



MASSACHUSETTS
GENERAL HOSPITAL



MassGeneral Hospital
for Children



HARVARD
MEDICAL SCHOOL

Ronald E. Kleinman, MD
175 Cambridge Street, 5th Floor
Boston, Massachusetts 02114
Tel: 617.724.2911 Fax: 617.643.5330

Physician in-Chief
Chair, Department of Pediatrics

Charles Wilder Professor of Pediatrics

A Pediatrician's Viewpoint on HB 5300—An Act Concerning the Use of Genetically Modified Organisms in Children's Food

My name is Dr. Ronald Kleinman, and I am the Physician in Chief of the Massachusetts General Hospital for Children, Chair of the Department of Pediatrics at the Massachusetts General Hospital and the Charles Wilder Professor of Pediatrics at Harvard Medical School. My research and clinical work focuses on gastrointestinal immunology, nutrition support of infants and children, and nutrition and public health policy. I have also served on the Medical Advisory Group on Diet and Nutrition Guidelines in Cancer for the American Cancer Society and as Chair of the Committee on Nutrition for the American Academy of Pediatrics (AAP). In my work with the AAP, I have served as editor of the fourth, fifth, and sixth and the current seventh edition of the Academy's Pediatric Nutrition Handbook.

Beyond my professional interest in the subject of infant nutrition, I grew up in Connecticut and attended Trinity College before pursuing my medical training out of state. Given my professional background and ties to Connecticut, I felt compelled to submit this testimony for your consideration as your committee evaluates the merits of HB 5300, An Act Concerning the Use of Genetically Modified Organisms in Children's Food.

At the outset, I have to express my objection to this legislation as a pediatrician and nutrition scientist. I know the weight new parents and caregivers place on every decision affecting their children, and I have made it my life's work to help guide parents through these challenges. In today's world, my efforts are often complicated as a result of the conflicting messages, information and misinformation about genetically engineered (GE) foods. In counseling caregivers, what is most important is to help them separate myth from fact, and recognize when emotion has trumped hard science.

HB 5300 is based on emotion, not science. There is no scientific evidence to support the proposed labeling requirement and, even worse, the label has the potential to lead to unintended consequences that could prove serious. As a medical professional, I have personally reviewed the scientific data and safety information related to GE foods. I can tell you that there is no credible evidence that GE foods pose any risk to infants, children or people from any other age groups. Consuming foods produced through biotechnology is safe for all populations, including infants, children and women who are pregnant or nursing. The idea that special labels are needed for certain populations is not supported by science and has no basis other than emotion.

Putting my personal observations aside, a vast and growing body of scientific evidence supports the safety of GE foods and ingredients whether they are consumed by adults or infants and young children. More than 2,000 studies have been conducted on these foods and have consistently found that GE foods and ingredients present no unique risks or dangers to human health. While you may hear testimony from supporters of this bill that there has been limited testing of safety, that is simply false. Agricultural biotechnology is one of the most well researched technologies of our time and the scientific consensus is clear, these foods are safe.

Despite the lack of any credible science demonstrating harm or risk from these products, some will try to convince you that there are safety concerns by citing research like the 2012 study by Gilles-Eric Séralini "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize." Let me be clear, the findings of this study have been overwhelmingly discredited, and it was even retracted by the journal that published it when the authors refused to withdraw it.

Others may testify that these labels are necessary to help parents avoid pesticides and herbicides, including the common herbicide glyphosate. Let me start by noting that I have also personally reviewed all of the scientific literature regarding glyphosate, the active ingredient in Roundup, and found it to be of no consequence to the health or safety of infants. I have provided some more information on this topic below.

It also deserves mentioning that the scientific consensus of safety of GE foods and ingredients derived from them is reflected in the position of the U.S. Food and Drug Administration (FDA), which has concluded most recently in November 2015 that these foods and ingredients are equivalent in composition, nutritional value and quality as conventionally produced foods and ingredients. The FDA is the federal agency with jurisdiction over infant formula and baby food and, in the case of infant formula, is required by law (the Infant Formula Act) to review all ingredients before they are used in infant formula. Infant formula ingredients are only approved after they have been found to be safe and suitable. Current infant formulas produced in the United States are the most highly regulated and tested foods available in the world and their ingredients are unequivocally safe.

