PETITION TO MODIFY THE TOLERANCE OF GLYPHOSATE IN OATS TO 0.1ppm AND REQUIRE GLYPHOSATE-CONTAINING PRODUCT LABELS TO EXPLICITLY PROHIBIT THE USE OF GLYPHOSATE AS A PREHARVEST DESICCANT

Amended 28 March 2019

The Environmental Working Group (EWG), joined by Amy's Kitchen, Ben & Jerry's Homemade, Inc., Clif Bar and Company, Earth's Best Organic, GrandyOats, Happy Family Organics, Independent Natural Food Retailers Association, KIND Healthy Snacks, Lundberg Family Farms, MegaFood, MOM's Organic Market, National Co+op Grocers, Nature's Path Foods Inc., One Degree Organic Foods USA, Inc., Organic Valley, Patagonia Provisions, PCC Community Markets and Stonyfield Farm, Inc., petition the U.S. Environmental Protection Agency (EPA) to modify the registered conditions of use for glyphosate by reducing the tolerance level of glyphosate in oats from 30 ppm to 0.1 ppm and to require glyphosate-containing product labels to explicitly prohibit the use of glyphosate as a preharvest desiccant on oats. This petition is filed pursuant to 21 U.S.C. § 346a(d) and concurrently as a Citizen's Petition under 5 U.S.C. §553(e). This document also serves as public comment to the agency to be considered with the registration review of glyphosate pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act. 7 U.S.C. § 136a(g). EWG does not have any financial interest in the modification of the glyphosate residual tolerance level in oat crops.

I. Introduction

The Environmental Working Group (EWG) is a public interest, nonprofit, nonpartisan organization, with offices in Washington, D.C., San Francisco and Sacramento, California, and Minneapolis, Minnesota. EWG's mission is to empower people to live healthier lives in a healthier environment. For more than two decades, EWG has strived to protect human health and the environment through breakthrough research and education, driving consumer choice and civic action. This includes substantial work to support safe, sustainable agriculture.

Glyphosate has been in use in the United States since the 1970s. It is the most widely used pesticide in the world.[1] In the past decade, the use of glyphosate has soared, with more than 250 million pounds sprayed in the U.S. annually according to data from the U.S. Geological Survey.[2] In 1996, the Agency approved the use of genetically engineered crops that could withstand direct application of glyphosate. Glyphosate is also now used for crop management, applied preharvest to a variety of non-genetically engineered crops, including oats outside of the U.S.[3] Presently, the EPA and the U.S. Department of Agriculture do not monitor glyphosate residues on most food crops. Yet, by all indications, Americans' exposures have increased dramatically.

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[1] Charles Benbrook, *Trends in glyphosate herbicide use in the U.S. and Globally,* 28 Envtl. Sciences Eur. 3 *(2016),* https://doi.org/10.1186/s12302-016-0070-0

[2] USGS, PESTICIDE NAT'L SYNTHESIS PROJECT, ESTIMATED ANNUAL AGRIC. PESTICIDE USE, PESTICIDE USE MAPS – GLYPHOSATE (2015), https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2015&map=GLYPHOSATE&hilo=L&disp=Glyphosate

[3] Monsanto, *Preharvest Staging Guide*, http://www.roundup.ca/_uploads/documents/MON-Preharvest%20Staging%20Guide.pdf

Between 2014 and 2016, at least 70 percent of American adults surveyed had detectable traces of glyphosate in their bodies, compared to 12 percent of American adults between 1993 and 1996.[4] The actual current exposure levels may be higher because glyphosate has not been included in nationwide biomonitoring studies, and there are no comprehensive datasets on glyphosate intake for young children and teenagers.

Under FIFRA, pesticides are required to be registered with the EPA. 7 U.S.C. § 136 (a). The agency reviews registration applications submitted by industry to determine tolerance levels and conditions of use. By law, the agency must consider human health and environmental costs in the pesticide approval process.[5] However, the current tolerance level for food residue in oats is less protective than EWG believes necessary to protect children's health based on independent studies on dietary exposure, international findings of cancer risk, and possible reproductive toxicity.

Americans' widespread exposure to glyphosate is of growing concern, particularly in the context of children's health, because of the potential risk of cancer. Yet, EPA deviated from its own established risk assessment guidelines, and took the position that glyphosate is "unlikely to cause cancer."[6] As a result, the high food tolerance levels of glyphosate remain set without an evaluation of carcinogenicity as an endpoint. In contrast, the International Agency for Research on Cancer, an agency of the World Health Organization, determined that glyphosate is a probable human carcinogen.[7] Based in part on the IARC classification, California's Office of Environmental Health Hazard Assessment recently finalized its No Significant Risk Level for Glyphosate, which is roughly 50 to 70 times lower than EPA's proposed Population Adjusted Dose for an adult.[8] California also added glyphosate to its official Proposition 65 list of chemicals known to the state to cause cancer.[9]

There have been at least 14 multiyear studies of glyphosate's ability to cause cancer in laboratory animals, most of which were conducted by the pesticide industry.[10] More than half of the studies the EPA reviewed detected elevated rates of cancer in study animals.[11] EPA's own Science

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[4] Mills PJ et al., *Excretion of the Herbicide Glyphosate in Older Adults Between 1993 and 2016*, 318(16) JAMA 1610-1611 (2017), 10.1001/jama.2017.11726; EWG, *Comments on the EPA's Assessment of Herbicide Glyphosate*, EPA-HQ-OPP-2009-0361(April 30, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-1689

[5] 7 U.S.C. § 136(bb); EPA, LAWS & REGS., SUMMARY OF FOOD QUALITY PROT. ACT, (Last visited Sept. 26, 2018), https://www.epa.gov/laws-regulations/summary-food-quality-protection-act

[6] EPA, Glyphosate Draft Human Health Risk Assessment for Registration Review, Docket EPA-HQ-OPP-2009-0361-0068 (Dec 12, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0068; EPA, Registration Eligibility Decision (RED), Glyphosate (1993), https://www3.epa.gov/pesticides/endanger/litstatus/effects/glyphosate-red.pdf

[7] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

[8] CA, Notice of Proposed Rulemaking: Amendment to Section 25705, Specific Regulatory Levels Posing No Significant Risk: Glyphosate (Mar 28, 2017), https://oehha.ca.gov/proposition-65/crnr/notice-proposed-rulemaking-amendment-section-25705-specific-regulatory-levels

[9] CA, Glyphosate Listed Effective July 7, 2017, as Known to the State of CA to Cause Cancer, CAS No. 1071-83-6 (Jun 26, 2017), https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer#_ftn1

[10] EWG, *Comments on the EPA's Assessment of Herbicide Glyphosate*, EPA-HQ-OPP-2009-0361(April 30, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-1689

