

**The Safe Drinking Water and Toxics Enforcement Act of 1986
Proposition 65**

Final Statement of Reasons

**Title 27, California Code of Regulations
Proposed Amendments to Article 6
Clear and Reasonable Warnings**

**New Sections 25607.48 and 25607.49
Warnings for Exposures to Glyphosate from Consumer
Products**

July 2022



**California Environmental Protection Agency
Office of Environmental Health Hazard Assessment**

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General Information

Overview of Regulation

This is the Final Statement of Reasons for the proposal to add Sections 25607.48 and 25607.49 to Article 6, Title 27 of the California Code of Regulations¹. The Office of Environmental Health Hazard Assessment (OEHHA) proposes to adopt this regulation to provide a new non-mandatory, safe harbor warning for exposures to glyphosate from consumer products that require a warning. If adopted, the regulation would provide safe harbor language for businesses that determine they must provide a “clear and reasonable” warning under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Act or Proposition 65) for exposures² to glyphosate. The warning provided in the regulation is deemed “clear and reasonable” for purposes of compliance with the Act.

The proposed warning consists of multiple parts that draw from existing OEHHA safe harbor warnings for consumer products³: a warning symbol, signal words, the name of the chemical, and the URL where consumers can access more information about the chemical, including ways to reduce exposure.

The proposed warning, which OEHHA proposes to adopt in Section 25607.49(a), is displayed below:⁴

⚠ 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. US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations. A wide variety of factors affect your potential risk, including the level and duration of exposure to the chemical. For more

¹ All further citations are to sections of Title 27 of the California Code of Regulations, unless otherwise stated.

² For carcinogens, a warning is not required when the person responsible can show the exposure poses no significant risk assuming lifetime exposure at the level in question (Health and Safety Code Section 25249.10). OEHHA adopted a No Significant Risk Level (NSRL) for glyphosate of 1100 micrograms per day in Section 25705. Exposures at or below this safe harbor level do not require warning.

³ Section 25603(a).

⁴ The content differs from that in the original proposal. The language “US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations” replaced the originally proposed language, “Other authorities, including USEPA, have determined that glyphosate is unlikely to cause cancer, or that the evidence is inconclusive.” Also, the word “potential” replaced the word “personal” in “personal cancer risk”.

information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate.

The proposed warning reflects the range of opinion by authorities on the carcinogenicity of glyphosate: the International Agency for Research on Cancer (IARC) classified glyphosate as “probably carcinogenic to humans”, the US Environmental Protection Agency (US EPA) found glyphosate is unlikely to be a human carcinogen, and other bodies have made determinations similar to US EPA’s. Additionally, the warning states the reality that the level and duration of exposures to the chemical affect a person’s risk and refers consumers to a website where they can obtain more information on glyphosate, including details on the findings of IARC, US EPA, and other national and international public health agencies and organizations. Thus, the proposed warning, which US EPA confirmed it would allow on a product label⁵, provides balanced, clear, and understandable information to individuals who could be exposed to glyphosate through use of the product at levels requiring a warning.

OEHHA notes that on June 17, 2022, the Ninth Circuit Court of Appeals issued an opinion in *Natural Resources Defense Council et al. v. US Environmental Protection Agency et al.*⁶ (*NRDC v. US EPA*) that vacated the human-health portion of US EPA’s 2020 Interim Registration Review Decision for glyphosate and remanded it to US EPA “for further consideration.” However, in prior related documents^{7 8}, US EPA also stated that glyphosate was “not likely to be carcinogenic to humans”, and that remains the current US EPA classification for glyphosate⁹. If US EPA changes its classification for

⁵ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at: <https://oehha.ca.gov/media/downloads/cnr/usepaaafreedhofftoehhadirzeiseglyphosate40822.pdf>

⁶ *Natural Resources Defense Council et al. v. US Environmental Protection Agency et al.*⁶ (9th Cir. Jun. 17, 2022, Nos. 20-70787, 20-70801) (*NRDC v. US EPA*) __ F.4th __ [2022 WL 2184936, at *21] Available online at: <https://cdn.ca9.uscourts.gov/datastore/opinions/2022/04/20/20-72794.pdf>

⁷ US Environmental Protection Agency (US EPA 2015). Glyphosate: Report of the Cancer Assessment Review Committee. Evaluation of the Carcinogenic Potential of Glyphosate. October 1, 2015. U.S. Environmental Protection Agency, Health Effects Division, Office of Pesticide Programs, available at: <https://downloads.regulations.gov/EPA-HQ-OPP-2016-0385-0014/content.pdf>.

⁸ US Environmental Protection Agency (US EPA 2017). Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential. December 12, 2017. U.S. Environmental Protection Agency, Office of Pesticide Programs, available at: https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487.

⁹ Confirmed in June 30, 2022, email from Michael Goodis, Deputy Director of Programs, Office of Pesticide Programs, US Environmental Protection Agency to Lauren Zeise, Director, OEHHA stating: “The Ninth Circuit’s ruling vacated the human health portion of the glyphosate interim decision and remanded it to EPA for further analysis and explanation; but the scientific conclusions regarding the cancer classification and associated documents remain the same at this time. Therefore, the Agency continues to have the same position on the proposed language for the Proposition 65 safe harbor warning

glyphosate after reconsidering the human-health portion of the 2020 Interim Registration Review Decision, or at some other time in the future, OEHHA will propose an amendment to this regulation to align the warning with the changed classification.

Consistent with safe harbor warning content for occupational exposures to pesticides given in existing Section 25603(d), new Section 25607.49(b) provides that the signal words “ATTENTION” or “NOTICE” in capital letters and bold font may be substituted for the words “CALIFORNIA PROPOSITION 65 WARNING” where the warning is provided on a product label and the label is regulated by both US EPA and the California Department of Pesticide Regulation (CDPR). This provision was adopted to avoid any conflict with standard signal words used on product labels for chemicals regulated by US EPA and CDPR.

Section 25607.48 allows for the glyphosate warning to be provided using the same methods available for other consumer product warnings set forth in existing Section 25602, that is, warnings may be given:

- on a posted sign, shelf tag, or shelf sign, for the consumer product at each point of display of the product;
- via any electronic device or process that automatically provides the warning to the purchaser prior to or during the purchase of the consumer product, without requiring the purchaser to seek out the warning; or
- on the product label.

For internet purchases, in addition to one of the above warning methods, the warning must be provided on the product display page or by a clearly marked hyperlink using the word “WARNING” on that page.

Process and Timeline

OEHHA published the Notice of Proposed Rulemaking, proposed text, and Initial Statement of Reasons (ISOR) for this action on July 23, 2021, initiating a public comment period that was to close on September 7, 2021. In response to requests from the Consumer Brands Association and the California Chamber of Commerce to extend the deadline, OEHHA issued a notice on August 27, 2021, extending the comment period by 30 days, to October 7, 2021. In the same notice, OEHHA announced that it would hold a public hearing on the proposed regulation on September 9, 2021. In accordance with Governor Newsom’s Executive Orders N-29-20¹⁰ and N-33-20,

expressed in Assistant Administrator Freedhoff’s April 8, 2022 letter to OEHHA” [letter referenced in footnote 5].

¹⁰ Available at: <https://www.gov.ca.gov/wp-content/uploads/2020/03/3.17.20-N-29-20-EO.pdf>

OEHHA conducted the hearing remotely. During the public comment period, OEHHA received one oral comment at the hearing and 17 submissions of written comments.

After the close of the comment period, OEHHA determined modifications of the original regulatory text were needed. On April 13, 2022, OEHHA published a Notice of Modification and Addition of Documents to the Rulemaking File and released for public comment the modified version of the proposed regulation along with four documents that OEHHA added to the administrative record. The public comment period was to run from April 13, 2022, through April 28, 2022. In response to an April 19, 2022, request in a letter from a coalition of industry stakeholders,¹¹ the comment period was extended to May 5, 2022.

Following publication of the June 17, 2022 decision in *NRDC v. US EPA* discussed above, OEHHA determined it should augment the record for this proposed action by adding two additional US EPA documents to the administrative record. On June 28, 2022, OEHHA provided a public Notice of Augmentation of the record and opened a 15-day comment period on the addition of those documents. The public comment period closed on July 13, 2022.

In this FSOR, OEHHA summarizes the public comments received on the regulatory proposal, together with an explanation of how the proposal changed to address them, or the reasons for making no change. Responses are provided for relevant comments received on the original proposal during the initial July 23–October 7, 2021, comment period; on the modified proposal during the April 13–May 5, 2022, comment period; and on the Notice of Augmentation during the June 28–July 13, 2022, comment period. OEHHA received some comments that were not relevant because they were not specifically directed at the proposed action, or the procedures followed in this rulemaking action¹². OEHHA has no obligation under the Administrative Procedure Act to respond to irrelevant comments. The lack of responses should not be construed to mean that OEHHA in any way agrees or disagrees with these comments.

¹¹ Agricultural Council of California, American Chemistry Council, American Pistachio Growers, California Agricultural Aircraft Association, California Association of Winegrape Growers, California Chamber of Commerce, California Cherry Growers and Industry Association, California Ginners and Growers Association, Western Agricultural Processors Association, California Farm Bureau Federation, California Fresh Fruit Association, California Grain and Feed Association, California Pear Growers Association, California Seed Association, California Walnut Commission, Plant California Alliance, and Western Plant Health Association.

¹² Government Code section 11346.9 (a)(3)

Comments on the Original Proposal During the July 23 to October 7, 2021 Comment Period and OEHHA's Responses

The organizations and individuals listed in the table below submitted written or oral comments on the proposed regulation during the July 23 – October 7, 2021, comment period. The designation column in the table indicates how the commenter is referenced in the summary and responses in this section.

Commenting Organization	Designation
Baum Hedlund, Aristei, & Goldman, P.C. ¹³	Baum Hedlund
California Chamber of Commerce, Consumer Brands Association and 15 other signatories ¹⁴	CalChamber/CB Coalition
Center for Environmental Health and 18 other signatories ¹⁵	CEH Coalition
CropLife America & Responsible Industry for a Sound Environment	CropLife RISE
Moms Across America	Moms Across America
Turning Green & Conscious Kitchen	Turning Green & Conscious Kitchen
Commenting Individual	
Bragman, Larry	BragmanL
Brooks, William	BrooksW
Caswell, Susan, Dr.	CaswellS
Dodd, Catherine, RN	DoddC
Jetley, Gabriele	JetleyG

¹³ Pedram Esfandiary, the signatory of the Baum Hedlund, Aristei, & Goldman letter, commented at the September 9, 2021, hearing. Oral and written comments are denoted here as Baum Hedlund.

¹⁴ California Chamber of Commerce and Consumer Brands Association and 15 other signatories: Agricultural Council of California, American Bakers Association, American Chemistry Council, Asian Food Trade Association, California Food Producers, Carlsbad Chamber of Commerce, Chemical Industry Council of California, Consumer Healthcare Products Association, Council for Responsible Nutrition, Flexible Packaging Association, Gilroy Chamber of Commerce, Household & Commercial Products Association, Juice Products Association, SNAC International, and The Peanut & Tree Nut Processors Association – collectively referred to here as the CalChamber/CB Coalition.

¹⁵ Center for Environmental Health and 18 other signatories: 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, and Just Transition Alliance.

Rappaport, William	RappaportW
Rusch, Erica	RuschE
Seneff, Stephanie, Ph.D.	SeneffS
S, Mel	SMel
VerDuin, Melissa	VerDuinM
Uttam	Uttam

Comments received are grouped by subject and summarized below along with OEHHA's responses to them.

Several comments discussed the warning language originally proposed for adoption in Section 25607.49(a). The original language, signal words, and warning symbol are given here for reference:

⚠ 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.

Comments Recommending Modifications to the Proposed Warning

Level of Detail and Types of Impacts Covered

Comment 1 (BragmanL, SeneffS): BragmanL recommends that the “warning label indicate that glyphosate has been determined to be a probable carcinogen by the World Health Organization and is not biodegradable. Hence, precautionary protective measures should be used when handling glyphosate to avoid skin contact or respiratory exposure. Similar precautions should be used if it is applied to vegetation or other surfaces.” The commenter further recommends that the label include information about exposures to pets and minor children, food consumption by individuals with immune deficiencies, and toxicity to fish and amphibians.

SeneffS states: “At the very least, glyphosate should be labeled as a probable carcinogen and as an endocrine disruptor,” indicating that recent papers demonstrate glyphosate disrupts endocrine function “at exposure levels below current regulatory limits.”

Response: The proposed warning states that the World Health Organization's International Agency for Research on Cancer (IARC) has determined that glyphosate is "probably carcinogenic to humans", which is very similar to the commenters' proposed change to "a probable carcinogen". However, including the words "World Health Organization" in addition to the existing "International Agency for Research on Cancer" language would not add clarity to the warning and would make the warning unnecessarily longer.

OEHHA agrees that additional information regarding ways to reduce human exposure could be useful to consumers, but disagrees that all such information, which would significantly increase the length of the warning, should be provided in the warning itself. The proposed warning includes a link to an OEHHA web page.¹⁶ This web page has two fact sheets on glyphosate that include information about the chemical, exposure routes, and ways to reduce human exposure, along with direct links to information on glyphosate from IARC, US EPA and other national and international agencies and organizations. This is significantly more information than could be included in a Proposition 65 consumer product warning.

Without commenting on whether the chemical causes the non-cancer hazards indicated, Proposition 65 does not require a warning about endocrine disruption or effects on people with immune deficiencies, or on vegetation, fish, amphibians, or pets, and OEHHA declines to include such information in the proposed safe harbor warning. However, non-cancer health effects are discussed in some of the documents linked in the fact sheets on the OEHHA webpage at www.P65Warnings.ca.gov/glyphosate.

No changes to the proposed regulation were made based on these comments.

Comment 2 (SMel): SMel requests: "Please put on the label of glyphosate herbicides (aka Roundup, Ranger Pro, and 750 other generic brands) when used in California: Causes cancer and DNA damage". The commenter quotes a 2021 preprint of a scientific article they coauthored finding that "Roundup herbicides are more toxic than glyphosate, activating mechanisms involved in cellular carcinogenesis and causing gene expression changes reflecting DNA damage ..."¹⁷

Response: Regarding the recommended cancer warning, under the unusual circumstances of this case, a tailored warning that provides additional context is

¹⁶ www.P65Warnings.ca.gov/glyphosate.

