

**Center for Environmental Health • Environmental Working Group • Natural Resources Defense Council • California Alliance of Nurses for Healthy Environments • Environmental Law Foundation • Clean Water Action • San Francisco Bay Physicians for Social Responsibility • Clean and Healthy New York • Breast Cancer Prevention Partners • As You Sow • Families Advocating for Chemical and Toxics Safety (FACTS) • Friends of the Earth • Center for Food Safety • Earthjustice • Women’s Voices for the Earth • Environmental Health Coalition • California Healthy Nail Salon Collaborative • Californians for Pesticide Reform • East Yard Communities for Environmental Justice • Just Transition Alliance**

These comments are submitted on behalf of the above-listed organizations, which include health practitioners, labor groups, environmental and environmental health advocates, environmental justice organizations, and consumer and shareholder advocacy groups.

We oppose California’s Office of Environmental Health Hazard Assessment (OEHHA) proposed amendments to warnings for exposure to glyphosate from consumer products.<sup>1</sup>

Glyphosate was listed under Proposition 65 in 2017, following the findings of the World Health Organization’s International Agency for Research on Cancer (IARC). The proposed rulemaking recommends changes to the safe harbor Proposition 65 warning language based on the different conclusions reached by authoritative health agencies regarding the carcinogenicity of glyphosate—specifically, IARC’s finding that glyphosate is “probably carcinogenic to humans,”<sup>2</sup> and the U.S. Environmental Protection Agency’s (EPA) finding that the chemical is “not likely to be carcinogenic to humans.”<sup>3</sup>

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<sup>1</sup> See OEHHA, Initial Statement of Reasons: Proposed Amendments to Article 6, Clear and Reasonable Warnings—Warnings for Exposures to Glyphosate from Consumer Products (July 23, 2021), <https://oehha.ca.gov/media/downloads/crnrr/glyphosateisor071921.pdf> [hereafter “OEHHA, Initial Statement of Reasons”].

<sup>2</sup> International Agency for Research on Cancer, Monograph on Glyphosate 78 (updated Aug. 11, 2016), <http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-10.pdf>.

<sup>3</sup> EPA, Glyphosate: Interim Registration Review Decision, Case Number 0178, at 10 (Jan. 22, 2020), <https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf>.

OEHHA's proposed language reads:

Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. Other authorities, including US EPA, have determined that glyphosate is unlikely to cause cancer, or that the evidence is inconclusive. A wide variety of factors affect your personal cancer risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to [www.P65Warnings.ca.gov/glyphosate](http://www.P65Warnings.ca.gov/glyphosate).

OEHHA suggests that this new language presents "a balanced description of the likelihood that glyphosate can cause human cancer," despite the agency's acknowledgment in the Initial Statement of Reasons that "the lack of consensus in scientific opinions is not unusual in risk evaluation of chemicals."<sup>4</sup> Indeed, in enacting Proposition 65, California's voters rejected a consensus-based approach. Rather, a chemical "is known to the state to cause cancer" if it is listed under the relevant Labor Code provision or if "a body considered to be authoritative by [the state's] experts has formally identified it as causing cancer or reproductive toxicity." See Cal. Health & Safety Code § 25249.8(a)-(b) (emphasis added). IARC is one such expert body. Cal. Labor Code § 6382(b)(1); see also Cal. Code Regs. tit. 27, § 25306(m)(1).

The proposed amendments have major flaws and do not provide a "clear and reasonable" warning because:

- It inaccurately frames IARC's and EPA's findings as inconsistent, when in fact the two bodies reached conclusions based on different inquiries;
- It fails to note that other expert scientific bodies support IARC's finding, including the U.S. Agency for Toxic Substances and Disease Registry (ATSDR), a respected federal public health agency;
- OEHHA failed to consider alternative modifications to the warnings to note EPA's exposure analysis without undermining OEHHA's hazard-based listing; and
- It fails to articulate a principle for when differences of conclusions among scientific bodies should be noted.

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<sup>4</sup> OEHHA, Initial Statement of Reasons, at 6.

