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Submitted electronically via https://oehha.ca.gov/comments

RE: CropLife America and RISE Comments in Opposition to the California Environmental Protection Agency on Proposed Amendments to Article 6 Clear and Reasonable Warnings, New Sections 25607.48 and 25607.49 Warnings for Exposures to Glyphosate from Consumer Products

Dear Ms. Vela:

CropLife America and RISE (Responsible Industry for a Sound Environment) appreciate the opportunity to provide these comments to the Office of Environmental Health Hazard Assessment (OEHHA or the Agency) in response to the proposed rulemaking that would add Sections 25607.48 and 25607.49, relating to warnings for exposures to glyphosate from consumer products, to the Title 27, Article 6 Clear and Reasonable Warnings regulations (the Proposed Amendments).

Under the Proposed Amendments—specifically the new Section 25607.49—OEHHA would require consumer products containing glyphosate to include the following warning on its label:

> **CALIFORNIA PROPOSITION 65 WARNING.** 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 USEPA, 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.[1]

As outlined more fully below, CropLife America and RISE oppose the Proposed Amendments.

- *First*, the proposed warning violates the First Amendment and is at odds with both the weight of scientific authority and the decision of the U.S. District Court for the Eastern District of California in *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (E.D. Cal. 2020).

- *Second*, federal law preempts OEHHA's proposed rulemaking. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) expressly preempts state-law labeling requirements that are "in addition to or different from" those imposed by EPA. 7 U.S.C. § 136v(b). EPA has concluded that glyphosate is not likely be carcinogenic in humans and that a cancer warning is not appropriate on the FIFRA label for glyphosate. In fact, EPA has already informed glyphosate registrants that a Proposition 65 cancer warning would be false and misleading, and in violation of FIFRA. The warning in the Proposed Amendments is in addition to and different from the label requirements imposed by EPA under FIFRA and is, therefore, preempted.

- *Finally*, rather than impose unlawful and unconstitutional labeling requirements on glyphosate products, OEHHA should adopt a regulation for glyphosate-based herbicides that parallels the longstanding regulation for prescription drugs. This solution would provide far more useful information to consumers and adequately ensure the safe use of glyphosate-based products.

I. BACKGROUND ON CROPLIFE AMERICA AND RISE

Established in 1933, CropLife America is a national, private, not-for-profit trade association representing companies that develop and sell crop protection products for agriculture and pest management in the United States. Established in 1991, RISE is a national trade association representing manufacturers, formulators, distributors and other industry leaders involved with the specialty pesticide and fertilizer products used by professionals and consumers. CropLife America and RISE's member companies produce most of the crop protection and pest management products regulated by the U.S. Environmental Protection Agency (EPA) under FIFRA and by the California Department of Pesticide Regulation under state law. CropLife America and RISE represent its members' interests by, among other things, monitoring and participating in state and federal agency actions and related litigation of concern to the crop protection and pest control industries.

[1] The draft Section 25607.49(b) makes a small concession to the comprehensive federal regulation of pesticide labeling, noting that if the label is regulated by EPA under FIFRA "the word 'ATTENTION' or 'NOTICE' in capital letters and bold type may be substituted for the words 'CALIFORNIA PROPOSITION 65 WARNING."

CropLife America and RISE have extensive experience with the regulatory processes, scientific assessments, and requirements under FIFRA that govern pesticide product approvals and can offer a unique perspective on the interaction of the federal regulatory framework with California's state framework. Moreover, CropLife America and RISE's member companies have submitted voluminous scientific data, comments, and analyses to support EPA's finding that glyphosate-based herbicides and their approved uses are safe, consistent with FIFRA's legal criteria for pesticide registration.

CropLife America is also a plaintiff in *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (E.D. Cal. 2020), *appeal docketed*, No. 20-16758 (9th Cir.), in which the Eastern District of California held that adding California's Proposition 65 warning to glyphosate-based products would be false, misleading, and in violation of the First Amendment.

II. OEHHA'S PROPOSED AMENDMENTS TO ARTICLE 6 VIOLATE THE FIRST AMENDMENT TO THE CONSTITUTION AND RUN CONTRARY TO THE WEIGHT OF EVIDENCE

OEHHA's warning violates the First Amendment for the reasons explained in Judge Shubb's ruling in *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (E.D. Cal. 2020). There, Judge Shubb permanently enjoined California from imposing a Proposition 65 warning on glyphosate products. Because Judge Shubb found that the Proposition 65 warning was neither "purely factual" nor "uncontroversial," he applied intermediate scrutiny and determined that "misleading statements about glyphosate's carcinogenicity" did not directly advance the state's interest in informing the public about exposures to chemicals that cause cancer. *Id.* at 1258–59, 1264. Because "California has options available to inform consumers of its determination that glyphosate is a carcinogen, without burdening the free speech of businesses," the court found that requiring glyphosate products to carry the Proposition 65 warning violated the First Amendment. *Id.* at 1264–65; *see also id.* at 1259 ("This court has previously found that the Proposition 65 warning requirement for glyphosate was false and misleading given the weight of authority showing that glyphosate was not known to cause cancer and did not cause cancer."). The court ruled that "the State of California may not skew the public debate by forcing companies to adopt the state's determination that glyphosate is a carcinogen, relying solely on the IARC's determination, when the great weight of evidence indicates that glyphosate is not known to cause cancer." *Id.* at 1260.