¹⁷ <https://www.biorxiv.org/content/10.1101/2021.04.12.439463v1>. Mesnage R, Ibragim M, Mandrioli D, Falcioni L, Belpoggi F, Brandsma I, Bourne E, Savage E, Mein CA, Antoniou MN, In-depth comparative toxicogenomics of glyphosate and Roundup herbicides: histopathology, transcriptome and epigenome signatures, and DNA damage. bioRxiv preprint. Cold Springs Harbor.

appropriate. While a lack of scientific consensus about the carcinogenicity of a chemical is not uncommon, here, several agencies, including US EPA, which is an authoritative body under Proposition 65, reached a conclusion about the carcinogenicity of glyphosate that was different from IARC's, which is also an authoritative body under Proposition 65. Thus, OEHHA is proposing language that presents a balanced summary of the expert agencies' assessments of the likelihood that glyphosate can cause human cancer, by providing the exact IARC and US EPA narrative classifications and by noting that other bodies have reached findings similar to US EPA's.

Regarding including the endpoint "DNA damage" in the warning, OEHHA declines to include health effects other than carcinogenicity in the warning language (see responses to comments 1 and 3), as the chemical listing is based on carcinogenicity. However, information relevant to DNA damage is covered in some of the documents with links in the fact sheets on the OEHHA webpage at www.p65warnings.ca.gov/glyphosate.

No changes to the proposed regulation were made based on these comments.

Comment 3 (Moms Across America): Moms Across America states, if continued use of glyphosate is allowed, all labeling, including for agricultural use, should include the following:

"This product has been shown to contain chemicals that may cause birth defects, miscarriage, and reproductive effects, as well as cancer, neurotoxicity, liver and kidney disease in humans and, is therefore not allowed for use around humans. This product has been shown to be carcinogenic and to cause reproductive damage to animals, so it is not allowed for use where pets and wildlife may be present. This product has been shown to be a reproductive effector, neurotoxin, and to be harmful to the gut microbiome, which is especially damaging to developing children and pollinators, therefore, it is not allowed for use in residential, schools, gardens, parks, or areas where children and pollinators congregate. This product is highly toxic to marine life and is not allowed for use where there is any possibility of runoff into waterways. The chemicals in this product have been shown to cause damage to the microbes and soil life, therefore it is not allowed for use on soil. The chemicals in this product have been shown to drift and collect in rainfall, contaminating waterways and soil there it is not allowed for outdoor use. To use this product, the sprayer is advised to wear a full protective body covering including a full face mask, protective eye covering, and head covering which restricts inhalation or any skin contact with this product. Link to studies and resources for the above findings can be found here: <https://www.momsacrossamerica.com/>"

Response: The listing of glyphosate is based only on carcinogenicity. Proposition 65 does not require a warning about endocrine disruption, DNA damage, neurotoxicity, or liver and kidney disease. Without agreeing or disagreeing that the specific information requested for inclusion in the warning is correct, OEHHA agrees that additional information, including ways to reduce human exposure, can be useful to consumers, but disagrees that all such information must be included in the warning, which would significantly increase the length of the warning. The proposed warning includes a link to a page on OEHHA's warnings website (prop65warnings.ca.gov/glyphosate). This web page has two fact sheets on glyphosate that include information about the chemical, exposure routes and ways to reduce human exposure, along with direct links to information on glyphosate from IARC, US EPA and other authoritative sources.

No changes to the proposed regulation were made based on these comments.

Comment 4 (BrooksW): The commenter asks: "Why not have a respected EPA Toxicologist write the label? ...'Glyphosate Causes Cancer'". The commenter then quotes a March 4, 2013, letter from a former and now deceased US EPA employee, Marion Copley,¹⁸ to Jess Rowland, Deputy Director of the Health Effects Division in the Office of Pesticide Programs at US EPA. The commenter begins with the quote from Dr. Copley that "Glyphosate Causes Cancer". That letter lays out Dr. Copley's reasons for concluding that glyphosate is a carcinogen, emphasizing the evidence on the mechanisms of cancer, and discusses the internal US EPA debate about the evidence and internal US EPA politics.

Response: The commenter appears to recommend or support a more concise warning, that "glyphosate causes cancer", and provides insight into the internal debate at US EPA regarding glyphosate's carcinogenicity during the 2013 timeframe. Notwithstanding this comment, OEHHA believes that, under the unusual circumstances of this case, a tailored warning for exposures to glyphosate that provides additional context is appropriate. See response to comment 2 above for discussion of the content of the proposed warning.

No changes to the proposed regulation were made based on these comments.

Comment 5 (CEH Coalition): The commenter states that "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 US Agency for Toxic Substances and Disease Registry (ATSDR) final toxicological profile for glyphosate." The commenter goes on to

¹⁸ Obituary, Washington Post, January 27, 2014. [MARION COPLEY Obituary \(2014\) - Washington, DC - The Washington Post \(legacy.com\)](http://www.washingtonpost.com/archive/local/2014/01/27/local-obituary-marion-copley-2014/).

quote from the ATSDR report. The commenter states that: “Papers published after 2015 in peer-reviewed literature reinforce IARC’s findings.”

Response: In addition to the IARC conclusion regarding glyphosate’s carcinogenicity, the proposed warning refers specifically to the “not likely” conclusion of US EPA and the findings of other authorities. While other bodies do not use the exact same terminology as US EPA, several use similar language, or they do not make a positive overall classification of glyphosate’s carcinogenicity using terms like “possible,” “probable”, or “likely” carcinogen. The findings of several other bodies are laid out in the ISOR¹⁹ (pages 5-6).

The commenter makes specific reference to ATSDR. However, ATSDR did not make its own conclusion or classification regarding the carcinogenicity of glyphosate. The summary of health effects in the ATSDR Toxicological Profile²⁰ cited by the commenter states the following:

“Cancer Effects. The carcinogenic potential of glyphosate has been evaluated in six meta-analyses (Chang and Delzell 2016; IARC 2017; Schinasi and Leon 2014; Leon et al. 2019; Pahwa et al. 2019; Zhang et al. 2019a) and a number of case-control and cohort epidemiology studies (see Section 2.19 for detailed information and specific citations). The meta-analyses reported positive associations between glyphosate use and selected lymphohematopoietic cancers. Most of the case-control and cohort studies used self-reported ever/never glyphosate use as the biomarker of exposure, and subjects were likely exposed to other pesticides as well. Numerous studies reported risk ratios greater than 1 for associations between glyphosate exposure and risk of non-Hodgkin’s lymphoma or multiple myeloma; however, the reported associations were statistically significant only in a few studies.”

The ATSDR Toxicological Profile also states the following regarding other agencies’ reviews of glyphosate:

“Several national and international agencies and organizations have assessed the carcinogenicity of glyphosate (Table 2-13). These evaluations provide different types of determinations—some focused on hazard identification, or whether there is evidence that a chemical can cause an effect, and others focused on carcinogenic risk, or the likelihood of cancer effects at levels of exposure typically experienced by humans. In addition, there are large numbers

¹⁹ Available online at: <https://oehha.ca.gov/media/downloads/crn/glyphosateisor071921.pdf>

²⁰ ATSDR, Toxicological Profile for Glyphosate 6 (Aug. 2020), Available online at: <https://www.atsdr.cdc.gov/ToxProfiles/tp214.pdf>.

of unpublished guideline studies on glyphosate and the inclusion or exclusion of these may account for the differences in the conclusions reached by these various agencies. For additional discussion regarding the carcinogenicity of glyphosate, refer to the following sources: Acquavella et al. 2016; Greim et al. 2015; McClellan 2016; Portier et al. 2016; Samsel and Seneff 2015; Tarazona et al. 2017; Williams et al. 2016.”

Thus, ATSDR is citing the evaluations made by other agencies and does not reach its own conclusions.

Finally, all the papers published after 2015 to which the commenter refers were cited in the ISOR²¹ for the proposed regulation, except for two studies: 1) Kabat et al. 2021 and 2) Truzzi et al. 2021.²² Kabat et al. (2021) is a meta-analysis of epidemiologic studies that was consistent with high exposure to glyphosate leading to non-Hodgkin lymphoma in humans, particularly in analyses with a 15- or 20-year latency period between exposure and onset of disease. Truzzi et al. (2021) was an *in vitro* study of cytotoxicity and is not directly relevant to carcinogenicity.

However, in response to this comment and other comments, OEHHA modified the proposed regulation to use the precise language used by US EPA in its classification of glyphosate.

US EPA's Classification of Glyphosate

Comment 6 (Baum Hedlund): The commenter states that a sentence in the glyphosate safe harbor warning proposed in July 2021 is inaccurate and potentially misleading. The relevant sentence states: “Other authorities, including USEPA, have determined that

²¹ Weisenburger DD (2021). 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* 21(9):621-630 Available at: <https://www.sciencedirect.com/science/article/pii/S2152265021001518>; Meloni F, Satta G, Padoan M et al. (2021). Occupational exposure to glyphosate and risk of lymphoma: results of an Italian multicenter case-control study. *Environ Health* 20(1):49 Available online at doi: [10.1186/s12940-021-00729-8](https://doi.org/10.1186/s12940-021-00729-8); Portier CJ (2020). A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies. *Environmental Health*, 19:18. Available online at <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-020-00574-1>.

²² Kabat GC, Price WJ, Tarone RE (2021). On recent meta-analyses of exposure to glyphosate and risk of non-Hodgkin's lymphoma in humans. *Cancer Causes Control* 32(4):409-414, Available at: <https://pubmed.ncbi.nlm.nih.gov/33447891/>; Truzzi F, Mandrioli D, Gnudi F, Scheepers PTJ, Silbergeld EK, Belpoggi F, Dinelli G (2021). Comparative evaluation of the cytotoxicity of glyphosate-based herbicides and glycine in L929 and Caco2 cells. *Front. Public Health* 9:643898. Available online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2021.643898/full>

glyphosate is unlikely to cause cancer, or that the evidence is inconclusive.”²³ The commenter states that an internal 2016 report by US EPA’s Office of Research and Development:

“concluded that four of the highest-quality studies ‘all reported elevated risks of NHL associated with exposure to glyphosate even after controlling for other pesticide exposures’ and proceeded to conclude that ‘available epidemiologic studies provide suggestive evidence of carcinogenic potential between glyphosate exposure and increased risk of non-Hodgkin lymphoma’”.

The commenter states that, subsequently, US EPA acceded to industry pressure and reached a contrary conclusion. The commenter recommends that OEHHA “omit any reference to the EPA’s published classification of glyphosate.” It suggests that OEHHA instead revise the proposed warning language to “inform consumers of the IARC glyphosate classification while generally referencing the conclusions of other agencies without identifying US EPA for the reasons stated above.”

Response: OEHHA declines to omit explicit mention of US EPA and its classification of glyphosate²⁴ from the warning. The conclusions of US EPA and other authorities are referenced (along with IARC’s conclusion, on which the Proposition 65 listing of glyphosate is based) because the proposed warning presents a balanced description of the differences between IARC’s conclusion and those of other agencies, including US EPA, which is an authoritative body for identifying carcinogens for purposes of Proposition 65²⁵. US EPA, which, among other things, is responsible for approving pesticide registrants’ product labels, has indicated that it would approve the current proposed form of Proposition 65 warning on glyphosate product labels:

US EPA “has determined that the new glyphosate-specific safe harbor language proposed in OEHHA’s recent letter²⁶ is sufficiently clear regarding EPA’s position and thus would not be considered false and misleading. Therefore, this revised

²³ In the modified regulatory proposal, the statement in the warning regarding US EPA and other authorities is, “US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations.”

²⁴ The classification of glyphosate by US EPA remains “not likely to be carcinogenic to humans” notwithstanding the decision in NRDC v US EPA. See pages 4 and 5 for discussion.

²⁵ Section 25305(m) - designated authoritative bodies include both IARC and US EPA (pursuant to Health and Safety Code section 25249.8(b), and Section 25904(b) – IARC identified as authoritative for Labor Code listings (pursuant to Health and Safety Code section 25249.8(a)). Glyphosate was listed via the Labor Code mechanism based on IARC’s finding it is “probably carcinogenic to humans” with sufficient evidence of carcinogenicity in animals.

²⁶ OEHHA, letter from Lauren Zeise, Director, to Michal Freedhoff, US EPA Assistant Administrator, Office of Chemical Safety and Pollution Prevention, March 21, 2022. Available online at:

<https://oehha.ca.gov/media/downloads/cnr/oehhadirzeisetousepaaafreedhoffglyphosate32122.pdf>

language could be approved by EPA if pesticide registrants requested it for inclusion on glyphosate product labels, and the products would not be considered misbranded.”²⁷

In addition, the district court held in *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247, 1259 (E.D. Cal. 2020) that a warning that does not provide such contextual information about contrary determinations regarding the carcinogenicity of glyphosate would be misleading. While OEHHA does not agree with the court’s conclusion that the general consumer product safe harbor warning would be misleading or otherwise trigger First Amendment concerns, OEHHA, as the lead agency for implementation of Proposition 65, is proposing this alternative safe harbor warning for consumer product exposures to glyphosate that require a warning. The current proposed warning addresses the district court’s concerns and is accurate. However, in response to this and other comments, OEHHA modified the warning language it initially proposed to use the precise wording used by US EPA in its classification of glyphosate.

The current version of the proposed warning (provided on page 8) accurately states US EPA’s current carcinogenicity classification, notwithstanding the recent decision in *NRDC v US EPA*. See discussion above on pages 4 and 5. In the event US EPA changes its designation in the future, OEHHA will propose an amendment to this regulation.

Comment 7 (CEH Coalition): The commenters state that IARC and US EPA reached consistent conclusions regarding glyphosate. They state that IARC performed a hazard identification, and US EPA “performed a risk assessment that considered carcinogenicity at low exposure levels.” Consequently, the commenters state, “[US] EPA did not find that glyphosate is not carcinogenic to humans at sufficiently high exposures.” They further state that “[t]he language can be modified to address EPA’s narrow exposure inquiry without undermining OEHHA’s listing based on hazard... 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].”

Response: Both US EPA and IARC conducted hazard identifications and reached different conclusions. Hazard identification is the process of determining whether

²⁷ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at: <https://oehha.ca.gov/media/downloads/cnr/usepaaafreedhofftoehhadirzeiseglyphosate40822.pdf>

exposure to a chemical can cause an increase in the incidence of cancer. In risk assessment, the risk characterization step incorporates hazard identification, dose-response information, and exposure data to characterize carcinogenic risk for a particular exposure scenario or scenarios. US EPA first conducted a hazard identification process to determine if glyphosate can cause cancer or other health effects in humans, and then characterized the risk to humans from anticipated exposures when the product is used consistent with label instructions. US EPA's hazard identification process resulted in the carcinogenicity classification that glyphosate is "not likely to be carcinogenic to humans."²⁸ The current version of the proposed warning accurately states US EPA's current carcinogenicity classification for glyphosate.²⁹

Further, in a letter dated April 8, 2022, US EPA stated that³⁰:

"... EPA recognizes that the revised safe harbor language proposed by the Office of Environmental Health Hazard Assessment (OEHHA) acknowledges the EPA position: 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. *US EPA has determined that glyphosate is not likely to be carcinogenic to humans*; other authorities have made similar determinations." [Emphasis added.]