## **The proposal overlooks that EPA was engaged in a different inquiry than the hazard identification relevant to OEHHA's listing of glyphosate**

EPA's statement that glyphosate is "not likely to be carcinogenic" at the exposure levels EPA expects is not at odds with IARC's hazard identification of glyphosate as a carcinogen. The proposed amended warning language erroneously conflates two fundamentally different inquiries. IARC performed a hazard identification—the inquiry that Proposition 65 mandates—considering whether glyphosate exposure is causally linked to any health effects. EPA, by contrast, performed a risk assessment that considered carcinogenicity at low exposure levels.

In other words, EPA did not find that glyphosate is not carcinogenic to humans at sufficiently high exposures. The agency's analysis excluded findings of increased tumors and other negative health effects because they occurred at doses that EPA thought was unlikely to occur.<sup>5</sup> That finding is distinct from a Proposition 65 listing decision, which is a hazard identification that asks whether glyphosate is a human carcinogen. That identification—which IARC performed and ATSDR recently confirmed—precedes a risk assessment.

EPA's statement that glyphosate is "not likely to be carcinogenic" requires qualification and context, since EPA acknowledges "increased tumor incidences were observed in some of the animal carcinogenicity studies."<sup>6</sup> For further discussion of the differences between IARC's and EPA's analyses, the critical data gaps in EPA's methodology, and evidence of industry influence on EPA's findings, please see the attached amicus brief filed in a federal court of appeals case concerning glyphosate warnings.<sup>7</sup>

EPA's assessment of glyphosate's effects at low exposure levels does not conflict with IARC's hazard identification of glyphosate as a carcinogen. Rather, EPA was

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<sup>5</sup> EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential. Office of Pesticide Programs, at 136 (Dec. 12, 2017), [https://cfpub.epa.gov/si/si\\_public\\_file\\_download.cfm?p\\_download\\_id=534487](https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487).

<sup>6</sup> *Id.*

<sup>7</sup> Among the signatories of this comment letter are organizations that filed an amicus brief in support of the State of California in a pending First Amendment challenge to the glyphosate warning. See Amicus Brief of Natural Resources Defense Council, et al., Urging Reversal in Support of Defendants-Appellants, *Bonta v. Nat'l Ass'n of Wheat Growers*, No. 20-16758 (9th Cir. filed Feb. 19, 2021).

responding to a different question. OEHHA's proposed warning language is inaccurate because it does not reflect this fundamental distinction.

### **Other scientific analyses support IARC's hazard finding**

OEHHA's proposed amendment is incomplete and risks misleading or confusing consumers because it highlights EPA's "not likely" finding while omitting reference to expert agencies whose conclusions bolster IARC's, including the U.S. Agency for Toxic Substances and Disease Registry's final toxicological profile for glyphosate. The comprehensive report, issued last year, notes the link between glyphosate exposure and blood cancers like non-Hodgkin's lymphoma. ATSDR explained that "[t]he meta-analyses reported positive associations between glyphosate use and selected lymphohematopoietic cancers." The agency also highlighted "[n]umerous studies reported risk ratios greater than 1 for associations between glyphosate exposure and risk of non-Hodgkin's lymphoma or multiple myeloma..."<sup>8</sup>

Papers published in the peer-reviewed literature after 2015 also reinforce IARC's findings.<sup>9</sup> The results of these studies include additional epidemiological evidence and meta-analyses that find a significant association between occupational exposure to glyphosate and increased risk of lymphoma,<sup>10</sup> including non-Hodgkin's lymphoma,<sup>11</sup>

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<sup>8</sup> ATSDR, Toxicological Profile for Glyphosate 6 (Aug. 2020), <https://www.atsdr.cdc.gov/ToxProfiles/tp214.pdf>.

<sup>9</sup> Dennis D. Weisenburger, A Review and Update with Perspective of Evidence that the Herbicide Glyphosate (Roundup) is a Cause of Non-Hodgkin Lymphoma, *Clinical Lymphoma, Myeloma and Leukemia* vol. 21, issue 9 (Sept. 2021), <https://www.sciencedirect.com/science/article/pii/S2152265021001518>.

<sup>10</sup> Federico Meloni, et al., Occupational exposure to glyphosate and risk of lymphoma: results of an Italian multicenter case-control study, *Envtl. Health* (Apr. 28, 2021), <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-021-00729-8>.