[11] *Id.*

Advisory Panel met in 2016 to review the Agency's assessment of the cancer evidence, and split over its assessment of the strength of the evidence.[12]

EWG contends that the EPA Office of Pesticide Programs incorrectly dismissed many study findings that showed statistically significant dose-response trends for glyphosate carcinogenicity. EPA's dismissal of those studies has enabled the continued approval of increasingly high tolerance levels of glyphosate as a residue on common foods. Specifically, the tolerance level for glyphosate in oat grain has been increased from 0.1 ppm in 1993 to current tolerance of 30 ppm.[13] The higher tolerance for oats and certain other grains was first raised to 20 ppm in 1997 and then increased to 30 ppm in 2008 to be consistent with the CODEX maximum residue limit (MRL) recommendations upon petition by Monsanto Inc.[14]

Oat products are widely consumed by children in the United States in cereals, breakfast bars, cookies, and other various foods. In 2018, EWG tested oatmeal or oat-based cereal, granola and snack bar products, and detected glyphosate in all but two of 45 samples of products.[15] In addition, the levels detected were at higher concentrations than glyphosate levels found in other studies for common foods such as wheat and corn.[16] These results suggest that children are likely consuming potentially harmful levels of glyphosate daily, as real dietary exposure is not limited to the oat products sampled. While all levels were within legal tolerance limits established by the Agency, the omission of cancer risk in the EPA's assessment of glyphosate undermines the credibility of current tolerance limits. EWG urges the agency to reduce the current tolerance limit of oats from 30 ppm back to the 1993 level of 0.1 ppm.

II. Legal Framework

The EPA regulates pesticides under the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA), 7 U.S.C §136 et seq. and the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346(a). A pesticide includes "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest," including any "weed," and thus includes chemicals commonly known as herbicides. 7 U.S.C. § 136(t)-(u). FIFRA authorizes EPA to register a pesticide only upon determining that the pesticide "will perform its intended function without unreasonable adverse effects on the environment" as defined to include "(1) the economic, social, and environmental costs and benefits of the use of any pesticide, and (2) a human dietary risk from residues that result from a use of a pesticide in or on any food

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[12] *Id*.; EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[13] 40 C.F.R. § 180.364 (July 1, 2017)

[14] *Id., see also* EPA Rule, Glyphosate; Tolerance Actions, EPA-HQ-OPP-2007-1170 FRL-8379-3 (Sept 10, 2008), https://www.federalregister.gov/documents/2008/09/10/E8-20993/benfluralin-carbaryl-diazinon-dicrotophos-fluometuron-formetanate-hydrochloride-glyphosate; EPA Rule, Glyphosate; Pesticide Tolerances at 6 (April 11, 1997), https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/tred_PC-417300_11-Apr-97.pdf; EPA OPP, Review PP No. 6E04645 Glyphosate in or on Imported Oats (May 8, 1996), https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-285.pdf

[15] Alexis Temkin, EWG, CHILDREN'S HEALTH INITIATIVE, *Breakfast with a dose of Roundup?* (Aug 15, 2018), https://www.ewg.org/childrenshealth/glyphosateincereal/#.W6wWYxNKiRYattached as Exhibit 1

[16] *Id*.

inconsistent with the standard under 21 U.S.C. § 346(a)." 7 U.S.C. § 136(bb); *accord* 40 CFR §152.112(e).

EPA must periodically review the registration to make sure it is still considered safe in light of new science. 7 U.S.C. § 136a(g). EPA must complete its review of each existing pesticide registration by either October 2022 or within fifteen years after the date on which a pesticide containing a new active ingredient is first registered, whichever is later. *Id*. § 136a(g)(1)(A)(iii). Thereafter, EPA is required to conduct subsequent reviews of each pesticide registration every fifteen years. *Id*. § 136a(g)(1)(A)(iv).

The Food Quality Protection Act of 1996 (FQPA) amended both the FFDCA and FIFRA by requiring the EPA to consider health-based and child-protective standards when defining acceptable levels of pesticide residues in food and the environment. 7 U.S.C. 136; accord 21 U.S.C. § 346(b)(2)(C).[17] Tolerances for a pesticide chemical residue in or on a food may only be established or left in effect if that tolerance is "safe." 21 U.S.C. § 346(b)(2)(A). "Safe" means that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures. 21 U.S.C. § 346 (b)(2)(A).

The EPA may establish, modify or revoke a tolerance for a pesticide chemical residue at its own initiative or in response to a petition filed under 21 U.S.C. § 346(d). Any interested party may file such a petition upon showing of reasonable grounds for a modification or revocation of a pesticide tolerance when the party has a substantial interest in the action sought. 40 C.F.R. §180.32.

In addition, the Administrative Procedure Act provides that "each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C § 553(e).

The Environmental Working Group, and co-petitioners, file this petition concurrently as both

(1) a tolerance modification petition under 21 U.S.C. § 346(d) requesting that the EPA reduce the established tolerance of glyphosate in oat grain from 30ppm to 0.1ppm, and
(2) a citizen petition pursuant to 40 C.F.R. § 180.32 requesting a label clarification on glyphosate-containing products that explicitly prohibits preharvest application to oats as a desiccant in the United States.

Petitioners request a fee waiver pursuant to 40 C.F.R § 180.33(l) due to the substantial public interest in the reduction of dietary exposure to glyphosate from oats.

III. Glyphosate Production, Use, and Residue Monitoring

Glyphosate has the highest production volume of all herbicides in the U.S. and is currently used worldwide in agriculture, forestry, urban, and home applications.[18] Glyphosate was first synthesized and tested as an herbicide in 1970 and EPA registered the first products for use in

[17] 7 U.S.C. §136; *see* EPA, LAWS & REGS., SUMMARY OF FOOD QUALITY PROT. ACT, (Last visited Sept. 26, 2018), https://www.epa.gov/laws-regulations/summary-food-quality-protection-act
[18] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

the United States in 1974.[19] Labeled uses of glyphosate include over 100 terrestrial food crops as well as other non-agricultural sites.[20] Globally, glyphosate use has risen almost 15-fold since genetically engineered glyphosate-tolerant crops were introduced in 1996.[21]

There are approximately 800 EPA registered pesticide products containing glyphosate, however not all may be for sale or use at any one time.[22] Glyphosate was registered in over 130 countries as of 2010 and is likely the most commonly used herbicide in the world.[23] Since 1974 in the U.S., over 3.5 billion pounds of glyphosate active ingredient have been applied to crop and non-crop land, or 19 percent of the estimated global use of glyphosate.[24] Two-thirds of the total volume of glyphosate applied in the U.S. from 1974 to 2014 has been sprayed in just the last 10 years.[25]

Widespread adoption of no-till and conservation-till practices and the introduction of transgenic crop varieties engineered to be resistant to glyphosate have transformed glyphosate to a post-emergent, selective herbicide for use on some annual crops.[26] When applied at lower rates, glyphosate is a plant-growth regulator and desiccant.[27] While alternative drying methods exist, glyphosate offers a cheap and rapid option and has been widely adopted for oat crop management in recent years.[28] Although preharvest and desiccant applications of glyphosate are minor uses, the timing of these applications results in higher residuals on food crops. Preharvest and desiccant use are not approved for oat crops in the United States, however these applications are registered on label uses in other nations, including Canada a large supplier of oats to the U.S.

