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July 1, 2013

Registration Division
Office of Pesticides Programs,
E.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington DC 20460-0001

Re: Glyphosate: Pesticide Tolerances. Docket Number: EPA-HQ-OPP-2012-0132

Dear Sir/Madam:

We, and the 21 organizations signatory to this comment, would like to express our concerns about the U.S. Environmental Protection Agency's (EPA) action to increase certain tolerances for residues of glyphosate on multiple food commodities. We are firmly against increasing residues on food due to human and environmental health concerns associated with herbicide glyphosate, and any subsequent increase in the use of the chemical. We do not believe the agency should be supporting an increase in human exposures to this herbicide given the incompleteness of the agency's database on the chemical's ecological effects and subchronic neurotoxic and immunotoxic human health impacts. As a part of glyphosate's current registration review, EPA's work plan identifies "a number of ecological fate and effects studies, an acute and subchronic neurotoxicity study, and an immunotoxicity study" that are required. As a result, a comprehensive ecological risk assessment, including an endangered species assessment, as well as a revised occupational human health risk assessment, are important missing pieces of information that must be considered and subject to public comment, since an EPA tolerance adjustment in this case will allow for an increase in glyphosate use.

While EPA in the tolerance setting process has focused on human health effects from dietary exposure, which we believe is incomplete, the agency as a part of this process must consider that its tolerance decision also drives the allowable use patterns of glyphosate. Therefore, this tolerance decision affects overall environmental health, which EPA is obligated to consider in its rulemaking when adjusting tolerances. Without this analysis of environmental impacts associated with tolerance setting, EPA is not fulfilling its statutory responsibility under the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) to protect against "unreasonable adverse effects on the environment." [7 U.S.C. 136a] Food tolerances should serve as a deterrent to pesticide misuse and abuse. Theoretically, tolerance limits help ensure that pesticide applications do not exceed federal application rates, and that the human population is

not exposed to residues that can adversely impact health. These set limits must be based on human health data and should not be amended without complete information or to simply accommodate special interests.

While major commodities like corn and soybeans are not affected by the tolerance adjustments, increasing tolerances can pave the way for further increases in glyphosate applications given the prevalence of genetically engineered (GE) crops tolerant to glyphosate (Roundup Ready crops), including a new number of stacked GE versions being petitioned, and the simultaneous increase in glyphosate-resistant weed species across the country.

Adjusting tolerances for crops like carrots, sweet potato, and oilseed crops should not be done without adequate review of all the current independent, peer-reviewed science on glyphosate. While EPA suggests that increases in glyphosate exposure and use do not pose unreasonable risks to human and environmental health, recent independent, scientific, peer reviewed data paint a very different picture.

Independent, Peer Reviewed Science Shows Glyphosate Is Hazardous and Exposure and Use Should Be Reduced, Not Increased

EPA claims that glyphosate is of "low toxicity" is a "safer" option for human health and the environment, compared to older generation pesticide technologies. However, recent independent, peer reviewed science is showing this is not the case. A paper by scientists at Massachusetts Institute of Technology (MIT), examining the toxic effects of glyphosate, links the herbicide to a wide range of diseases and suggests that more research is needed.[1] Here the scientists argue that glyphosate's inhibition of cytochrome P450 (CYP) enzymes is an overlooked component of its toxicity to mammals. Glyphosate's interference with CYP enzymes acts synergistically with disruption of the biosynthesis of aromatic amino acids by gut bacteria, as well as impairment in serum sulfate transport. Given that glyphosate residues are found in a wide range of food, the authors suggest glyphosate exposure can contribute to many diseases and conditions associated with a Western diet, including gastrointestinal disorders, obesity, diabetes, heart disease, depression, autism, infertility, cancer and Alzheimer's disease. A 2013 study entitled, "Glyphosate induces human breast cancer cells growth via estrogen receptors," finds that low and environmentally relevant concentrations of glyphosate possess estrogenic activity.[2] In this study, glyphosate exerted proliferative effects in human hormone-dependent breast cancer, T47D cells. Interestingly, the authors of the study found that there was an additive estrogenic effect between glyphosate and genistein, a phytoestrogen in soybeans, which they note warrants further research. Glyphosate, in another study, was observed to promote hematological and hepatic alterations, even at sub-acute exposure.[3]

