



July 13, 2022

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RE: Article 6 Clear and Reasonable Warnings: Warnings for Exposures to Glyphosate from Consumer Products; Notice of Augmentation of Record and 15-Day Public Comment Period, June 28, 2022

Center for Food Safety appreciates the opportunity to offer comments on the above-mentioned matter, on behalf of itself and its 970,000 members and supporters. Center for Food Safety (CFS) is a public interest, nonprofit membership organization with offices in Washington, D.C., San Francisco, California, and Portland, Oregon. CFS's mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. Through groundbreaking legal, scientific, and grassroots action, CFS protects and promotes the public's right to safe food and the environment. CFS has considerable expertise in pesticide regulation and frequently engages the US Environmental Protection Agency and other pesticide regulators with the intent of reducing their harmful effects to human health and the environment.

Introduction

Ever since the State of California's Office of Environmental Health Hazard Assessment (OEHHA) listed glyphosate under the cancer provisions of Proposition 65 on July 7, 2017, there has been dissension and litigation regarding the listing – first an effort to overturn the listing, then over the appropriate wording of the cancer warning. Central to these controversies has been the divergence between the hazard assessments of glyphosate's carcinogenic potential by the International Agency for Research on Cancer (IARC) and the U.S. Environmental Protection Agency's Office of Pesticide Programs (henceforth EPA OPP or OPP).

While IARC deems glyphosate "probably carcinogenic to humans," EPA OPP chose the hazard descriptor "not likely to be carcinogenic." However, the Ninth Circuit Court of Appeals recently vacated (overturned) EPA OPP's human health assessment of glyphosate because of numerous serious flaws in its cancer assessment, in a lawsuit brought against the EPA by the Center for Food Safety and allied farming and environmental organizations (Rural Coalition vs US Environmental Protection Agency, Case No. 20-70801, June 17, 2022).

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The June 17th ruling in this case prompted OEHHA to augment the glyphosate administrative record with two EPA assessments of glyphosate: one conducted by OPP's Cancer Assessment Review Committee (CARC) in 2015, and the second in 2017 that formed the basis for EPA OPP's "not likely to be carcinogenic" determination in the Agency's Interim Registration Review Decision, issued in January 2020.¹ OEHHA has requested comments on these two documents.

While these two cancer assessments were undertaken in the context of OPP's registration review of glyphosate, which began in 2009, the motivation was to undermine IARC's assessment. This intent is evident in both reviews, and the circumstances surrounding them.

EPA OPP's Cancer Assessment Review Committee (CARC) Report on Glyphosate (2015)

The CARC report is a highly biased and inaccurate rebuttal of IARC's assessment (EPA OPP 2015, pp. 7-10). CARC's most egregious distortion was to pretend that IARC based its "probably carcinogenic" classification on animal studies alone (EPA OPP 2015, p. 74), when in fact positive evidence from human epidemiology and mechanistic studies were also critical to reaching that conclusion (Guyton et al. 2015).

In its executive summary, CARC pretends that "no association" was found between glyphosate exposure and non-Hodgkin lymphoma in case-control studies done in the U.S. and Canada (EPA OPP 2015, p. 8), but later admits a suggestive association in the U.S. study, De Roos et al. 2003, while ignoring the significant association found in the Canadian study for those exposed two days or more per year (EPA OPP 2015, pp. 26-27, McDuffie et al. 2001, Table 8). CARC mentions but gives no weight to meta-analyses that show statistically significant increased odds of NHL in those exposed to glyphosate.

CARC likewise mischaracterized IARC's review of animal studies, maintaining that its conclusion of sufficient evidence of carcinogenicity was based only on two studies in CD-1 mice, when in fact IARC also found evidence for pancreatic tumors in two studies of Sprague-Dawley rats (EPA OPP 2015, p. 9; Guyton et al. 2015). CARC dismissed the pancreatic tumors despite significantly increased incidence in two treatment groups (both exceeding the historical control range of the performing lab²), and significantly increased incidence in one treatment group in the other (EPA OPP 2015, pp. 40-43; IARC 2017, pp. 356-359).

