust information from industry scientists, government scientists, academic scientists at institutions that receive private funding or organizations like the AMA and, I will presume, the National Academy of Sciences. I point this out because there was an article published recently that discusses exactly this expectation of corruption that may be of interest (see page 8).

I will begin by sorting out and clarifying some items. Crops are not "doused" in anything. The word implies a haphazard and presumably excessive application of materials, and this is not the case. Although you expressed concern only for pesticide use in GM crops, the same regulatory assessments are done for GM and non-GM crops. Pesticide application rates and application times are subject to regulation, and maximum allowable levels of residue in various food or feed crops are subject to regulation. In the case of glyphosate in the United States, even worst-case-scenario estimates (assuming crops contain maximum allowable levels, grossly overestimating exposure) indicate that intakes are well below levels of regulatory concern.

The recently established or altered tolerances for glyphosate received a great deal of attention in the media. You can view the decision here. You will note that contrary to most internet coverage of this topic 1) the petition was not submitted by Monsanto, 2) the petition was for use in a variety of minor use crops and forage, 3) none of the crops involved was genetically modified and 4) glyphosate is not applied directly to these crops for weed control, as they are not glyphosate-resistant.

Data for pesticide registration - as is the case for drugs, food additives and every other product you use from cosmetics to cars are generated by or on behalf of manufacturers. The requirements for data generation are, however, established by the Federal Government. For glyphosate specifically, there are now six sets of independent (of one another) toxicology data for glyphosate from the various registrants, all of which are consistent and none of which suggests risks of cancer or other long-term health effects. Newer studies that have been mandated more recently (immunotoxicology and developmental neurotoxicology), as well as endocrine testing do not raise concerns.

You seem to be highly skeptical of these data, and I respect your right to be skeptical of all data that you review. For instance, the paper by Samsel and Seneff appears in a physics journal, is published by individuals with no formal background in biology or medicine and in fact has no data in the paper at all. Rather, it weaves together a series of complex but unproven theories. Even Huffington Post, not a great fan of GMOs, has criticized this work, and others have chimed in as well (When Media Uncritically

Cover Pseudoscience, I Was Going To Write Some Words But Keith Kloor Beat Me To It).

I do agree with Jeffrey Smith on one point: the paper is hard to get through. In fact, to a scientist, the paper is a rambling string of unsubstantiated assertions, with claims around effects on exogenous semiotic entropy - three words that do not appear together anywhere else in the scientific literature. She has proven nothing-merely generated intricate but unsupportable hypotheses. If you listen to the full interview with Stephanie Seneff, she admits that there are no new data.

The Mercola citation takes you to one of several postings on Mercola's website. Like Stephanie Seneff, Mercola makes myriad claims but presents no data. Dr. Mercola plays out prominently on the Quackwatch website and has been warned or ordered by FDA on several occasions to cease making illegal claims for products sold via his various websites and organizations. In the interest of space, I will not try to address all of Mercola's claims here (I suspect GMO Answers will get to them all), but let's look at a few examples:

- •Claims supported by Samsel and Seneff (so-called "ground-breaking research"). These are, as noted above, unsubstantiated hypotheses that have been widely subject to criticism.
- •The Séralini two-year rat study. Bottom line Séralini and colleagues demonstrated the normal tumor incidence in SD rats fed on unlimited diets. It is not difficult to speculate about why a photo of a test rat with a tumor with no scientific value was included, and why the comparable photo of control rats with tumors was not included, in the paper. There was no difference demonstrated between exposed and control animals. This study was rebutted widely. The most definitive treatise is from the European Food Safety Authority (EFSA), and the situation is extensively reviewed on Monsanto's website, with multiple links to independent agencies and scientific organizations who have rejected this study.

As time and space permit, we will get to the remaining allegations, and I think you will find that they are similarly unsubstantiated.

#### http://tiny.cc/d4brhx

Is Roundup safe to drink in trace amounts? Where is the line between safe levels and toxic levels of Roundup?

## By: David Saltmiras, Monsanto

Most of us have picked up a bottle of Roundup from a home center and used it to kill weeds in our driveways and gardens. Roundup-brand herbicides have a long history of safe use at home and in agricultural settings. As with most chemical products, appropriate precautions must be taken during handling, and use of these products and the directions for use must be followed carefully. Almost all nonfood products, including herbicides, would not be safe for human consumption straight out of the container, because most chemical products contain ingredients at levels significantly higher than would be acceptable for daily human consumption.

