Testimony of Jennifer Sass, Ph.D., Senior Scientist
Natural Resources Defense Council
Healthy People & Thriving Communities Program

For a Full Committee Hearing –
In Defense of Scientific Integrity:
Examining the IARC Monograph Programme
and Glyphosate Review[1]

Tuesday, February 6, 2018 - 10:00am
2318 Rayburn House Office Building

[1] https://science.house.gov/legislation/hearings/full-committee-hearing-defense-scientific-integrity-examining-iarc-monograph

Introduction

Thank you for the opportunity to speak before this Committee on this very important topic of Scientific Integrity, the IARC Monographs, and Glyphosate.

I have been employed full-time as a Senior Scientist with the Natural Resources Defense Council (NRDC) since 2001. I have advanced degrees in Anatomy and Cell Biology, with specific expertise in developmental biology, neurobiology, molecular biology, and environmental health. In my position with NRDC, I am responsible for reviewing the science underlying many of the federal regulations of industrial chemicals and pesticides. I have published over forty-five articles in peer-reviewed scientific journals, including many pertaining to pesticide hazards and regulations.

I developed an understanding of U.S. pesticide regulations and of the operations of the EPA Office of Pesticide Programs through various activities. On numerous occasions, I have provided written and oral testimony to the Pesticide Office on the registration of dozens of pesticides, including glyphosate. Additionally, I represented NRDC for over a decade as an active member of the EPA/U.S. Department of Agriculture (USDA) Pesticide Program Dialogue Committee (PPDC), a stakeholder committee that provides feedback to the Pesticide Office on various issues related to pesticide regulatory, policy, and program implementation issues. Through my years of work on the PPDC, from 2001 to 2013, I also served on issue-specific PPDC workgroups to provide more in-depth perspectives and advice on pesticide issues, including input on strategic approaches for implementation of the Food Quality Protection Act (FQPA).

I also have knowledge of the policies and practices of the International Agency for Research on Cancer (IARC), having read and referenced many IARC chemical assessments over almost two decades. In 2002, when IARC was reviewing styrene (Volume 82) I was publicly critical of IARC's practice at the time of allowing financially-conflicted scientists to participate as voting members of the Committee. In response, the Chief of the Programme at that time, Dr. Jerry Rice, invited me to attend a week-long meeting at which IARC would review arsenic and some drinking water disinfection byproducts (Volume 84). I attended as an observer (non-voting), and was given full access to observe the Working Group and its sub-discipline groups, as well as join participants for meals, etc. Dr. Rice was correct, I was extremely impressed with the scientific rigor of the process and the output. While I continued to advocate for financially-conflicted individuals to be prevented from voting, I acknowledged even then that Dr. Rice was right to be proud of the Monograph Programme's scientific work, then and even more so now. I have not participated in any IARC Monograph meetings since that one single time. There have been two Chiefs of the Monograph Programme since Dr. Rice, with the current one, Dr. Kurt Straif, having worked for the Monograph Programme under both his predecessors. Dr. Straif's leadership brings continuity to IARC's commitment to environmental public health and scientific excellence.

IARC has undertaken the evaluation of over 900 substances including asbestos, tobacco smoke and later second-hand smoke, diesel exhaust, formaldehyde, vinyl chloride, viruses, carbon nanotubes, arsenic, methylene chloride, benzene, and about nine hundred others. IARC assessments inform global cancer prevention strategies.

Because of its scientific excellence and its scientific and regulatory relevance, IARC enjoys overwhelming support from the global scientific and medical community. A few years ago, 124 scientists and health professionals from diverse scientific disciplines, from around the world co-authored a published account of the last forty years of IARC Monographs, noting the Programme's role in identifying carcinogenic substances to inform policies and practices that prevent harm and save lives (Pearce et al, 2015).

In a published review on the industry-led criticisms of the IARC Monographs, Dr. Jonathan Samet, a prestigious medical professor and frequent Chair of National Academies committees, writes, "the types *of concerns raised about the IARC monograph program are also archetypical of strategies for creating 'doubt' about scientific evidence that has policy implications. Such strategies can be traced to the 'playbook' of the tobacco industry for discrediting findings related to active and passive smoking (14,15). One tactic has been to question the processes used to draw causal inferences and the integrity and potential conflicts of interest of those doing so. The IARC processes are robust and transparent and as concluded by Pearce and his 123 colleagues, not flawed and biased*." (Samet 2015)[2]

In my testimony I address a few examples of those tobacco-industry tactics applied to glyphosate, and the agrochemical industry attack on the IARC Monographs.