CARC purports to have done a more thorough assessment, since it reviewed 11 rodent studies vs. IARC's six. But the additional five studies were based on summary descriptions in a review article published by pesticide industry scientists and their consultants (Greim et al. 2015, which included one Monsanto co-author), and an online data supplement (EPA OPP 2015, p. 8). CARC provides scanty descriptions of these five studies, deferring entirely to its pesticide

¹ Registration review is EPA's program for reviewing each registered pesticide every 15 years in order to determine if it still meets the safety standards prescribed by federal pesticide law in light of new scientific knowledge, statutory or regulatory changes, etc.

² CARC then cites a literature study for a range of historical control group incidence for this tumor type in Sprague-Dawley rats of 0-17%, but of course EPA Guidelines for Carcinogen Risk Assessment properly permit use of historical control data only from the performing lab in the same time span as the study under question.

industry source for the critical “Discussion of Tumor Data” section of each study (EPA OPP 2015, pp. 48-50; 55-56). In contrast, IARC described these studies, but did not include them in its formal assessment because “the information provided in the review article and its supplement was insufficient (e.g. information was lacking on statistical methods, choice of doses, body-weight gain, survival data, details of histopathological examination, and/or stability of dosed feed mixture” (IARC 2017, pp. 354, 360).

Finally, CARC also relied heavily on a review of genotoxicity studies funded by glyphosate manufacturers (Kier and Kirkland 2003) and a safety assessment prepared in part by Monsanto officers (Williams et al. 2000), without revealing the conflict of interest (EPA OPP 2015, p. 8). Monsanto has a history of ghostwriting scientific articles for publication under the names of third parties, presumably to increase their credibility (Waldman et al. 2017).

The bias and distortions in the CARC review may be explained, at least in part, by the leadership of its Chair, Jess Rowland. Rowland was identified by Monsanto as an EPA scientist who “could be useful as we move forward with ongoing [glyphosate defense](#).” He was also a point person in EPA’s effort to kill an independent assessment of glyphosate by the Agency for Toxic Substances and Disease Registry, a division of the U.S. Department of Health and Human Services, activities which prompted the EPA’s Inspector General to investigate him for collusion with Monsanto (Thacker 2017). OPP also prematurely posted the CARC report to its website for several days before taking it down, which gave Monsanto the opportunity to tout EPA’s “not likely” conclusion at a time when it was defending itself against lawsuits filed by people alleging the company’s glyphosate herbicides helped bring on their cancers (Gillam 2016).

EPA OPP’s Revised Evaluation of Glyphosate’s Carcinogenic Potential (2017)

Although the 2015 CARC review was designated a “final report,” EPA OPP decided to conduct another review of glyphosate’s cancer-causing potential. This effort resulted in its Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, issued on Sept. 9, 2016 (EPA OPP 2016). The EPA convened a Scientific Advisory Panel (SAP) to vet this draft report, and a docket was opened for the public to offer comments on it. Center for Food Safety was among those submitting comments to the SAP (CFS 2016a). The SAP then issued its own report in March of 2017 (SAP 2017), and in response EPA OPP minimally revised the draft issue paper to yield the final December 2017 paper (EPA OPP 2017) that OEHHA added to the administrative record.

First, it should be noted that less than a week before the SAP was to convene, the pesticide lobby group CropLife sent a letter to EPA requesting that one well-qualified and distinguished panel member, Dr. Peter Infante, be dismissed on specious grounds. In response, EPA removed Dr. Infante from the Panel without explanation, and postponed the meeting nearly two months (for details, see CFS 2016b).

Study Selection

For its draft 2016 issue paper, EPA OPP reviewed 15 rodent carcinogenicity studies: the 11 reviewed by CARC, plus four additional studies that should never have been included:

- Burnett et al. (1979) is a rat study with a glyphosate contaminant, not glyphosate, and had disqualifying deficiencies even for testing the carcinogenicity of the contaminant;
- Reyna and Gordon (1973) was ruled an invalid mouse study by EPA in 1983 for numerous deficiencies;³ and
- Pavkov and Wyand (1987) are Pavkov and Turnier (1987) are rat and mouse studies, respectively, testing the carcinogenicity of sulfosate, the trimesium salt of glyphosate that exhibits very different toxicological effects than other salts of glyphosate, and which EPA had always regulated separately from them (CFS 2016a, pp. 13-14, 17-18, 19-21, 25).

These criticisms made by CFS were mostly ignored by OPP, which removed only one of the four studies from its revised Issue Paper (EPA OPP 2017, p. 74, ft. 15). Interestingly, the four illegitimate studies did not provide any evidence of treatment-related tumors, unlike the majority of the other 11, which did; hence, OPP may have included them to shift the “weight of the evidence” to support a conclusion that glyphosate is not likely to be carcinogenic.