Drinking dishwashing detergent or shampoo out of the container, for example, is not advised, because these chemical products contain surfactants that should not be intentionally consumed,

yet low levels of dishwashing detergent and shampoo residues are consumed daily off of cups, plates and utensils and during showering, without adverse health effects. And rightfully so, people are not concerned about use or consumption of trace amounts of detergents.

The same is true for herbicides. Roundup-brand products also contain surfactants like those found in dishwashing detergents and shampoos and, like these consumer products, should not be intentionally consumed. However, low levels of these surfactants and the active ingredient in Roundup-brand products (glyphosate), which gives it its weed-killing power, ingested from the food we eat are well below what has been determined acceptable for daily human consumption.

The use of every herbicide on food crops in the United States is considered and evaluated by the Environmental Protection Agency (EPA) against a standard of reasonable certainty that the use would cause no harm to human health or the environment. In order to make this safety determination for Roundup products, EPA considers how much glyphosate residue the use would contribute to the daily intake and then adds that amount to the amount of glyphosate residue consumed by all other possible routes of exposure, including on other foods, in drinking water, through accidental ingestion of water during swimming, etc. This total consumption of glyphosate residues are then compared to the total acceptable daily intake, or ADI, that has been established for glyphosate, based on toxicity studies that look at a variety of toxic effects, such as immediate or acute toxicity, effects on reproductive processes, cancer-causing and other long-term effects, etc. Just to be on the safe side, the EPA sets the acceptable daily intake (ADI) a minimum of 100-times lower than any dose level that showed any kind of toxicity in any study conducted. No more uses of a pesticide like Roundup-brand products can be added once the ADI has been reached. If use of a pesticide is expanded, the additional consumption has to be considered.

The ADI of glyphosate, and many other herbicide active ingredients, has been established by the EPA and independently by regulatory authorities in different parts of the world, including the World Health Organization. Whether taken in as food or drink, these ADI levels are conservatively calculated based on animal models, crop residues and typical diets to account for daily exposures throughout our lives. Daily consumption of residues below the ADI is considered safe.

A recent risk assessment was conducted by EPA for glyphosate exposures through both food (agricultural products) and water, and it concluded glyphosate exposure is no more than 13 percent of the ADI. This risk assessment takes the conservative approach that all fruits, vegetables and grains in the diet treated with glyphosate had the maximum allowable residue levels remaining on those food crops when eaten, which is a very conservative assumption for glyphosate residue levels in food.

I realize that this has been a very technical answer for what was a simple question, but it emphasizes the scrutiny that is required to ensure your family and mine have safe food to eat.

## http://tiny.cc/wccrhx

Does Glyphosate cause development abnormalities in frogs, if so, are there scientific resources that can be referenced?

## By: Steven L. Levine, Monsanto

There are data that suggest this, but the simple fact is that these studies utilized conditions that are not relevant to real-world exposures. These studies were conducted either using exposure routes (e.g. injection or cell culture) not relevant for environmental exposure or using exposure concentrations or durations that greatly exceed worst-case environmental exposures, and environmental fate has not been included in the exposure regimen. Consequently, these types of studies must be interpreted with extreme caution.

Exposure of tadpoles to glyphosate under environmentally-realistic conditions (concentrations and routes of exposure) has not resulted in developmental abnormalities. For example, no adverse effects on tadpole growth or development were observed when tadpoles were continuously exposed for 21 days to glyphosate in water at the highest concentration required to be tested by the U.S. Environmental Protection Agency under test guideline OPPTS 890.1100 (U.S. EPA).[1] Similarly, growth and development were not affected when tadpoles were chronically exposed to a glyphosate formulation in natural wetlands at environmentally relevant concentrations.[2]

It is also worth noting that some have alleged that effects on development, if true, would be due to endocrine activity. However, glyphosate was recently screened in the EPA's Tier 1 screening battery under the Endocrine Disruptor Screening Program [3] and based on the results of the validated EDSP Tier 1 assays glyphosate did not have endocrine activity.[4] Additionally, Williams et al (2012)[5] performed a comprehensive review of the available literature to assess the developmental and reproductive safety of glyphosate and concluded "the literature shows no solid evidence linking glyphosate exposure to adverse developmental or reproductive effects at environmentally realistic exposure concentrations."