Agrochemical Industry Opposition

IARC Director Christopher Wild stated that his Agency has experienced "unprecedented, coordinated efforts to undermine the evaluation, the program and the organization" in response to listing glyphosate in 2015 as a probable human carcinogen (Group 2A). [3] These efforts are largely sponsored and coordinated by the agrochemical industry that has sought to: support glyphosate registration and approval; defend itself against litigation claims by thousands of farmers that were once Monsanto Co. customers and are now cancer patients; and, prevent labeling of glyphosate-containing products as a carcinogen in the State of California.

[2] Samet JM. The IARC monographs: critics and controversy. Carcinogenesis. 2015 Jul;36(7):707-9. https://academic.oup.com/carcin/article/36/7/707/1800366

[3] IARC briefing paper Jan 2018 http://governance.iarc.fr/ENG/Docs/BriefingGCSC_FINAL_29012018.pdf and IARC webpage on glyphosate: https://www.iarc.fr/en/media-centre/iarcnews/2016/glyphosate_IARC2016.php

Today's hearing supports the agrochemical industry agenda to discredit and ultimately defund IARC. In September 2015 the New York Times reported that emeritus food professor Bruce Chassy received funding from Monsanto Co. to lobby the EPA to block regulation of GMO products.[4] Almost a year later Chassy wrote an opinion-editorial in The Hill, "NIH needs public examination after giving millions to rogue UN agency".[5] However, Chassy's editorial failed to disclose his work with Monsanto Co., instead identifying himself only as, "a researcher at the NIH for 21 years before moving to the University of Illinois at Urbana-Champaign as a department head and assistant dean, and is now professor emeritus of Food Science and Human Nutrition." What Chassy failed to disclose is that the nonprofit he runs called Academics Review received $300,000 from the Monsanto Co.-funded trade group BIO in both 2014 and 2015. This industry money is the majority of Academics Review's funding and Chassy runs it with his wife.[6]

What I've touched upon here is only a small part of the well documented public relations campaign to soften up public opinion about the agrichemical industry and create a venue to pressure agencies to block regulations, and try to discredit and silence public health and scientific institutes that may show some harm from their profitable products.

IARC Response

IARC has ably defended itself from all substantive criticisms in public documents, letters to this Committee which are publicly accessible on the IARC website, or in other public reports. [7] Additionally, over 100 non-industry scientists across many scientific and medical disciplines and from dozens of public Universities and Institutes in the US and worldwide – including myself - have expressed confidence generally for the IARC process and specifically in the IARC Monograph for glyphosate (Portier et al 2016).[8]

---

[4] Food Industry Enlisted Academics in G.M.O. Lobbying War, Emails Show. Eric Lipton. Sept 5, 2015. NY Times. https://www.nytimes.com/2015/09/06/us/food-industry-enlisted-academics-in-gmo-lobbying-war-emails-show.html

[5] Bruce Chassy. The Hill. 10/24/16. http://thehill.com/blogs/pundits-blog/healthcare/302484-nih-needs-public-examination-after-giving-millions-to-rouge-un

[6] Paul Thacker, 07/21/2017. The Progressive. http://progressive.org/magazine/how-the-biotech-industry-cultivates-positive-media/

[7] IARC briefing paper Jan 2018 http://governance.iarc.fr/ENG/Docs/BriefingGCSC_FINAL_29012018.pdf

[8] Portier CJ, Armstrong BK, Baguley BC, Baur X, Belyaev I, Bellé R, Belpoggi F, Biggeri A, Bosland MC, Bruzzi P, Budnik LT, Bugge MD, Burns K, Calaf GM, Carpenter DO, Carpenter HM, López-Carrillo L, Clapp R, Cocco P, Consonni D, Comba P, Craft E, Dalvie MA, Davis D, Demers PA, De Roos AJ, DeWitt J, Forastiere F, Freedman JH, Fritschi L, Gaus C, Gohlke JM, Goldberg M, Greiser E, Hansen J, Hardell L, Hauptmann M, Huang W, Huff J, James MO, Jameson CW, Kortenkamp A, Kopp-Schneider A, Kromhout H, Larramendy ML, Landrigan PJ, Lash LH, Leszczynski D, Lynch CF, Magnani C, Mandrioli D, Martin FL, Merler E, Michelozzi P, Miligi L, Miller AB, Mirabelli D, Mirer FE, Naidoo S, Perry MJ, Petronio MG, Pirastu R, Portier RJ, Ramos KS, Robertson LW, Rodriguez T, Röösli M, Ross MK, Roy D, Rusyn I, Saldiva P, Sass J, Savolainen K, Scheepers PT, Sergi C, Silbergeld EK, Smith MT, Stewart BW, Sutton P, Tateo F,