<sup>11</sup> Geoffrey C. Kabat, et al., On recent meta-analyses of exposure to glyphosate and risk of non-Hodgkin's lymphoma in humans, *Cancer Causes Control* (Apr. 2021), <https://pubmed.ncbi.nlm.nih.gov/33447891/>.

development of lymphoma and other cancers in animals exposed to glyphosate,<sup>12</sup> and evidence of DNA damage and cytotoxicity to human cells by glyphosate and glyphosate based herbicides.<sup>13</sup> And lawsuits across the country have presented such evidence of glyphosate's deleterious health effects, in cases brought by groundskeepers and farmers who contracted non-Hodgkin's lymphoma or other related cancers after exposure to glyphosate-containing weedkillers.<sup>14</sup>

Notably, OEHHA's Initial Statement of Reasons includes some of this critical data and scientific evidence.<sup>15</sup> The record before OEHHA does not support the agency's proposed changes to the warning language.

### **The language can be modified to address EPA's narrow exposure inquiry without undermining OEHHA's listing based on hazard**

Any modification to glyphosate warning language should present clear and reasonable information to the consumer, without undermining the warning or providing inaccurate information, while directing consumers to more information. OEHHA failed to consider alternative language that meet these objectives. One such alternative would be:

Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. For more information on exposures of concern, see [links to state website, including content about No Significant Risk Level].

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<sup>12</sup> Christopher J. Portier, A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies, *Envtl. Health* (Feb. 12, 2020), <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-020-00574-1>.

<sup>13</sup> Francesca Truzzi, et al., Comparative Evaluation of the Cytotoxicity of Glyphosate-Based Herbicides and Glycine in L929 and Caco2 Cells, *Frontiers in Public Health* (May 2021), <https://www.frontiersin.org/articles/10.3389/fpubh.2021.643898/full>.

<sup>14</sup> See Patricia Cohen, Roundup Maker to Pay \$10 Billion to Settle Cancer Suits, *N.Y. Times*, June 24, 2020 (summarizing 2018 jury award of \$289 million to a school groundskeeper "after concluding that glyphosate caused his cancer"), <https://www.nytimes.com/2020/06/24/business/roundup-settlementlawsuits.html>.

<sup>15</sup> OEHHA, Initial Statement of Reasons, at 9-11.

To the extent that a Proposition 65 warning should account for EPA's exposure analysis, that concern is already addressed by the No Significant Risk Level established by OEHHA in 2018—any exposures below that level would not require a warning under Proposition 65.

**The proposal sets a dangerous precedent for noting differences of views without clear principles for when or how such differences should be noted**

The proposed amendments that note a lack of unanimity in agency views have not previously been considered for any other chemical listed under California's Proposition 65. Doing so here would set a dangerous precedent. The proposal presents no limiting principle for noting disagreement among scientific bodies. Would a determination by a city health agency trigger a similar notice, or a determination by a different state agency or another country's health agency? What criteria have to be met before a contrasting view is noted? When should a supporting decision by a respected expert body also be noted—for example, here, ATSDR? OEHHA's proposal notes that it is unusual for several agencies to disagree with IARC, but how many agencies, and which ones, have to disagree, and to what extent, before additional language is added?

Proposition 65 does not require consensus in the scientific record. Here, IARC, a scientific body the state considers authoritative, has found that glyphosate is "probably carcinogenic to humans" based on a robust synthesis of publicly available information, including published reports, peer-reviewed studies, and government data. This finding is reinforced by ATSDR's report, as well as numerous peer-reviewed studies.

We urge OEHHA not to adopt the proposed language because it is inaccurate, unclear, does not provide clear and reasonable information to consumers to aid their decision making, and does not articulate clear principles for the inclusion of additional information.

Thank you for your consideration of these comments.

Sincerely,

Center for Environmental Health

Environmental Working Group

Natural Resources Defense Council

California Alliance of Nurses for Healthy Environments

Environmental Law Foundation

Clean Water Action

San Francisco Bay Physicians for Social Responsibility

Clean and Healthy New York

Breast Cancer Prevention Partners

As You Sow

Families Advocating for Chemical and Toxics Safety (FACTS)

Friends of the Earth

Center for Food Safety

Earthjustice, Women's Voices for the Earth

Environmental Health Coalition

California Healthy Nail Salon Collaborative

Californians for Pesticide Reform

East Yard Communities for Environmental Justice

Just Transition Alliance

*Submitted October 7, 2021*