The conclusions of the studies cited here and other relevant environmental studies with amphibians clearly show that when glyphosate is used following label directions it does not result in developmental abnormalities in frogs and other vertebrates.

## http://tiny.cc/dicrhx

## What is the impact Glyphosate has on the obesity epidemic?

#### By: Dan Goldstein, Monsanto

It is a common misunderstanding that pesticides, in general, accumulate in body fat. While this phenomenon may occur with some older compounds and a very few compounds currently in use, pesticides that bioaccumulate to any significant degree have been removed from use or are highly restricted to specialized applications needs that limit environmental exposures. Glyphosate is structurally related to the amino acid (protein component) glycine and is readily soluble in water, as demonstrated by the fact that you can buy water-based formulations containing as much as 62% glyphosate salts in agricultural formulations. If ingested,

glyphosate is excreted rapidly, does not accumulate in body fat or tissues, and does not undergo metabolism in humans. Rather, it is excreted unchanged in the urine (EU Review Report of the active substance glyphosate, 2002, at: >http://tiny.cc/pncrhx).

## http://tiny.cc/1pcrhx

Have studies been performed to provide safety data on the surfactants and inert ingredients used in Roundup?

## By: Jim Gaffney, Dupont Pioneer

If you're interested in learning more about agriculture chemical use over time, please see an earlier response I drafted, posted here.

Pesticides in use today have been thoroughly evaluated for environmental and human safety. The Environmental Protection Agency regulates the sale and use of pesticides and requires robust studies and lengthy testing to demonstrate safety before any product reaches the market. Many products on the market today have specific modes of action for a target pest. An example of a class of crop protection chemistry that is marketed by DuPont and remains popular is sulfonylurea herbicides. These herbicides are used at very low rates (often less than one-tenth of a pound per acre) and disrupt an enzymatic pathway found only in plants, and therefore have minimal impact on other organisms (e.g., humans, birds, insects). For all products, strict handling requirements are implemented to limit potential farmworker exposure and also to limit products' potential exposure to the environment and other non–target organisms.

As for surfactants and inert ingredients that are used in these crop protection products, government regulators maintain tight control and oversight. Ingredients used in any product have undergone a similar level of scrutiny, as has the active ingredient in any product. A substantial number of studies for toxicity and non–target organisms are required before an inert ingredient is approved for use.

## http://tiny.cc/kycrhx

What measures are in place to ensure the safety of Glyphosate, particularly because countries have banned it?

#### By: Donna Farmer, Monsanto

Glyphosate, the active ingredient in Roundup branded herbicides, is not banned in any country and is registered in more than 100 countries around the world.

Regulatory agencies such as the U.S. Environmental Protection Agency (EPA) and scientific bodies such as the World Health Organization have reviewed numerous studies conducted according to international

guidelines and good laboratory practices and concluded that glyphosate does not cause cancer or birth defects.

There have been some publications claiming that glyphosate causes cancer and/or birth defects, however regulators and independent scientists have reviewed those studies and concluded that they don¹t support the claims because the studies were conducted under artificial conditions not relevant to real world exposures or were not designed to appropriately assess the health outcome.

Do the surfactant ingredients in Roundup increase the toxicity level?

#### By: Donna Farmer, Monsanto

Thanks for asking about the toxicity of glyphosate versus that of surfactants used with glyphosate. For herbicides like glyphosate to be most effective at controlling unwanted plants, they need to be applied with a surfactant. Surfactants (short for "surface-acting agents") are soapy substances that help to reduce surface tension of the water so the drop of spray solution can spread over the surface of a leaf and help to penetrate the waxy layer (the cuticle) of the plant. Herbicidal soaps are often used in organic gardening to help penetrate the waxy layer of plants and cause the plant to dehydrate and die.

The surfactants used with glyphosate are similar to those used in personal-care and household cleaning products that we are exposed to every day when we wash our hands, hair and dishes. The surfactants in these products perform the same function as they do when mixed with an herbicide like glyphosate. For example, surfactants found in shampoos reduce the surface tension of water to help it spread and move around our hair and help remove the oily layer with dirt from our hair.