Importantly for the Proposed Amendments at issue here, Judge Shubb rejected as unconstitutional three alternative warnings proposed by California that bear remarkable similarity to OEHHA's proposed Section 25607.49.[2] Each of those alternative warnings was defective

[2] For example, the court denied California's alternative warning that stated:

> WARNING: This product can expose you to glyphosate, a chemical listed as causing cancer pursuant to the requirements of California law. The listing is based on a determination by the United Nations International Agency for Research on Cancer that glyphosate presents a cancer hazard. The U.S. Environmental Protection Agency has tentatively concluded in a

because each misleadingly "convey[ed] the message that there is equal weight for and against the authority that glyphosate causes cancer, when the weight of evidence is that glyphosate does not cause cancer." *Id.* at 1263.[3]

Given Judge Shubb's finding that "the great weight of evidence indicates that glyphosate is not known to cause cancer," *id.* at 1260, the proposed Section 25607.49 would *also* be misleading and contrary to the First Amendment because it falsely suggests that there is equal weight of authority for and against the proposition that glyphosate causes cancer. In reality, there is nothing even close to an equal weight of authority. Rather, the overwhelming scientific consensus from expert regulators worldwide is that glyphosate is not likely to be a human carcinogen. OEHHA therefore presents a misleading statement of the science in its "statement of reasons," and the proposed warning is not supported by the record.

Most of OEHHA's assertions about glyphosate's purported carcinogenicity rely on refuted evidence and arguments. For example, OEHHA's "Initial Statement of Reasons," recounts that certain panelists on the FIFRA Scientific Advisory Panel (FIFRA SAP)—which EPA convened in 2016 to assess glyphosate carcinogenicity—suggested that EPA's evaluation departed in some respects from the 2005 Guidelines for Carcinogen Risk Assessment when evaluating statistical analyses of tumor incidence in laboratory rodents. *See* Initial Statement of Reasons at 9–10. But OEHHA fails to acknowledge that EPA provided a reasoned justification of how its data evaluation complied with the 2005 Guidelines, including its reasoned basis for adopting a holistic presentation, its justification for using a weight-of-evidence approach that included both trend and pairwise analyses, and a discussion of each rodent tumor type. *See* EPA, *Response to the Final Report of the FIFRA SAP on the Evaluation of the Human Carcinogenic Potential of Glyphosate* 6–9, EPA-HQ-OPP-2009-0361-0072 (Dec. 12, 2017), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0072 ("EPA Response to FIFRA SAP"). EPA also updated its approach to historic control data in response to the SAP comments. *Id.* at 8. OEHHA's observation also mischaracterizes the facts. EPA has been transparent that SAP panelists did not achieve consensus about how to properly interpret tumor

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> draft document that glyphosate does not present a cancer hazard. For more information go to www.P65warnings.ca.gov.

Id. at 1262–63. And it denied another alternative warning that stated:

> WARNING: This product can expose you to glyphosate. The State of California has determined that glyphosate is known to cause cancer under Proposition 65 because the International Agency for Research on Cancer has classified it as a carcinogen, concluding that there is sufficient evidence of carcinogenicity from studies in experimental animals and limited evidence in humans, and that it is probably carcinogenic to humans. The EPA has concluded that glyphosate is not likely to be carcinogenic to humans. For more information about glyphosate and Proposition 65, see www.P65warnings.ca.gov.

Id. at 1263.

[3] Judge Shubb had previously rejected two alternative warnings on California's motion for reconsideration for the same reason. *Id.* 1253 (rejecting alternative warnings that "suggested that there was equal or more weight for the proposition that glyphosate caused cancer than for the proposition that it did not").

responses in rodent bioassays: some panelists believed sufficient data existed to conclude glyphosate is a rodent carcinogen, while others strongly disagreed and found "no reliable and consistent evidence that glyphosate induces or promotes tumors in laboratory rodents." FIFRA Scientific Advisory Panel, *Meeting Minutes and Final Report: EPA's Evaluation of the Carcinogenic Potential of Glyphosate*, No. 2017-01 (Mar. 16., 2017), https://www.epa.gov/sites/default/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf ("FIFRA SAP Report"); *see also* EPA Response to FIFRA SAP at 7–8. But *not one* of the panelists believed glyphosate should be classified as "likely to be carcinogenic to humans" or "carcinogenic to humans." EPA Response to FIFRA SAP at 11.