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[19] SZÉKÁCS & DARVAS, *Forty Years with Glyphosate*, in HERBICIDES – PROPERTIES, SYNTHESIS, AND CONTROL OF WEEDS (2012), 10.5772/32491

[20] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf; *see generally* USDA PESTICIDE DATA PROGRAM https://www.ams.usda.gov/datasets/pdp.

[21] *Id.;* Charles Benbrook, *Trends in glyphosate herbicide use in the U.S. and Globally,* 28 Envtl. Sciences Eur. 3 *(2016),* https://doi.org/10.1186/s12302-016-0070-0

[22] See generally EPA, PESTICIDE PRODUCT AND LABEL SYSTEM (PPLS), Glyphosate (Last visited Sept 27, 2018), https://iaspub.epa.gov/apex/pesticides/f?p=113:1:::NO:RP,1::; *see also* USGS PESTICIDE NAT'L SYNTHESIS PROJECT, Estimated Annual Agric. Pesticide Use Glyphosate (2018), https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2016&map=GLYPHOSATE&hilo=L&disp=Glyphosate

[23] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf; DILL ET AL., *Glyphosate: Discovery, Development, Applications, and Properties*, in GLYPHOSATE RESISTANCE IN CROPS AND WEEDS: HISTORY, DEV., AND MGMT. (July 21 2010), https://doi.org/10.1002/9780470634394.ch1

[24] Charles Benbrook, *Trends in glyphosate herbicide use in the U.S. and Globally,* 28 Envtl. Sciences Eur. 3 *(2016),* https://doi.org/10.1186/s12302-016-0070-0

[25] *Id*.

[26] Duke & Powles, *Glyphosate Resistant Crops and Weeds, Now and in the Future,* 12 Agro Bio Forum, 346- 357 (2009); DILL ET AL., *Glyphosate: Discovery, Development, Applications, and Properties*, in GLYPHOSATE RESISTANCE IN CROPS AND WEEDS: HISTORY, DEV., AND MGMT. (July 21 2010), https://doi.org/10.1002/9780470634394.ch1

[27] GLYPHOSATE FACTS, *Clarification of Pre-harvest uses of glyphosate*, Transparency on safety aspects and use of glyphosate-containing herbicides in Eur. (Last visited Sept 25, 2018), https://www.glyphosate.eu/system/files/sidebox-files/clarification_of_pre-harvest_uses_of_glyphsate_en_0.pdf

[28] Charles Benbrook, *Trends in glyphosate herbicide use in the U.S. and Globally,* 28 Envtl. Sciences Eur. 3 *(2016),* https://doi.org/10.1186/s12302-016-0070-0

market.[29] The existing tolerance level for glyphosate in oats was set to achieve international harmonization to reduce barriers for agricultural imports.[30]

FDA has begun testing glyphosate in a limited number of foods, however, results have yet to be published.[31] In a 2016 presentation at the North American Chemical Residue Workshop, an FDA scientist showed data indicating the presence of glyphosate in several oat-based food products, but the full results have not been made public.[32]

In recent years, European and Canadian authorities have sampled glyphosate residues in foods. Canadian assessments did not test oats but detected glyphosate in over 30 percent of tested infant food and infant cereal.[33] In 2015, 9.1 percent of oat-based cereals surveyed in Europe had detectable levels of glyphosate, however, only 22 samples were analyzed.[34] In 2016, the non-profit Food Democracy Now tested single samples of a variety of popular American food items. Most notably, the highest levels of glyphosate were detected in Cheerios, but over 30 percent of samples had only "estimated" values due to uncertainties with the analytical method used in the study.[35]

EWG's independent lab results found that oat products have more concentrated levels of glyphosate compared to other common grains including wheat and corn.[36] While the detected glyphosate levels in oat products were all within federal legal limits, EWG asserts that these levels are inappropriately high based on EPA's omission of critical health data when setting tolerance limits.

Of the 45 product samples purchased and tested by EWG, 31 had glyphosate concentrations of 0.160 ppm and greater. The highest levels of glyphosate, greater than 1.0 ppm, were detected in two samples of Quaker Old Fashioned Oats. Only two product samples had no detectable glyphosate and 12 out of 45 product samples contained lower levels of glyphosate, from 0.01 to 0.120 ppm. Glyphosate was also detected, at concentrations of 0.010 to 0.030 ppm in five of 16

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[29] USDA, World Markets and Trade at 33 (Sept 2018), https://apps.fas.usda.gov/psdonline/circulars/grain.pdf; *see also* Monsanto Inc., *Preharvest Staging Guide*, http://www.roundup.ca/_uploads/documents/MON-Preharvest%20Staging%20Guide.pdf; Monsanto Inc. Roundup WeatherMax with Transorb 2 Technology Registration NO. 27487 (Feb 20 2018) http://www.roundup.ca/_uploads/documents/27487_WeatherMax_Approved%20All%20Uses_ENG_Re-eval_20Feb2018.pdf

[30] Roni A. Neff et al., *A comparative study of allowable pesticide residue levels on produce in the U.S.*, 8 Global Health 2 (2012), 10.1186/1744-8603-8-2

[31] GAO, Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations, GAO-15-38 (Oct 7, 2014), https://www.gao.gov/products/GAO-15-38

[32] Narong Chamkasem, FDA, Method Dev. Validation of the direct determination of glyphosate, glufosinate, and AMPA in Food by LC/MS (2016), https://www.nacrw.org/2016/presentations/O-27.pdf

[33] European Food Safety Authority (EFSA), The 2015 European Union report on pesticide residues in food, (April 7, 2017) doi:10.2903/j.efsa.2017.4791; Canada Food Inspection Agency (CFIA) Science Branch Survey Report, Safegaurding with Science: Glyphosate Testing in 2015-2016, http://www.inspection.gc.ca/food/chemical-residues-microbiology/food-safety-testing-bulletins/2017-04-13/executive-summary/glyphosate-testing/eng/1491846907641/1491846907985