You are correct that glyphosate for acute oral toxicity is placed in the US Environmental Protection Agency Toxicity Category III. The surfactants used with glyphosate are also in Toxicity Category III for acute oral toxicity, as are many of the surfactants used in personal and household cleaning products. The surfactants mixed with glyphosate in Roundup-brand products do not increase this acute toxicity level. For example, Roundup-brand products (containing primarily glyphosate, surfactants and water) are in Toxicity Category IV for acute oral toxicity. The reason for the change from Category III to Category IV is the result of the formulated product being diluted with water.

You may have read claims on the Internet that when glyphosate is mixed with surfactants, the formulated Roundup-brand products are more toxic. These claims relate to the results of petri dish experiments. Glyphosate and Roundup-brand products were poured over unprotected cells in a petri dish. This direct exposure to high concentrations used in these studies intentionally bypasses normal processes and limits exposure. While glyphosate had very little effect on cell function, the Roundup formulations because of the surfactant component did alter cell function. This is not a surprise, given that the surfactants in the Roundup-brand product in the petri dish were doing what any surfactant would do: they were disrupting the biological membrane of the unprotected cell. In fact, surfactants are routinely used in cell biology to disrupt cell membranes to isolate membrane proteins. Petri dish experiments with surfactants from personal and home care products, as well as caffeine and citric acid (normal components in coffee and orange juice, respectively), have shown they, too, can disrupt cell function.

Glyphosate, the surfactants used with glyphosate and Roundup-brand products, when used according to label directions, all have a long history of safe use and will not pose any unreasonable risk to human health. Studies are showing that Glyphosate is linked to birth defects, why are pesticides and herbicides being used when organic farming has been shown to be just as successful?

#### By: Donna Farmer, Monsanto

As a toxicologist who focuses on pesticide safety, I can tell you that glyphosate herbicides are backed by one of the most extensive worldwide human health, safety and environmental databases ever compiled for a pesticide product. This herbicide has been thoroughly reviewed and registered by the U.S. Environmental Protection Agency and other regulatory agencies around the world.

Regulatory authorities and independent experts agree that glyphosate does not cause adverse reproductive effects in adult animals or birth defects in offspring of these adults exposed to glyphosate, even at doses far higher than relevant environmental or occupational exposure. As a mother, I am always reviewing studies with that eye – assuring that my children and yours would not be harmed by appropriate uses of our products.

The authors of the Earth Open Source document that you refer to provide an account of glyphosate toxicity from a biased selection of studies. It is important not to ignore other data establishing the safety of glyphosate including the fact that glyphosate is not a reproductive toxin or teratogen (cause of birth defects), for example:

- http://tiny.cc/5hdrhx
- •>http://tiny.cc/6idrhx
- •>http://tiny.cc/akdrhx
- •>http://tiny.cc/vkdrhx

Following are a few other details about glyphosate that I'd ask you to consider:

- •When used according to label directions, Roundup branded products have a long history of safe use. The safe use of these products is backed by extensive studies as well by the first-hand experience of millions of farmers and home gardeners who have used these products for decades.
- •Glyphosate inhibits an enzyme that is essential to plant growth; this enzyme is not found in humans or other animals, contributing to the low risk to human health from the use of glyphosate according to label directions.
- •Biotech crops undergo a rigorous safety assessment following international guidelines and no verifiable cases of harm to human or animal health have occurred.
- •Roundup herbicides are the cornerstone of weed management programs on many farms and provide environmental and economic benefits of conservation tillage which are sustainable and provide effective weed management.
- •Regarding your comments and questions about organic farming:
- •Organic farmers still use pesticides to control weeds and prevent insects/diseases from destroying their crops. So the belief that organic farming does not include the use of pesticides is not true. See: >http://tiny.cc/9ldrhx
- •The National Organic Program (NOP) is a regulatory program

housed within the USDA Agricultural Marketing Service. The NOP is responsible for developing national standards for organically-produced agricultural products. These standards assure consumers that products with the USDA organic seal meet consistent, uniform standards. Their regulations do not address food safety or nutrition. Organic is therefore a labeling term that indicates that the food or other agricultural product has been produced through approved methods.

- •One of the key activities of the NOP is to manage the National List of Allowed and Prohibited Substances. This list identifies substances (including pesticides) that may and may not be used in organic crop and livestock production. Below are the links to the NOP home page and the National List of Allowed and Prohibited Substances:
- •>http://tiny.cc/3mdrhx
- •>http://tiny.cc/indrhx

#### http://tiny.cc/dodrhx

How do you respond to a recent Entropy publication blaming Glyphosate as disrupting our chemical pathways and potentially being responsible for most primary diseases of Americans that have been on the rise in the last 5 years?