Finally, OEHHA relies on "multi-million dollar verdicts" "based on the allegation that exposures to glyphosate caused individuals' non-Hodgkin lymphoma." Initial Statement of Reasons at 11. Respectfully, lay jury verdicts based on limited expert testimony do not have the same weight as the consistent contrary determinations of national and international expert regulators, based on their analysis and review of the available scientific evidence.

In contrast to those lay juries, the scientists at EPA have studied glyphosate for decades and have repeatedly reached the same conclusion: Glyphosate is *not* likely to be carcinogenic to humans. EPA has thus consistently classified glyphosate in its lowest risk category since 1991, spanning the past six presidential administrations.[4] More recently—

- In its 2020 interim registration review decision, EPA "thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." EPA, *Glyphosate: Interim Registration Review Decision* 10, EPA-HQ-OPP-2009-0361 (Jan. 22, 2020), https://www.epa.gov/sites/default/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf.

- In its 2019 proposed interim registration review decision, "EPA conducted an independent evaluation of the carcinogenic potential of glyphosate and has determined that glyphosate is 'not likely to be carcinogenic to humans' . . . based on a thorough weight-of-evidence review of all relevant data and is in accordance with the agency's 2005 *Guidelines for Carcinogen Risk Assessment*." EPA, *Glyphosate: Proposed Interim Registration Review Decision* 7, EPA-HQ-OPP-2009-0361-2344 (Apr. 23, 2019), https://downloads.regulations.gov/EPA-HQ-OPP-2009-0361-2344/content.pdf ("2019 Proposed Interim Decision").

[4] *See* Br. for the U.S. Envtl. Prot. Agency at 17, *Nat. Resources Def. Council v. U.S. Envtl. Prot. Agency*, Nos. 20-70787, 20-70801 (9th Cir. filed May 18, 2021), Dkt. 80-1 (summarizing EPA's conclusion following the Biden Administration's review under Executive Order 13990) ("EPA reasonably concluded that glyphosate is not likely to be a human carcinogen and that it does not pose human-health risks of concern. . . . This conclusion is the result of a decade of analysis, review by a scientific advisory panel, revisions in light of that review, and EPA's expert judgment on how the evidence should be weighed. None of the scientific advisory panel believed that glyphosate should be categorized as a likely human carcinogen.").

- In 2017, EPA reviewed an "extensive database . . . evaluating the carcinogenic potential of glyphosate, including 63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies for the active ingredient glyphosate" and concluded that the "available data at this time do no support a carcinogenic process for glyphosate." EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 144, Off. of Pesticide Programs (Dec. 12, 2017), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487&Lab=OPP; *see also id.* at 143 ("Overall, there is not strong support for the 'suggestive evidence of carcinogenic potential' cancer classification descriptor.").

- In another 2017 analysis, EPA "reevaluated the human carcinogenic potential of glyphosate, which included a weight-of-evidence evaluation of data from animal toxicity, genotoxicity, and epidemiological studies," "presented [it] to the Federal Insecticide, Fungicide, and Rodenticide Scientific Advisory Panel (FIFRA SAP)," "updated [it] based on their review," and "concluded that glyphosate should be classified as 'not likely to be carcinogenic to humans." EPA, *Glyphosate: Draft Human Health Risk Assessment*, EPA-HQ-OPP-2009-0361-0068 (Dec. 12, 2017), https://downloads.regulations.gov/EPA-HQ-OPP-2009-0361-0068/content.pdf.

In reaching these conclusions, EPA reviewed thousands of studies, including human epidemiology studies, animal carcinogenicity studies, and experimental data.[5]

Practically every other national and international regulatory agency—including regulators for the European Union, Canada, Germany, Australia, Japan, and New Zealand—has reached the same conclusion:

- "The AGG proposes that classification of glyphosate as for germ cell mutagenicity genotoxic or mutagenic is not justified." Assessment Group on Glyphosate (AGG),