Because the FDA has concluded GE foods are safe and equivalent to their conventional counterparts, whether used in infant formula, baby food or food for other age groups, the Agency finalized its position in 2015 that mandatory labeling of GE foods as a class is not required. However, if, for example, the Agency were to determine that a new genetic trait was likely to introduce potential allergens, labeling would be required. And, if FDA or any of the other Federal agencies involved in the review of new GE crops or the foods derived from them were to determine that a new trait was unsafe, the product would not be permitted on the market.

I recognize that many supporters of mandatory GE labeling bills like HB 5300 claim that this legislation is about "right to know." While a compelling argument on the surface, "right to know," and HB 5300 specifically, has the potential for significant unintended consequences. First, the proposed labels are fundamentally unnecessary because they do not provide useful information. If scientific data shows that GE foods and the ingredients derived from them are safe and nutritionally equivalent to

conventional foods, then the only thing that these labels do is serve to satisfy consumer curiosity. In my opinion, curiosity is best addressed through voluntary labeling, and I point to certified organic and voluntarily labeled GE-free infant formulas available in Connecticut, as well as organic baby food and baby food that has been certified GE free by third-party programs like the Non-GMO Project. Organic and non-GE foods are also widely available for older children and their parents if they wish to purchase them. Because these products already exist in the marketplace, anyone wishing to avoid GE ingredients is free to do so.

Furthermore, given the misinformation about GE foods, particularly questions about safety that will be raised by proponents of HB 5300 despite overwhelming peer reviewed published scientific evidence from independent researchers opposing their position, these labels will confuse and will clearly alarm parents and caregivers about the products they are feeding infants and young children. Not only does this confusion and alarm lead to unnecessary angst for Connecticut parents and cause them to needlessly question the safety of what they are feeding their infants, it may also lead to the use of inappropriate infant feeding methods that are not recommended by any reputable medical authority and may be extremely dangerous to infant health. An example is homemade infant formula. A quick search of the internet shows that some anti-GE food groups, natural food proponents and parents are promoting homemade infant formula recipes and recommending that caregivers use homemade infant formula to avoid GE ingredients. As a pediatrician, I would never recommend that a family use homemade infant formula.

The bottom line is that the labeling requirement proposed in HB 5300 will confuse and scare parents without any benefit to public health or safety, and may even lead some to use unsafe alternative feeding methods that could put the health of infants at risk. This is a return to the days before the Infant Formula Act was passed by the Congress and similar to the situation that existed in the 19th and early 20th century. Do we really want to return to those days where every infant was at risk for serious illness from being fed an infant formula?

Another point that I touched on above, but want to provide some more information about here are the claims by some that this legislation is intended to help parents avoid pesticides, particularly glyphosate, the active ingredient in Roundup. Roundup is a product widely used for over 30 years for weed control. It has an exceptionally well documented safety record for humans of all ages as well as the environment. Glyphosate is often cited by those opposed to GE foods because some GE crops have been engineered to withstand applications of glyphosate. These individuals often fuel fears and raise safety concerns about GE crops, claiming that they are vectors that expose adults and children to harmful glyphosate. As I suspect some will testify to the dangers of glyphosate and in particular will likely cite the report issued at the March 2015 meeting of the International Agency for Research on Cancer (IARC, of the WHO) that has now classified glyphosate as a class 2A probable human carcinogen, I want to be sure the Committee considers the following information.

- 1. The IARC decision flies in the face of recent evaluations by the German BfR, US EPA, Australia/New Zealand, and even WHO/FAO itself and is based on a limited subset of the available data and on a highly selective view of the epidemiology data**

U.S. Environmental Protection Agency: "EPA has concluded that glyphosate does not pose a cancer risk to humans." *2013 Federal Register Notice (FR 25396, Vol. 78, No. 84, May 1, 2013)*. U.S. Environmental Protection Agency "Several chronic toxicity/carcinogenicity studies...resulted in no effects based on the parameters examined, or resulted in findings that glyphosate was not carcinogenic in the study" and "Glyphosate does not cause mutations." *U.S. EPA. (1993) EPA: Glyphosate. EPA-738-F-93-011. U.S. Environmental Protection Agency, Washington, D.C.*