In response to these comments and others, OEHHA modified the proposed regulation to use the precise language used by US EPA in its classification of glyphosate.

Comment 8 (CEH Coalition): The commenters state that US EPA "performed a risk assessment that considered carcinogenicity at low exposure levels." They further state that, "[t]o the extent that a Proposition 65 warning should account for US EPA's exposure analysis, the concern is already addressed by the No Significant Risk Level adopted by OEHHA in 2018."

²⁸ US EPA (2017). Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential. December 12, 2017. U.S. Environmental Protection Agency, Office of Pesticide Programs, available at: https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487. US EPA (2015) Glyphosate: Report of the Cancer Assessment Review Committee. Evaluation of the Carcinogenic Potential of Glyphosate. October 1, 2015. U.S. Environmental Protection Agency, Health Effects Division, Office of Pesticide Programs, available at: <https://downloads.regulations.gov/EPA-HQ-OPP-2016-0385-0014/content.pdf>. The hazard classification was also contained in the human-health portion of US EPA's 2020 Interim Registration Review Decision for Glyphosate, vacated by the Ninth Circuit in *NRDC v EPA* and remanded for reconsideration to the Agency. See pages 4 and 5 for further discussion.

²⁹ See pages 4 and 5 for additional discussion.

³⁰ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at: <https://oehha.ca.gov/media/downloads/cnr/usepaaafreedhofftoehhadirzeiseglyphosate40822.pdf>

Response: OEHHA agrees with the commenter that US EPA performed a risk assessment that considered the anticipated level of human exposure, and that OEHHA adopted a safe harbor No Significant Risk Level (NSRL) in 2018. Under Proposition 65, a warning for a carcinogen is not required when the exposure falls below the NSRL. US EPA also performed a hazard identification analysis for glyphosate. (See response to comment 7.)

No changes to the proposed regulation were made based on these comments.

General Comments on the Proposed Regulation

First Amendment

Comment 9 (CropLife Rise, CalChamber/CB Coalition): CropLife Rise alleges that a Proposition 65 warning for glyphosate – including the proposed safe harbor warning – violates the First Amendment because it is “at odds with both the weight of scientific authority and the decision” of the district court in *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (E.D. Cal. 2020), which they cited in support of this position. CropLife Rise further comments that: “... the Proposition 65 warning was neither ‘purely factual’ nor ‘uncontroversial’.” CropLife Rise notes that the court found the general consumer product safe harbor warning violated the First Amendment and permanently enjoined California from enforcing the warning requirement for glyphosate exposures. Relatedly, CalChamber/CB Coalition contends that, “[a]s long as there is a scientific controversy about the carcinogenicity of glyphosate, OEHHA will not be able to craft a glyphosate safe harbor warning that is consistent with the First Amendment.”

Response: While a lack of scientific consensus about the carcinogenicity of a chemical is not uncommon, here, several agencies, including US EPA, reached a conclusion about the carcinogenicity of glyphosate that was different from IARC’s. Thus, OEHHA is proposing language that presents a balanced summary of the agencies’ assessments of the likelihood that glyphosate can cause human cancer, by providing the exact IARC and US EPA narrative classifications, and by noting that other bodies have reached findings similar to US EPA’s.

The district court held in *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247, 1259 (E.D. Cal. 2020) that a warning that does not provide such contextual information about contrary determinations regarding the carcinogenicity of glyphosate would be misleading. While OEHHA does not agree with the court’s conclusion that the general consumer product safe harbor warning would be misleading or otherwise trigger First Amendment concerns, OEHHA, as the lead agency for implementation of Proposition 65, is proposing this alternative safe harbor warning for

consumer product exposures to glyphosate that require a warning. The proposed warning addresses the district court's concerns and is accurate.

In a statement regarding whether it would approve inclusion of the proposed warning on pesticide labels, US EPA agreed that the proposed warning "would not be considered false and misleading."³¹

Comment 10 (CropLife RISE): The proposed warning would 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."

Response: OEHHA disagrees that the proposed warning as initially proposed was contrary to the First Amendment.

In response to these comments and others, OEHHA modified the language in proposed Section 25607.49 to state that US EPA determined that the chemical was "not likely to be carcinogenic to humans", the exact nomenclature used by US EPA. Then it states that "other bodies have made similar determinations." These statements regarding findings of IARC, US EPA and other authorities, taken together reflect the fact that more authorities have determined glyphosate is not likely to be carcinogenic to humans or have made similar determinations.

OEHHA modified the proposed warning as follows:

"Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations. ~~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 potential 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."

Comment 11 (CropLife RISE): Most of OEHHA's assertions in the ISOR about glyphosate's purported carcinogenicity rely on refuted evidence and arguments. OEHHA's observations regarding certain members of the FIFRA Scientific Advisory Panel (SAP) regarding rodent tumors mischaracterizes the facts. "EPA

³¹ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at: <https://oehha.ca.gov/media/downloads/cnr/usepaaafreedhofftoehhadirzeiseglyphosate40822.pdf>

has been transparent that SAP panelists did not achieve consensus about how to interpret tumor responses in rodent bioassays.” OEHHA relies on “multimillion-dollar verdicts” “based on the allegation that exposures to glyphosate caused individuals’ non-Hodgkin lymphoma.” US EPA has studied glyphosate for decades and has reached the same conclusion: that the chemical is “not likely to be carcinogenic to humans”.

Response: OEHHA listed glyphosate as a carcinogen under Proposition 65 based on IARC’s classification of the chemical. The listing was completed in 2017 and upheld in *Monsanto Co. v. OEHHA* (2018) 22 Cal.App.5th 534. OEHHA has proposed adopting a tailored safe harbor warning for glyphosate exposures in the present rulemaking in part because of the difference between IARC’s classification and that of US EPA and other authorities.

The ISOR³² lays out the background related to why, for public health reasons, it is important to provide a warning for products that can result in high levels of exposure to glyphosate. The ISOR comments regarding the glyphosate personal injury verdicts were not made to bolster a finding of carcinogenicity but rather to note that juries and courts have found warning to be an important safeguard that was missing. The safe harbor Proposition 65 warning can provide information to people to allow them to make informed decisions prior to significant exposures to Proposition 65 listed chemicals. OEHHA agrees that US EPA has found the chemical not likely to be carcinogenic to humans, and that finding is referenced in the new proposed safe harbor warning for exposures to glyphosate.

Potential Preemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Comment 12 (CropLife RISE, CalChamber/CB Coalition): The commenters state that FIFRA expressly preempts state law labeling requirements that are “in addition to or different from” those imposed by US EPA. 7 U.S.C. § 136v(b). US EPA has concluded that glyphosate is not likely to be carcinogenic in humans and that a cancer warning is not appropriate on the FIFRA label for glyphosate. US EPA has informed glyphosate registrants that a Proposition 65 cancer warning would be false and misleading, and in violation of FIFRA.

³² ISOR, page 9 et seq. Available online at:
<https://oehha.ca.gov/media/downloads/cnrn/glyphosateisor071921.pdf>

Response: OEHHA disagrees with the commenter that FIFRA preempts all state law labeling requirements.³³ Both federal and state courts have found that cancer warnings for glyphosate are not preempted by FIFRA. (See, e.g., *Hardeman v. Monsanto Co.*, 997 F.3d 941, 950 (9th Cir. 2021, cert denied on June 22, 2022, 142 S.Ct. 2834),³⁴ and *Pilliod v. Monsanto Co.*, 67 Cal. App. 5th 591, 591 (2021))³⁵.

OEHHA acknowledges that US EPA informed glyphosate registrants in August 2019³⁶ that the general Proposition 65 safe harbor warning would constitute a false and misleading statement and that it would not approve warning labels with that language. The language proposed in this rulemaking differs substantially from the general safe harbor warning for consumer products in Section 25603 that US EPA considered in making its determination.

³³ See *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby*, United States Court of Appeals, Ninth Circuit (1992), 958 F.2d 94. In that case, the court found that off-product warnings provided at the point of sale, for example, were not preempted by FIFRA.

³⁴ “We affirm the district court and hold that (1) Hardeman's state failure-to-warn claims are not preempted by FIFRA. . . .” (“Nor does EPA's 2019 letter, sent after the conclusion of Hardeman's trial to all registrants of products containing glyphosate, carry the force of law. Generally, ‘Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force.’ *United States v. Mead Corp.*, 533 U.S. 218, 230, 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001). But the 2019 letter—stating that EPA believes any pesticide label with a cancer warning due to the presence of glyphosate will be misbranded—did not follow any ‘formal administrative procedure’ that would give the letter the force of law.[8] See *id.* The 2019 letter was issued without any written notice, gave no hearing or opportunity to respond, and lacked any sort of dispute-resolution process. See *Merck Sharp & Dohme Corp. v. Albrecht*, — U.S. —, 139 S. Ct. 1668, 1679, 203 L.Ed.2d 822 (2019). Instead, the 2019 letter is similar to the letter in *Fellner v. Tri-Union Seafoods, LLC*, which lacked preemptive effect because the FDA ‘merely expressed an informal policy opinion in a letter, and it did so only after [the plaintiff's] injuries were allegedly suffered.’ 539 F.3d 237, 255 (3d Cir. 2008).” *Id.* at 957 (text of footnote 8 omitted).

³⁵ “Monsanto contends that because the Pilliods' failure to warn and design defect claims are based on state law labeling and packaging requirements that are ‘in addition to’ and ‘different from’ requirements imposed by FIFRA, the claims are expressly preempted. Even assuming that the Pilliods' claims, including their design defect claim, are entirely based on labeling and packaging requirements, we conclude that there is no express preemption here. That is because Monsanto identifies no state law requirements that are in addition to or different from the misbranding requirements imposed by FIFRA, which is what it must do to show that the claims are preempted.”

³⁶ US EPA Office of Chemical Safety and Pollution Prevention, Letter from Michael L. Goodis, Director Registration Division, Office of Pesticide Programs, to registrants of products that contain glyphosate, Aug. 7, 2019. Available at:

<https://oehha.ca.gov/media/downloads/cnr/usepaoppgoodistoglyphosaterregistrants8-7-19.pdf>

Further, OEHHA has worked with US EPA to facilitate pesticide registrants receiving permission from US EPA to add Proposition 65 warnings to pesticide product labels.³⁷ OEHHA sought input from US EPA on whether US EPA could approve the warning language set forth in the April 13, 2022, modified proposed safe harbor regulation, if a pesticide registrant requested approval to include such language on labels of products containing glyphosate sold in California³⁸. US EPA reviewed the language, found it to be accurate, and responded that it could approve the proposed language and that products containing that language would not be considered misbranded.³⁹ Specifically, US EPA stated that it:

“has determined that the new glyphosate-specific safe harbor language proposed in OEHHA’s recent letter is sufficiently clear regarding EPA’s position and thus would not be considered false and misleading. Therefore, this revised language could be approved by EPA if pesticide registrants requested it for inclusion on glyphosate product labels, and the products would not be considered misbranded.”

OEHHA concurs with US EPA’s analysis that the proposed warning is clear, is not false or misleading, and that products containing such a warning would not be misbranded under FIFRA. Moreover, if a business’s product requires a warning, under Proposition 65, the warning may be provided by methods other than product labels, including shelf signs, shelf tags, invoices, and by electronic means that would not conflict with FIFRA⁴⁰. For all these reasons, the requirement to provide glyphosate warnings under Proposition 65, particularly given the current proposed safe harbor warning language, is not preempted.

Comment 13 (CropLife RISE): The commenter states that “[t]he proposed subsection (b) to Section 25607.49 does not alleviate the preemption issue. This subsection defers to US 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. §

³⁷E.g., US EPA Office of Pesticide Programs, Label Review Manual, Chapter 7 Precautionary Statements (Revised March 2018), section IV Determining the precautionary labeling, Part A, Signal word, Section 4 Related information on Proposition 65 warnings, page 7-4.

³⁸ OEHHA, letter from Lauren Zeise, Director, to Michal Freedhoff, US EPA Assistant Administrator, Office of Chemical Safety and Pollution Prevention, March 21, 2022. Available online at:

<https://oehha.ca.gov/media/downloads/cnr/oehhadirzeisetousepaaafreedhoffglyphosate32122.pdf>

³⁹ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at:

<https://oehha.ca.gov/media/downloads/cnr/usepaaafreedhofftoehhadirzeiseglyphosate40822.pdf>

⁴⁰ See *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby*, United States Court of Appeals, Ninth Circuit (1992), 958 F.2d 94. In that case, the court found that off-product warnings provided at the point of sale, for example, were not preempted by FIFRA.

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.”

Response: OEHHA disagrees with the commenter that the proposed warning is preempted under FIFRA for the reasons stated in earlier responses (see, e.g., response to comment 12). Indeed, US EPA has approved general Proposition 65 warnings on FIFRA-regulated labels and provides guidance on signal words to use for Proposition 65 warnings, as discussed below.

In 2019, OEHHA promulgated a regulation on the use of signal words in warnings for pesticide products regulated by US EPA. That regulation, found at Section 25603(d), states:

Notwithstanding subsection (a)(2) or (b)(2), where a warning for a consumer product exposure or occupational exposure from use of a pesticide is provided on a product label, and the pesticide label is regulated by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, Title 40 Code of Federal Regulations, Part 156; and by the California Department of Pesticide Regulation under Food and Agricultural Code Section 14005, and Cal. Code of Regs., title 3, Section 6242; the word “**ATTENTION**” or “**NOTICE**” in capital letters and bold type may be substituted for the word “**WARNING**.”

In addition, US EPA provides guidance on signal words to use for Proposition 65 warnings, as indicated in Chapter 7, section IV.A.4⁴¹ of US EPA’s Label Review Manual (page 4):

“Because of the potential for confusion, the Agency historically has not approved labels containing the terms “caution,” “warning,” or “danger,” unless it is the signal word for that label (e.g., “CAUTION: Wash hands before eating or smoking” on a label with the signal word of “CAUTION”). If the Prop 65 term would conflict with the EPA signal word, then registrants should use “Notice” or “Attention” for the Prop 65 statement so that it does not conflict with the EPA signal word.”

⁴¹ Section IV Determining precautionary labeling, subsection A.4 Signal word, Related information on California Proposition 65 warnings. In: US EPA Label Review Manual, Chapter 7 Precautionary Statements, US EPA Office of Pesticide Programs, Revised March 2018. Available online at:

OEHHA included a virtually identical provision in the proposed rulemaking for glyphosate exposures. That provision – in proposed Section 25607.49(b) – states:

Notwithstanding subsection (a), and pursuant to Section 25603(d), where the warning is provided on the product label, and the label is regulated by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, Title 40 Code of Federal Regulations, Part 156; and by the California Department of Pesticide Regulation under Food and Agricultural Code section 14005, and Cal. Code of Regs., title 3, section 6242; the word “ATTENTION” or “NOTICE” in capital letters and bold type may be substituted for the words “CALIFORNIA PROPOSITION 65 WARNING”.