[5] *See, e.g.*, EPA, *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* 3–5 (Apr. 23, 2018) https://www.epa.gov/sites/default/files/2019-04/documents/hed-rtc-signed.pdf (describing EPA's process of considering toxicological studies); EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, Off. of Pesticide Programs 34–43, 47–52, 60–62, 83–84, 91–92, 101–05, 107, 111–13, 117–21, 125–28, 187–89, 192–98, 203–215 (Dec. 12, 2017), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487&Lab=OPP (providing references to or summaries of studies that EPA considered and analyzed); *id.* at 13 (incorporating FIFRA SAP findings and data from the Agricultural Health Study, Gabriella Andreotti et al., *Glyphosate Use and Cancer Incidence in the Agricultural Health Study*, 110 J. Nat'l Cancer Inst. 509 (2017)); EPA, *Glyphosate – Systematic Review of Open Literature* (Dec. 12, 2017), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0067 (providing EPA's assessment of open literature toxicity studies of glyphosate and glyphosate formulations); EPA, *Summary Reviews from 2016 Epidemiology Literature Review for Glyphosate* (Sept. 7, 2016), https://www.regulations.gov/document/EPA-HQ-OPP-2016-0385-0467 (EPA evaluation of glyphosate cancer epidemiology studies published as of September 2016); EPA, *Updated Statistics Performed on Animal Carcinogenicity Study Date for Glyphosate* (Sept. 9, 2016), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0075 (setting forth EPA statistical evaluation of animal cancer data adjusting for multiple comparisons); EPA, *Glyphosate. Study summaries for genotoxicity studies* (Sept. 13, 2016), https://www.regulations.gov/document/EPA-HQ-OPP-2016-0385-0098 (EPA review of glyphosate genotoxicity studies).

Procedure and outcome of the draft Renewal Assessment Report on glyphosate (June 15, 2021), https://ec.europa.eu/food/system/files/2021-06/pesticides_aas_agg_report_202106.pdf (France, Hungary, the Netherlands and Sweden as rapporteurs on behalf of the European Union).

- "[T]he available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction." European Chemicals Agency, *Glyphosate Not Classified as a Carcinogen by ECHA* (Mar. 15, 2017), https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa.

- Glyphosate is "unlikely to pose a carcinogenic hazard to humans." European Food Safety Authority, *Glyphosate: EFSA Updates Toxicological Profile* (Nov. 12, 2015), https://www.efsa.europa.eu/en/press/news/151112.

- "[G]lyphosate is unlikely to pose a carcinogenic risk to humans." Food & Agric. Org. of U.N. (FAO) & WHO, *Joint FAO/WHO Meeting on Pesticide Residues Summary Report* 2 (May 16, 2016), https://www.who.int/foodsafety/jmprsummary2016.pdf.

- "[T]he Federal Institute for Risk Assessment (BfR) was responsible for the human health risk assessment and has assessed glyphosate as non-carcinogenic. This was supported by competent national, European and other international institutions for health assessment." Fed. Inst. for Risk Assessment (BfR, Germany), BfR Comm'cn No. 007/2015, *Does Glyphosate Cause Cancer?* (rejecting carcinogenic conclusion for glyphosate), https://www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer.pdf.

- "Glyphosate is not genotoxic and is unlikely to pose a human cancer risk." Pest Mgmt. Regulatory Agency, Health Canada, RVD2017-01, *Re-evaluation Decision: Glyphosate* 1 (Apr. 28, 2017), https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2017/glyphosate-rvd-2017-01.html.

- "The scientific weight-of-evidence indicates that . . . exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans." Australian Pesticides & Veterinary Medicines Authority, Austl. Gov't, *Final Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate* 9 (Mar. 2017), https://apvma.gov.au/sites/default/files/publication/26561-glyphosate-final-regulatory-position-report-final_0.pdf.

- "The overall conclusion is that – based on a weight of evidence approach, taking into account the quality and reliability of the available data – glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification under HSNO as a carcinogen or mutagen." Dr. Wayne Temple, *Review of Evidence Relating to Glyphosate and Carcinogenicity* 16, New Zealand Envtl. Prot. Agency, (Aug. 2016), https://www.epa.govt.nz/assets/Uploads/Documents/Everyday-Environment/Publications/EPA-glyphosate-review.pdf.

- "The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of glyphosate (CAS No. 1071-83-6), an amino acid herbicide, based on results from various studies. . . . Glyphosate had no neurotoxicity, carcinogenicity, reproductive toxicity, teratogenicity, and genotoxicity." Food Safety Comm'n of Japan, *Risk Assessment Report: Pesticides: Glyphosate Summary* 93 (Sept. 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6989167/pdf/foodsafetyfscj-4-93.pdf.

EPA and other national and international regulators also reviewed the International Agency for Research on Cancer's (IARC) 2015 monograph addressing glyphosate, which OEHHA references in its proposed Section 25607.49. For example, EPA noted that its

> cancer evaluation is more robust than IARC's evaluation. IARC's evaluation only considers data that have been published or accepted for publication in the openly available scientific literature. As a result IARC only considered a subset of the studies included in the EPA's evaluation. For instance, IARC only considered 8 animal carcinogenicity studies while the agency used 15 acceptable carcinogenicity studies in its evaluation. The EPA also excluded some studies that were not appropriate for determining the human carcinogenic potential of glyphosate, such as studies in non-mammalian species (i.e., worms, fish, reptiles, and plants) which IARC used in its evaluation."