[34] John Peterson Meyers et al., *Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement*, 15 Envtl. Health 19 (2016), 10.1186/s12940-016-0117-0

[35] FOOD DEMOCRACY NOW! *Glyphosate: Unsafe on any plate* (2016), https://usrtk.org/wp-content/uploads/2016/11/FDN_Glyphosate_FoodTesting_Report_p2016-3.pdf

[36] *Id*., *see also* Alexis Temkin, EWG, CHILDREN'S HEALTH INITIATIVE, *Breakfast with a dose of Roundup?* (Aug 15, 2018), https://www.ewg.org/childrenshealth/glyphosateincereal/#.W6wWYxNKiRY

organic product samples tested. These five samples came from two brands of organic rolled oats, Bob's Red Mill and Nature's Path. A third brand of organic rolled oats and all other organic oat products tested did not contain detectable concentrations of glyphosate. Glyphosate contamination of organic brand products could potentially come from glyphosate drift from conventional oats grown next to organically grown oats, or cross-contamination during food production.[37] This finding underscores the need for more data on actual dietary exposure to glyphosate. Without an accurate account of exposure the risk assessment by EPA cannot adequately consider lifetime exposure risk nor make a definitive finding that there is a reasonable certainty of no harm under the current tolerance level of 30 ppm. Full results are provided in the following table:

Type of Food	Product Name	Glyphosate (ppm)		
		Sample 1	Sample 2	Sample 3
Granola	Nature's Path Organic Honey Almond Granola	ND	ND	
	Back to Nature Granola Clusters - classic	.620	.170	
	Quaker Simply Granola Oats, Honey, Raisins & Almonds	.430	.400	
	Back to Nature Granola Clusters - Banana and Walnut	.030	.030	.340
	Nature Valley Granola Protein Oats 'n Honey	.220	.170	
	Kind Granola, Vanilla, Blueberry Clusters	.050	.060	
Instant Oats	Simple Truth Organic Instant Oatmeal	ND	ND	
	Quaker Instant Oats, Dinosaur Egg	.620	.780	
	Great Value Instant Oats	.450	.760	
	Umpqua Oats - Maple Pecan	.220	.220	
	Target Market Pantry Instant Oat - Strawberries + Cream	.120	.520	
Oat Breakfast Cereal	Kashi Organic Heart to Heart oat cereal	ND	ND	
	Cheerios	.490	.470	.530
	Lucky Charms**	.400	.230	
	Barbara's Multigrain Spoonfuls	.340	.300	
	Crackling Oat Bran	.250	.120	
Snack Bar	Cascadian Farm Organic Harvest Berry Granola Bar	ND	ND	
	KIND Oats & Honey Granola Bar	ND	.120	
	Nature Valley Crunchy Granola Bars Oats 'n Honey	.340	.420	
	Quaker Chewy Chocolate Chip Granola Bar	.120	.160	
	Nutrigrain Strawberry Cereal Bars	.030	.080	
Whole Oats	365 Organic Rolled Oats	ND	ND	
	Quaker Steel Cut Oats	.530	.290	
	Old Fashioned Oats	.390	1.10	1.30
	Bob's Red Mill (non-organic) Steel Cut Oats	.300	ND	
	Nature's Path Organic Rolled Oats	.030	.020	
	Bulk Bin (non-organic) Rolled Oats	.010	.040	
	Bob's Red Mill Organic Rolled Oats (4 samples tested)	ND	.010	.020, .020*

[37] Sarah West, NATURE'S PATH, ORGANIC NEWS & ENVT., *Are you eating glyphosate? How organic farming can help* (Jan 23, 2018), https://www.naturespath.com/en-us/blog/are-you-eating-glyphosate-organic-farming-can-help/

Source: EWG, from tests by Eurofin Analytical Laboratories

ND = none detected

**Two product samples tested both had 20 ppb glyphosate concentration.*

***Lucky Charms Frosted Toasted Oat Cereal with Marshmallows. Marshmallows were manually removed from the samples prior to shipping to the lab and testing for glyphosate.*

IV. Glyphosate is a Possible Carcinogen

Concerns have been raised about glyphosate's potential to cause cancer, particularly non-Hodgkin's lymphoma and other blood cancers.[38] Glyphosate exposure has also been associated with harm to the developing fetus, the reproductive system, liver, and kidney.[39] In 2015, the International Agency for Research on Cancer, a subdivision of the World Health Organization, reviewed existing data on glyphosate toxicity from epidemiological studies in people and research on laboratory animals and classified the chemical as "probably carcinogenic to humans" under Group 2A.[40] The Group 2A category is used when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals.[41] Limited evidence means that a positive association has been observed between exposure to the agent and cancer but that other explanations for the observations (called chance, bias, or confounding) could not be ruled out.[42] This evaluation considered the significant findings from the original 1984 U.S. EPA report [43] and several more recent positive results in concluding that there is sufficient evidence of carcinogenicity in experimental animals.[44]

Since then, additional reviews have contradicted the classification. In November 2015, the European Food Safety Authority (EFSA) concluded that glyphosate was unlikely to pose a carcinogenic hazard to humans. In May 2016, the Joint Food and Agriculture Organization (FAO) / WHO Meeting on Pesticide Residues (JMPR), another subdivision of the WHO, concluded that glyphosate was unlikely to pose a carcinogenic risk to humans from exposure through the diet. The EPA also reviewed the literature and found glyphosate to be "not likely to be carcinogenic to humans at doses relevant to human health risk assessment." After comments from the FIFRA Scientific Advisory Panel (SAP), they revised their determination to "not likely to be carcinogenic to humans," dropping the modifier.[45]

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[38] John Peterson Meyers et al., *Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement*, 15 Envtl. Health 19 (2016), 10.1186/s12940-016-0117-0

[39] *Id*.

[40] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

[41] *Id*.

[42] *Id*.

[43] EPA, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Sept 12, 2016), https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf US EPA originally classified glyphosate as possibly carcinogenic to humans (Group C) in 1985. After a re-evaluation of that mouse study, the US EPA changed its classification to evidence of non-carcinogenicity in humans (Group E) in 1991. The US EPA Scientific Advisory Panel noted that the re-evaluated glyphosate results were still significant using two statistical tests recommended in the IARC Preamble.