#### By: Dan Goldstein, Monsanto

This publication claims that there is a causal connection between glyphosate and numerous diseases, including autism, Alzheimer's, obesity, anorexia nervosa, liver disease, reproductive and developmental disorders, and cancer.

In actuality, the manuscript offers no new data. Instead it presents multiple hypotheses, none of which are tested, and in order for the story to be true, every one of the hypotheses must be true. It is an attempt to make correlations between glyphosate and common health ailments. None of the disease associations are supported by available toxicology testing, experimentation, or by observations associating glyphosate exposure with these disease outcomes in human populations. Proponents of the paper like to point out that it was in a peer-reviewed scientific journal, but it was published in a Physics journal with an editorial board that has no members qualified in the areas of biology, metabolism or medicine.

The paper is interesting because it strings together so many hypothetical allegations that the details would be confusing even to scientists not skilled in each field of science implicated in the allegations, and therefore, the temptation of many would be to just read the conclusions. Always be suspicious of associations without cause and effect, in vitro data extended to in vivo conclusions, without regard to experimental conditions such as dose, and extraordinary hypotheses not supported by years of research.

If you watch the video you will note that Stephanie Seneff states clearly that they have no new data and that the paper raises hypotheses but offers no proof that they are correct.

Dr. Kevin Folta offered more information about the quality of the science in this publication in a similar answer: >http://tiny.cc/ovdrhx

## http://tiny.cc/2wdrhx

## How long does Glyphosate remain in Roundup Ready corn after it is applied?

## By: Donna Farmer, Monsanto

That is a great question, and I wish I could give you a short answer, but a lot of work and scientific evaluation have gone into understanding what happens to glyphosate after it is applied to Roundup Ready crops like corn and to ensuring your family and mine have safe food to eat.

Most glyphosate applications in Roundup Ready corn occur before the corn kernels start to develop; therefore, very little glyphosate is present in the kernels, so residues in the kernels are low. Typical Roundup Ready corn grain residues are well below one part per million (ppm). Levels this low do not pose any health concerns. Studies of Roundup Ready corn have shown that the amount of glyphosate in the corn plant following a foliar application drops fairly quickly, due to wash-off of surface residues, dilution as the plant grows and distribution throughout the plant and roots.

Before glyphosate could be applied to Roundup Ready corn, that "over the top" use had to be approved by the US Environmental Protection Agency (EPA). The EPA must evaluate herbicides thoroughly before they can be marketed and used in the United States, to ensure that they meet the federal safety standards for protecting human health and the environment.

The process of registering an herbicide like glyphosate and Roundup-branded products is a scientific, legal and administrative procedure in which the EPA examines all the ingredients in the product; the crop on which it is to be used; and the amount, frequency and time of use.

Before allowing the use of an herbicide on food crops, the EPA sets a tolerance, or maximum residue limit. This tolerance is the amount of herbicide residue that is legally allowed to remain in or on each treated food commodity. In establishing the tolerance, the EPA must make a determination that the herbicide can be used with "reasonable certainty of no harm." In making this determination, the EPA considers the toxicity of the herbicide and its breakdown products, how much of the herbicide is applied and how often and how much of the herbicide (i.e., the residue) remains in or on food.

The EPA requires companies seeking registrations on herbicides and other types of pesticides to conduct many different kinds of studies. The EPA uses the results of those studies in its evaluations to ensure that the product meets the federal safety standards.

The types of studies conducted to determine the maximum residue levels likely to result in or on food crops from registered uses are called crop field trial residue studies. These studies are conducted in multiple locations (for corn, 20 locations are required) that are representative of growing conditions in areas where the crop is grown and reflect maximum use rates, maximum number of applications and minimum duration after application that the crop may be harvested, as defined by the pesticide registration and label.

Residue samples are obtained immediately upon harvest of the food commodity. Residues expected on food, as consumed gener-

ally, are lower than the values measured in crop field trial residue studies because of variations in use practices (either not using the pesticide at all or using it in a manner not likely to produce maximum residues), degradation of residues between time of harvest and consumption and cooking and processing practices that break down residues.