While the proposed regulation allows businesses to use an alternative signal word on product labels, as with other tailored warnings, the safe harbor warning for significant exposures to glyphosate can be provided on posted signs, shelf tags, shelf signs, or via electronic device. (See section 25607.49(a).) Proposition 65 does not require the warning to be placed on a product label.

No changes to the proposed regulation were made based on these comments.

Form of Proposition 65 Safe Harbor Warnings

Comment 14 (CalChamber/CB Coalition): The commenters state that OEHHA has consistently required safe harbor warnings to communicate that the chemical is known to the state to cause cancer or reproductive harm, and that the California Supreme Court held in [*Dowhal v. SmithKline Beecham Consumer Healthcare*] that a warning must communicate that the chemical is “known to the state to cause cancer or words to that effect”. The commenters state that all OEHHA’s safe harbor warnings use this longstanding formulation, and that the Attorney General’s Office has a longstanding requirement that Proposition 65 safe harbor warnings clearly communicate that the chemical is known to the state to cause cancer.

The commenters argue that OEHHA’s longstanding formulation of the “known to the state to cause cancer” wording has been deemed “clear and reasonable” and required for safe harbor warnings for decades.

Response: Regarding the argument that OEHHA must always use the phrase “known to the state to cause” (cancer, reproductive toxicity or both) in the safe harbor warning regulations it promulgates, the commenters are incorrect. OEHHA has the statutory authority to adopt regulations that further the purposes of the statute. The statute does not require any specific warning content. The warnings simply must be “clear and

reasonable.” In fact, OEHHA has adopted tailored safe harbor warnings in Article 6, such as for alcoholic beverages,⁴² occupational exposure warnings,⁴³ and prescription drug warnings,⁴⁴ that do not include that phrase. OEHHA continues to propose specific and understandable warnings tailored to the chemicals and exposures for which the warning is proposed. For example, OEHHA has proposed to adopt safe harbor warnings for cannabis smoke and THC (delta-9-tetrahydrocannabinol) exposures; none of the proposed safe harbor warnings include the phrase “known to the state to cause.”

*Dowhal v. SmithKline Beecham Consumer Healthcare*⁴⁵ was a decision in a private enforcement action on the question of whether, based on the facts of that case, the Proposition 65 warning for nicotine exposures could be included on a product label for an over-the-counter nicotine patch with an existing warning approved by FDA that did not comply with Proposition 65. The court found that a Proposition 65 warning on the label was preempted because the Proposition 65 warning conflicted with the FDA purpose of encouraging pregnant women to stop smoking. FDA was concerned that pregnant women would continue to smoke, rather than use the nicotine patches, if a Proposition 65 warning were on the product label. The court discussed the Proposition 65 regulations and the content of the warnings as they existed in 2004.⁴⁶ The court did not find that OEHHA could not change its “known to cause” or any other language in its warning regulations.

As the commenter notes, the warning regulations discussed in the *Dowhal* case were repealed and replaced in 2016, and these regulations included changes to the safe harbor warning content. OEHHA has continued to propose and adopt safe harbor warning regulations, including tailored warnings, in Section 25607 et seq., some of which do not include the “known to cause” language (as discussed above).

The regulations promulgated by the Attorney General’s Office provide guidance to *parties negotiating Proposition 65 settlements*. They do not limit OEHHA’s ability to modify, repeal, or propose new regulations relating to safe harbor warnings, including

⁴² Section 25607.4. Alcoholic Beverage Exposure Warnings: **⚠ WARNING:** Drinking distilled spirits, beer, coolers, wine and other alcoholic beverages may increase cancer risk, and, during pregnancy, can cause birth defects. For more information go to www.P65Warnings.ca.gov/alcohol

⁴³ Section 25606(e), OSHA Hazard Communications Standard complies with warning requirement,

⁴⁴ Section 25607.7, FDA package inserts comply with the warning requirement.

⁴⁵ *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 918 (2004)

⁴⁶ 27 Cal. Code Regs. § 25601 (repealed in 2018); *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 918 (2004) (quoting the regulation); *Environmental Law Foundation v. Wykle Research, Inc.*, 134 Cal. App. 4th 60, 66 n.6 (2005) (“[T]he method of transmission relates to the reasonableness of the warning, whereas the content of the message relates to its clarity.”).

specifying warning content. The Attorney General's regulatory guidelines expressly provide as follows:

“This guideline provides additional information concerning the Attorney General's interpretation of the statute and existing regulations governing clear and reasonable warnings and factors that will be considered in the Attorney General's review of settlements. Nothing in this guideline shall be construed to authorize any warning that does not comply with the statute and regulations, or to preclude any warning that complies with the statute and regulations *or to conflict with regulations adopted by the Office of Environmental Health Hazard Assessment*. This guideline is intended to address some of the types of warnings commonly found in settlements, not to provide comprehensive standards.”⁴⁷

No changes to the proposed regulation were made based on these comments.

Comment 15 (CalChamber/CB Coalition): The commenters state that glyphosate is not an unusual case in that there are many listed chemicals about which there is substantial controversy as to whether they cause the relevant toxicological endpoint in humans. The commenters discuss di(2-ethylhexyl)phthalate (DEHP) as an example, and state that it was “determined after trial not to cause cancer in humans” and that this may not have been litigated had OEHHA taken the position that the warning would use the phrase, “known to the state to cause reproductive toxicity [sic] in animals.” The proposed rulemaking provides no policy basis for determining which chemicals are entitled to use language other than “known to the state to cause” or words to that effect.

Response: Under the Act, OEHHA has discretion to develop chemical-specific warnings. OEHHA decided to develop the glyphosate-specific warning that is the subject of this rulemaking because of the unique factual context surrounding the chemical, as discussed throughout this FSOR. This new proposed warning also addresses the concerns articulated by the district court in the *National Association of Wheat Growers* case.

Moreover, in support of its broad claim about the controversies allegedly surrounding many listed chemicals, the commenters cite to just one example – DEHP. The trial court in *Baxter v Denton*⁴⁸ found that DEHP poses no significant risk of cancer from its use in certain medical devices⁴⁹ based on the evidence presented in that case. The court did

⁴⁷ Title 11, Cal Code of Regs., section 3202 (emphasis added).

⁴⁸ *Baxter Healthcare Corp. v. Denton*, 120 Cal.App.4th 333, 15 Cal.Rptr.3d 430 (2004)

⁴⁹ Key evidence cited by the court – 2000 IARC's reclassification of the chemical from “possibly carcinogenic to humans” to “not classifiable as to its carcinogenicity to humans” due to biological mechanisms - was reversed by IARC in 2011 based on further evidence on biological mechanisms.

not order OEHHA to de-list the chemical and did not find the safe harbor warning to be inadequate. Whether Baxter would have sued OEHHA if it had been allowed to say the chemical causes cancer “in animals” is speculative and not relevant to the proposed rulemaking.

The Proposition 65 “State’s Qualified Experts” added DEHP to the Proposition 65 list, and several Proposition 65 authoritative bodies⁵⁰ classify DEHP as posing a “possible”, “probable”, or “reasonably anticipated” cancer hazard *for humans* based on its carcinogenicity in animals.⁵¹ Thus, the DEHP example provided by the commenters does not support their claim that glyphosate is not an unusual case of significant discrepancy in carcinogenicity classification across governmental bodies. Indeed, because there is no significant disagreement about the carcinogenicity of DEHP, this example is irrelevant here.

No changes to the proposed regulation were made based on these comments.

Comment 16 (CalChamber/CB Coalition): The commenters state that OEHHA’s current Article 6 safe harbor warning regulations prohibit businesses from adding anything to the safe harbor warnings other than the route of exposure and ways to avoid exposure. The commenters state that OEHHA is now proposing a safe harbor warning for glyphosate that is “engaging in the public discourse regarding listing decisions”, which businesses were prohibited from doing in the 2016 regulation if they intended to take advantage of the safe harbor warnings. The commenters allege the proposed glyphosate warning rulemaking is a litigation tactic, and a reversal of an unwavering practice that is not sound policy.

Response: As discussed in the FSOR to the Article 6 safe harbor regulations⁵², if businesses engage in “public discourse” concerning their opinions about listed

⁵⁰ Section 25306(l)

⁵¹ See National Toxicology Program (NTP): “reasonably anticipated to be a human carcinogen”, NTP, 2021. Report on Carcinogens, Fifteenth Edition.; Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service, available at: <https://ntp.niehs.nih.gov/go/roc15>; IARC: “possibly carcinogenic to humans”, IARC (2013) IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 101, Some Chemicals Present in Industrial and Consumer Products, Food and Drinking Water, Di(2-Ethylhexyl) phthalate, pages 149-284, available at: <https://publications.iarc.fr/125>; National Institute of Occupational Safety and Health (NIOSH): “DEHP is carcinogenic”, NIOH and NIOSH basis for an occupational health standard: Di(2-ethylhexyl)phthalate, US Department of Health and Human Services, Centers for Disease Control, available at: <https://www.cdc.gov/niosh/docs/90-110/pdfs/90-110.pdf?id=10.26616/NIOSH PUB90110>; US EPA: probable human carcinogen, Integrated Risk Information System (IRIS), US EPA National Center for Environmental Assessment, available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0014_summary.pdf.

⁵²OEHHA, Final Statement of Reasons, Title 27, California Code of Regulations, Proposed Repeal of Article 6 and Adoption of New Article 6, Regulations for Clear and Reasonable Warnings, page 20. Available at: <https://oehha.ca.gov/media/downloads/cmr/art6fsor090116.pdf>

chemicals they must do so separate from the Proposition 65 warning. The commenter argues the warning proposed here includes such “public discourse”. On the contrary, the proposed warning is clearly identified as a California Proposition 65 Warning, succinctly states the factual findings of two authoritative bodies, and broadly references the opinions of other agencies and scientific bodies. This is appropriate given the unusual circumstances here, in which several regulatory agencies reached a conclusion different from IARC’s.⁵³ Where the proposed warning is given, people who may be exposed to significant amounts of glyphosate will be warned prior to exposure, while also being advised of the range of scientific opinions concerning its carcinogenicity.

OEHHA is the lead agency for the implementation of Proposition 65. It has developed more specific warnings for certain chemicals and exposures that do not use the “known to the state to cause” language, as discussed in response to Comment 14. Under OEHHA’s safe harbor regulations, businesses can provide truthful contextual information, just not in or with the warning. OEHHA, however, is not constrained by the safe harbor regulations. OEHHA is proposing warning content that provides more clarity and context to the warning message for this chemical which furthers the right-to-know purposes of Proposition 65.

This alternative warning for exposures to the chemical addresses the concerns articulated by the district court in the *National Association of Wheat Growers* case. The proposed safe harbor warning accounts for a specific set of factual circumstances. The statute requires the warning to be clear and reasonable but does not specify the warning’s form or content. OEHHA has the express authority to adopt regulations that further the purposes of the statute. Adopting a warning that provides additional contextual information furthers the purposes of Proposition 65 by ensuring that the warning provides Californians with the factual information they need about glyphosate and carcinogenicity.

No changes to the proposed regulation were made based on these comments.

Comment 17: (CalChamber/CB Coalition) The commenters support the use of “contextual warnings” that place the risks of chemical exposure in context and help inform consumers of substantiated hazards as well as ways to reduce or avoid the risks of exposure. The proposed rulemaking does not provide a contextual warning, it is a “controversy warning.” It is unreasonable to expect ordinary consumers to review the science and come to their own conclusion as to whether a chemical is appropriately

⁵³ ISOR, pp. 5-6, available online at:

<https://oehha.ca.gov/media/downloads/crnrglyphosateisor071921.pdf>

considered a carcinogen. This approach does not further the purposes of a right-to-know statute like Proposition 65.

Response: OEHHA believes that the right-to-know function of Proposition 65 is served by providing clear, understandable information to consumers and allowing them to make choices accordingly. OEHHA disagrees with the conclusion of the commenters that ordinary citizens would be unable to understand a warning that explains the positions of different scientific entities concerning the carcinogenicity of a chemical. The proposed warning is factual, understandable, and clearly states the views of IARC and US EPA, two authoritative bodies, and references the findings of other agencies that made determinations similar to US EPA's.

US EPA reviewed the modified proposed language, found it to be sufficiently clear, and stated that the language could be approved by US EPA if pesticide registrants requested it for inclusion on glyphosate product labels⁵⁴. See response to comment 12 for further details.

Providing this information along with other contextual information in the proposed warning alerts consumers to the range of scientific opinions concerning the carcinogenicity of this chemical. For products that can cause significant exposures, a business can provide the warning language, and consumers can use the information provided to make their own decisions about whether to limit their exposure to glyphosate. The warning contains the following language, with a link to a website providing more information:

“For more information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate.”

Consumers who want to do their own research can use this link to access OEHHA's website, and find additional links to glyphosate information on IARC, US EPA, and other agencies' websites.

No changes to the proposed regulation were made based on these comments

Benefits of the Proposed Safe Harbor Warning

Comment 18 (CalChamber/CB Coalition): The commenters state that OEHHA makes “significant unfounded claims of the purported benefits of the proposed rulemaking.” The commenters quote statements from OEHHA about the importance of the proposed

⁵⁴ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at: <https://oehha.ca.gov/media/downloads/cnr/usepaaafreedhofftoehhadirzeiseglyphosate40822.pdf>

warning providing consumers with more information about glyphosate. The commenters allege that OEHHA “lacks expertise” in risk communication, and “offers no basis to determine how consumers will understand its proposed glyphosate warning or modify their behavior in response to it.” The commenters state that OEHHA “does not know how consumers will react to this nuanced and confusing glyphosate safe harbor warning, and any potential benefit from the warning cannot be presumed.”

Response: The commenters offer no factual evidence in support of their claim that the proposed warning is “confusing” or their presumption that OEHHA “lacks expertise” in risk communication. Proposition 65 is a landmark right-to-know law, and OEHHA is the agency charged with administering it. OEHHA has developed considerable expertise in administering the law, including drafting warning language for its safe harbor regulations. Providing consumers with the information in the proposed warning will afford Californians who may be exposed to significant levels of glyphosate the opportunity to learn more about the chemical. This would yield a significant public health benefit.