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[1] Samsel A, Seneff S. Glyphosate's Suppression of Cytochrome P450 Enzymes and Amino Acid Biosynthesis by the Gut Microbiome: Pathways to Modern Diseases. *Entropy*. 2013; 15(4):1416-1463.

2 Thongprakaisang S, Thiantanawat A, et al. 2013. Glyphosate induces human breast cancer cells growth via estrogen receptors. Food Chem Toxicol. pii: S0278-6915(13)00363-3. doi: 10.1016/j.fct.2013.05.057.

3 Jasper R, et al. 2012. Evaluation of biochemical, hematological and oxidative parameters in mice exposed to the herbicide glyphosate-Roundup(®). Interdiscip Toxicol. 5(3):133-40

One study found that people exposed to glyphosate are 2.7 times more likely to contract non-Hodgkin's Lymphoma (NHL)[4]. In 2002, a study of Swedish men showed that glyphosate exposure was *significantly* associated with an increased risk of NHL, and hairy cell leukemia, a rare subtype of NHL.[5] Further, a 2003 review of studies conducted on farmers by researchers at the National Cancer Institute shows that exposure to glyphosate is associated with an increased incidence of NHL.[6] Glyphosate has also been *suggestively* associated with an increased risk of multiple myeloma, according to an Agricultural Health Study published in 2005.[7] Glyphosate has also been associated with ADD/ADHD,[8] increased risks of late abortion,[9] and endocrine disruption.[10]

Additionally, formulated glyphosate products, which include the surfactant polyethoxylated tallowamine (POEA), have been found to be more toxic than glyphosate itself. Glyphosate formulated products kill human cells, particularly embryonic, placental and umbilical cord cells, even at very low concentrations, according to another study.[11] These researchers found that the formulations with POEA cause total cell death within 24 hrs. Other studies have found that the formulated glyphosate products reduces human placental JEG3 cell viability at least two times more efficiently than glyphosate, disrupts aromatase activity and mRNA levels,[12] induce a dose-dependent formation of DNA adducts in the kidneys and liver of mice[13] (a process that can lead to carcinogenesis), and induce developmental retardation of the fetal skeleton, a decrease in sperm number and increase in the percentage of abnormal sperms.[14] A 2011 study observed that crayfish exposed to two different glyphosate and POEA mixtures had lower somatic growth and decreased muscle protein levels, hindering health growth and

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4 Hardell, L., & Eriksson, M. 1999. A Case-Control Study of Non-Hodgkin Lymphoma and Exposure to Pesticides. Cancer, 85(6), 1353–1360.

[5] Hardell L, Eriksson M, & Nordstrom M. 2002. Exposure to pesticides as risk factor for non-Hodgkin's lymphoma and hairy cell leukemia: pooled analysis of two Swedish case-control studies. *Leuk Lymphoma*, 43(5), 1043-1049.

[6] De Roos, et al. 2003. Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men. *Occup Environ Med*, 60(9).

[7] De Roos, A. J. D., Blair, A., Rusiecki, J. A., Hoppin, J. A., Svec, M., Dosemeci, M., Sandler, D. P., & Alavanja, MC .2005. Cancer Incidence among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study. *Environmental Health Perspectives*, 113(1), 49-54.

[8] Garry, V. F., et al. 2002. Birth defects, season of conception, and sex of children born to pesticide applicators living in the Red River Valley of Minnesota, USA. *Environ Health Perspect*, 110(Suppl 3), 441–449.