Guideline Violations

The various iterations of EPA OPP’s cancer assessment were heavily criticized by scientists at OPP’s sister agency, the Office of Research and Development (ORD); by the Scientific Advisory Panel mentioned above; and by the Ninth Circuit Court of Appeal in its ruling. The points raised by these three bodies, and by CFS in comments to the SAP, are remarkably consistent, and center on OPP’s egregious violations of its 2005 Guidelines for Carcinogen Risk Assessment (henceforth “Guidelines,” or EPA 2005)

Human epidemiology

EPA ORD scientists pointed out that OPP’s approach to the epidemiology on glyphosate and NHL (and other cancers) was to label each study as “causal” or “not causal,”⁴ rather than recognize “gradations of causality,” as demanded by the Guidelines. Thus, OPP’s approach could only lead to the strongest hazard descriptor (“carcinogenic to humans”) or the weakest (“not likely to be carcinogenic to humans”). In contrast, ORD sided with IARC’s assessment that epidemiology provided plausible if not definitively causal evidence of an association between glyphosate exposure and NHL, and noted that this alone would rule out OPP’s “not likely” designation (EPA 12/14/15). ORD scientists favored an overall assessment of either “likely carcinogenic” or “suggestive evidence of carcinogenicity” (EPA 12/7/15).

The SAP emphasized that three different meta-analyses of the six studies examining potential associations between glyphosate and NHL arrived at statistically significant results: “all meta-analysis results point to a statistically significant association with the increased risks from 30-50% (meta-RRs = 1.3-1.5) for ever exposure to glyphosate” (SAP 2017, p. 44). SAP

³ Both of these studies were conducted by the infamous Industrial Bio-Test Laboratories, which falsified or fabricated data for hundreds of pesticide studies on behalf of Monsanto and other companies in the 1970s, in what has been called one of the biggest scientific scandals in U.S. history (Schneider 1983).

⁴ EPA OPP ruled each and every epidemiology study as “not causal.”

members called out EPA's assessment of epidemiological evidence as "highly imbalanced," with EPA focusing excessively on weaknesses and limitations of epidemiology in general; improperly dividing the epidemiology studies into two groups to justify a specious finding that results were "contradictory," and unwillingness to accord the meta-analyses sufficient weight (SAP 2017, p. 46).

Animal studies

EPA OPP employed excessively stringent criteria to rule out rodent tumors as not being treatment-related, far in excess of the criteria delineated in the Guidelines. In fact, OPP invented interpretive rules out of whole cloth to enable dismissal of tumors, rules that find no support in either the Guidelines or any other standard toxicological assessment schemes.

In interpreting rodent tumor data, EPA generally only looked for statistically significant differences in the incidence of tumors in treatment (especially high-dose) groups vs. control group (in so-called "pairwise" comparisons), and ignored statistically significant trends of increasing tumors with rising dose of glyphosate. As ORD notes, the Guidelines state that "[s]ignificance in either kind of test is sufficient to reject the hypothesis that chance accounts for the result" (EPA 12/14/15). The Ninth Circuit also addressed this point (*Rural Coalition vs. EPA*, pp. 27-28). Not only did EPA mostly ignore significant trends, in those instances when such a trend was recognized (among others), it was discounted on the grounds that tumor incidences did not rise with dosage in a perfectly monotonic pattern. Lack of monotonic dose-response played a role in EPA discounting four positive tumor response trends (SAP 2017, p. 50). The SAP strongly objected to this made-up rule, which is unsound scientifically and finds zero support in EPA's Guidelines (SAP 2017, pp. 50, 76). Still more indicative of OPP's bias, it deemed tumors as not treatment related even when they exhibited a significant trend and monotonic dose-response, as in two studies in CD-1 mice: malignant lymphomas in males, and hemangiomas in females (CFS 2016a, p. 24, re: Wood et al. 2009b and Sugimoto 1997).

The SAP also chastised OPP for utilizing historical control data in a biased manner only to discount tumors as not treatment-related, and never to support their linkage to glyphosate, thereby violating the Guidelines (SAP 2017, p. 76), as did the Ninth Circuit (*Rural Coalition vs. EPA*, pp. 25-27). In fact, the SAP describes two cases where OPP erroneously used historical control data to discount tumors when in fact these data clearly supported a treatment-related tumor response (SAP 2017, pp. 60-63). The SAP also found that OPP frequently ignored Guideline limitations on using historical control data only from the same lab in experiments conducted within a few years of the study in question (*Ibid*).