As stated in the ISOR (page 11) for this proposal:

“Proposition 65 was enacted to fill gaps⁵⁵ between various regulators where chemical hazard information is not being provided. It is important for individuals who are exposed to Proposition 65 listed chemicals to be given hazard information so they can make their own decisions about exposures to these chemicals. This issue has been discussed in tort cases brought by the plaintiffs’ bar that are based on the allegation that exposures to glyphosate caused individuals’ non-Hodgkin lymphoma. . . . In these cases, juries and courts have found warning to be an important safeguard that was missing in these situations. The safe harbor Proposition 65 warning can thus provide information to people to allow them to make informed decisions prior to exposure to Proposition 65 listed chemicals.’

No changes to the proposed regulation were made based on these comments.

Comment 19 (VerDuinM, Uttam, JetleyG): VerDuinM states that consumers and families have a right to know when they are exposed to glyphosate. Uttam expresses

⁵⁵ “The people of California find that hazardous chemicals pose a serious potential threat to their health and well-being, that state government agencies have failed to provide them with adequate protection, and that these failures have been serious enough to lead to investigations by federal agencies of the administration of California’s toxic protection programs. The people therefore declare their rights: ... (b) To be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm...” (Preamble to Proposition 65, the Safe Drinking Water and Toxic Enforcement Act, Available at: <https://oehha.ca.gov/media/downloads/proposition-65/general-info/prop65ballot1986.pdf>).

support for the proposed rulemaking. JetleyG states that, “[a]t the very least consumers should have the right to see clear Warnings for Exposures to Glyphosate on Consumer Products.”

Response: OEHHA acknowledges these comments.

No changes to the proposed regulation were made based on these comments.

Need for Proposed Safe Harbor Warning

Comment 20 (CalChamber/CB Coalition): The commenters argue that there is no need for a tailored Proposition 65 glyphosate warning because FIFRA already requires registered pesticides, including glyphosate products, to include a label with “hazard and precautionary statements for humans and domestic animals.” The commenters state that a FIFRA warning is different from a Proposition 65 warning because it does not “expressly call out cancer risk.” The commenters state, FIFRA warnings “provide clear, concise, practical directions to consumers that go far beyond the controversy warning proposed by OEHHA and instruct consumers as to how to reduce exposure to glyphosate.” Consequently, the commenters claim, a Proposition 65 warning “would not provide any marginal improvement to public health and welfare.”

Response: When voters passed Proposition 65, one of the supporting arguments was that there are gaps in the current regulation of toxic materials and that people have the right to know when they are being exposed to a carcinogen or reproductive toxin prior to exposure. The standard US EPA-approved product label for consumer products containing glyphosate does not provide any information about carcinogenicity. Therefore, the product label, without a clear and reasonable carcinogenicity warning, would not comply with the requirements of Proposition 65. Regarding the interaction between FIFRA and Proposition 65, see responses to comments 12 and 13 above.

No changes to the proposed regulation were made based on these comments.

Comment 21 (CalChamber/CB Coalition): The commenters state that “[c]onsumer residential use of glyphosate will be drastically reduced as Bayer, the maker of the most popular consumer products containing glyphosate (primarily sold under the RoundUp brand name) has announced that it “will replace its glyphosate-based products in the U.S. residential Lawn and Garden market with new formulations that rely on alternative active ingredients beginning in 2023.” As a result, the commenters argue, “glyphosate is not going to be used ‘extensively in consumer products’ in the United States, including California, for much longer,” and therefore a tailored warning is unnecessary.

Response: Bayer is not the only manufacturer of consumer products containing glyphosate, and it is not clear how many such products will remain on the market after 2023. The potential voluntary phaseout of glyphosate in certain of Bayer's products is not a reason to abandon the present rulemaking.

No changes to the proposed regulation were made based on these comments.

Comment 22 (CalChamber/CB Coalition): OEHHA has stated that the only exposures to glyphosate that will require a Proposition 65 warning are likely to be occupational exposures because other exposures are likely to be below the No Significant Risk Level ("NSRL"). Occupational exposures to glyphosate are subject to the federal Hazard Communication Standard (HCS). Since glyphosate does not present a situation where its exposure is not otherwise subject to the California HCS, there is no need for a glyphosate consumer product warning to be used for occupational exposure.

Response: The commenters misstate OEHHA's position regarding warnings for significant exposures to glyphosate from consumer products. OEHHA discusses this issue on page 7 of the ISOR:

"Exposures below the safe harbor NSRL do not require a Proposition 65 warning. Currently available information indicates that exposures to glyphosate from the use of many consumer products are likely to be lower than the NSRL and therefore will not require a warning. For example, lifetime exposure estimates for a typical home user of dilute, ready-to-use glyphosate-containing weed killer product can be estimated to be less than the NSRL of 1100 micrograms per day. Where products result in exposures to consumers above the NSRL, a safe harbor warning can be used. Occupational users of some glyphosate-containing consumer products may have significant exposures because these products may be used frequently throughout the day and year and in greater quantity, for example by independent landscapers."

No changes to the proposed regulation were made based on these comments.

Comment 23 (DoddC): The commenter tells the personal story of her struggle with a rare form of non-Hodgkin's lymphoma and recounts her experience early in her career working as a nurse in a mobile health unit providing care to agricultural workers. She states that she found the proposed warning language confusing and that consumers cannot interpret the complex proposed statement and decide which government agency to believe. She indicates that from court documents US EPA's risk assessment is in question. The commenter asks OEHHA not to adopt the proposed amendment, which she believes weakens the warning, but retain the existing general consumer product safe harbor warning.

Response: OEHHA acknowledges the hardship experienced by the commenter and appreciates the commenter sharing their personal story. As noted previously, the district court ruling in *National Association of Wheat Growers* found that not providing contextual information about contrary determinations as to the carcinogenicity of glyphosate rendered the general safe harbor warning misleading.⁵⁶ While OEHHA does not agree with the district court's decision, as the lead agency for implementation of Proposition 65, the alternative warning OEHHA is proposing addresses these concerns and is accurate. See also response to Comment 6.

The proposed safe harbor warning provides users of products containing glyphosate with more specific information about the conclusions reached by IARC, US EPA, and others so that they can evaluate their exposures to the pesticide and make informed decisions about using these products, considering the current range of opinions about glyphosate's carcinogenicity. The specific warning language addresses the unusual facts related to glyphosate discussed in this FSOR.

As stated in the ISOR (page 6):

“While the lack of consensus in scientific opinions is not unusual in risk evaluation of chemicals, this is an unusual case because several regulatory agencies did not reach a similar conclusion as IARC. . . . OEHHA is proposing tailored language for warnings for glyphosate that presents a balanced description of the likelihood that glyphosate can cause human cancer.”

No changes to the proposed regulation were made based on these comments.

Outside of the Scope of this Rulemaking

Comment 24 (Moms Across America, JetleyG, RuschE, RappaportW, CaswellS): Several commenters discussed the harmfulness of glyphosate and/or indicated it should be banned. CaswellS expressed general concern about toxic chemical exposures but did not name glyphosate.

Response: OEHHA acknowledges the comments and notes that banning use of glyphosate is outside OEHHA's authority under Proposition 65, and beyond the scope of this rulemaking.

No changes to the proposed regulation were made based on these comments.

⁵⁶ *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (E.D. Cal. 2020)

Comment 25 (Turning Green and Conscious Kitchen): The commenters support the warning proposal for glyphosate but ask OEHHA to require a warning for glyphosate on food products that contain more than 160 parts per billion, as recommended by the Environmental Working Group. The commenters support OEHHA in adding a clear, reasonable, and truthful consumer warning to food products containing glyphosate.

Response: OEHHA acknowledges the comment. OEHHA has adopted a safe harbor intake level of 1100 µg/day in regulation for this chemical. Exposures to glyphosate below this “No Significant Risk Level” from consumption of a food product do not require a Proposition 65 warning. The comments discuss a potential limit of 160 ppb concentration of glyphosate in food. However, Proposition 65 concerns exposures to the chemical from use of a product, not the concentration of the chemical in the product. The amount of glyphosate in the product at which a warning will be required is calculated based on how the product is used and the estimated exposure (intake) for the average user of the specific product. Section 25721 of the implementing regulations addresses how to calculate exposures to carcinogens from such products.

No changes to the proposed regulation were made based on these comments.

Comment 26 (CropLife RISE): The commenters state that OEHHA should adopt a regulation that establishes that labels for any pesticide approved or otherwise provided under federal law are sufficient to warn consumers about risks from pesticide exposure. They lay out the similarities and differences of this proposal to the prescription drug warning regulation found at Section 25607.7(a).

Response: The comment does not address the safe harbor warning proposed for glyphosate in the present rulemaking. Instead, it essentially proposes a blanket exemption from Proposition 65 warning for all pesticide consumer products of any kind so long as they are registered for use by the federal government. This recommendation is not relevant to the present rulemaking, which proposes a specific warning for exposures to glyphosate in consumer products.

No changes to the proposed regulation were made based on these comments.

Comments on the Modified Proposal and Documents Added to the Record During the April 13 to May 5, 2022 Comment Period and OEHHA's Responses

Comments Submitted

The organizations and individuals listed in the table below submitted comments during the April 13 – May 5, 2022, comment period on the modification of the proposed regulation and the four documents added to the administrative record.

Commenting Organizations	Designation
Consumer Brands Association, California Chamber of Commerce, Agricultural Council of California, American Bakers Association, American Chemistry Council, California Farm Bureau Federation, California Chamber of Commerce, California Grain & Feed Association, California League of Food Producers, California Pear Growers Association, California Seed Association, Chemical Industry Council of California, Peanut and Tree Nut Processors association, Plant California Alliance, and Western Plant Health Association	CalChamber/CB Coalition
CleanEarth4Kids.org	CleanEarth4Kids
CropLife America and Responsible Industry for a Sound Environment	CropLife RISE
GMO Free Florida	GMO Free Florida
Public Awareness for Preventive Healthcare - PAPHC, Inc.	PAPHC
Commenting Individuals	
Anderson, Mike	AndersonM
Anonymous (received at 3:53 pm on April 20, 2022)	Anon1
Anonymous (received at 2:06 pm on April 20, 2022)	Anon2
Anonymous (received at 4:00 pm on April 20, 2022)	Anon3
Anonymous (received at 2:52 pm on April 20, 2022)	Anon4
Anonymous (received at 2:18 pm on April 20, 2022)	Anon5
Anonymous (received 6:50 pm on May 4, 2022)	Anon6
Anonymous (received 3:56 pm on April 21, 2022)	Anon7
Anonymous (received 8:31 am on April 21, 2022) (signed Nancy)	Anon8
Anonymous (received 7:30 am on April 21, 2022)	Anon9
Anonymous (received 6:18 am on April 21, 2022)	Anon10
Applegate, Ralph	ApplegateR

Benbrook, Charles	BenbrookC
Blechman, Karen	BlechmanK
Boner, Liz	BonerL
Brandt, Emily S	BrandtE
Brynn	Brynn
Cara	Cara
Celia	Celia
Cooper, Marc	CooperM
Daniel DeShane	DeShaneD
DeSimone, Sandy	DeSimoneS
Dobi	Dobi
Edwards, Eric	EdwardsE
Engle, I	EngleI
Flynn, Edward	FlynnE
Fuller, Victoria	FullerV
Furey, K	FureyK
Gardner, Angela	GardnerA
Gardner, Christine	GardnerC
Graves, Caryn	GravesC
Gregg, Daniel	GreggD
Grigoriou, Visileios	GrigoriouV
Hearnley, Jay	HearnleyJ
Hitson, Tim	HitsonT
Hood, SL	HoodS
Jacques, Karn	JacquesK
Lieber, Leo	LieberL
Mamdani, Tahera	MamdaniT
Makishima, Harvey, CEO of PAPHC ⁵⁷	MakishimaH
Mathison, Brian	MathisonB
McAllister, Mary	McAllisterM
McClintock, B A	McClintockB
McCann, Annie	McCannA
Miller, Jane	MillerJ
Miller, Pamela	MillerP
M, Suzanne	SuzanneM
Nackazel-Ruck, Jane	Nackazel-RuckJ

⁵⁷ Public Awareness for Preventative Healthcare, Inc (PAPHC) separately submitted comments.

Neumann, Nancy	NeumannN
Nguyen, Alice	NguyenA
Palla, Paul	PallaP
Leotien Parlevliet	ParlevlietL
Ray, Thomas	RayT
Rich, Christine	RichC
Seralini, Professor, University of Caen Normandy, France	Prof Seralini
Škalič, Dita	ŠkaličD
Snapp, Frank	SnappF
Stern, Richard	SternR
Tomsists, Pati	TomsitsP

The comments in the 66 submissions received are summarized below along with OEHHA's responses to them. In the April 13, 2022 Notice of Modification, OEHHA advised prospective commenters that it would "only address comments received during this comment period that address the modifications to the text of the proposed regulation, documents added to the record, or the procedures followed [in this rulemaking]." OEHHA received a number of comments that do not address the modifications to the text, added documents, or procedures, and are therefore not relevant.

The modified proposed Section 25607.49, subsection (a)(3), is shown below for reference. Additions and deletions to the proposed text are shown in underline (example) and strike-out (~~example~~), respectively.

(3) The words, "Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations. ~~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 potential ~~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."

The four documents noticed on April 13, 2022, and added to the administrative record are:

- US EPA Office of Pesticide Programs, Label Review Manual, Chapter 7 Precautionary Statements (Revised March 2018), section IV Determining the

precautionary labeling, Part A, Signal word, Section 4 Related information on Proposition 65 warnings, page 7- 4.

- OEHHA, letter from Lauren Zeise, Director, to Michal Freedhoff, US EPA Assistant Administrator, Office of Chemical Safety and Pollution Prevention, March 21, 2022.
- US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022.
- US EPA Office of Chemical Safety and Pollution Prevention, Letter from Michael L. Goodis, Director Registration Division, Office of Pesticide Programs, to registrants of products that contain glyphosate, August 7, 2019.

Summary of Comments and Responses

Comment 27 (Commenters identified below): Commenters recommend glyphosate product labels contain the language “known to cause cancer” or “causes cancer”, or similar language. Some refer to this as a “proper Prop 65 label”; some explicitly object to the change in language regarding US EPA classification⁵⁸. In calling for the safe harbor language to revert to the “known to cause cancer” or “causes cancer” wording, the following reasons are given:

- To keep people safe from glyphosate containing products or protect health or the health of our planet (AndersonM, Anon2, Anon5, Anon7, GardnerA, MamdaniT, NeumannN, MillerP)
- Glyphosate is still oncogenic (attached internal US EPA 1984 memorandum⁵⁹) and use of Roundup is linked with non-Hodgkin’s lymphoma (FureyK, RichC)
- To allow consumers to make informed choices or noting Californians have a right to know (Anon10, Celia)
- More transparency (Anon9)
- To do the right thing (DeShane, HoodS)
- Anything less is providing inaccurate, incomplete, and potentially dangerous information to consumers (MillerJ)
- The product causes cancer (EdwardsE) and in addition kills our bees (ParlevlietL)

⁵⁸ US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations.