[9] Arbuckle, T.E., Z. Lin, and L.S. Mery. 2001. An Exploratory Analysis of the Effect of Pesticide Exposure on the Risk of Spontaneous Abortion in an Ontario Farm Population. *Environmental Health Perspectives* 109:851-857.

[10] Walsh, L. P., McCormick, C., Martin, C., & Stocco, D. M. 2000. Roundup Inhibits Steroidogenesis by Disrupting Steroidogenic Acute Regulatory (StAR) Protein Expression. *Environ Health Perspect*, 108, 769–776.

[11] Benachour, N., & Seralini, G.-E. 2008. Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells. *Chemical Research in Toxicology*, 22(1), 97-105.

[12] Richard S, Moslemi S, Sipahutar H, Benachour N, & Seralini GE. 2005. Differential effects of glyphosate and roundup on human placental cells and aromatase. *Environ Health Perspect*, 113(6), 716-720.

[13] Marco, P., Armelle, M., Claudia, B., & Silvio, P. 1998. ^{32}P-postlabeling detection of DNA adducts in mice treated with the herbicide roundup. *Environmental and Molecular Mutagenesis*, 31(1), 55-59.

[14] Dallegrave, E., et al. 2003. The teratogenic potential of the herbicide glyphosate-Roundup® in Wistar rats. *Toxicology Letters*, 142(1-2), 45-52.; Dallegrave, E., et al. (2007). Pre- and postnatal toxicity of the commercial glyphosate formulation in Wistar rats. *Arch Toxicol*, 81(9), 665-673.

development.[15] A 2011 study by Glusczak et al. found that glyphosate changed the toxicological parameters in certain fish.[16] Another found that sublethal residues of glyphosate induced immunological responses in fish and alters their natural immune response to bacterial and possibly to other aquatic microorganism.[17] Chronic exposure has been associated with histopathological damage in the gills and liver, some of which was irreversible.[18] A study by Relyea found that Roundup alone is "extremely lethal" to amphibians in concentrations found in the environment.[19]

Glyphosate and glyphosate-formulated products pose unreasonable human health and environmental risks to the applicators, bystanders and wildlife in the vicinity exposed to the product due to pesticide application. Increasing tolerance limits, which would lead to an increase in glyphosate usage poses many not yet understood risks to human and environmental health, and should not at this time be supported by EPA. EPA should instead, under its registration review, look at the recent available science and conduct its revised assessment before allowing any adjustments in glyphosate's tolerances.

Glyphosate Contamination of Waterways Could Be Exacerbated

More than 180 million pounds of glyphosate are used annually in the U.S. The widespread use of glyphosate, especially on GE crops has contributed to the high rates of glyphosate contamination in agricultural regions. The U.S. Geological Survey (USGS) recently published a report which documents the distribution and trends of pesticide use from 1992-2009.[20] Not surprisingly, glyphosate use is extensive throughout the U.S., especially in the Midwestern states and the Mississippi River valley. In these states, glyphosate is routinely detected in surface and groundwater samples. A USGS survey detected glyphosate in 36% of samples, and aminomethylphosphonic acid or AMPA (a degradation product of glyphosate) in 69% of the samples.[21] EPA acknowledges that glyphosate has the potential to contaminate surface water because it does not readily break down in water or sunlight. Due to glyphosate's potential for water contamination, the agency established a maximum contaminant level (MCL) for

[15] Frontera JL, Vatnick I, Chaulet A, Rodríguez EM. 2011. Effects of Glyphosate and Polyoxyethylenamine on Growth and Energetic Reserves in the Freshwater Crayfish Cherax quadricarinatus (Decapoda, Parastacidae). *Arch Environ Contam Toxicol.* 61(4):590-8

[16] Glusczak L, et al. 2011. Acute Exposure to Glyphosate Herbicide Affects Oxidative Parameters in Piava (Leporinus obtusidens). *Arch Environ Contam Toxicol*.61(4):624-30

[17] Kreutz LC, et al. 2010. Exposure to sublethal concentration of glyphosate or atrazine-based herbicides alters the phagocytic function and increases the susceptibility of silver catfish fingerlings (Rhamdia quelen) to Aeromonas hydrophila challenge. *Fish Shellfish Immunol*.;29(4):694-7.