[44] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

[45] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, EPA-HQ-OPP-2009-0361-0073 at 144 (Dec 12, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073

The EPA's Office of Research and Development epidemiologists agree with IARC that there is "limited evidence" of carcinogenicity in humans and understand IARC's definition of "limited evidence" as "a positive association has been observed" for which a causal association is "[c]redible, but chance, bias, or confounding could not be ruled out with reasonable confidence [IARC Preamble, section B6]." [46] Critically however, OPP decided to dichotomize the epidemiological evidence to be either "causal" or "not causal," resulting in different positions between EPA OPP and IARC. Generally, the data analysis and causal determinations in use for risk assessments include gradations of causality, however the OPP risk assessment did not follow this approach. Rather, it utilized a yes/no approach that does not provide for the possibility of carcinogenicity, despite the limited yet present data suggesting a possible causality. [47]

However, the EPA identified significant data gaps and internal disagreement on the implications of the science. In particular the SAP found that EPA did not adhere to the EPA Guidelines for Carcinogen Risk Assessment.[48] Some panel members found the weight of evidence, based on EPA's 2005 Guidelines, suggests potential carcinogenic effects. In their view, epidemiologic and rodent studies contain findings that together (coherence and consistency) suggest a potential for glyphosate to affect cancer incidence."[49]

These panel members felt that EPA's discussion of the epidemiological evidence appeared to discount statistical findings and overemphasize non-statistical criteria, and concluded that there is limited but suggestive evidence of a positive association between glyphosate exposure and risk of cancer, emphasizing the value and importance of the findings reported from several dose-response analyses and meta-analyses. [50] They recommended the Agency revise its conclusion along the lines of:

> "Based on the weight-of-evidence from epidemiological studies and meta-analyses, the Agency cannot exclude the possibility that observed positive associations between glyphosate exposure and risk of NHL suggest human carcinogenic potential of glyphosate, even though study limitations and concerns about potential biases remain."[51]

In addition, the panel identified critical data gaps due to limited epidemiological studies and no studies on glyphosate for highly exposed populations including children and manufacturers.[52]

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[46] EPA, Summary of ORD comments on OPP's glyphosate cancer assessment (Dec 14, 2015), https://usrtk.org/wp-content/uploads/2017/03/ORDcommentsonOPPglyphosate.pdf

[47] *Id*.

[48] *see generally* EPA, Guidelines for Carcinogen Risk Assessment (March 2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf; *compare* EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[49] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate at 88 (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[50] *Id*. at 16

[51] *Id*. EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate at 16-17 (Mar 16, 2017)

[52] *Id.* at 15, 29 "Even the estimated highest exposures experienced by glyphosate mixers and loaders of 0.03-7 mg/kg/day overlap with those potentially experienced by children. Thus applicators' occupational exposures may

The panel also identified remaining areas of uncertainty related to the potential for glyphosate-induced inflammation and genotoxic effects secondary to toxicity caused by high dose exposures (i.e., glyphosate-induced inflammation, oxidative stress, 8-OH-dG, and sister chromatid exchanges or 20 SCE) and whether the glyphosate-containing formulations have genotoxic potential.[53] Considered together, these data gaps undermine EPA's conclusion that glyphosate poses a reasonable certainty of no harm.

There have been many studies attempting to characterize the carcinogenic potential of glyphosate, using both human epidemiological data and experimental animal models. However, issues concerning the reproducibility of the results, the utilization of different animal strains, the difficulties comparing research published decades ago with recent work, the association of farming with increased incidence of some cancers, recall biases and co-exposure with other pesticides, and the latency of disease onset contribute to the difficulty of analyzing the (both positive and negative) findings.

a. Human studies demonstrate likely link between glyphosate exposure and non-Hodgkin lymphoma

Review of human epidemiological studies suggests an association between glyphosate and non-Hodgkin lymphoma (NHL). Although individual studies may not be statistically significant, when the data are merged, the relationship becomes evident.

Meta-analysis is used to combine results from different studies, to increase the power of the analysis. Specifically, for NHL and occupational exposure to glyphosate, IARC cites a 2014 study which combined six human epidemiological studies to find a meta risk-ratio of 1.5 (95% CI, 1.1–2.0). IARC added two additional epidemiological studies to the analysis and found a meta risk-ratio of 1.3 (95% CI, 1.03–1.65).[54] IARC also noted that case-control studies in three countries reported an increased risk of NHL resulting from glyphosate exposure.[55] These data lead IARC to conclude that there is "limited evidence in humans for the carcinogenicity of glyphosate."[56]

EPA's Science Advisory Panel (SAP) noted a third, more recent meta-analysis examining the relationship between glyphosate and NHL. The third meta-analysis created four different models that varied which studies were included in the analysis and the statistical method used. The lower bound for the 95 percent confidence interval for all four meta risk-ratios was 1.00 or greater, suggesting a positive association between NHL and glyphosate.[57] Because of this, some panelists noted that "since all the studies evaluated for NHL were of acceptable quality and three meta-analyses included by EPA show similar positive meta-RRs with uncertainties suggesting the risk estimates are above 1.0, the evidence from human data is suggestive of the carcinogenic potential

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not distinguish them from the general population with regard to absorbed doses of glyphosate, and it is not clear then that epidemiologic studies of such users are of much probative value."

[53] *Id*. at 18

[54] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017) at 30, https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

[55] *Id*. at 75.

[56] *Id*. at 78.

[57] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate at 42-45 (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

of glyphosate. All potential biases described . . . [were] plausible, but not sufficient . . . to disregard the meta-analyses findings."[58]

EPA performed its own meta-analysis and calculated a meta-effect estimate of 1.27 (95 percent CI, 1.01–1.59).[59] However, EPA immediately discounts this finding and the other meta-analyses because "Any of the meta-analysis estimates that were statistically significant were all borderline with the lower limit of the 95% CI just slightly over 1."[60] EPA advises that the number of studies in the meta-analysis is low and suggests that there could be bias and confounding variables influencing the results.[61] The Agency concludes that "Based on the weight-of-evidence, the agency cannot exclude chance and/or bias as an explanation for observed associations in the database. Due to study limitations and contradictory results across studies of at least equal quality, a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data."[62]At the earlier SAP meeting, some panelists, knowing the EPA was inclined to make this statement, expressed concern that "EPA's overall discussion appeared to focus on weaknesses and limitations of epidemiology in general as well as in each of the specific studies. It appeared to some Panel members that the Agency did not provide any alternative perspective that the evidence could be suggestive of an underlying effect of glyphosate on NHL."[63] It was proffered that the descriptor "Suggestive Evidence of Carcinogenic Potential" would be a better fit with the meta-analyses results.[64]

In 2017, a new analysis of the AHS cohort demonstrated an increased risk of acute myeloid leukemia in the most highly exposed pesticide applicators (relative to those who did not use glyphosate) that did not reach statistical significance ($P_{trend}T_{rend} = .11$).[65] The EPA included these results in its Final Issue Paper by stating, "This study reported no association between glyphosate exposure and all lymphohematopoietic cancers, NHL, or any of its subtypes across exposure metrics," which may be an overstatement based on the suggestive trend finding.[66]

b. Despite discrepancies, animal models, when viewed in toto, suggest glyphosate is a rodent carcinogen

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[58] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate at 45 (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[59] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017) (DP Barcode: D444689), at 64, https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487; EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate, at 43 (Mar 16, 2017) , https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[60] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 64 (Dec. 12, 2017) (DP Barcode: D444689), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487

[61] *Id*. at 64-68.