⁵⁹ Memorandum from William Dykstra, PhD, Toxicology Branch, Hazard Evaluation Division, US EPA Office of Pesticides and Toxic Substances, to Hoyt Jamerson, Registration Division, Subject: Glyphosate; oncogenicity study in the mouse; PP#3E2845; Caswell No.: 661, February 10, 1984.

- Importance of warning. The commenter used the chemical for many years and was diagnosed with stage 4 non-Hodgkin's lymphoma (CooperM)
- The need to have a "proper P65 label" (AndersonM, Anon2, Anon5, Anon7, Anon9, Anon10, Cara, Celia, Dobi, EdwardsE, FullerV, FureyK, GravesC, GrigoriouV, LieberL, MillerJ, Nachazel-RuckJ, NeumannN, ParlevlietL, SternR, SuzanneM, TomsitsP)
- No reason given (Anon4)

Other commenters recommend warning language be stronger than the proposed modified text, without being more specific:

- "CleanEarth4Kids.org asks you not to weaken the warning label on products containing glyphosate. ... We ask you to make the label stronger. Please do not add 'US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations.' "
(CleanEarth4Kids)
- "Glyphosate warnings need to be made even stronger... It is the main reason why my Mother contracted lymphoma and died." (FlynnE)
- " 'increase the warning label toxicity language' rather than reduce it". Commenter also provides text from the late Dr. Copley's memorandum cited by BrooksW in comments on the original proposal (HearnleyJ)
- "...please don't downplay the known negative health effects of glyphosate to human health and function. This chemical is banned in other countries..."
(Anon8)

Other commenters indicate:

- "follow the precautionary principle and include glyphosate in its Prop 65 notification as a probable carcinogen..." (JacquesK)
- the labelling "should state clearly that the container has a product that *may* cause cancer and/or endocrine disruption" [emphasis added] "Whether or not it causes cancer is not the issue. The real issue is that people must be given the ability to make an informed decision based on truthful information." (PAPHC)
- the label should contain "cancer" and "endocrine disruption" and "not for use in any area that could come in contact with water, soil, endangered species habitats, humans, or pets." (GMO Free Florida)

Response: OEHHA acknowledges the numerous comments that ask OEHHA to strengthen the warning language or revert to the general safe harbor warning for consumer products in Section 25603: "known to cause cancer". For the reasons

discussed above, including US EPA's determination that it will permit pesticide registrants to use the warning⁶⁰ adopted here, OEHHA declines to follow this approach.

Some commenters recommended the use of "probable carcinogen" or "may cause cancer". That concept is generally captured in the sentence indicating IARC's finding that glyphosate is "probably carcinogenic to humans."

OEHHA declines to omit explicit mention of US EPA and its classification of glyphosate from the warning and the reference to findings by other bodies. US EPA's determination is included, along with IARC's, on which the Proposition 65 listing of glyphosate is based, because, on these facts, the proposed warning presents a balanced description of the conflict between IARC's conclusion and the conclusions of US EPA, as well as other agencies.

The district court held in *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (E.D. Cal. 2020), that a warning that does not provide such contextual information about contrary determinations regarding the carcinogenicity of glyphosate would be misleading. While OEHHA does not agree with the court's conclusion that the general consumer product safe harbor warning would be misleading or otherwise trigger First Amendment concerns, OEHHA, as the lead agency for implementation of Proposition 65, is proposing this modified alternative warning for consumer product exposures to glyphosate that require a warning. The proposed warning addresses the district court's concerns and is accurate.⁶¹

Finally, the general safe harbor warning for consumer products in Section 25603 that uses the phrase "known to cause cancer" was language US EPA would not approve for glyphosate, should a pesticide registrant request to use it on the product label to provide a Proposition 65 warning for glyphosate exposures⁶². In contrast, pesticide registrants who wish to place a Proposition 65 warning on their products using the proposed language can receive the required approval from the US EPA, since:

[US EPA] "has determined that the new glyphosate-specific safe harbor language proposed in OEHHA's recent letter is sufficiently clear regarding EPA's position and thus would not be considered false and misleading. Therefore, this revised

⁶⁰ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at: <https://oehha.ca.gov/media/downloads/cnr/usepaaafreedhofftoeohhadirzeiseglyphosate40822.pdf>

⁶¹ See responses to comments 9 and 10 and pages 4 and 5.

⁶² US EPA Office of Chemical Safety and Pollution Prevention, Letter from Michael L. Goodis, Director Registration Division, Office of Pesticide Programs, to registrants of products that contain glyphosate, Aug. 7, 2019. Available at: <https://oehha.ca.gov/media/downloads/cnr/usepaoppgoodistoglyphosaterregistrants8-7-19.pdf>

language could be approved by EPA if pesticide registrants requested it for inclusion on glyphosate product labels, and the products would not be considered misbranded.”⁶³

Some commenters recommended the inclusion in the glyphosate safe harbor warning language of statements relating to other endpoints or additional topics. OEHHA declines to do so for the reasons discussed in its response to comments on the original proposal. OEHHA also notes those recommendations relate to topics outside the scope of the proposed modifications and are unrelated to the addition of documents to the record, and therefore are irrelevant to this phase of the rulemaking.

No changes to the proposed rulemaking were made based on these comments

Comment 28 (Commenters identified below): General statements of opposition or support for the modification to the proposal without specific recommendations for change are:

- OEHHA “is proposing changes to its messaging to consumers regarding the cancer risk associated with products made with ... glyphosate... This is outlandish ... I will support opposition to these changes ...” (RayT)
- “The EPA has not found that glyphosate poses no risk of cancer, they simply want to state that they have. There is plenty of evidence that there is significant risk, and EPA's own scientists disagree on this proposed statement. Your job is to protect the people, not Monsanto.” (HitsonT)
- “How is this even a consideration? ... the precautionary principle would be the standard to follow. If there is possible concern for harm, we should take all precaution to protect human health and our environment.” (GardnerC)
- Stated “please do everything you can to warn the public of health risks associated with glyphosate” (BlechmanK).
- Stated “ensure that these products are labeled so that Californians can see clearly what is contained in these products” (BonerL)
- Indicated “we should take all precaution to protect human health and our environment” but does not recommend specific changes (GardnerC)
- Stated that “there are good reasons to assume glyphosate can cause cancer, and when evidence is inconclusive, we should take precautions and err on the

⁶³ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at: <https://oehha.ca.gov/media/downloads/cnr/usepaaafreedhofftoehhadirzeiseglyphosate40822.pdf>

safe side. I believe glyphosate-containing products should, for now, be labelled as causing cancer.” (Škalič, D)

One commenter reiterated the modifications without a comment of support or objection (Englel) and another submitted apparent instructions to comment to OEHHA without providing a specific comment of support or objection (LleberL).

Response: OEHHA acknowledges the comments. The proposed warning is factual, understandable, and clearly states the views of authorities regarding glyphosate’s carcinogenicity. It is a Proposition 65 warning for glyphosate exposures that US EPA would approve for placement on a pesticide product label; it addresses the concerns expressed by the court in the *National Association of Wheat Growers* case; and it is accurate. For further discussion, see response to comment 12 above.

No changes to the proposed rulemaking were made based on these comments.

Comment 29 (MathisonB, CalChamber, CropLife RISE, McAllisterM): Commenters question the weight given to US EPA versus IARC or vice versa in the modified proposed language.

The CalChamber/CB Coalition, CropLife RISE and MathisonB comment that having the IARC determination before the language regarding US EPA and other authorities is misleading and implies that IARC’s minority view is the predominant one and that there is equal weight for and against the proposition that glyphosate causes cancer, arguing the great weight of evidence is that glyphosate does not cause cancer.

McAllisterM states that the originally proposed glyphosate safe harbor warning is biased, and the proposed revision is also biased because it refers to “other authorities” that agree with US EPA’s assessment that glyphosate is “not likely to be carcinogenic to humans” “without making a similar statement about” bodies that agree with IARC “that glyphosate is ‘probably carcinogenic.’ The commenter notes that numerous cities, counties, states and countries throughout the world have taken steps to restrict or ban glyphosate based on the IARC assessment of glyphosate and calls for the label for glyphosate to be revised to add the phrase ‘other authorities have made similar determinations’” to the sentence expressing the IARC finding.

Response: During pesticide registration, US EPA determines whether the registrant’s request for a product label change complies with FIFRA, and is not misbranded; for example, it may not contain false or misleading statements. US EPA has found the modified language⁶⁴ is not misleading. US EPA stated:

⁶⁴ See pages 3 and 36.

“Therefore, this revised language could be approved by EPA if pesticide registrants requested it for inclusion on glyphosate product labels, and the products would not be considered misbranded.”⁶⁵

OEHHA notes that most of the comments described above do not take the view expressed by CalChamber/CB Coalition, CropLife RISE and MathisonB. Most commenters express concerns about the messaging regarding carcinogenicity in the modified warning and are concerned that the message does not convey that the chemical causes cancer. A number call for more direct language that glyphosate causes cancer or is known to cause cancer, or a strengthening of the language. Some recommend that glyphosate at least be called a probable carcinogen.

McAllisterM recommends an additional sentence regarding other bodies to provide more equal weight to the IARC vs US EPA classifications. OEHHA declines to make that change. OEHHA notes that while several local, regional, and national governments may curtail the use of glyphosate due to carcinogenicity and environmental concerns, the comment indicates these bodies rely on IARC’s determination for doing so rather than making their own independent scientific determinations.

No changes to the proposed rulemaking were made based on these comments.

Comment 30 (CropLife RISE, MathisonB): Commenters recommend replacing the modified language about the findings by US EPA and other authorities:

- CropLife RISE opposes the proposed regulation and states it does not believe a glyphosate warning could comply with the First Amendment or avoid federal preemption but in the event OEHHA adopts a regulation it recommends the following replacement⁶⁶ language:

“The United States Environmental Protection Agency (“US EPA”) has determined that glyphosate is not likely to be carcinogenic to humans. Numerous other authorities worldwide have also determined that glyphosate is not likely to be carcinogenic to humans. The International Agency for Research on Cancer (“IARC”) classified glyphosate as

⁶⁵ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at: <https://oehha.ca.gov/media/downloads/cnrn/usepaaafreedhofftoehhadirzeiseglyphosate40822.pdf>.

⁶⁶ The commenter’s proposed language would replace the following sentences in the proposed warning: “The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations.”

probably carcinogenic to humans. US EPA has reviewed and rejected IARC's determination."

- MathisonB recommends the language regarding US EPA and other authorities⁶⁷ in the proposed warning be changed to:

"US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other worldwide regulatory authorities including EFSA, ECHA, the Canadian PMRA, the German BfR, the Australian PRMA, the FSJC of Japan, the New Zealand [sic] EPA, and more have also concluded that glyphosate is not likely carcinogenic."

Response: OEHHA declines to modify the proposed warning in the manner suggested by either commenter. The proposed warning is consistent with the First Amendment and not preempted under FIFRA for the reasons stated in responses to earlier comments (see for example responses to comments 9 and 12).

Further, the language in both commenters' proposed warnings is inaccurate. The referenced authorities have not all used the wording "not likely to be carcinogenic".

The major European agencies, the European Chemicals Agency (ECHA) and the European Food Safety Agency (EFSA), did not make a determination that glyphosate was "not likely to be carcinogenic to humans". Rather, ECHA found that the data were insufficient to place glyphosate⁶⁸ in the European classifications⁶⁹ "known" carcinogen (Category 1A), "presumed" (Category 1B) carcinogen, or "presumed" (Category 2) carcinogen. ECHA⁷⁰, in its 2016 evaluation, essentially agreed with IARC's conclusion regarding the human evidence:

⁶⁷ "US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations."

⁶⁸ European Chemicals Agency (ECHA), CLH report. Proposal for Harmonised Classification and Labelling. Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2. Substance name: N-(phosphonomethyl)glycine; Glyphosate (ISO), May 2016, Available at: <https://echa.europa.eu/documents/10162/9fb5d873-2034-42d9-9e53-e09e479e2612>.

⁶⁹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, December 21, 2008, L353, page 104. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=EN>

⁷⁰ European Chemicals Agency (ECHA), CLH report. Proposal for Harmonised Classification and Labelling. Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2. Substance name: N-(phosphonomethyl)glycine; Glyphosate (ISO), May 2016, Available at: <https://echa.europa.eu/documents/10162/9fb5d873-2034-42d9-9e53-e09e479e2612>

“The DS [dossier submitter] concluded in accordance with IARC (2015) ‘There is limited evidence in humans for the carcinogenicity of glyphosate.’ This is perhaps the best description of the available data since the other IARC categories (“Evidence suggesting lack of carcinogenicity”; “Inadequate evidence of carcinogenicity”; “Sufficient evidence of carcinogenicity”) are even less suitable.”

ECHA found inconsistencies within each of the three tumor types that had positive findings in multiple experiments in mice (malignant lymphoma, renal tumors, hemangiosarcoma). Overall ECHA found that the data were insufficient to classify glyphosate⁷¹ as a “known” or “presumed carcinogen” in European categories 1A or 1B. ECHA and EFSA have been engaged in a process to re-evaluate the carcinogenicity of glyphosate. On May 30, 2022 the ECHA Committee for Risk Assessment declined to change the ECHA classification of glyphosate.⁷² That Committee expects to finalize its opinion and send it to EFSA for consideration in its peer review of the pesticide⁷³.

The German Federal Institute of Risk Assessment (BfR) is participating in the ongoing European assessment process. The German Cabinet on February 9, 2021 approved draft legislation to ban glyphosate by the end of 2023. They did not address carcinogenicity in their statement. As noted in the ISOR, the French Agency for Food, Environmental and Occupational Health and Safety (ANSES)⁷⁴ determined that the evidence was insufficient to find glyphosate to be a presumed carcinogen, that the substance could possibly be classified in Category 2 [suspected human carcinogen], but that it could not reach a decision absent a detailed analysis of the data. ANSES has called on ECHA to rapidly re-review glyphosate, a process expected to be complete by fall 2022. Health Canada’s Pest Management Regulatory Agency has been working collaboratively with US EPA on the re-evaluation of glyphosate. Its ultimate conclusion in 2017 regarding carcinogenicity was expressed in terms of risk: that glyphosate was “unlikely to pose a human cancer risk”.⁷⁵ Dr. Wayne Temple, who wrote the New Zealand Environmental Protection Authority review of glyphosate, reached a hazard

⁷¹ Reference in footnote 68.

⁷² ECHA/NR/22/10. May 30, 2022 web posting. Glyphosate: no change proposed to classification. available at <https://echa.europa.eu/-/glyphosate-no-change-proposed-to-hazard-classification> The adopted opinion will be sent to the European Commission and EFSA by mid-August, 2022.