German Federal Institute for Risk Assessment (BfR) : "In epidemiological studies in humans, there was no evidence of carcinogenicity and there were no effects on fertility, reproduction and development of neurotoxicity that might be attributed to glyphosate." *Glyphosate Renewal Assessment Report, Germany, Rapporteur Member State for the European Renewal of Approval for Glyphosate (2014)*

Australian Pesticides and Veterinary Medicines Authority: "The APVMA currently has no data before it suggesting that glyphosate products registered in Australia and used according to label instructions present any unacceptable risks to human health, the environment and trade. ... The weight and strength of evidence shows that glyphosate is not genotoxic, carcinogenic or neurotoxic." *Australian Government, Australian Pesticides and Veterinary Medicines Authority (2013)*

WHO/FAO- JMPR: The Toxicological Monograph presented to the 2004 Joint FAO / WHO Meeting on Pesticide Residues concluded, "In view of the absence of a carcinogenic potential in animals and the lack of genotoxicity in standard tests, the Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans."

Agricultural Health Study from the US National Cancer Institute: the largest study ever done- the prospective cohort Agricultural Health Study from the US National Cancer Institute found no relationship between glyphosate to any cancer in humans.

2. Glyphosate controls weed growth by interfering with the metabolism of plants; it has no effect on the metabolism of humans and animals and therefore has a very strong safety profile, documented over the past 40 years and confirmed by multiple independent international agencies.
3. Human exposure to glyphosate most often occurs from the very minute amounts that remain on food that is consumed. Because it is among the safest agents used to control weed growth the US Environmental Protection Agency has set an Allowable Daily Intake (ADI) of 1750 micrograms (ug) of glyphosate for every kilogram (kg) of body weight.
4. The current daily intake of glyphosate by individuals in the US is estimated, based on food intake data and assuming all foods carry maximal allowable residues, at about 13% of the ADI (or 230 ug per kg of body weight) from residues in or on foods. This is a maximum-case estimate. Tests for glyphosate in samples of urine suggest the typical dietary intake is well below 1% of the ADI or less than 17.5 ug per kg of body weight.

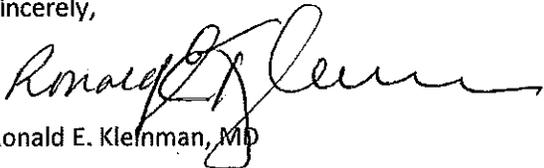
5. Glyphosate that is ingested is mostly passed unchanged in the stool. About one third is absorbed into the body and is promptly removed into the urine.
 - a. Glyphosate does not accumulate in the body or in breast milk based on its chemical properties.
 - b. No harm has been associated with the typical amount of glyphosate that passes into the body and then out in the urine.
6. In a recent report from Moms Across America, the levels of glyphosate detected in 3 of 10 samples of breast milk, detected by an assay that was never intended for breast milk suggest that a breastfeeding infant might be exposed to about 1/50th of the Allowable Daily Intake and do not support any risk, either to the mother or infant. A subsequent study by investigators at the Washington State University using validated assay methods for breast milk, performed in a fully independent laboratory, show that breast milk is in fact free of glyphosate.
7. There is no significant risk to infant health from glyphosate based on current use levels.

If you wish to learn more about glyphosate, I am enclosing with this testimony an article I wrote for the *Genetic Literacy Project* on glyphosate and infant health for your consideration.

In closing, I want to underscore my opposition to HB 5300. This legislation is not based on science and is likely to lead to unintended consequences ranging from parental confusion and concern to potential use of unrecommended and potentially dangerous infant feeding methods. I applaud the Committee for your attention and service to Connecticut's children. We share a commitment to keeping children and their families safe, healthy and happy. Unfortunately, HB 5300 will not advance these goals.

I call on you to take the tough position of rejecting the unfounded claims on which this bill is ultimately based—namely, that GE foods are unsafe and special labeling of infant formula and baby food is needed to help parents and caregivers avoid them. This scientific evidence of safety is clear and options already exist through organic certification and voluntary non-GE claims for parents who wish to avoid GE foods. This legislation will not protect children, but it will have unintended consequences that will needless worry families and could harm children. In the end, forced labeling will only serve to give false credibility to misinformation and discourage people from eating foods that are perfectly safe. My charge to the Committee is to stand up against the scare tactics and vote against HB 5300.