[18] Ortiz-Ordoñez E, et al. 2011. Effect of Yerbimat Herbicide on Lipid Peroxidation, Catalase Activity, and Histological Damage in Gills and Liver of the Freshwater Fish Goodea Atripinnis. Arch Environ Contam Toxicol;61(3):443-52

[19] Relyea, R. 2005. "The lethal impact of Roundup on aquatic and terrestrial amphibians." *Ecological Applications*, 15(4), 1118–1124

[20] USGS. 2013. National Assessment Shows Geographic Distributions and Trends of Pesticide Use, 1992-2009. Available at http://www.usgs.gov/newsroom/article.asp?ID=3594

[21] Scribner, E. A., Battaglin, W. A., Dietze, J. E., & Thurman, E. M. 2003. Reconnaissance Data for Glyphosate, Other Selected Herbicides, Their Degradation Products, and Antibiotics in 51 Streams in Nine Midwestern States, 2002 *U.S. Geological Survey*, Open-File Report 03–217(101 p).

glyphosate (0.7ppm).[22] The agency lists the short- and long-term health effects for drinking water exposures: for relatively short periods of time, congestion of the lungs and increased breathing rate; for lifetime exposure at levels above the MCL, kidney damage and reproductive effects can occur.

Given the already widespread contamination of U.S. waterways with glyphosate, it is inappropriate for the agency to increase dietary tolerances for this chemical when dietary exposures risks as a result of contaminated water are already elevated and hazardous.

Increasing Glyphosate Tolerances and Use Contributes to the Onset of Glyphosate-Resistant Weeds

Glyphosate is now the world's most widely used herbicide, whose use has doubled over the last decade.[23] With the advent of Roundup Ready crops, glyphosate use has soared, leaving herbicide-resistant weeds that have ballooned in recent years, particularly with the expansion of Roundup Ready crops into soybeans and alfalfa. In general, in regions of the U.S. where Roundup-ready crops dominate, there are now evolved glyphosate-resistant populations of economically-damaging weed species including *Ambrosia artemissifolia* L., *Ambrosia trifida* L., *Amaranthus palmeri* S, *Amaranthus rudis, Amaranthus tuberculatus* (Moq) *Conyza* and *Lolium* spp.[24] One survey of farmers' herbicide use patterns found that glyphosate use continued to increase, with concomitant decreases in utilization of other herbicides, with a high number of farmers making one to three post applications per year.[25] Similarly, stacked versions of glyphosate-tolerant crops have provided farmers the ability to use other herbicides in addition to glyphosate to control resistant weeds.

The proliferation of glyphosate-resistant weeds presents an ever-growing economic concern to farmers, since a widespread distribution of hard-to-control weeds has the potential to cause significant economic losses. Scientists studying the phenomenon agree that it is of economic concern and advise against the dependence on glyphosate, and advise the use of crop rotations and the rotation to non Roundup-ready crops.[26] However industry and EPA chose not to go in this direction. Instead, increasing glyphosate tolerances green-lights increased reliance on glyphosate. It is well-established that herbicide resistance will evolve fastest where herbicide selection intensity is most persistent. Increasing glyphosate use on even minor crops like mustard seed and sweet potato can exacerbate the nation's growing battle against resistant

[22] USEPA. Basic Information about Glyphosate in Drinking Water. Available at http://water.epa.gov/drink/contaminants/basicinformation/glyphosate.cfm

[23] USEPA. 2006-2007 Pesticide Market Estimates: Usage. Available at http://www.epa.gov/opp00001/pestsales/07pestsales/usage2007_2.htm#3_6

[24] Powles, S. B. 2008. Evolved glyphosate-resistant weeds around the world: lessons to be learnt. *Pest Manag Sci*, 64(4), 360-365.