2019 Proposed Interim Decision at 7.

Other expert regulatory agencies issued similar responses to the IARC monograph:

- "Due to the assessment approach used, the assessment of IARC is not in line with the assessments of BfR, EFSA and the competent national, European and other international institutions including the WHO/FAO Joint Meeting on Pesticide Residues (JMPR). . . . Following a renewed review of its assessment of the health risk, the Federal Institute for Risk Assessment (BfR) came to the conclusion that, based on current knowledge, no carcinogenic risk to humans can be concluded if glyphosate is used in the proper manner and for the intended purpose." Fed. Inst. for Risk Assessment (BfR, Germany), BfR FAQ, *Frequently asked questions regarding the different assessments of the carcinogenic effect of glyphosate by BfR and IARC* at 1 (Dec. 11, 2015), https://www.bfr.bund.de/cm/349/frequently-asked-questions-regarding-the-different-assessment-of-the-carcinogenic-effect-of-glyphosate-by-bfr-and-iarc.pdf.

- "It is important to note that the IARC classification is a hazard classification and not a health risk assessment. This means that the level of human exposure, which determines the actual risk, was not taken into account by IARC. . . . Currently, no pesticide regulatory authority, including Health Canada, considers glyphosate to be a carcinogenic risk of concern to humans." Pest Mgmt. Regulatory Agency, Health Canada, RVD2017-01, *Re-evaluation Decision: Glyphosate* (Apr. 28, 2017), https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2017/glyphosate-rvd-2017-01.html.

Judge Shubb ruled that "the State of California may not skew the public debate by forcing companies to adopt the state's determination that glyphosate is a carcinogen, relying solely on the IARC's determination, when the great weight of evidence indicates that glyphosate is not known to cause cancer." *Nat'l Ass'n of Wheat Growers*, 468 F. Supp. 3d at 1260. Yet that is precisely what OEHHA attempts to do in the Proposed Amendments, which falsely suggest that IARC's determination creates a near-equal split of authority regarding glyphosate's purported carcinogenicity.[6]

III. FEDERAL LAW PREEMPTS OEHHA'S PROPOSED AMENDMENTS

FIFRA establishes a comprehensive statutory scheme that governs the use, sale, and labeling of pesticides. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 437 (2005). Under that statutory scheme and its implementing regulations, EPA evaluates human health risks and safety before registering any pesticide. EPA may not register a pesticide unless it first finds that, "when considered with any restrictions imposed" by EPA, the pesticide will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). FIFRA defines "unreasonable adverse effects on the environment" to include "*unreasonable risk to man*" and "*human dietary risk* from residues that result from a use of a pesticide in or on any food inconsistent with the standard under [the Federal Food, Drug, and Cosmetics Act (FFDCA)]." *Id.* § 136(bb) (emphasis added). EPA cannot make such a no-unreasonable-risk determination unless it concludes, among other things, that the information before the agency supports such a determination and that the proposed labeling and packaging complies with FIFRA's requirements. *Id.* § 152.112.

FIFRA expressly prohibits labeling and packaging that is "misbranded" or "false or misleading in any particular." 40 C.F.R. § 152.112(f); *see also* 7 U.S.C. § 136(q)(1)(A). Accordingly, in registering a pesticide product, EPA must determine that the accompanying label provisions—including the "precautionary statements"—are not false or misleading. And EPA's approval of a label has substantive legal effect: it compels manufacturers to label and manufacture their products in a particular fashion, *see* 7 U.S.C. § 136j(a); compels distributors and retailers to comply with the label's terms, including by restricting how and for what uses the product can be sold, *see id.*; and compels many hundreds of thousands of users to apply the pesticide only in the manners permitted by the pesticide's label terms, *see* § 136j(a)(2). Any violation of the label by any of those entities can result in criminal and civil penalties. *See* § 136l(a)–(b).

When reviewing a proposed pesticide label, EPA exercises its expert judgment on risks to the health and safety of applicators and others, and on other scientific issues. 40 C.F.R. § 152.112. Based on those expert technical judgments, EPA-approved label provisions relevant to health and safety must include appropriate "human hazard and precautionary statements" warning about

[6] Against this avalanche of evidence and the tens of thousands of studies reviewed by EPA, OEHHA cites just *three* studies that have been published since EPA's evaluation in support of OEHHA's Proposed Amendments. Initial Statement of Reasons 10–11. But OEHHA offers no explanation why these studies are contrary to EPA's risk assessment of the voluminous scientific record before it. And two of these studies are authored by paid, plaintiff-side expert witnesses in glyphosate tort litigation—Dennis Weisenburger and Christopher Portier.

potential health risks and mitigation actions. *Id*. § 156.60–156.70.[7] Crucially for the Proposed Amendments, ***once a pesticide is registered, the registrant is prohibited from adding a new "health hazard" to the "precautionary statement" of the label or changing the formulation of the pesticide without first obtaining EPA's approval***. *See* 40 C.F.R. §§ 152.44, 152.46 (permitting only "certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment" to be made without EPA's prior approval); EPA, *Notifications, Non-Notifications and Minor Formulation Amendments* 8, PR Notice 98-10 (Oct. 22, 1998), https://www.epa.gov/sites/default/files/2014-04/documents/pr98-10.pdf ("PR Notice 98-10") (listing the registration amendments that may be accomplished by notification and excluding changes in warnings and "precautionary statements").