Sincerely,


Ronald E. Klefman, MD

Glyphosate and Breast Milk: A Pediatrician's Viewpoint

A recent on-line article from the anti-GMO group Moms Across America reported that 3 of 10 breast milk samples they sent for analysis had measurable levels of glyphosate, the active ingredient in Roundup, a product widely used for weed control for over 30 years, with a very well documented safety record for humans of all ages as well as the environment. As a result of this finding they suggest that glyphosate accumulates in the body and they raise concerns about the safety of glyphosate and therefore indirectly the safety of breast milk. In the following discussion I address the safety of glyphosate and the conclusions of this particular report from my perspective as a Pediatrician and nutrition scientist.

Summary:

- 1. Glyphosate controls weed growth by interfering with the metabolism of plants; it has no effect on the metabolism of humans and animals and therefore has a very strong safety profile, documented over the past 40 years and confirmed by multiple independent international agencies.**
- 2. Human exposure to glyphosate most often occurs from the very minute amounts that remain on food that is consumed. Because it is among the safest agents used to control weed growth the US Environmental Protection Agency has set an Allowable Daily Intake (ADI) of 1750 micrograms (ug) of glyphosate for every kilogram (kg) of body weight.**
- 3. The current daily intake of glyphosate by individuals in the US is estimated, based on food intake data and assuming all foods carry maximal allowable residues, at about 13% of the ADI (or 230 ug per kg of body weight) from residues in or on foods. This is a maximum-case estimate. Tests for glyphosate in samples of urine suggest the typical dietary intake is well below 1% of the ADI or less than 17.5 ug per kg of body weight.**
- 4. Glyphosate that is ingested is mostly passed unchanged in the stool. About one third is absorbed into the body and is promptly removed into the urine.**
 - a. Glyphosate does not accumulate in the body or in breast milk based on its chemical properties.**
 - b. No harm has been associated with the typical amount of glyphosate that passes into the body and then out in the urine.**
- 5. In the recent report from Moms Across America, the levels of glyphosate detected in 3 of 10 samples of breast milk, if accurate (they still must be confirmed by using an assay validated**

for breast milk), suggest that a breastfeeding infant might be exposed to about 1/50th of the Allowable Daily Intake and do not support any risk, either to the mother or infant .

6. Mothers should be encouraged to breastfeed their infants. Even if the results of the recent study prove to be correct, there is no significant risk to infant health, and the benefits of breastfeeding far outweigh any theoretical risks.

Is glyphosate toxic to humans?

Glyphosate acts on a specific pathway in the metabolism plants. This pathway does not occur in animals (including humans), and thus glyphosate itself has very limited toxicity for humans or animals. While there are many allegations about glyphosate safety to be found on the internet, including allegations about cancer, endocrine disruption, and birth defects, these allegations largely emerge from misinterpretation of limited scientific studies, often times performed under test conditions that have no relevance to human exposure. Glyphosate now has an over-30-year history of safe use and has been the subject of repeated independent regulatory assessments. It should be reassuring that glyphosate is now undergoing re-evaluation in the European Union and that the German Agency for Risk Assessment (Bundesinstitut für Risikobewertung, or BfR) has now issued their draft assessment of glyphosate safety following a thorough review of publications which include many of these allegations. BfR concludes that “the 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.” References regarding glyphosate safety are provided at the end of this discussion.

What does it mean when a chemical is found in body fluids?

The US Centers for Disease Control monitors a variety of chemicals in the blood and urine of Americans (it does not currently measure breast milk). Whether natural or synthetic, every chemical can be toxic at a sufficiently high dose. As the CDC states (see CDC link below): *“The measurement of an environmental chemical in a person’s blood or urine is an indication of exposure; it does not by itself mean that the chemical causes disease or an adverse effect. Research studies, separate from these data, are required to determine which blood or urine levels are safe and which are associated with disease or an adverse effect.”* There is an extensive body of knowledge about glyphosate (see references at end of document) which helps us to understand the meaning of recent reports of glyphosate in breast milk.

How are safe levels of intake for glyphosate determined?

The US EPA looks at all available long term animal studies for herbicides (and other pesticides) to determine an Allowable Daily Intake (ADI). In the case of glyphosate, because there are multiple manufacturers, there are now six independent sets of animal studies. The agency takes the highest dose tested in the various animal species which produces no effect (the highest tested non-toxic dose) and uses this to set an ADI by applying a 100 fold safety factor. This means that the allowable daily intake is set at 100 times LESS than a dose which produces no effect, in the most sensitive animal species tested. The US ADI is 1750 micrograms (ug) of glyphosate for every kilogram (kg = 2.2 pounds) of body weight.