EPA's test guidelines for animal studies to assess carcinogenicity state that the high dose should elicit signs of toxicity without substantially altering the normal life span due to effects other than tumors, but need not exceed 1,000 mg/kg/day. EPA OPP distorted this directive by inventing the concept of a "limit dose." According to this new doctrine, tumors in animals receiving more than the "limit dose" of 1,000 mg/kg/day can be discounted. The SAP called out EPA OPP for this clear Guideline violation, noting that tumors in animals treated with amounts up to the maximum tolerated dose (MTD) deserve full consideration, even if greater than 1,000 mg/kg/day; and that the Guidelines prescribe only a practical limit for the test compound of 5%

of the feed, which was not exceeded in any of the rodent studies at issue (SAP 2017, pp. 76-77). The SAP also pointed out that OPP did in fact indirectly concede that glyphosate doses exceeding the “limit dose” were responsible for tumors, that rodent doses as high as this could indicate a carcinogenic hazard to highly-exposed occupational workers, and finally that treatment-related tumors and preneoplastic lesions occurred in some studies at doses below the “limit dose” (Ibid., pp. 72-74).

EPA OPP does not seem to routinely violate its Guidelines. In supplemental comments to the EPA, CFS examined EPA OPP’s assessment of the carcinogenicity of two pesticides it deemed “likely carcinogenic to humans” – isoxaflutole and iprovalicarb (CFS 2016c). We found, first, that EPA followed Guideline data (e.g. tumor) interpretation rules much more closely than it did with glyphosate; and second, that had EPA taken that Guideline-compliant approach with glyphosate, the classification would have also been “likely carcinogenic.”

Carcinogenic hazard descriptor

OPP chose to designate glyphosate as “not likely to be carcinogenic” by invoking the Guidelines’ criterion that this descriptor can apply when there is “convincing evidence that carcinogenic effects are not likely below a defined dose range” (EPA 2005, pp. 2-57 to 2-58), which for OPP (but not the SAP) means below the “limit dose.” OPP then asserted that because the estimated maximum human exposure levels (discussed further below) are “well-below” the “limit dose” in rodents, any rodent tumors caused by glyphosate are irrelevant to human health, and hence glyphosate is best described as “not likely to be carcinogenic to humans” (EPA OPP 2017, pp. 142-143). This quasi-risk assessment is illegitimate (see next section), but as explained below is invalid even on its own terms.

As the Ninth Circuit so ably explains (*Rural Coalition vs. EPA*, pp. 28-30), this use of the “not likely” descriptor violates the Guidelines, which permit it to be applied only “when the mode of action is sufficiently understood to conclude that a key event in tumor development would not occur below a certain dose range,” in which case multiple descriptors – “likely” above and “not likely” below a specified dose – would be applied (EPA 2005, pp. 2-52, 2-58). However, OPP freely concedes it does not understand glyphosate’s mode of action, nor the reasons for the greater toxicity of glyphosate formulations, which OPP did not assess in this Issue Paper (EPA OPP 2017, pp. 144-146).

According to the Guidelines, “not likely to be carcinogenic to humans” applies only “when the available data are considered robust for deciding that there is no basis for human hazard concern” (EPA 2005, p. 2-57). OPP comes nowhere near refuting glyphosate’s carcinogenic potential, much less providing “robust data” in support. Its inability to come to any conclusion on NHL is alone sufficient to nix this descriptor; as for animal studies, OPP was constrained to repeatedly and blatantly violate its Guidelines to avoid acknowledging the clear evidence of treatment-related tumors in animals. The proper choice would have been “likely carcinogenic to humans,” as when “an agent demonstrat[es] a plausible (but not definitively causal) association between human exposure and cancer, in most cases with some supporting biological, experimental evidence, though not necessarily carcinogenicity data from animal experiments” (EPA 2005, p. 2-55), equivalent to IARC’s “probably carcinogenic to humans.”