FIFRA also specifically delineates—and limits—the role of the states in pesticide regulation. In Section 136v, titled "Authority of States," FIFRA defines the respective roles of the federal and state governments in setting standards for labeling and other aspects of pesticide sale and use. States may regulate pesticide sale and use "only if and to the extent the regulation does not permit any sale or use prohibited by [FIFRA]." 7 U.S.C. § 136v(a). To ensure nationwide "uniformity" in labeling, moreover, FIFRA expressly prohibits states from "impos[ing] . . . any requirements for labeling or packaging in addition to or different from those required under [FIFRA]." *Id.* § 136v(b); *Bates*, 544 U.S. at 438. In *Bates*, the Supreme Court agreed with the United States' position that state common-law requirements "for labeling or packing" that impose duties "in addition to or different from those required" under FIFRA are preempted by FIFRA's express preemption "uniformity" provision. 544 U.S. at 438, 444. Thus, the comprehensive statutory and regulatory scheme established in FIFRA defines what the uniform nationwide label must include, and thus provides substantive content to FIFRA's "uniformity" preemption clause in 7 U.S.C. § 136v(b).

As a result of these principles, OEHHA cannot mandate (and glyphosate registrants cannot add) the proposed cancer warning without having first obtained EPA's approval for such a labeling change. But EPA has already considered and rejected a Proposition 65 warning. In August 2019, EPA issued a letter to all glyphosate registrants addressing this issue—and the agency definitively and categorically concluded that no such warning should be required, or even permitted, under FIFRA. EPA, Off. of Pesticide Programs, Letter to Glyphosate Registrants Regarding Labeling Requirements 1 (Aug. 7, 2019), https://www.epa.gov/sites/default/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf. In that letter, EPA noted its unequivocal disagreement with IARC's assessment, explaining that "EPA scientists have performed an independent evaluation of available data since the IARC classification to reexamine the carcinogenic potential of glyphosate and concluded that glyphosate is 'not likely to be carcinogenic to humans.'" *Id.* at 1. EPA further explained that because glyphosate is *not* carcinogenic, a cancer warning on glyphosate-based products would be "false and misleading" and glyphosate product labels bearing the cancer warning would be misbranded under FIFRA section 2(q)(1)(A). *See id.* Accordingly, EPA affirmed that it will *not* approve any labeling with a cancer warning, and it directed any labeling potentially containing such a statement to be changed. *See*

[7] Based upon EPA's assessment of risk, EPA mandates appropriate label requirements for applicator personal protective equipment, *id*. § 156.212; detailed application directions to protect human health and safety, *id*. § 156.10(i)(2); and designation for use by "general" or "certified applicators" based on possible health, safety or other risks, 7 U.S.C. § 136a(d); 40 C.F.R. § 156.10(j).

id. at 1–2. The warning in the Proposed Amendments is, therefore, in addition to and different from the label requirements imposed by EPA under FIFRA and is preempted by FIFRA.[8]

In an amicus brief filed with the Ninth Circuit, EPA reiterated its position that "[i]t is unlawful for manufacturers and sellers to make claims on their labels that differ from what EPA approves." Br. of the United States as Amicus Curiae in Support of Monsanto at 1, *Monsanto Co. v. Hardeman*, No. 19-16636 (9th Cir. filed Dec. 20, 2019), Dkt. 32. The United States emphasized that "proposed edits warn[ing] of a cancer risk that according to EPA's assessment, does not exist" would "constitute[] prohibited misbranding. *Id.* at 10. And EPA can approve "an application under FIFRA" to change a pesticide label "only where the Agency has determined that the product is not misbranded." *Id.* at 10–11 (alteration and internal quotation marks omitted).[9]

The proposed subsection 25607.49(b) does not alleviate the preemption issue. This subsection defers to EPA's binding determination as to whether a particular pesticide should carry a particular signal word, such as "DANGER," WARNING," or "CAUTION." *See* 40 C.F.R. § 156.64. But modification of the signal word does not change the underlying problem: OEHHA's proposed warning—regardless of whether that warning is couched as a "NOTICE"—would render glyphosate-based herbicides misbranded under FIFRA.