Do these intake limits apply to infants and children?

Yes. The limit is intended to apply to males and females at all ages. The large body of data on this issue includes reproductive and multi-generational studies in animals.

How close to the ADI limit is the typical US intake of glyphosate?

If we assume that all of the foods we consume contains the maximum allowable amount of glyphosate for that particular crop or food, and calculate a maximum estimate of glyphosate intake, the highest level of intake (adjusted for weight) occurs in young children (children eat a lot per pound of body weight to support growth and energy needs). The current maximum intake of glyphosate by individuals in the US is estimated to be about 13% of the ADI, about seven-and-a-half times less than the ADI. This is an over-estimate of exposure. More refined estimates can be developed based on actual residue levels, but this is not usually performed when conservative estimates provide good assurance that excessive intake is not occurring.

Another approach to determining glyphosate intake takes advantage of the fact that glyphosate is not broken down or metabolized in the body. Absorbed glyphosate is promptly eliminated in the urine and thus the absorbed glyphosate dose can be measured directly by looking at glyphosate in urine. Based on animal data, about 1/3 of ingested glyphosate is absorbed (the rest comes out in the stool). Therefore a 15 kg (35 lb) toddler taking in 13% of the ADI would have a urine value of 1000 micrograms per liter or greater (this calculation assumes 1 liter of urine per day, about 3 times the minimal urine output expected). Urine levels of glyphosate have been measured in several studies, including studies supported by industry (Farm Family Exposure Study) and studies by non-governmental independent organizations. Many individuals have no detectable glyphosate in urine at a detection limit of 1

microgram per liter, and if found, levels in non-farmers are typically in the 1-3 microgram per liter range. The available data from Moms Across America indicates the highest level in the urine from the mothers that were tested as 7.5 micrograms per liter (as of April 17, 2014)- so it seems that these individuals have urine values in the range of 1 (or less) to 10 micrograms per liter. This is 100 to 1000 times LESS than you would expect based on current intake estimates. While the estimates of urine value at 13% of ADI are only approximate, these urine data suggest that intakes of glyphosate are far below the ADI.

How can glyphosate get into blood, urine, and breast milk?

For most people on any given day, glyphosate exposure is primarily in the form of food residues following use to control weeds on or around crops. Although we wash fruits and vegetables before cooking or eating them, a small amount of glyphosate may remain as a residue in foods, including seeds and grains (wheat, soybean). The residual glyphosate can be absorbed from the diet, circulate briefly in the blood, and is rapidly eliminated by the kidney like many other waste products- natural or otherwise, without causing any known ill effects. Glyphosate readily dissolves in water (and not in fat) and is a small molecule, so it can enter into breast milk and other body fluids.

Individuals using glyphosate products during planting or farming, or using consumer glyphosate products on the lawn or in the garden can also get exposed during the application process and may have additional exposure to glyphosate via skin or incidental ingestion (touching the face and mouth while using the product). The levels in the blood and urine of these individuals may be higher than seen in the general population with exclusively dietary intake. But, urine samples from adult and teen farmers involved in glyphosate application, (Farm Family Study) indicate that even these users have exposures within the Allowable Daily Intake.

Does glyphosate bio-accumulate in humans?

No. The Moms Across America website suggests that their data support bioaccumulation of glyphosate. Bioaccumulation is a phenomenon in which chemicals that dissolve in fat build up in the body over an extended period of time.

We know from extensive studies that glyphosate is water soluble, not fat soluble, does not accumulate and is not stored in body fat, and is readily excreted in urine. The Moms Across America data indicate the presence of glyphosate in urine samples and in some breast milk samples, but do not demonstrate that glyphosate accumulates in the body over time.

Is glyphosate concentrated in breast milk?

This issue has not been studied in detail for glyphosate in human milk. We do know that glyphosate does not concentrate in cow's milk and that glyphosate does not have the characteristics of substances that accumulate in milk. Materials that concentrate in breast milk (have higher milk concentrations than blood concentrations) are generally fat soluble and accumulate in milk-fat within breast milk.