As I mentioned earlier, in establishing the tolerance, the EPA must make a determination that the herbicide can be used with "reasonable certainty of no harm." In order to make this safety determination for glyphosate-based products, the EPA considers how much glyphosate residue the use would contribute to the daily intake and then adds that amount to the amount of glyphosate residue consumed by all other possible routes of exposure, including on other foods, in drinking water, etc. This total consumption of glyphosate residues is then compared with the total acceptable daily intake (ADI) that has been established for glyphosate, based on toxicity studies that look at a variety of toxic effects, such as immediate or acute toxicity, effects on reproductive processes, cancer-causing and other long-term effects, etc. Just to be on the safe side, the EPA sets the ADI a minimum of 100 times lower than any dose level that showed any kind of toxicity in any study conducted. No more uses of product can be added once the ADI has been reached. The ADI of glyphosate, and many other herbicide-active ingredients, has been established by the US EPA and independently by regulatory authorities in different parts of the world, including the World Health Organization. Whether taken in as food or drink, these ADI levels are conservatively calculated based on animal models, crop residues and typical diets to account for daily exposures throughout our lives. Daily consumption of residues below the ADI is considered safe.

A risk assessment was conducted in May 2013 by EPA for glyphosate exposures through both food (agricultural products) and water, and it concluded that glyphosate exposure is no more than 13 percent of the ADI. Therefore, even when one takes the conservative approach that all fruits, vegetables and grains in the diet treated with glyphosate would have the maximum allowable residue levels remaining on those food crops when eaten, the use of glyphosate is well within what is considered to be safe.

## http://tiny.cc/wcerhx

Dr. Huber is quoted as suggesting that Glyphosate was patented as a mineral chelator as well as an antibiotic, both of which in my opinion have enormous negative implications, why would this be the case?

## By: John Vicini, Monsanto

Dr. Huber's assertions have been addressed previously, and I'd refer you to this response (>http://gmoanswers.com/ask/i-dont-understand-how-you-can-say-gmo-food-safe-when-farmers-are-spraying-glyphosate-their-crops) on GMO Answers, by Marian Bleeke, as well as this blog post (>http://thefanningmill.com/2014/01/10/deconstructing-don-huber-a-tale-of-two-talks/), written by organic farmer Rob Wallbridge.

Regarding your question, it is true that glyphosate is a chelator and that it has some antimicrobial properties. However, it is important when looking at an effect of any compound to understand the whole story. For instance, red blood cells bind oxygen. That's an indisputable fact. So to say that blood prevents muscle

cells of the body from gaining access to oxygen would be obviously faulty logic and would be based on looking at only half of the story. To extend the analogy, oxygen is also a potent antimicrobial compound for many good anaerobic gut organisms. That doesn't mean that small amounts of oxygen in the gut will kill all of the organisms in the gut. Obviously, just the label "antimicrobial" is not very informative without more information.

In the glyphosate example that you cite, it appears that there is also a jump in logic that looks at only half of the story. In 2012, Dr. Stephen Duke et al. wrote a comprehensive review of glyphosate in which they explain that there are many natural chelators in soil, and that they are beneficial for facilitating transport of minerals into plants: >http://pubs.acs.org/doi/abs/10.1021/jf302436u?prevSearch=%5BTitle%3A+glyphosate%5D+and+%5BContrib%3A+duke%5D&searchHistoryKey=. Moreover, to suggest that glyphosate as an antimicrobial preferentially affects good bacteria implies that all "good" and "bad" microbes can be defined by their metabolism, and there is no basis for this conclusion.

In risk assessment, hazard and exposure (dose) need to be considered for each organism. In 2013, the German BfR did a reevaluation of glyphosate, and, based on accusations about glyphosate affecting animal gut microbes, it commissioned a study to look at effects of glyphosate in an artificial rumen microbial system. As we've discussed previously on this site, ruminants rely on the microbes (bacteria, fungi, protozoa) in the rumen to predigest their feed before any other digestion occurs in the lower parts of their gastrointestinal tract. The BfR concluded that "no adverse effects on animal health are to be anticipated." Likewise, animals have been fed glyphosate in long-term studies, and histological examination of gut tissues has not revealed any pathologies like you describe. Furthermore, these in vitro results are consistent with what has been observed with billions of animals fed diets containing ingredients derived from biotech crops.