Because glyphosate registrants cannot add the cancer warning OEHHA's proposes in Section 25607.49 without EPA approval, and because EPA has unequivocally expressed its position that a cancer warning would render glyphosate products unlawfully misbranded under FIFRA, the Proposed Amendments are unlawful and preempted by federal law.

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[8] OEHHA suggests that "other tailored exposure warning methods," such as "additional warning signs" at the point of sale, can evade FIFRA preemption of different or additional state-law labeling requirements. *See* Initial Statement of Reasons at 8–9 & n.24 (citing *Chemical Specialties Manufacturers Association v. Allenby*, 958 F.2d 941 (9th Cir. 1992)). But that is not so. FIFRA defines labeling broadly to include "all other written, printed, or graphic matter [] accompanying the pesticide or device at any time." 7 U.S.C. § 136(p)(2). A point-of-sale sign, by its very nature, accompanies the pesticide at the time of distribution or sale—it would not serve its warning function if it did not accompany the pesticide. *Allenby* assumed it is "implausible that the EPA would prosecute a company for, in essence, complying with Proposition 65… [and] contradictory to assert that the EPA will prosecute a company for satisfying the standards developed by the EPA but deemed insufficient by the State of California." 958 F.2d at 947. But EPA has made clear in its August 7, 2019 letter that it would do precisely that.

[9] The Ninth Circuit ultimately held in *Hardeman* that FIFRA did not preempt the plaintiff's common-law failure-to-warn claims. *See Hardeman v. Monsanto Co.*, 997 F.3d 941, 954–60 (9th Cir. 2021), *petition for cert. filed*, No. 21-241 (U.S. Aug. 18, 2021). The Ninth Circuit erred because it misinterpreted FIFRA's provision specifying that "registration" of a pesticide shall not "be construed as a defense for the commission of any offense under this subchapter." 7 U.S.C. § 136a(f)(2). Subsection (f)(2) "has no bearing on the question" of whether Section 136v(b) preempts common-law failure-to-warn claims. *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994). No one is claiming that the mere registration of glyphosate products preempts such claims; it is EPA's requirement of labeling with no cancer warning that does so. The defendant in *Hardeman* has petitioned for certiorari to the U.S. Supreme Court to correct the Ninth Circuit's error.

IV. OEHHA SHOULD ADOPT A REGULATION FOR PESTICIDES THAT PARALLELS THE LONGSTANDING REGULATION FOR PRESCRIPTION DRUGS

Rather than adopt the Proposed Amendments, OEHHA should pursue pesticide regulation that parallels its longstanding approach to prescription-drug regulation. As explained in the previous section, there are complex issues of federal preemption involved in pesticide regulation. CropLife America and RISE appreciate OEHHA's efforts to begin addressing those issues by approving the use of the terms "ATTENTION" or "NOTICE" instead of "WARNING" in the proposed Section 25607.49(b). But other preemption issues remain because Proposition 65 provides many opportunities for conflict with federal law in light of the federal government's extensive regulation of pesticides.

For these reasons, OEHHA should take a similar approach to pesticides as it took with respect to another category of consumer products that are heavily regulated at the federal level: prescription drugs. In that realm, OEHHA's regulations provide a safe harbor that, "[f]or prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent comply with this subarticle." Cal. Code Regs. tit. 27, § 25607.7(a).

There are substantial similarities between pesticide regulation under FIFRA and prescription-drug regulation under the FFDCA. Among other similarities, both regulatory regimes require:

- **Pre-market approval of product safety.** Both federal regulatory regimes require manufacturers to register and obtain pre-approval for products before marketing them for sale and distribution. *Compare* 7 U.S.C. § 136a(a) ("Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter."), with 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug."). Unlike food, cosmetics, or other products, both pesticides and prescription drugs are subject to rigorous pre-marketing testing, analysis, and approval.

- **Pre-approval of labeling changes.** Both federal regulatory regimes require manufacturers to obtain pre-approval of major labeling changes from the relevant federal agency prior to distribution and sale. *Compare* 40 C.F.R. § 152.44 (requiring pesticide registrants to obtain EPA's approval for a labeling change), *and id.* § 152.46 (permitting only "certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment" to be made without EPA's prior approval), *and* PR Notice 98-10 at 8 (excluding health hazards and precautionary statements from minor modifications), *with* 21 C.F.R. § 314.70(b)(2)(v) (requiring pre-approval of prescription-drug labeling changes, except changes designated as moderate or minor by regulation or guidance).