The Moms Across America data may have demonstrated glyphosate in breast milk (see discussion below), but very importantly there was no comparison of breast milk and blood concentrations of glyphosate in the same individual. Thus, no statement can be made from these data about glyphosate concentrating or accumulating in breast milk.

What else is in breast milk?

There are many natural and synthetic chemicals present in body fluids (blood, urine), and a number of these are measured and followed over time by the US Centers for Disease Control.¹ The CDC has not routinely studied breast milk, but there is no fundamental barrier between blood and breast milk and most of the chemicals found in body fluids will exist in breast milk at some concentration as well. The most focus for breastfeeding moms, for obvious reasons, has been on those chemicals which are persistent, fat soluble and thus tend to concentrate in breast milk or body fat relative to other body tissues and fluids. These substances remain in the body, gradually declining over time if there is no further exposure.²

Are the reported levels in urine and breast milk correct?

The Moms Across America data report breast milk levels using an assay designed for water. However, no data standardizing this assay for breast milk have been published. In the assay used to generate the MAA data, milk is diluted down by 100-fold and measured using the assumption that it is essentially water. Urine levels are obtained using a 10-fold dilution and using the water assay. The accuracy of the test in breast milk remains unclear and, because of the dilution, levels of glyphosate below 75 ug/L cannot be detected by this assay method.

Given what we know about usual urine levels in individuals in the US, which are between 1 and 10 ug/L if detected at all, the reported breast milk values do not make sense. Glyphosate is eliminated in urine and, like most wastes, is concentrated in the urine. Blood levels and breast milk levels should therefore

be less than urine levels on average. As discussed above, glyphosate should not concentrate in breast milk. This means that typical breast milk levels should be close to blood levels and less than urine levels- but this is not what Moms Across America found- three of ten samples had levels above the detection limit of 75 ug/L, with the highest value of 165 ug/l and all three levels were above those levels reported in the mothers' urine samples.

Something seems to be wrong with the data. There are two possibilities. This assay has not been used for breast milk in the past and therefore the analytical method may be in error, either because it is not properly calibrated or because of some interfering factors, as there are many things present in breast milk (chemicals, vitamins, medications, etc.). Another possibility is that the breast milk samples with detectable glyphosate (over 75 ug/L) reflect exposures much larger than the typical exposure to glyphosate in the general population. Without any knowledge of how the samples were obtained and under what circumstances, we cannot speculate on the analytical accuracy. However, the mere fact that the breast milk levels seem highly irregular in comparison to existing urine data should have prompted the laboratory to confirm analytical results using a better, validated method.

Are breast milk levels of glyphosate "high"?

The Moms Across America information suggests that glyphosate levels are "high"- but they define "high" as anything above the limit of detection. Stated another way- anything they can measure is "high". This is faulty reasoning of course- the limit of detection is determined by how samples are processed and what type of analysis is performed and is determined by laboratory procedures, not by safety considerations. Twenty years ago, we would not have been able to detect glyphosate levels in anyone- but laboratory methods have improved tremendously. Continued improvements will result in assays that are capable of detecting even lower levels of glyphosate.

The proper question is whether breast milk levels result in glyphosate intake above the ADI in the nursing infant. Even the highest value reported by Moms Across America results in infant exposure well below the ADI and also does not suggest that the mother is above the ADI.

The Moms Across America document also compares breast milk levels to the European drinking water standard "for glyphosate"- put in quotes because there is no standard for glyphosate in particular. Rather, the EU set a non-risk-based limit of 0.1 ug/L for all herbicides (and pesticides) in drinking water.

Again, this level is independent of any risk assessment concerns and therefore this level is not useful in assessing whether intakes are safe or unsafe.

The World Health Organization (2005) concluded that because of low toxicity, a health based drinking water limit for glyphosate is not warranted and that the presence of glyphosate in drinking-water under usual conditions does not represent a hazard to human health.³

How do the reported levels compare to levels expected at safe levels of intake?

A mother consuming glyphosate in the diet at 100% of the ADI (assuming 50 kg weight and 1/3 of glyphosate absorbed) should be excreting almost 30 milligrams- or 30,000 micrograms of glyphosate in urine per day- about 15,000 ug/L, assuming normal urine output. As noted, most people have no detectable glyphosate in urine. For those with detectable levels in the range of 1-10 ug/L, this is 1500 to 15,000 times LESS than expected from intake at the ADI. Urinary levels suggest maternal intakes well within acceptable limits.