⁷³ The EFSA process is expected to be completed in July 2023.

<https://www.efsa.europa.eu/en/news/glyphosate-efsa-and-echa-update-timelines-assessments>

⁷⁴ ANSES (2016). Opinion of the French Agency for Food, Environmental and Occupational Health and Safety on the glyphosate request No 2015-SA-0093. Available at: <https://www.anses.fr/en/system/files/SUBCHIM2015sa0093EN.pdf>.

⁷⁵ Health Canada, Glyphosate Re-evaluation Decision, RVD2017-01, April 28, 2017.

conclusion similar to US EPA's, but used different wording from that used by US EPA, concluding that it was "unlikely" to be carcinogenic to humans.

OEHHA modified the proposed regulation by listing the conclusion reached by US EPA before the conclusions reached by other authorities. The language used to describe US EPA's conclusion was also modified to use US EPA's precise language, namely that glyphosate is "not likely to be carcinogenic to humans." However, because of the varied descriptors used by other bodies and the varying level of evidence they capture, the description of other bodies now states "other authorities have made similar determinations." It would be factually inaccurate to state that "Numerous other authorities worldwide have also determined that glyphosate is not likely to be carcinogenic to humans" or to attribute that language to all the organizations named in MathisonB's recommended warning language.

No changes to the proposed rulemaking were made based on these comments.

Comment 31 (CropLife RISE, CalChamber/CB Coalition, RayT, MillerJ): The term "personal cancer risk" was changed in the modification to "potential risk".

- CropLife RISE recommends deleting the entire sentence containing the term and do not comment on the change from "personal cancer" risk to "potential" risk. They do, however, assert that it and the next sentence "misleadingly convey that exposure to glyphosate in fact poses a risk of cancer."
- CalChamber indicates that the proposed warning refers to "potential risk" and encourages consumers to consider "ways to reduce [their] exposure" and that this misleadingly conveys that exposure to glyphosate in fact poses a risk of cancer such that consumers should reduce their exposure to glyphosate.
- RayT states: "OEHHA is also changing the phrase "personal cancer risk" to "potential risk." This is outlandish and anyone with half a brain knows it. I will support opposition to these changes as well as excessive corporate influence in public policy." MillerJ states: "I also oppose OEHHA proposed change of the phrase "personal cancer risk" to "potential risk." Any glyphosate-containing products should have a proper Prop 65 label on them."

Response: Changing the modifier of the term "risk" in the proposed modification of the warning text accounts for the different conclusions that IARC, US EPA and other authorities reached. The approach of deleting the entire sentence downplays any possibility of adverse effects from use of the product. Thus, it would not further the purposes of Proposition 65. RayT and MillerJ see the change as weakening the association of the chemical with cancer risk. Given the various opinions on the carcinogenicity of the chemical, OEHHA declines to revert to the original text. OEHHA's

proposed language provides a clear, balanced message aimed at allowing consumers to make informed choices.

No changes to the proposed rulemaking were made based on these comments.

Comment 32 (CropLife RISE): CropLife RISE acknowledges the addition of the April 8, 2022, US EPA letter stating that the modified warning does not violate FIFRA’s “misbranding provision because it ‘acknowledges the EPA position’ that ‘US EPA has determined that glyphosate is not likely to be carcinogenic to humans.’” CropLife RISE quotes other statements from the letter. “The letter states that ‘[t]he Agency continues to stand behind its robust scientific evaluation of the carcinogenic potential of glyphosate.’” CropLife RISE states that EPA’s conclusion remains consistent with many international expert panels and regulatory authorities,” and that the letter explicitly affirms that “EPA’s scientific conclusions regarding the glyphosate cancer classification have not changed since the August 7, 2019, letter to glyphosate registrants.”

CropLife RISE also notes the addition of US EPA’s August 7, 2019 letter to the record and quotes from it: “EPA disagrees with IARC’s assessment of glyphosate. 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.’” CropLife RISE asserts that US EPA therefore “found the safe-harbor Proposition 65 warning language for glyphosate ‘to constitute a false and misleading statement.’”

Response: OEHHA acknowledges the quoted material from US EPA letters. OEHHA notes that the April 8, 2022 US EPA letter speaks for itself, and that US EPA did not find the revised proposed safe harbor language to be false or misleading.

No changes to the proposed rulemaking were made based on these comments.

Comment 33 (CropLife RISE): CropLife RISE reiterates general comments and arguments raised with respect to the original proposal, contending that the proposed safe harbor warning violates the First Amendment, and that federal law preempts the application of Proposition 65 warnings to labels for glyphosate. It states its continued opposition to the proposed rulemaking.

Response: OEHHA acknowledges the commenters’ continued opposition to the rulemaking. OEHHA disagrees with the commenters’ conclusions regarding the First Amendment and preemption for the reasons stated in the ISOR and in the responses to comments 9,10 and 12 above on the initial proposal.

No changes to the proposed rulemaking were made based on these comments.

Comment 34 (BenbrookC): The commenter expresses approval of the language used in the modified proposed safe harbor warning. The commenter encourages OEHHA and US EPA to finalize a GBH [glyphosate base herbicides] cancer-warning statement that is compliant with Proposition 65 requirements and acceptable to US EPA Office of Pesticide Programs. Commenter recognizes the 2019 US EPA letter indicating that US EPA found the Proposition 65 glyphosate warning language available at the time “would be ‘false and misleading’ and therefor [sic] render the products misbranded under federal law and illegal for sale.” Regarding the specific language proposed in Section 25607.49, subsection (a)(3), commenter states:

“The first sentence in the warning states: ‘Using this product can expose you to glyphosate.’ No one disputes this statement. The use of the word ‘can’ instead of ‘will’ is appropriate because there are ways to apply Roundup that lead to essentially no applicator exposure....In the interest of technical accuracy and full disclosure, the statement could be revised to read ‘...expose you to glyphosate and other chemicals used in the formulation of this glyphosate-based herbicide.’ However, such an addition would add complexity and give rise to confusion that should be avoided.”

“The next two sentences are clear, accurate statements of the glyphosate cancer-risk classification decisions issued by IARC and [US EPA] OPP.”

“I enthusiastically applaud the final sentence⁷⁶ in the proposed OEHHA warning:

‘A wide variety of factors affect your potential risk including the level and duration of exposure to the chemical.’

“This is one of the first cautionary or warning statements destined for a pesticide product label that overtly acknowledges the obvious -- how often and how intensively a person applies a pesticide will impact lifetime exposure levels, and the higher a person’s exposures, the higher the associated risks. It is an appropriate and important message to deliver because it will help convince and motivate some heavy users, and hopefully most, to exercise discipline and care as they apply GBHs.”

The commenter offers an alternative, longer version of the last sentences of the warning “to motivate a higher degree of care among those applying GBHs”.

“A wide variety of factors affect your potential risk if you handle, mix or apply this

⁷⁶ While the quoted language is not from not the final sentence of the proposed warning, the commenter identifies the specific language he is commenting on.

product. The frequency of applications, number of hours per day spent handling or spraying this product, the equipment used to make your applications, and the clothes, footwear and personal protective equipment (i.e. gloves) you use will impact your daily and lifetime exposures to the chemical.”

The commenter also offers background information and sometimes first-hand impressions on the actions and coordination of relevant California state and US EPA entities over the past 40 years, as well as on the science surrounding glyphosate, and his perspective on the differences in the IARC and US EPA carcinogenicity classifications for glyphosate.

Response: OEHHA acknowledges the commenter’s support for the proposed warning language, including the language in the modified regulatory proposal. This response focuses on his recommended modifications to the proposed text and his comments related to the documents added to the record.

The commenter refers to US EPA’s 2019 letter⁷⁷, one of the documents added to the administrative record on April 13, 2022, highlighting its importance without further commenting on the letter. Regarding encouraging a cancer warning statement that is compliant with Proposition 65 requirements and acceptable to US EPA Office of Pesticide Programs, the modified regulatory proposal provides language that does just that. Specifically, US EPA indicated that it:⁷⁸

“...has determined that the new glyphosate-specific safe harbor language proposed in OEHHA’s recent letter is sufficiently clear regarding EPA’s position and thus would not be considered false and misleading. Therefore, this revised language could be approved by EPA if pesticide registrants requested it for inclusion on glyphosate product labels, and the products would not be considered misbranded.”

OEHHA further acknowledges the commenter’s support for the sentence:

‘A wide variety of factors affect your potential risk including the level and duration of exposure to the chemical.’

⁷⁷ US EPA Office of Chemical Safety and Pollution Prevention, Letter from Michael L. Goodis, Director Registration Division, Office of Pesticide Programs, to registrants of products that contain glyphosate, Aug. 7, 2019. Available at:

<https://oehha.ca.gov/media/downloads/cnrn/usepaoppgoodistoglyphosaterregistrants8-7-19.pdf>

⁷⁸ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at:

<https://oehha.ca.gov/media/downloads/cnrn/usepaaafreedhofftoehhadirzeiseglyphosate40822.pdf>

The modification changed the words “personal cancer risk” to “potential risk”. The commenter “enthusiastically applaud[s]” that sentence. He also suggests the possibility of alternative language, which also used the term “potential risk” in the same context. The alternative, longer version of the last sentences of the warning offered by the commenter is beyond the scope of OEHHA’s proposed modification of the text and would unnecessarily lengthen the warning.

No changes to the proposed rulemaking were made based on these comments.

Comment 35 (CalChamber/CB Coalition): The CalChamber/CB Coalition states its continued opposition to the proposed modifications, indicating they oppose the modifications on the same grounds stated in their October 7, 2021, comments on the original proposal. They call for the proposed rulemaking to be withdrawn and reiterate issues raised earlier. They state the modification addresses only one of their objections without stating what objection that was. They mention two of the documents added to the record – the letters from the OEHHA Director and the letter from US EPA Assistant Administrator – without commenting on the substance. They mention these letters and refer to “minor” changes to the proposed warning in stating that “OEHHA appears to believe it has succeeded in creating a Proposition 65 warning for glyphosate that is not misbranded within the meaning of” FIFRA. They state the safe harbor warning remains misleading because it conveys the message that there is equal weight for and against the proposition that glyphosate causes cancer when the greater weight of evidence is that it does not.

Response: The continued objection to the rulemaking is acknowledged. Regarding FIFRA and the commenters’ assertion that the proposed warning remains misleading, the pesticide registrants who wish to place a Proposition 65 warning on their products label using the proposed language can request the required approval from US EPA. Specifically, US EPA stated that the proposed warning “is sufficiently clear regarding EPA’s position and thus would not be considered false and misleading,” and further stated, “this revised language could be approved by EPA if pesticide registrants requested it for inclusion on glyphosate product labels, and the products would not be considered misbranded.”⁷⁹ The remaining comments restating earlier objections that do not address the modifications to the text of the proposed regulation, documents added to the record, or the procedure used in the rulemaking, are not relevant and require no response.

No changes to the proposed rulemaking were made based on these comments.

⁷⁹ US EPA Office of Chemical Safety and Pollution Prevention, letter from Michal Freedhoff, Assistant Administrator, to Lauren Zeise, OEHHA Director, April 8, 2022. Available online at: <https://oehha.ca.gov/media/downloads/cnr/usepaaafreedhofftoehhadirzeiseglyphosate40822.pdf>

Comment 36 (MathisonB): The commenter discusses the underlying basis for the IARC identification of glyphosate as probably carcinogenic to humans; findings of other authoritative bodies; various listing mechanisms under Proposition 65; and prior OEHHA rulemakings adopting a no significant risk level (NSRL) for glyphosate, addressing chemicals in coffee, and addressing acrylamide exposures from food. The commenter provides his opinions concerning certain legal issues, court proceedings and witnesses in those cases along with an appendix discussing his opinions about the science around glyphosate and whether a warning should be given at all. The commenter also suggests alternative warning text as follows:

CALIFORNIA NOTICE

Using this product can expose you to glyphosate. The US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other worldwide regulatory authorities including EFSA, ECHA, the Canadian PMRA, the German BfR, the Australian PRMA, the FSJC of Japan, the New Zealand EPA, and more have also concluded glyphosate is not likely carcinogenic. The International Agency for Research on Cancer (IARC) has classified glyphosate as probably carcinogenic to humans, however the IARC: (1) does not review all scientific data; (2) promotes 'key characteristics' wherein some are no better than a chance in predicting cancer risk; (3) lacks competency in performing quantitative risk characterizations; and therefore (4) has little or no regulatory authority with the exception of compelling OEHHA and the State of California to force listing under Proposition 65. OEHHA has set a non-significant risk level (NSRL) of 1,100 µg/day based on liver tumors in rodents that were not reproducible in additional rodent bioassays. A wide variety of factors affect your potential 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)

Response: Much of the commentary does not address the modifications to the text of the proposed regulation, documents added to the record, or the procedures followed in the rulemaking and requires no response.

The commenter's suggested warning language in the second sentence, which is directed at the proposed modification, is addressed in responses to comments 29 and 30. Also, the commenter includes the proposed modified sentence on personal risk without change in his suggested warning: "A wide variety of factors affect your personal risk...."

A large segment of the suggested text for the warning is not directed at OEHHA's modified proposed language. For example, "however, IARC (1) does not review all the scientific data...OEHHA has set a non-significant risk level (NSRL); (2) promotes 'key characteristics wherein some ...were not reproducible in additional rodent bioassays.'" It is essentially a statement of opinion concerning IARC as an agency and the basis for

the OEHHA NSRL. It uses language that is technical and not understandable in a consumer product warning and is beyond the scope of the proposed modifications.

See also summary and responses to comments 38 and 39.

No changes to the proposed rulemaking were made based on these comments.

Comment 37 (NguyenA): The proposed changes to the text are “unacceptably incautious”. The commenter raises concerns about the credibility of US EPA's opinion and its reliance on industry studies versus the published and peer-reviewed research used by IARC. The commenter further raises issues about the scientific literature used in these determinations. The commenter states: “If OEHHA's Prop 65 label language counterweights IARC determination with US EPA's opposite conclusion, OEHHA must honestly inform the consumer of the differences in the 2 bodies' sources of data and methodology.”

Response: While there are differences in the approaches used by US EPA and IARC in reaching their conclusions, explaining them in the text of the warning would make it unnecessarily long. The relevant documents from US EPA and IARC are linked in the glyphosate fact sheets available on the OEHHA website via the URL in the warning (www.P65Warnings.ca.gov/glyphosate) in the event a consumer is interested in exploring the two agencies' methodologies. The proposed warning text provides a balanced view of the differing opinions of the various agencies while providing consumers with sufficient information to make informed decisions about their exposures to glyphosate.

No changes to the proposed rulemaking were made based on these comments.