- **Close scientific review by outside and inside scientific bodies and committees.** Both federal regulatory regimes rely on thorough, in-depth reviews of available scientific data performed by internal and external bodies and review committees. For pesticides, EPA

relies on its internal Cancer Assessment Review Committee, *see* 7 U.S.C. § 136w(e), and sometimes convenes FIFRA Scientific Advisory Panels composed of outside experts, *see id.* § 136w(d); *see also* 42 U.S.C. § 4365(g). In fact, both of these bodies have assessed glyphosate's carcinogenicity. *See* EPA, *Glyphosate: Report of the Cancer Assessment Review Committee*, EPA-HQ-OPP-2016-0385-0014 (Oct. 1, 2015), https://www.regulations.gov/document/EPA-HQ-OPP-2016-0385-0014; FIFRA SAP Report. A similar expert review process exists under the FFDCA for prescription drugs. *See* 21 U.S.C. § 360bbb–1 (providing for internal agency review); *id.* § 355(n) (providing for the establishment of scientific advisory panels).

- **Careful monitoring of adverse events in post-approval use.** Both federal regulatory regimes require manufacturers to closely monitor and report adverse effects resulting from consumer use after agency approval. *Compare* 7 U.S.C. § 136d(a)(2) (mandating reporting of adverse effects from pesticide use), *with* 21 C.F.R. § 310.305 (mandating reporting of adverse effects from prescription-drug use).

- **Elaborate warning and information communication regimes.** Both federal regulatory regimes impose complex information communication regimes, including through the use of tiered warnings, based on the federal agency's careful consideration of what consumers understand from warnings and how they behave in response. *Compare* 40 C.F.R. §§ 156.60–.78 (providing detailed pesticide labeling instructions to communicate human hazard and precautionary statements), *with* 21 C.F.R. § 201 subparts A–B (providing detailed labeling instructions applicable to prescription drugs).

Insofar as differences exist between the pesticide and prescription-drug regimes, those differences only strengthen the case for treating federal pesticide warnings as sufficient to satisfy Proposition 65's requirements. Although prescription drugs have the additional involvement of a doctor or other authorized prescriber, pesticides often involve licensed distributors and applicators who help ensure that appropriate warnings are provided, which fulfills a similar function. In fact, the State of California requires advance approval of certain individual pesticide applications to agricultural fields by county agricultural commissioners as part of its Restricted Use Permitting Program.[10] In the prescription-drug context, moreover, a warning about a listed chemical may never be communicated to the patient—it might be contained in the package insert, but the drug may be administered to a patient without the consumer ever opening a package (such as in a hospital or clinical setting). *See Env't L. Found. v. Wykle Rsch., Inc.*, 134 Cal. App. 4th 60, 68–71 (2005). And in any event, the consumer is not likely to read a lengthy prescription-drug insert, while a pesticide applicator must read the entire pesticide label to ensure he or she can comply with the law.

Another difference is that a medical professional may prescribe drugs for off-label uses. By contrast, it is unlawful to apply pesticides in a manner contrary to the label, *see* 7 U.S.C. § 136j(a)(2), and labeling warnings for consumer-use pesticides are carefully evaluated by EPA, which has expertise in ensuring that such warnings are written and delivered effectively.

[10] https://www.cdpr.ca.gov/docs/enforce/compend/vol_3/rstrct_mat.htm.

Furthermore, FIFRA requires every pesticide active ingredient to undergo a registration review by EPA every fifteen years to determine whether it continues to meet the FIFRA standard for registration. *See* 7 U.S.C. § 136a(g)(1)(A)(iii), (iv); 40 C.F.R. § 155.53(a). During registration review, EPA often requires additional toxicological and environmental studies to address new needs or concerns. *See* 40 C.F.R. § 155.53(b). The FFDCA has no comparable requirement for the prescription drugs it oversees. Although the FDA maintains data regarding postmarket risk identification and analysis, *see* 21 U.S.C. § 355(k)(3), and may require prescription drug manufacturers at the time of approval to perform continuing postmarketing safety studies and clinical trials, *see id.* § 355(o), the FDA has no statutory obligation to review each previously approved prescription drug registration on a particular schedule.

Finally, unlike prescription drugs, pesticides are also heavily regulated at the state level, consistent with FIFRA's careful allocation of pesticide regulatory authority in 7 U.S.C. § 136v. As you know, California has a very active Department of Pesticide Regulation, which requires pesticide products to be registered before they can be used or offered for sale in California. Given the mutually reinforcing overlays of state and federal regulation of pesticide use, and comprehensive federal regulation of pesticide labeling, OEHHA should adopt a regulation that pesticide labels approved or otherwise provided under federal law are sufficient to warn consumers about risks from pesticide exposure. Such an approach would properly recognize that EPA's detailed labeling regime provides a more-than-adequate safeguard and far more useful information to consumers about the safe use of FIFRA-regulated products, including glyphosate-based products.

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CropLife America and RISE appreciate the opportunity to provide these comments on OEHHA's regulatory approach to glyphosate-based pesticides. Should OEHHA have any questions or wish to discuss these issues further, please do not hesitate to contact us.

Thank you for your consideration of these comments.

Sincerely,

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CropLife America

Megan J. Provost
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RISE