I will add my own perspective here.

The IARC Monographs have clearly described published guidelines called the "Preamble to the Monographs".[9] The guidelines describe the separate criteria for reviewing evidence from animal studies, epidemiologic information, and mechanistic data, and then integrating the data into an overall evaluation. All evaluations are made by Working Groups of experts, and have included over 1,200 scientists from over 50 countries. Scientific data is evaluated in subgroups, and then by all members of the Working Group in a plenary session, where revisions and extensive discussions often occur. There are also procedural guidelines for ensuring transparency, and for identifying and managing conflicts of interest and stakeholder involvement. Government, industry, NGO observers, and others can attend the Working Group meetings; the glyphosate meeting was attended by Monsanto Co. and other agrochemical industry representatives as observers.[10]

For its glyphosate assessment, IARC identified 17 scientific experts from 11 countries (Volume 112, 2017).[11] A list of Working Group candidates is posted in advance of the meeting, along with their disclosure of relevant financial conflicts, and public comments are invited. In advance of the meeting, Working Group members are asked to review an often very large stack of scientific papers relevant to each person's area of expertise, and provide a draft summary for discussion at the in-person meeting.

All information used for the evaluation must be published or otherwise publicly available with enough detail to enable independent scientific examination. For this reason, some Monsanto-sponsored review articles were left out, where the underlying studies cited in the review article were not available to the Working Group or to the public. For example, Greim et al (2015), a review article of animal toxicology that was sponsored and co-authored by Monsanto Co., is discussed in the IARC monograph, but was not relied upon because the studies in the paper were not publicly available.[12]

Terracini B, Thielmann HW, Thomas DB, Vainio H, Vena JE, Vineis P, Weiderpass E, Weisenburger DD, Woodruff TJ, Yorifuji T, Yu IJ, Zambon P, Zeeb H, Zhou SF. Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA). J Epidemiol Community Health. 2016 Aug;70(8):741-5. doi: 10.1136/jech-2015-207005. Epub 2016 Mar 3.

[9] http://monographs.iarc.fr/ENG/Preamble/index.php

[10] Participants for the IARC Monograph Volume 112. https://monographs.iarc.fr/ENG/Meetings/vol112-participants.pdf

[11] http://monographs.iarc.fr/ENG/Monographs/vol112/index.php

[12] Greim H, Saltmiras D, Mostert V, Strupp C. Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies. Crit Rev Toxicol. 2015 Mar;45(3):185-208.

Helmut Greim also chaired a 'scientific panel' funded by auto companies to respond to the 2005 IARC evaluation of diesel exhaust. Greim's panel conducted studies on monkeys at a lab in Albuquerque New Mexico, exposed them in a chamber to diesel exhaust. However, the studies were rigged because the

IARC has been criticized by Dr. Tarone, also a paid Monsanto Co. consultant, arguing that IARC could have used, "A supplement to the review paper [that] contains summary pathology tables for each of the rodent studies reviewed".[13] But, summary tables are not original studies, and do not provide the detail necessary for an independent examination, and thus the Working Group could not independently verify the conclusions. Similarly, the IARC Monograph determined that a Monsanto-sponsored review of genotoxicity studies by Kier and Kirkland (2013) also "did not meet the criteria for data inclusion as laid out in the Preamble to the IARC Monographs" because the original studies were not available publicly available. IARC requires information to be publicly available as a requirement for full transparency of how the Working Group came to its conclusions. In addition, peer reviewed publications and reports contain enough detail on the study materials, methods, and results so that peer reviewers and readers can independently evaluate the study quality, including any possible confounders and biases.