[62] *Id*. at 68; EPA, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 68 (Sept. 12, 2016), https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf

[63] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate, at 46 (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

[64] *Id.* at 48.

[65] Andreotti G, Koutros S, Hofmann JN, et al., Glyphosate Use and Cancer Incidence in the Agricultural Health Study, 110(5) J Nat'l Cancer Inst. 509-516 (2018).

[66] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 67 (Dec. 12, 2017) (DP Barcode: D444689), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487

After reviewing studies of rat and mouse models exposed to different doses of glyphosate, IARC concluded that "there is sufficient evidence in experimental animals for the carcinogenicity of glyphosate."[67] The EPA, in its analysis of the data, evaluated 14 animal studies. Of six mouse studies, three revealed a glyphosate-related trend in tumor incidence in "hemangiosarcomas, malignant lymphomas, or hemangiomas following adjustment for multiple comparisons."[68] Of eight rat studies, four demonstrated "a statistically significant trend . . . for tumor incidences in the testes, liver, or mammary gland following adjustment for multiple comparisons."[69] However, the agency immediately discounted these findings if the pairwise comparisons also were not significant, if there was not a monotonic dose response, if there was no evidence of tumor progression or pre-neoplastic lesions, or if the incidence of tumors was within historical controls.[70] EPA noted that the positive results were not reproducible.[71] The agency concluded that "based on the weight-of-evidence evaluations . . . none of the tumors evaluated in individual rat and mouse carcinogenicity studies are treatment-related . . ."[72]

During the earlier SAP meeting, some panelists agreed with the EPA's proposed conclusion (which mirrored its final conclusion closely), although others believed that the agency was giving disproportionate significance to certain factors such as the historical tumor rates.[73] Some panelists also did not agree with the EPA's downplaying of significant trends that were not monotonic, and thought that this was a violation of the 2005 Guidelines for Carcinogen Risk Assessment.[74] Other criticisms were that the EPA discounted doses above the limit dosage and did not explain why it chose to use historical controls in some comparisons.[75] The requirement for pairwise significance in addition to trend significance was also incongruent with the 2005 Guidelines.[76]

Some SAP panelists argued that the question was whether, individually, there is evidence of carcinogenic potential in any endpoint in a species or gender, not whether there is consistency between genders or among species and endpoints.[77] These panelists referred to comments submitted by Dr. Christopher Portier suggesting a pooled analysis and demonstrating that such an analysis revealed carcinogenic potential for some endpoints (see below for greater discussion

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[67] IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans, at 78 (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf
[68] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 90 (Dec. 12, 2017) (DP Barcode: D444689) https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487
[69] *Id*. at 82.
[70] *Id*. at 82, 90; EPA, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 82, 90-91, (Sept. 12, 2016) https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf
[71] *Id*. at 97.
[72] *Id.* at 97.
[73] EPA, Meeting Minutes and Final Report of Dec 13-16, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate, at 18 (Mar 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf
[74] *Id.* at 18, 50.
[75] *Id*. at 50.
[76] *Id*. at 53.
[77] *Id.* at 56.

of Dr. Portier's analysis of the animal carcinogenicity data).[78] Based on the "totality of tumor data," some panelists believed there was evidence that glyphosate is a rodent carcinogen.[79]

c. Open letter from former director of NCEH/ATSDR suggests analyses of glyphosate animal studies were flawed, and that the incidence of tumors is higher than reported

The data behind the analyses by the European Food Safety Authority (EFSA) and European Chemicals Agency (EChA) of the carcinogenic potential of glyphosate were made available to the public. This allowed Dr. Portier to examine the data more carefully, and, upon doing so, he found additional instances of tumor formation which had been missed by the earlier analyses.[80] He calls for the agencies to comprehensively re-evaluate their data in light of his findings to identify all the tumor sites.[81] Accordingly, the new results should be incorporated into their conclusions about glyphosate.

Portier notes that some of the results, although positive, were categorized by EFSA and EChA as unrelated to glyphosate exposure. He points out that some of the proffered reasons for excluding positive data in animal studies are not scientifically appropriate. Investigators should not have concluded that studies' results were inconsistent with each other because they should not have been comparing studies which used different strains of animal models. Reviewers also should not have compared the results of studies that were of different durations, because the rate of spontaneous tumor formation in older rodents is much higher than in middle-aged rodents.[82] Moreover, the use of historical controls in place of concurrent controls to show that tumor incidence did not vary between groups also undermines the validity of the analysis—the outcome of a study is more robust when the animals are closely related genetically, eat the same food, and live in the same type of housing.[83] Reviewers also rejected positive findings if there was a sex difference in the rate of tumor formation, but Portier asserts this is not a valid analytical technique, and notes that there are known human carcinogens which have demonstrated discrepancies based on sex in tumor incidence in animal models.[84] Finally, he counters the

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[78] *Id*. at 59.
[79] *Id.* at 77; Christopher Portier, PhD, Glyphosate Cancer Risks and Failures of the Pesticide Regulatory Process: Presentation to European Parliament, slides 13-15 (Oct. 11, 2017), https://www.nrdc.org/sites/default/files/glyphosate-cancer-risks-and-failures-of-the-pesticide-regulatory-process_christopher-portier_2017-10-11.pdf; Christopher Portier, PhD, Slide Narrative (Oct. 11, 2017), at 3, https://www.nrdc.org/sites/default/files/slide-narrative_christopher-portier_2017-10-11.pdf
[80] Dr. Portier states: "In the last two years, I have systematically gone through these data to identify any statistically significant findings that might have been missed in the other evaluations. I found three additional tumors [in mice studies] that had not been discussed in any of the previous evaluations . . . . [For rats,] there are 7 tumors not discussed in any of the evaluations . . . ." Christopher Portier, PhD, Slide Narrative (Oct. 11, 2017), at 3, https://www.nrdc.org/sites/default/files/slide-narrative_christopher-portier_2017-10-11.pdf; Christopher Portier, PhD, Glyphosate Cancer Risks and Failures of the Pesticide Regulatory Process: Presentation to European Parliament, slides 13-15 (Oct. 11, 2017), https://www.nrdc.org/sites/default/files/glyphosate-cancer-risks-and-failures-of-the-pesticide-regulatory-process_christopher-portier_2017-10-11.pdf
[81] Letter from Christopher Portier, PhD, to Jean Claude Juncker, President, European Comm'n (May 28, 2017), at 5, https://www.nrdc.org/sites/default/files/open-letter-from-dr-christopher-portier.pdf
[82] Christopher Portier, PhD, Glyphosate Cancer Risks and Failures of the Pesticide Regulatory Process: Presentation to European Parliament, slide 21 (Oct. 11, 2017),; https://www.nrdc.org/sites/default/files/glyphosate-cancer-risks-and-failures-of-the-pesticide-regulatory-process_christopher-portier_2017-10-11.pdf; Christopher Portier, PhD, Slide Narrative (Oct. 11, 2017), at 5-6, https://www.nrdc.org/sites/default/files/slide-narrative_christopher-portier_2017-10-11.pdf
[83] *Id.* slide 19; slide narrative at 4-5, 5-6.
[84] *Id.* slide 20.