Dr. Van Eenennaam published in 2013 that "large numbers of livestock in many countries have been consuming GE feed for over a decade. For example, in 2011 alone approximately 9 billion broiler chickens, weighing over 22.5 billion kg liveweight were produced in the United States. During that year 30 million tonnes of corn and 13.6 million tonnes of soy were used as broiler and breeder poultry feed of which 88% and 94%, respectively, was likely from GE crops. Production parameters, mortality and condemnation rates for the more than 105 billion broilers that have been processed in the US since 2000 are shown in Figure 2. In 2000 approximately 25% of corn and 50% of soy grown in the US was GE and hence poultry diets have likely contained an ever increasing proportion of GE feed from 2000 to 2011. This very large field data set does not reveal overt health problems associated with the consumption of GE feed, but rather shows a continuation of industry trends that were observed prior to the introduction of GE crops (Figure 2)." This link will allow you to see the figure and read the paper: >http://tiny.cc/therhx.

#### http://tinyurl.com/lohpr6u

Why are there several studies indicating that Glyphosate poses a potential hazard to an unborn child when the other argument suggests there is no scientific evidence to suggest this?

## By: Dan Goldstein, Monsanto

Typically, scientists who focus on reproductive and developmental safety look at two different sources of information: animal studies and epidemiologic investigations. In regard to animal data, glyphosate is relatively unique in having multiple independent companies perform reproductive and developmental toxicology studies in rodents and rabbits. These studies show no reproducible reproductive or developmental effects. Most recently, in 2012, a group of toxicologists conducted a detailed review of all of the animal and epidemiologic data and summarized: "An evaluation of this database found no consistent effects of glyphosate exposure on reproductive health or the developing offspring. Furthermore, no plausible mechanisms of action for such effects were elucidated."

This analysis can be viewed online (Williams et al., 2012: >http://www.tandfonline.com/doi/abs/10.1080/10937404.2012.632361).

So, what other studies are there, and do they in fact provide any convincing evidence of reproductive or developmental effect?

The most commonly cited study would be Paganelli et al. (Carrasco). These authors investigated the effects of a glyphosate-surfactant herbicide using two models: effects on frog embryos and effects following injection into the eggs of chickens. These models are not routine, and the predictive value for effects in mammals (including humans) is not clear. However, on the basis of findings in this study, the authors postulated an effect mediated by changes in retinoic acid (vitamin A) metabolism and speculated that these findings would apply to humans and, indeed, across the animal kingdom. It was a nice theory, but the problem is that there are lots of mammalian studies conducted by different groups, and the effects that Paganelli et al. predicted simply don't happen in mammals.

The epidemiology literature (see Williams et al., 2012: >http://www.tandfonline.com/doi/abs/10.1080/10937404.2012.63236 1) to date contains six studies looking at a variety of outcomes, including miscarriage, preterm delivery, spontaneous abortion, fetal death, neural tube defects and birth defects in general. Four studies showed no effect. One study (Bell, 2001) was a study of exposure to more pesticides than just glyphosate, and the same author could not replicate the study's results in a larger study in the same state.

The other study alleging an effect (Garry et al.) demonstrated an overall birth defect rate far above that of earlier studies by the same author. The study asked participants to recall their exposure to chemistries without verifying their recollections, which is not a very reliable process. It resulted in an elevated risk of birth defects across all categories of chemistry studied. Of five studies looking at reproductive health (see Williams, 2012), four demonstrated no statistically significant adverse effects (one study showed statistically significant improved male fertility), and one study involved overall herbicide exposure, inclusive of glyphosate and other chemicals, precluding any ability to draw conclusions related to glyphosate itself. In short, there is no convincing or reproduc-

ible epidemiologic evidence of developmental effects related to glyphosate.

The final piece worth noting would be allegations out of Argentina that communities in the vicinity of spray applications of pesticides, including glyphosate and other materials, have experienced an increased rate ofbirth defects. This information has not been systematically collected, and the underlying population from which these individual cases have been collected is not defined. Hence, it is difficult to assess, because there is no measure of the true rates of birth defects. Alleged rates of birth defects actually fall below rates of birth defects seen in the general US population and populations in developed nations globally. This strongly suggests that any changes in rate have more to do with changes in data collection than with changes in actual rates. Finally, there is no way to disentangle exposure to glyphosate from exposure to other agents or, for that matter, from nutritional or other factors in the available data. The bottom line is that birth defect rates alleged in this population are simply not reliable, and conclusions cannot be made regarding relationship to glyphosate.

## http://tiny.cc/zmerhx



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