In stark contrast to IARC, the 2017 EPA glyphosate assessment acknowledges that, "data and summaries provided in Greim et al (2015) and Kier and Kirkland (2013)[14] were relied upon for the current evaluation" (EPA 2016, 2017). Thus, EPA relied upon a Monsanto-sponsored summary of a Monsanto-sponsored study that EPA could not independently scrutinize – the full studies are not available to the public and do not even seem to have been made available to EPA. In a small footnote, EPA identified that all review articles except one "were funded and/or linked to Monsanto Co. or other registrants."[15]

On occasion, the Monographs have been wrongly accused of a bias towards too readily classifying a substance as carcinogenic. However, to date the IARC Monographs have evaluated over 1,000 agents, all with at least enough cancer data to support a nomination for consideration. Yet, only 120 are classified as known human carcinogens (Group 1) and only about 80, including glyphosate, as probable human carcinogens (Group 2A).[16] That makes a total of 200 agents, only about 20 percent, that are classified in the strongest two categories. The overwhelming majority of agents that have been reviewed by IARC – about 80 percent - are classified as either possibly carcinogenic to humans (Group 2B, 300 agents) or not classifiable (Group 3, 500 agents). The third category – not classifiable – has far more entries than any other single class, and even more than the first two combined (Group 1 and 2A). Thus,

---

cars in the chambers were using the "cheating" device that reduced emissions. In addition to bad science, it was also unethical, given that it is completely unnecessary to test monkeys in a chamber, when people are walking around exposed to these diesel fumes every day. The study was never published, but was widely criticized and the story reported in the NY Times. https://www.nytimes.com/2018/01/25/world/europe/volkswagen-diesel-emissions-monkeys.html

[13] Tarone RE. On the International Agency for Research on Cancer classification of glyphosate as a probable human carcinogen. Eur J Cancer Prev. 2018 Jan;27(1):82-87. https://www.ncbi.nlm.nih.gov/pubmed/27552246

[14] Kier LD, Kirkland DJ. Review of genotoxicity studies of glyphosate and glyphosate-based formulations. Crit Rev Toxicol. 2013 Apr;43(4):283-315. Review. https://www.ncbi.nlm.nih.gov/pubmed/23480780

[15] EPA 2017 glyphosate cancer assessment. See Page 22 and Footnote 11.

[16] http://monographs.iarc.fr/ENG/Classification/index.php

the data do not support a bias towards classifying chemicals in the higher groups; in fact, most are determined to have too little data to classify.

There has been public criticism by Monsanto Co. and some Majority Members of this Congressional Committee that a member of the glyphosate Working Group, Dr. Aaron Blair, withheld a pre-publication update of the National Cancer Institute Agricultural Health Study (AHS), and, further, that if the Working Group had been provided with this update, then it would have altered the final classification of glyphosate as a Group 2A probable human carcinogen.[17] That story was reported in Reuters, and subsequently shown by former Reuters reporter and veteran journalist Carey Gillam to contain critical factual errors, and to have been orchestrated by Monsanto Co..[18] The misleading Reuters story relies on court documents obtained from Monsanto Co., and quotes Monsanto Co. consultant Bob Tarone as an "independent" expert not associated with Monsanto Co. Dr. Blair himself states that his opinions held at the IARC meeting has not changed, which IARC pointed out in a response letter to this Committee.[19]

The IARC Director, Dr. Christopher Wild, responded in a letter to this Committee that in fact the AHS is a decades-long prospective epidemiologic study, with "incremental updates published periodically," all of which were included by the IARC Working Group in the Monograph.[20] Since the previous AHS reports did not identify an association between non-Hodgkin lymphoma (NHL) and glyphosate, and the most recent incremental update, in 2017, also did not identify such an association, then it's hard to see how the recent update alters the previous reports. In addition, the recent update was not published until 2017, a full 2.5 years after the meeting of the IARC Working Group, indicating that it was unpublished at the time of the meeting.

It is also inappropriate to argue that null studies can even nullify completely unrelated studies that are positive, that do report a link to NHL or other cancers. As if, just because you don't have cancer, my cancer goes away. That isn't the way science works, and it isn't the way cancer works either. The updated AHS report does not call into question the IARC conclusions, which are based on many studies across multiple disciplines, including studies sponsored by Monsanto Co.