argument that the animals in the highest dose exposure groups were suffering from general toxicity; thus, the effects observed at these exposure levels were likely due to glyphosate and should have been incorporated into EFSA's and EChA's assessments.[85]

d. Division within the EPA OPP's conclusion regarding carcinogenic potential of glyphosate

The EPA's Office of Research and Development (ORD) conducted an expedited review of OPP's conclusion that glyphosate was "not likely to be carcinogenic to humans." ORD points out that OPP seems to evaluate data in a binary (yes/no) manner: Epidemiological studies are categorized as either demonstrating carcinogenicity or not, ignoring the "gradations of causality" embodied in modern risk assessment approaches and the EPA Cancer Guidelines themselves.[86] IARC, in its review of glyphosate, and ORD utilize descriptors that may signify a plausible positive association between human cancer and glyphosate, without completely ruling out chance. OPP's failure to follow its own agency guidelines when evaluating the human epidemiological studies cast doubt on its conclusion that glyphosate is "not likely to be carcinogenic."

Another criticism that ORD made of OPP's evaluation is that OPP only used pairwise comparisons, while IARC used trend tests. The EPA Cancer Guidelines allow both tests to be used when evaluating the incidence of tumors, and state that a positive result using one test and a null effect in the other is still enough evidence to conclude that the relationship between exposure and tumors is not by chance. Under these circumstances, OPP should have been more circumspect about rejecting IARC's trend analyses and subsequent conclusions and concluding that glyphosate is "not likely to be carcinogenic."

Finally, ORD points out that OPP did not perform "an integrated analysis of the data" and instead reviewed each study individually. ORD also notes that the mutagenic potential of glyphosate was not thoroughly analyzed. Again, given that one office within EPA is pointing out the incompleteness of the analysis of another EPA office concerning their conclusions regarding glyphosate, and suggesting that a different conclusion is more appropriate, EPA should reduce the tolerance level to be more health-protective.[87]

V. Children's Health

Many common oat products are marketed to children, and the EPA has noted that children 1-2 years old have the highest dietary exposure to glyphosate.[88] As noted by the Scientific Advisory Panel, the epidemiologic data is limited and none of the studies addressed populations who have relatively high exposure.[89] However, because the EPA categorized glyphosate as "not likely to be carcinogenic," the greater vulnerability of children to this chemical remains inadequately

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[85] Id; slide narrative at 5
[86] EPA, Summary of ORD comments on OPP's glyphosate cancer assessment (Dec 14, 2015), https://usrtk.org/wp-content/uploads/2017/03/ORDcommentsonOPPglyphosate.pdf
[87] *Id., see also* https://www.nrdc.org/experts/jennifer-sass/split-within-epa-glyphosate-carcinogenicity
[88] EPA OPP, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 15 (Sept 12, 2016), https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf
[89] EPA, Meeting Minutes and Final Report of Dec, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate, at 15 (Mar 16, 2017)

evaluated. In addition to excluding cancer risk from the equation, EPA also used incorrect toxicological endpoints in its assessment of the pesticide and failed to include human studies. Taken together, the standard applied by the agency failed to comprehensively capture the risk potential of glyphosate exposure in children and proceeded to set a food residue tolerance level that is not protective enough.[90]

As described by EPA

> "Children 1-2 years old are considered the most highly exposed subpopulation with oral exposures from dietary (food and water) ingestion and incidental oral ingestion (e.g., hand-to-mouth activities) in treated areas. There is also potential for dermal exposures in previously treated areas. Using HED's standard exposure assessment methodologies which are based on peer-reviewed and validated exposure data and models6 , a high-end estimate of combined exposure for children 1-2 years old is 0.47 mg/kg/day".[91]

The FFDCA explicitly requires that EPA, in establishing a tolerance, must assess the risk that a pesticide poses to infants and children. 21 U.S.C. § 346(a)(b)(2)(C). The agency shall "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to the pesticide and shall "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children." §§ 346a(b)(2)(C)(ii)(I) & (II).

In ensuring that the statutory safety standard is met, EPA must consider available information concerning "the special susceptibility of infants and children," including "neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." §§ 346a(b)(2)(C)(i)(I) & (III). EPA must also base its tolerance decision on available information about "food consumption patterns unique to infants and children" and the "cumulative effects on infants and children of [pesticides] that have a common mechanism of toxicity." *Id*. §§ 346a(b)(2)(C)(i)(I) & (III).

Additionally, "a tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." 21 U.S.C. 346a(b)(2)(C). EPA can depart from this requirement and use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.*

A tenfold safety factor for children's health is fully supported by both the national pesticide law and by the recommendations of the country's top experts. In 1993, the National Research Council Report "Pesticides in the Diets of Infants and Children," highlighted that children are exposed to more pesticides than adults and are more susceptible to the toxic effects of pesticides, particularly those that cause cancer.[92] In 2009, the National Research Council again emphasized

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[90] Mills PJ et al., *Excretion of the Herbicide Glyphosate in Older Adults Between 1993 and 2016*, 318(16) JAMA 1610-1611 (2017), 10.1001/jama.2017.11726; IARC, *Glyphosate*, 112 Monographs on the Evaluation of Carcinogenic Risks to Humans (2017), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf

[91] EPA, Meeting Minutes and Final Report of Dec, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate, at 15 (Mar 16, 2017)

[92] NAT'L RESEARCH COUNCIL ET AL., PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN (1993), https://doi.org/10.17226/2126

the importance of applying an adjustment factor to account for varying susceptibility to cancer among humans.[93]

A risk assessment for glyphosate should include a tenfold safety factor to account for glyphosate exposures to children and the developing fetus. A 2009 report from the State of California points out that existing risk assessment approaches do not "adequately address the possibility that risk from early-in-life exposures may differ from that associated with exposures occurring in adulthood."[94] The report also noted that an adjustment factor of 10 is appropriate for calculating lifetime cancer risk in humans arising from carcinogen exposures that occur in utero.[95] A safety factor of 10 would account for potential increased susceptibility to glyphosate exposures occurring before birth and in the early years of life.