[25] Givens, W. A., Shaw, D. R., Johnson, W. G., Weller, S. C., Young, B. G., Wilson, R. G., Owen, M. D. K., & Jordan, D. 2009. A Grower Survey of Herbicide Use Patterns in Glyphosate-Resistant Cropping Systems. *Weed Technology*, 23(1), 156-161.

[26] Culpepper, A. S. 2006. Glyphosate-Induced Weed Shifts. *Weed Technology*, 20(2), 277–281.

weeds. Without a sound sustainable management plan in place to tackle resistant weeds, any increase in chemical application would only serve to worsen this problem.

Risks Are Unreasonable Given Alternative Methods

Given the recent science that has come out on glyphosate, human and environmental risks cannot be ignored. Increasing tolerance limits would increase the dietary exposure risks from this chemical, which is unacceptable given that commercially viable alternatives are in place for growing food and controlling weeds.

We must remember that while certain pesticides can have a place in farming, sustainable, integrated solutions and systems have been adopted as part of USDA certified organic farming systems that do not allow glyphosate but rather emphasize feeding and maintaining healthy soils and cooperating with nature. EPA has a statutory duty to evaluate glyphosate alternatives under the reasonable risk clause of FIFRA. Rigorous science-based decision-making that requires precaution on the allowance of chemical products in the face of hazards and scientific uncertainty must be adopted at the regulatory level to comply with FIFRA. The Organic Foods Production Act provides the framework for doing this with the independent stakeholder National Organic Standards Board (NOSB) of environmentalists, farmers, consumers and public input providing oversight on allowable synthetic materials in organic and policies that govern organic systems. Keeping in mind the underlying standards of the organic rule, which require that practices "maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances," is the only viable and sustainable path forward that can take us off the toxic tread mill.

EPA's Statutory Duty

In closing, EPA is violating its statutory authority in allowing the increase of glyphosate residues on certain food commodities. Section 408(b)(2)(A)(i) of the *Federal Food Drug and Cosmetics Act* states that EPA can establish a tolerance for a pesticide chemical residue in or on food only if EPA determines that the tolerance is safe. "Safe" is then defined as a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures." Beyond Pesticides believes that the agency has not met this standard. EPA has the statutory burden of "reasonable certainty that no harm," given glyphosate's dietary exposures as well as the multiple exposure pathways that will result from the increase in tolerances. Additionally, the agency has a statutory duty to consider all associated human and environmental impacts that will be caused by this ruling, but have not been evaluated in the notice and subject to public comment. Futhermore, EPA has a duty, which it has not fulfilled, to consider the independent peer reviewed science that raises key issues relating to dietary and aggregate risk factors that have been cited in its notice and subject to public comment. Given that EPA is undergoing the registration review of glyphosate and has called in for outstanding ecological and human health data, we believe that it is improper to modify tolerance limits for glyphosate at this time.

We appreciate the agency's consideration of these comments. An increase in glyphosate tolerances and associated increases in glyphosate use puts the public at additional unreasonable risk.

Respectfully,

Beyond Pesticides
Alaska Community Action on Toxics
Californians for Alternatives to Toxics
Center for Biological Diversity
Center for Environmental Health
Clean and Healthy New York, Inc.
Consumers Union
Empire State Consumer Project
Equal Exchange
Food and Water Watch
Midwest Organic Sustainable Education Service (MOSES)
National Organic Coalition
Northeast Organic Farming Association - Vermont
Northeast Organic Farming Association- Mass
Northeast Organic Farming Association -NH
Northeast Organic Farming Association-NJ
Northeast Organic Dairy Producers Alliance (NODPA)
Northeast Organic Farming Association -- Interstate Council (NOFA-IC
Northwest Center for Alternatives to Pesticides
Organic Seed Alliance
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