Lost or buried in much of the reporting of the recent update of the AHS study is that the study did find some evidence of a possible association between glyphosate and another type of blood cancer called acute myeloid leukemia (AML). The AHS study authors warn that, "Given the

---

[17] See Letter from Reps. Lamar Smith, Andy Biggs, and Frank Lucas to IARC Director Dr. Christopher Wild. December 8, 2017. http://governance.iarc.fr/ENG/Docs/SST_IARC12082017.pdf

[18] https://www.huffingtonpost.com/entry/monsanto-spin-doctors-target-cancer-scientist-in-flawed_us_594449eae4b0940f84fe2e57

[19] IARC letter January 11, 2018, referencing a videotaped deposition of Dr. Blair, March 20, 2017. http://governance.iarc.fr/ENG/Docs/CPWild_Smith_Biggs_Lucas_20180111.pdf

[20] See response from Dr. Wild to the Committee on Science, Space and Technology, January 11, 2018. http://governance.iarc.fr/ENG/Docs/CPWild_Smith_Biggs_Lucas_20180111.pdf

prevalence of use of this herbicide worldwide, expeditious efforts to replicate these findings are warranted".[21] The increase risk of AML was over 2-fold higher in highest exposed applicators compared with the never exposed applicators. The possible link with leukemia should be very concerning to the public and particularly to pesticide applicators, because AML is a very serious fast-growing cancer, with only about one-quarter of the people that have it surviving longer than 5 years. The EPA 2017 Cancer Assessment acknowledges these new data, but considers them too limited and simply says it will continue to follow the literature.[22]

In summary, the Monograph process: relies only on publicly available studies of sufficient detail for a peer assessment, including both industry and non-industry studies; follows a systematic review approach using internationally agreed upon best practices; is the consensus product of a Working Group of non-IARC experts; invites observers including industry stakeholders to attend all aspects of the Working Group meetings including sub-groups and plenary voting sessions; will report in the Monographs if there is a significant dissenting perspective among Working Group members (there was no such dissent on the glyphosate finding); does not alter any findings or conclusions that are not agreed to during the meeting of the Working Group.

EPA Glyphosate Cancer Assessment – Process Problems

The EPA Pesticide Office seems to have a questionable and non-transparent process for conducting its pesticide cancer assessments. Perhaps most alarming are revelations of a disturbing level of communication and collaboration between Monsanto Co. and senior EPA official Jess Rowland, who headed up the EPA Cancer Assessment Review Committee for glyphosate and many other pesticides. Monsanto Co. internal emails made available by U.S. RTK reveal that Rowland told a Monsanto Co. employee in 2015 that he would try to prevent the Department of Health and Human Services from conducting its own glyphosate hazard assessment, which then came to pass. Monsanto Co.'s regulatory liaison commented in a 2015 email that Rowland "could be useful as we move forward with ongoing glyphosate defense," and Rowland has since left EPA. The concerns of collusion sparked an investigation by the EPA Inspector General that is still ongoing.[23]

EPA's Pesticide Office seems to be failing the test of public scrutiny for its policy decisions as well. The Scientific Advisory Panel (SAP) that reviewed the 2016 assessment disagreed with EPA's classification of "not likely to be carcinogenic to humans' at doses relevant to human health risk assessment. First, the SAP agreed that the Pesticide Office had inappropriately

[21] Andreotti G, Koutros S, Hofmann JN, Sandler DP, Lubin JH, Lynch CF, Lerro CC, De Roos AJ, Parks CG, Alavanja MC, Silverman DT, Beane Freeman LE. Glyphosate Use and Cancer Incidence in the Agricultural Health Study. J Natl Cancer Inst. 2017 Nov 9. https://www.ncbi.nlm.nih.gov/pubmed/29136183

[22] Revised glyphosate issue paper: evaluation of carcinogenic potential. EPA Office of Pesticide Programs. December 12, 2017. Section 3.5.2 (1), p. 53

[23] Paul Thacker. Huffington Post. 06/06/2017. https://www.huffingtonpost.com/entry/epa-inspector-general-probing-collusion-with-monsanto_us_59372108e4b0aba888b99dca

conflated a hazard statement (not likely to be carcinogenic) with a risk characterization (at doses relevant to risk assessment) without having conducted an exposure and risk assessment. [24] Second, most of the SAP members supported the stronger classification of "suggestive evidence of cancer". Third, the SAP had concerns that the Pesticide Office had failed to follow its Agency-wide Cancer Guidelines in ways that biased the conclusions towards the least protective "not likely" classification. The SAP's report is in agreement with EPA's Office of Research and Development (ORD), including that the Pesticide Office had inappropriately dismissed cancer evidence by failing to conduct a systematic review and that a "not likely" cancer descriptor was inappropriate and inconsistent with the tumor evidence. [25]