If one assumes that the breast milk values are correct, even the highest value (165 ug/L) would not raise concerns regarding maternal exposure given that breast milk concentrations should be similar to blood concentrations. Even if urine levels are 10-times more concentrated than breast milk or blood, maternal intake is still estimated to be well below the ADI.

What does this mean for the health of an infant?

The highest reported concentration of glyphosate in the 3 breast milk samples (165 ug/L) does not appear to be representative of what may actually be found in breast milk and may be incorrect for analytical reasons. However, even if taken at face value, this would still result in infant intakes well below the ADI. (A 5 Kg or 11 pound infant will take in roughly one liter per day of breast milk, or 165 ug per day. This would be 33 ug per kilogram of body weight per day versus an ADI of 1750 ug per kilogram per day. The intake of glyphosate, even at the highest reported breast milk level, is well below levels which would raise health concerns.

Should mothers stop breastfeeding?

No- based on the low level of exposure relative to the ADI, there is no significant risk to infant health as a result of glyphosate in breast milk. The American Academy of Pediatrics⁴ and the Centers for Disease

Control⁵ agree that breastfeeding is the optimal way of feeding infants and that the benefits of breastfeeding clearly outweigh the risks of environmental chemicals found to date in breast milk, except in highly unusual exposure circumstances.

What can mothers do to minimize exposure? / Should they alter their diet or other practices?

There does not appear to be any need to reduce dietary exposure to glyphosate based on existing data. If you wish to reduce residue intake for glyphosate and other pesticides, choosing to eat an organic diet may help to reduce glyphosate intake and reduce breast milk levels. The health benefits / risk reduction resulting from this would appear to be minimal.

For users of the product containing glyphosate, follow all label directions. While all users in the Farm Family Exposure Study had acceptable levels of exposure, the use of rubber gloves is an effective means to limit exposure to the product (glyphosate is not volatile, so most applicator exposure comes from skin and incidental hand-to mouth contact).

If mothers are breastfeeding, should they have their breast milk tested for glyphosate?

Pending validation of the breast milk assay, and given that current reported levels do not raise a health concern, there is no need to test breast milk.

Should children be tested for glyphosate?

By all exposure estimates, children are well below the ADI for glyphosate intake. Actual urine values are limited- but in the farm family exposure study, urine glyphosate was undetectable in farm children (exception- teenagers who assisted in application), i.e. below 1 ug/L.

Urine testing of children for glyphosate would seem highly unlikely to document any exposure of possible concern and thus is not recommended.

Reviews on the safety of glyphosate:

1. BfR press release (current re-assessment):
[http://www.bfr.bund.de/en/the_bfr_has_finalised_its_draft_report_for_the_re_evaluation_of_glyphosat
e-188632.html](http://www.bfr.bund.de/en/the_bfr_has_finalised_its_draft_report_for_the_re_evaluation_of_glyphosate-188632.html)
2. Most recently completed review by the European Commission (Compounds are reviewed every 10 years and a review is in progress now.)
http://ec.europa.eu/food/plant/protection/evaluation/existactive/list1_glyphosate_en.pdf.

3. Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans" (Williams et al., 2000): <http://dx.doi.org/10.1006/rtph.1999.1371>
4. Epidemiologic studies of glyphosate and cancer: A review.
<http://www.sciencedirect.com/science/article/pii/S0273230012000943>
5. Epidemiologic Studies of Glyphosate and Non-Cancer Health Outcomes: A Review.
<http://www.sciencedirect.com/science/article/pii/S0273230011001516>
6. Developmental and Reproductive Outcomes in Humans and Animals after Glyphosate Exposure: A Critical Analysis. <http://www.tandfonline.com/doi/abs/10.1080/10937404.2012.632361>

References

1. <http://www.cdc.gov/exposurereport/>
2. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1242055/pdf/ehp0109-000075.pdf>.
3. http://www.who.int/water_sanitation_health/dwg/chemicals/glyphosateampa290605.pdf
4. <http://pediatrics.aappublications.org/content/108/3/776.full.html>
5. http://www.cdc.gov/breastfeeding/disease/environmental_toxins.htm