OPP's crude "risk assessment"

OPP directly compares the 1,000 mg/kg/day and above that "some believe" cause tumors in rodents to its estimated upperbound human exposure of 7 mg/kg/day, and concludes there is no human health hazard because the latter is "well-below" the former (EPA OPP, pp. 142-143). Yet for adverse effects that occur only above a certain threshold, toxicologists apply uncertainty factors to animal endpoints to calculate human safety thresholds. The total uncertainty factor is normally 100x, to account for potentially greater sensitivity of human vs. rodent, and inter-individual variability in humans. And this 100x factor is applied not to the lowest dose that causes harm to the animal, but to the next-lower dose that does not elicit adverse effects (the no observed adverse effect level or NOAEL). OPP's "well-below" – directly comparing animal to human exposure levels – does not constitute a risk assessment, even if one assumes that glyphosate, whose mode of action is unknown, exerts its cancer-causing effects only above a certain threshold dose (EPA 2005, pp. 3-23 to 3-24).

Carcinogenicity often follows a non-threshold model, and is normally assumed to do so if the mode of action is unknown, as is the case here with glyphosate. OPP's quasi-risk assessment does not address this scenario at all. The Guidelines prescribe low dose, linear extrapolation from an animal study chosen as the point of departure, yielding a cancer slope factor that represents a quantitative estimate of risk for any given exposure level (EPA 2005, p. 3-23).

In short, OPP tried to have it both ways, implicitly admitting treatment-related tumors above a "limit dose," but then officially denying them in all 14 rodent studies. The result was this quasi-risk assessment that doesn't begin to meet the standards established in the Guidelines. The proper procedure would have been low-dose linear extrapolation, as conducted by OEHHA and discussed below.

Risks of Cancer in Light of OEHHA's No Significant Risk Level

OEHHA has established a No Significant Risk Level of 1100 ug/day for glyphosate, the threshold estimated to result in 1 excess case of cancer among 100,000 exposed persons. The associated human cancer slope factor is 6.2×10^{-4} mg/kg/day (OEHHA 2017).

We do not have good empirical estimates of dietary, residential or occupational exposure to glyphosate. EPA relies upon residue testing by USDA's Pesticide Data Program (PDP) for refined estimates of dietary exposure to pesticides. But unfortunately, PDP has only tested for glyphosate residues on a single commodity (soybeans) in a single year (2010) – obviously insufficient for estimating dietary exposure given the hundreds of crops for which glyphosate is registered, and the hundreds commodities with glyphosate tolerances and hence potential residues. Likewise, EPA does not have any empirical data in its toxicology database on the predominant dermal component of occupational exposure to glyphosate, either active ingredient alone or as part of various formulations (EPA 12/12/17, p. 12: "A dermal absorption study is not available in the toxicity database").

In the absence of empirical data, we must rely on EPA estimates of maximum exposure to glyphosate: unrefined dietary exposure estimates for different subpopulations (see EPA

11/30/17), and the figures for upperbound aggregate (residential + dietary) and occupational exposures cited above, 0.47 mg/kg/day and 7 mg/kg/day, respectively (EPA OPP 2017, p. 143).

As shown in the Dietary Exposure table below, with a cancer slope factor of 6.2×10^{-4} mg/kg/day, one would expect 56 excess cancers per million people exposed to glyphosate in the diet at the upperbound level of 0.089771 mg/kg/day glyphosate over a lifetime. Exposure is up to 2.5x higher for children, and decreases after the age of two.⁵ While actual dietary exposure to glyphosate will likely be lower than these unrefined estimates suggest, as noted above we have virtually no representative, statistically robust glyphosate residue data upon which empirical dietary exposure estimates could be based.

Cancer Risk with Maximum Dietary Exposures				
Subpopulation	Exposure (mg/kg/day)	Cancer Slope Factor	Excess Cancers per 100,000 Exposed	Excess Cancers per 1 Million Exposed
General U.S. Population	0.089771	0.00062	5.6	56
All Infants (< 1 yr old)	0.138338	0.00062	8.6	86
Children 1-2 yrs old	0.228379	0.00062	14.2	142
Children 3-5 yrs old	0.212036	0.00062	13.1	131
Children 6-12 yrs old	0.147749	0.00062	9.2	92
Youth 13-19 yrs old	0.088362	0.00062	5.5	55
Adults 20-49 yrs old	0.07465	0.00062	4.6	46
Adults 50-99 yrs old	0.061258	0.00062	3.8	38
Females 13-49 yrs old	0.069318	0.00062	4.3	43
Cancer Risk with Maximum Aggregate (Dietary + Residential) Exposure				
Children 1-2 yrs old	0.47	0.00062	29.1	291

The upperbound aggregate (residential + dietary) exposure of 0.47 mg/kg/day yields an estimate of 291 excess cancers per 1 million exposed. This is likely an overestimate, since while the dietary component represents everyday exposure, the residential exposure would most often not be experienced on an everyday basis, but rather represents maximum estimated absorption of glyphosate by a toddler playing on glyphosate-treated turf, from both dermal contact and hand-to-mouth activity (EPA OPP 2017, Appendix E, pp. 200-201).