Both the 2016 and 2017 glyphosate cancer assessments follow a systematic review process being developed by EPA's Office of Chemical Safety and Pollution Prevention (OCSPP). This office, known as the Toxics Office, is now under the management of Nancy Beck, a chemical industry lobbyist prior to her recent political appointment at EPA. Dr. Beck's previous foray into developing risk assessment guidelines was a failure, as evidenced by the National Academies conclusion that the draft government-wide risk assessment bulletin which she authored while at the Office of Management and Budget (OMB) was "fundamentally flawed" and the unprecedented recommendation for its withdrawal (NAS 2007).[26]

The systematic review approach used by EPA in the glyphosate cancer assessment is inconsistent in critical ways with best practices, and recommendations of the National Academies (NRC 2014; NRC 2017). [27] The approaches used in OCSPP do not meet the standard of transparency and public review of the IRIS program, which recently received praise from EPA's Science Advisory Board (SAB): "The program has fully adopted the principles of systematic review ...it is now standard practice for the [IRIS] program to engage stakeholders in an early scoping and problem formulation phase, thereby allowing stakeholders to provide important input at the very beginning of the process." [28] It is unclear why the Pesticide Office is not coordinating with the IRIS program to share resources, save time, and implement the IRIS systematic review process that has been developed with public and stakeholder input, and favorable review by the National Academies and SAB.

---

[24] SAP meeting, December 2016. P. 80, 86-87. https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

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

[26] Available at http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11811

[27] National Research Council. 2014. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press. https://doi.org/10.17226/18764
National Academies of Sciences, Engineering, and Medicine. 2017. Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, DC: The National Academies Press. https://doi.org/10.17226/24758.

[28] Science Advisory Board comments on EPA's response to recommendations on the Integrated Risk Information System. September 1, 2017. EPA-SAB-17-008. Available at: https://yosemite.epa.gov/sab/SABPRODUCT.NSF/RSSRecentAdditionsBOARD/A9A9ACCE42B6AA0E8525818E004CC597/$File/EPA-SAB-17-008.pdf

Instead, the EPA's glyphosate cancer assessment is being conducted according to a purported systematic review process that has not been subjected to public and stakeholder engagement, or peer review. Further, it veers from the National Academies and IRIS best practices in several important ways, all of which are promoted by the chemical industry,[29] and favor industry outcomes:

- preferentially relying on Guideline studies, which are conducted by the regulated industry to support the approval of its products;
- preferentially relying on studies following so-called Good Laboratory Practices (GLP), which are required by industry product-testing labs to prevent malfeasance and misconduct;
- over-emphasizing the requirement to understand the mechanism of toxicity, so that many studies of adverse effects in people are dismissed because the mechanism of disease is not fully understood;
- using methods to score studies that score guideline and GLP studies higher;
- misusing a 'weight of evidence' (WOE) approach to pit studies that find adverse effects against studies that don't, to dismiss the effects studies.

The EPA Pesticides Office leans on all of the above chemical industry tactics to dismiss the following evidence that EPA acknowledges would support a "suggestive" classification for glyphosate (EPA Cancer Assessment, Section 6.6.2, p. 141-142):

- Non-statistically significant non-Hodgkin's lymphoma (NHL) across studies, and in a meta-analysis sponsored by Monsanto Co. (Chang and Delzell 2016)[30] that, according to EPA, found results similar to IARC (EPA Cancer Assessment, p. 64);
- Limited evidence of a possible exposure-response relationship between glyphosate exposure and NHL in case-control studies;
- A statistically significant trend in tumors in several animal cancer studies, and two studies with statistically significant tumor incidence at the highest doses tests, compared with concurrent controls;
- Evidence of genotoxic effects in a limited number of tests including damage to DNA and chromosomes.