EPA acknowledges the need for this heightened safety standard for children, yet the dietary risk assessment for glyphosate did not conduct acute or cancer risk assessments because of the preceding classification of "not likely to be a human carcinogen." In addition, the exposure scenarios relied only on animal studies and did not include comparable data based in human studies.[96] The chronic analysis assumed tolerance-level residues and 100 percent crop treatment.[97] The resulting chronic risk estimates were below 100 percent of the chronic population-adjusted dose (cPAD) and are therefore determined to be less than HED's level of concern.[98] However, the established cPAD is too high because it's not based on cancer data, thus any risk assessment even factoring for worst case scenarios like using tolerance-level residues and 100% crop treatment will result in chronic exposure estimates less than 100%. The resulting chronic risk estimates are incomplete as conducted for failing to consider the potential carcinogenicity of glyphosate.

In 2017, California listed glyphosate as "Known to the State to Cause Cancer" under the California Proposition 65 law that requires labeling of cancer-causing chemicals and proposed a No Significant Risk Level of 1.1 milligrams glyphosate per day, more than 60 times lower than the safety level set by the Environmental Protection Agency.[99] California's proposed limit under Proposition 65 is the dose of glyphosate expected to cause no more than one case of cancer in every 100,000 people who ingest it over a lifetime.[100] EWG strongly supports the state's move to set a health-protective limit for glyphosate based on cancer risk. But we believe the EPA should

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[93] NAT'L RESEARCH COUNCIL ET AL., SCIENCE AND DECISIONS; ADVANCING RISK ASSESSMENT (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment

[94] CA EPA OEHHA, IN UTERO AND EARLY LIFE SUSCEPTIBILITY TO CARCINOGENS: THE DERIVATION OF AGE-AT-EXPOSURE SENSITIVITY MEASURES, (May 2009), https://oehha.ca.gov/media/downloads/crnr/appendixjearly.pdf

[95] *Id.*

[96] EPA, Meeting Minutes and Final Report of Dec, 2016 FIFRA SAP, Evaluation of the Carcinogenic Potential of Glyphosate (Mar 16, 2017)

[97] EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, Appendix E, EPA-HQ-OPP-2009-0361-0073 at 200 (Dec 12, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073; *compare to* actual U.S. treatment of oats with Glyphosate, USDA QUICK STATS, AVERAGE OF DATA ITEMS ACROSS TIME PERIODS (Last visted Sept 26 2018) https://quickstats.nass.usda.gov/data/maps/1F600EE4-9DCA-32F5-86C2-75F947786B68

[98] EPA, Registration Eligibility Decision (RED), Glyphosate (1993), https://www3.epa.gov/pesticides/endanger/litstatus/effects/glyphosate-red.pdf

[99] CA, Glyphosate Listed Effective July 7, 2017, as Known to the State of CA to Cause Cancer, CAS No. 1071-83-6 (Jun 26, 2017), https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer#_ftn1

[100] *Id*.

go further and set a much lower limit for glyphosate at no more than 0.01 milligrams per day consistent to the 1993 tolerance level of 0.1ppm.[101]

Following the approach for deriving a cancer-specific risk level used by California's Office of Environmental Health Hazard Assessment in California, EWG calculated that a one-in-one-million cancer risk, protective of children's health would be 0.01 milligrams of glyphosate per day.[102] Eating a cup of cereal with a glyphosate level of 0.160 ppm would result in ingesting this amount of glyphosate – without taking into account the presence of glyphosate in other foods. The widespread dietary exposure to glyphosate prompts petitioners to request the EPA reduces the tolerance level of glyphosate on oats back to the a more protective 0.1 ppm residual level and take action to prevent oat products that were treated with preharvest glyphosate from entering the U.S. consumer market.

VI. Conclusion

The widespread exposure to glyphosate in high concentrations in oat products requires immediate action. EWG urges the EPA to follow its own internal guidelines when reviewing the evidence of increased cancer risks from human and animal studies. It must also consider ways to pool data across studies for cancers where authors report statistically significant trend tests. Recognizing that international practices and market trade have prompted the higher tolerance levels of glyphosate in oat products entering the United States, however, these interests should not outweigh the need for robust safety standards for domestic consumers. The current tolerance levels are not protective enough in consideration of actual dietary exposure to glyphosate in oats with and the potential carcinogenicity of glyphosate.

EWG and co-petitioners request that EPA lower the tolerance limit of glyphosate in oats from 30 ppm to 0.1 ppm to account for the carcinogenic risk of the pesticide and high dietary exposure of children. In addition, petitioners request that the EPA clarify labeling requirements to explicitly prohibit preharvest application of glyphosate on oats as a desiccant.

Respectfully Submitted,

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[101] EWG, RETHINKING CANCER, *California's Proposed Limit vs. The Amount Allowed by EPA*, (2016) https://www.ewg.org/research/california-proposes-safe-level-roundup-more-100-times-lower-epa-limit/californias-proposed#.W5majthKj-Y; EPA, Registration Eligibility Decision (RED), Glyphosate (1993), https://www3.epa.gov/pesticides/endanger/litstatus/effects/glyphosate-red.pdf

[102] *Id.*

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Clif Bar and Company
1451 66th St.
Emeryville, CA 94608

Earth's Best Organic
1111 Marcus Avenue
Lake Success, NY 11042

GrandyOats
34 Schoolhouse Rd
Hiram, ME 04041

Happy Family Organics
40 Fulton St. 17th FL
New York, NY, 10038

Independent Natural Food Retailers Association
2356 University Ave W #200
St. Paul, MN 55114

KIND Healthy Snacks
1372 Broadway
New York, NY 10018

Lundberg Family Farms
5311 Midway P.O. Box 369,
Richvale, CA 95974

MegaFood
380 Harvey Road
Manchester, NH 03103

MOM's Organic Market
5612 Randolph Rd
Rockville, MD 20902

National Co-op Grocers
14 S Linn Street
Iowa City, IA 52240

Nature's Path Foods Inc.
9100 Van Horne Way
Richmond, BC Canada V6X 1W3

One Degree Organic Foods USA, Inc.
P.O. Box 128 STN A
Abbotsford, BC Canada V2T 6Z5

Organic Valley
One Organic Way
La Farge, WI 54639

Patagonia Provisions
1750 Bridgeway A201
Sausalito, CA 94965

PCC Community Markets
3131 Elliott Avenue
Suite 500
Seattle, WA 98121

Stonyfield Farm Inc.
10 Burton Drive
Londonderry, NH 03053

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