⁵ It is hard to interpret the excess cancer estimates for younger age groups, since as noted their exposure levels are far higher than for the U.S. population as a whole, but fall considerably over time, and cancer most commonly emerges later in life after decades of exposure. On the other hand, if early-life exposures do cause cancerous changes (and one might expect them to be more likely or frequent at these higher exposure levels), their responsibility for causing cancer would in most cases be masked by latency periods of decades that are common with many cancers, including NHL.

Cancer Risk with Maximum Occupational Exposure					
Days of Use per Year	Maximum Exposure (mg/kg/day)	Max. Exposure Adjusted to Annual (mg/kg/day)	Cancer Slope Factor	Excess Cancers per 100,000	Excess Cancers per 1 million
7	7	0.13425	0.00062	8.3	83
14	7	0.26849	0.00062	16.6	166
30	7	0.57534	0.00062	35.7	357
60	7	1.15068	0.00062	71.3	713
90	7	1.72603	0.00062	107.0	1070

As is frequently the case with pesticides, workers who mix, spray and apply them take in considerably greater quantities than non-users. EPA’s estimate of maximum occupational exposure of 7 mg/kg/day is the amount of glyphosate absorbed (primarily via the dermal route) by workers who mix glyphosate concentrate and load it into an airplane’s holding tank for aerial application to high acreage crops at the maximum application rate (EPA OPP 2017, p. 18). This value is based primarily on data developed by a consortium of pesticide companies, the Agricultural Handler Exposure Task Force (AHETF), to assess occupational exposure to pesticides generically in hundreds of different scenarios (Ibid., p. 18, ft. 8:

<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data>).

While consumers are exposed to glyphosate every day of the year in food, workers do not handle glyphosate throughout the year, but only for parts of the year (primarily spring and summer, though also sometimes in the fall for desiccant applications). Commercial pesticide applicators serving many area farms might well spray a widely used herbicide like glyphosate every day or quite frequently for weeks or months. In the table above, we have calculated the annual exposure and excess cancer risk of mixers/loaders in the scenario described above based on how many days per year they handle glyphosate. Workers who mix/load glyphosate just 7 days in a year experience an excess cancer risk of 8.3 cases per 100,000 exposed, increasing to over 100 additional cases per 100,000 exposed for those who undertake this mixing/loading operation 90 days per year. The latter estimate is 1 additional cancer per 1,000 exposed, an extraordinarily high cancer risk by any measure.

Proposition 65 Glyphosate Warning in View of Vacated Human Health Assessment

Despite EPA OPP’s conclusion that glyphosate is “not likely” to be carcinogenic, it carved out an exemption for non-Hodgkin lymphoma, stating that “a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data” (EPA OPP 2017, p. 68). The Ninth Circuit cited this internal contradiction as one important ground for vacating OPP’s human health assessment. This exclusion of NHL from EPA’s overall cancer conclusion alone would seem to justify the highlighted portion of a

sentence in an earlier iteration of the warning: “Other authorities, including US EPA, have determined that glyphosate is unlikely to cause cancer, ***or that the evidence is inconclusive.***”

Given that EPA OPP’s human health, including cancer, assessment has been vacated by the Ninth Circuit’s June 17th decision, that “inconclusive” language above is even more justified. EPA now must go back to the drawing board and redo its human health risk assessment to avoid internal inconsistencies and support it with substantial evidence that will pass judicial review. EPA may well change its cancer conclusion in the revised assessment, so not only is the “inconclusive” language justified, OEHHA should also consider changing the following passage of the current warning: “US EPA has determined that glyphosate is not likely to be carcinogenic to humans...” As of now, EPA has not made that determination, and until it completes its court-ordered revisions, we do not know what conclusion EPA will make.

Regards,

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