In each of the cancer evidence streams summarized by EPA above – human, animal, and cellular studies – there were also studies that didn't find a link between glyphosate and cancer, or

[29] Rick Becker comments on behalf of the American Chemistry Council on Data Quality in Toxicology Studies: A key element in systematic review for evaluating chemical risks. March 20, 2013. Submitted to the National Toxicology Program. https://ntp.niehs.nih.gov/ntp/ohat/evaluationprocess/presentations/march2013/becker20130320_508.pdf

[30] Chang ET, Delzell E. Systematic review and meta-analysis of glyphosate exposure and risk of lymphohematopoietic cancers. J Environ Sci Health B. 2016;51(6):402-34.

glyphosate and cellular damage that could lead to cancer.[31] Most prominent among these no-effect studies are the industry-sponsored review articles of Greim et al (2015) and Kier and Kirkland (2013) that are heavily cited in EPA's cancer assessment, but dismissed by IARC because the underlying studies were not published or otherwise publicly available.

The Pesticide Office concludes that, "In summary, considering the entire range of information for the weight-of-evidence, the evidence outlined above to potentially support the 'suggestive evidence of carcinogenic potential' descriptor are [sic] contradicted by other studies of equal or higher quality and, therefore, the data do not support this cancer classification descriptor." (page 142) The Pesticide Office therefore concludes that, "The strongest support is for 'not likely to be carcinogenic to humans'. "(page 143). The OCSPP systematic review as applied to the glyphosate cancer assessment leads to the inclusion of systemic flaws that make the glyphosate assessment biased toward industry, inconsistent with best practices identified by the National Academy, unreliable and unprotective of human health.

Only one agent has ever been classified by IARC in the lowest category, Group 4, probably not carcinogenic. The chemical is caprolactam, used in nylon and plastics (Volume 39, 1999). This is because, in accordance with the IARC guidelines, to classify a chemical into Group 4 requires affirmative evidence of lack of carcinogenicity, as opposed to simply a lack of evidence. The U.S. EPA Cancer Guidelines apply similarly stringent criteria to classify a substance as "not likely to be carcinogenic to humans", that is, "when the available data are considered robust for deciding that there is no basis for human hazard concern" (Guidelines, p. 2-57). such as, "animal evidence that demonstrates lack of carcinogenic effect in both sexes in well-designed and well-conducted studies in at least two appropriate animal species (*in the absence of other animal or human data suggesting a potential for cancer effects*)." Against the requirements of its own guidelines, this is the category into which EPA has now placed glyphosate. We would welcome a committee hearing to more closely examine the scientific and procedural integrity of the Pesticide Office's assessment of glyphosate health risks.

Conclusion

Fundamentally, this hearing is about the ability of a public health agency to call a carcinogen a carcinogen, even if it makes a huge amount of money for a powerful corporation. Of course, even without IARC, or IRIS, (or the National Toxicology Program's Report on Carcinogens), the cancers will still occur – with their obvious terrible toll on individuals, families, health care costs, and the economy – but the suffering will be in vain because the tumors won't be counted, and the causes won't be tracked. IARC Monographs are considered essential for

[31] In some cases, the Pesticide Office tried to cast doubt on the glyphosate cancer evidence by: using a different statistical method (pair-wise instead of trend tests); comparing tumor evidence with historical laboratory records of control animals instead of control animals within the same experiment (some with lab records over 10 years old); or discounting the tumors in the high dose groups (EPA 2017 pages 141-142).

informing cancer prevention strategies and effective public health decision-making around the world.[32] As several cancer assessment experts recently wrote, "the interference by economic interests in cancer evaluations conducted by public heath institutions do not bode well for the free flow of scientific information that informs and protects the public and workers from clear risks of cancer".[33] Are we willing to sell out the public's right to know about harmful chemicals in the places we work, live, and play, just so that Monsanto Co. can sell more glyphosate?

[32] Lorenzo Richiardi, Benedetto Terracini; International Agency for Research on Cancer. The first 50 years, International Journal of Epidemiology, Volume 45, Issue 3, 1 June 2016, Pages 967–968, https://doi.org/10.1093/ije/dyv331

[33] Infante PF, Melnick R, Vainio H, Huff J. Commentary: IARC Monographs Program and public health under siege by corporate interests. Am J Ind Med, online 3 February 2018. DOI: 10.1002/ajim.22811. http://onlinelibrary.wiley.com/doi/10.1002/ajim.22811/full