Comment 38 (MathisonB): The commenter requests that OEHHA provide “any significant correspondence and consultations with the Carcinogen Identification Committee that contributed to the records and rulemaking” and “add information on benchmark dose models and model selected for safe harbor calculations in determining the no significant risk level (NSRL) of 1,100 µg/day.”

Response: Documents relied on in developing the present rulemaking were identified for public comment in the July 2021, Initial Statement of Reasons, in the April 13, 2022, Notice of Modification to Proposed Regulation and Addition of Documents to the Rulemaking File and in the June 28, 2022 Notice of Augmentation of Record. The Carcinogen Identification Committee was updated on OEHHA's rulemaking and other

activities at its December 2021 meeting⁸⁰ but is not otherwise involved in this rulemaking. The development of the NSRL for glyphosate was the subject of a separate rulemaking that was completed in 2018 and that was peer reviewed by members of the Carcinogen Identification Committee. The entire administrative record for that proceeding can be obtained from OEHHA. In addition, relevant notices, the Initial Statement of Reasons, and the Final Statement of Reasons that contain the information on the development of the NSRL are available on OEHHA's website.

No changes to the proposed rulemaking were made based on these comments.

Comment 39 (Mathison): The commenter states: "While the legal arguments may be as complex as those involving glyphosate science, it remains in the best interests of the State of California and the United States to await the pending brief of Solicitor General Prelogar and potential decisions by the Supreme Court."

Response: OEHHA declines to delay the rulemaking and notes the Supreme Court denied Monsanto's petition for certiorari on June 21, 2022, in *Monsanto Co. v. Edwin Hardeman*⁸¹. OEHHA further notes that the comment does not address the proposed modifications to the text, added documents, or procedures followed, and is therefore not relevant.

No changes to the proposed rulemaking were made based on these comments.

Comment 40 (DeSimoneS): The commenter raises concerns regarding industry influence on US EPA and internal US EPA debate on the carcinogenicity of glyphosate, stating, "One series of emails shows that scientists within the EPA's Office of Research and Development (ORD) advised in December of 2015 that the agency's conclusion that glyphosate was 'not likely' to cause cancer was 'inappropriate' given the scientific research." However, no specific recommendation or objection is provided.

Response: OEHHA acknowledges the comment; however, it is outside the scope of the proposed modifications to the text of the proposed regulation. See response to comment 6 above.

No changes to the proposed rulemaking were made based on this comment.

⁸⁰ Transcript available on OEHHA's website at:
<https://oehha.ca.gov/media/downloads/cnr/120621cictranscript.pdf>

⁸¹ *Monsanto Co. v. Edwin Hardeman*, 997 F.3d 941, 950 (9th Cir. 2021, cert denied on June 22, 2022).

Comment 41 (Anon1, Anon3, Anon8, Brandt, Brynn, Celia, CooperM, FlynnE, GreggD, McCannA, MillerP, PallaP, SnappF): The commenters call for a ban of glyphosate.

Response: The comments do not address the modifications to the text of the proposed regulation, the documents added to the record, or the procedures followed in this rulemaking, and therefore require no response.

No changes to the proposed rulemaking were made based on these comments.

Comment 42 (Prof Seralini): The commenter has conducted research to address the petroleum residues in glyphosate formulations and notes that glyphosate is never used alone. He recommends that “the regulation on glyphosate ... extend to all poisons associated with it in roundup.”

Response: The comment does not address the modifications to the text of the proposed regulation, the documents added to the record, or the procedures followed in this rulemaking, and therefore requires no response.

No changes to the proposed rulemaking were made based on these comments.

Comment 43 (Anon6): The commenter provides a copy of a 1984 US EPA memo⁸² indicating under the header “Recommendations” that the “review of the mouse oncogenicity study indicates that glyphosate is oncogenic...A risk assessment by Toxicology Branch is required.”

Response: OEHHA acknowledges receipt of the copy of the memorandum. However, the comment does not address the modifications to the text of the proposed regulation, the documents added to the record, or the procedures followed in this rulemaking, and therefore requires no response.

No changes to the proposed rulemaking were made based on this comment.

Comment 44 (ApplegateR, McClintockB): Commenters indicate illness due to glyphosate or other chemical exposures:

- One commenter indicates they were exposed to Roundup and inorganic arsenic and developed a blood cancer and another disease (ApplegateR)

⁸² Memorandum from William Dykstra, PhD, Toxicology Branch, Hazard Evaluation Division, US EPA Office of Pesticides and Toxic Substances, to Hoyt Jamerson, Registration Division, Subject: Glyphosate; oncogenicity study in the mouse; PP#3E2845; Caswell No.: 661, February 10, 1984.

- One commenter discusses Multiple Chemical Sensitivities in their patient population and their own reactions to chemical exposures and the need for more protection. (McClintockB)

Response: OEHHA acknowledges these comments and the associated hardship on the commenting individuals. However, the comments do not address the modifications to the text of the proposed regulation, the documents added to the record, or the procedures followed for this rulemaking, and therefore require no response.

No changes to the proposed rulemaking were made based on these comments.

Comment 45 (MakishimaH): The commenter refers to a paper he states finds glyphosate in vaccines for children and recommends that OEHHA and the California Department of Public Health meet to discuss this issue.

Response: These comments do not address the modifications to the text of the proposed regulation, the documents added to the record, or the procedures followed for this rulemaking, and therefore require no response.

No changes to the proposed rulemaking were made based on these comments.

Comment 46 (PAPHC): The commenter alleges that certain agencies and public officials have conflicts of interest regarding glyphosate. The commenter further alleges that a pesticide manufacturer attempted to conceal the potential carcinogenicity of glyphosate products.

Response: These comments do not address the modifications to the text of the proposed regulation, the documents added to the record, or the procedures followed for this rulemaking, and therefore require no response.

No changes to the proposed rulemaking were made based on these comments.

Comments on the Second Augmentation of the Record During the June 28 to July 13, 2022 Comment Period and OEHHA's Responses

On June 28, 2022, OEHHA published a Notice of Augmentation of Record that added two documents to the administrative record for this proposed rulemaking. The two documents are the following:

- US Environmental Protection Agency (US EPA 2017). Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential. December 12, 2017. U.S.

Environmental Protection Agency, Office of Pesticide Programs, available at: https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487.

- US Environmental Protection Agency (US EPA 2015). Glyphosate: Report of the Cancer Assessment Review Committee. Evaluation of the Carcinogenic Potential of Glyphosate. October 1, 2015. U.S. Environmental Protection Agency, Health Effects Division, Office of Pesticide Programs, available at: <https://downloads.regulations.gov/EPA-HQ-OPP-2016-0385-0014/content.pdf>.

In proposing this rulemaking, the US EPA document OEHHA had referenced for US EPA's classification of glyphosate as "not likely to be a human carcinogen" was the 2020 Interim Registration Review Decision.⁸³ The Ninth Circuit Court of Appeals in *NRDC v. US EPA*⁸⁴ vacated the human health assessment portion of that document and remanded it to US EPA "for further consideration." The prior evaluations US EPA performed in 2015 and 2017, namely the two documents added to the record pursuant to the notice referenced above (and cited in the 2020 US EPA document), identified glyphosate as "not likely to be carcinogenic to humans". This remains the current US EPA classification for glyphosate⁸⁵. Should EPA change its designation in the future, OEHHA will propose an amendment to this regulation to align the warning with the changed classification.

OEHHA received 68 comments on the Augmentation of the Record during the June 28-July 13 comment period. Those comments are summarized below, along with OEHHA's responses. As noted in the Notice and consistent with the Administrative Procedure Act, OEHHA will only address comments received during this comment period that address the documents added to the administrative record.

The organizations and individuals listed in the table below submitted comments in response to the June 28, 2022, Notice of Augmentation of the Record. The designation column in the table indicates how the commenter is referenced in the summary and responses in this section.

⁸³ US Environmental Protection Agency (US EPA 2020). Interim Registration Review Decision. Case Number 0178. January 22, 2020. U.S. Environmental Protection Agency, Office of Pesticide Programs, available at: <https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-regreview-decision-case-num-0178.pdf>

⁸⁴ *NRDC v US EPA* (9th Cir. Jun. 17, 2022, Nos. 20-70787, 20-70801) ___ F.4th ___ [2022 WL 2184936, at *21] Available online at: <https://cdn.ca9.uscourts.gov/datastore/opinions/2022/04/20/20-72794.pdf>

⁸⁵ See footnote 9.

Commenting Organization	Designation
Center for Food Safety	Center for Food Safety
CropLife America and Responsible Industry for a Sound Environment (RISE)	CropLife RISE
Moms Across America/Zen Honeycutt	Moms Across America
Commenting Individuals	Designation
Anonymous (received at 830 am on July 1, 2022)	Anon1
Anonymous (received at 10:17am on July 12, 2022)	Anon2
Anonymous (received at 8:30 am on July 1, 2022)	Anon3
Anonymous (received at 10:21 am on July 12, 2022)	Anon4
Anonymous (received at 11:01 am on July 12, 2022)	Anon5
Anonymous (received at 10:09 am on July 12, 2022)	Anon6
Anonymous (received at 10:15 am on July 12, 2022)	Anon7
Anonymous (received at 10:12 am on July 12, 2022)	Anon8
Anonymous (received at 12:29 pm on July 12, 2022)	Anon9
Anonymous (received at 12:18 pm on July 12, 2022)	Anon10
Anonymous (received at 4:10 pm on July 12, 2022)	Anon11
Anonymous (received at 8:46 pm on July 12, 2022)	Anon12
Anonymous (received at 7:38 am on July 13, 2022)	Anon13
Anonymous (received at 3:29 pm on July 13, 2022)	Anon14
Bell, Jessica	BellJ
Blasco, Nathalie	BlascoN
Brandt, Vicky	BrandtV
Cara	Cara
Charlebois, Stacie	CharleboisS
Costamagna, Marilyn	CostamagnaM
Crawford, Nigel	CrawfordN
Crum, Jen	CrumJ
Dane	Dane
Dobroslawa, Dobi	DobroslawaD
Doering, David	DoeringD
Dougherty, David P	DoughertyD
Estes, Douglas	EstesD
Futrell, Sherrill	FutrellS

Gal, P	GalP
Hamann, Karl	HamannK
Higgins, Mary	HigginsM
Hood, S	HoodS
House, Darrell	HouseD
Jarvis, Marsha	JarvisM
Khoe, Corwin	KhoeC
K, Laura	KLaura
Kriss, Evan Jane	KrissE
Landress, J	LandressJ
Langford, J	LangfordJ
Lee, Peter	LeeP
Marlin, Lynn	MarlinL
Martin	Martin
Moser, Janet	MoserJ
MPR	MPR
Mullen, Timothy	MullenT
Murphy, Linda	MurphyL
Nachazel-Ruck, Jane	Nachazel-RuckJ
Naiman, Karen L	NaimanK
Ng, Du	NgD
Ochoa, Chemen A	OchoaC
Pesini, Rita P	PesiniR
Pfister, Joe	PfisterJ
Povill, Jon	PovillJ
Rivoire, Christina, Dr.	RivoireC
Ryerson, Kelly, MBA	RyersonK
Schacht, Timothy, DVM	SchachtT
Scott, Carolyn M	ScottC
Smith, Malia	SmithM
Smith, Richard	SmithR
Somma, D	SommaD
Stern, Richard	SternR

Stradtman, George Gast Jr	StradtmanG
Taylor, Tanya	TaylorT
Treffry, Nancy	TreffryN
VerDuin, Melissa	VerDuinM

Comment 47 (BellJ, RyersonK): The commenters state that the 2017 document added to the Administrative Record for this proposal is not reliable because it includes the following two “ghostwritten” studies:

- Williams GM, Kroes R, Munro IC. Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans. *Regul Toxicol Pharmacol.* 2000 Apr;31(2 Pt 1):117-65. Doi: 10.1006/rtp.1999.1371. PMID: 10854122, and
- 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. Doi: 10.3109/10408444.2014.1003423. Epub 2015 Feb 26. PMID: 25716480; PMCID: PMC4819582.

The commenters state the Greim et al. paper was “ghostwritten” by persons working for Monsanto Company, the maker of Round-up, to call into question the finding by IARC that glyphosate, the active ingredient in Round-up, is a probable human carcinogen. The commenters state that the same approach was taken by Monsanto in producing the Williams et al. 2000 paper. The commenters provide links to documents that they state support their allegations.

The commenters further state that US EPA did not appropriately account for recent research, “including ... from members of the Scientific Advisory Panel to the EPA that concluded that exposure to glyphosate-based herbicides is linked with increased risk of developing NHL”.

Response: OEHHA is relying on US EPA’s current classification of glyphosate as “not likely to be carcinogenic to humans” as set forth in US EPA documents⁸⁶. OEHHA is neither evaluating the underlying studies cited in the 2015 or 2017 documents, nor evaluating how US EPA reached the conclusions set forth in the documents.

No changes to the rulemaking file or regulation were made based on these comments.

⁸⁶ See pages 4 and 5 above.

Comment 48 (CropLife RISE): Commenters agree with the inclusion of the two documents in the administrative record because “each of these documents confirms EPA’s longstanding conclusion that glyphosate is not likely to be carcinogenic to humans.”

Response: OEHHA acknowledges the commenters concurrence with the addition of the documents to the record.

No changes to the rulemaking file or regulation were made based on these comments.

Comment 49 (CropLife RISE): The commenters reiterate the findings in the US EPA 2015 and 2017 documents including that the 2017 document states that “the strongest support is for ‘not likely to be carcinogenic to humans,’” and the 2015 document states “based on the weight-of-evidence, glyphosate is classified as ‘Not Likely to be Carcinogenic to Humans.’”

Response: The commenters correctly quote US EPA statements regarding the classification of glyphosate in the 2015 and 2017 documents.

No changes to the rulemaking file or regulation were made based on these comments.

Comment 50 (CropLife RISE): The commenters continue to state their opposition to the rulemaking. They raise issues expressed in comments on the original proposal and/or the proposed modification to the regulatory language and continue to assert that the proposed Proposition 65 warning for glyphosate products violates the First Amendment. They state that the two added documents provide further support for the claim that glyphosate does not cause cancer, and that “OEHHA’s contrary proposed warning would be therefore false and highly misleading.”

Response: OEHHA acknowledges the commenters continued opposition to the proposed regulation, and its arguments raised in previous comments. See responses to comments 9 and 10. The added documents were referenced in the 2020 Interim Registration Review Decision. US EPA continues to classify glyphosate as “not likely to be carcinogenic to humans”. To the extent that the comments address issues other than the two documents added to the administrative record they are irrelevant and require no response.

No changes to the rulemaking file or regulation were made based on these comments.

Comment 51 (CropLife RISE): The commenter states that the decision by the Ninth Circuit court in *NRDC v EPA* does not change US EPA’s conclusion regarding the safety of glyphosate use and “did not vacate or otherwise disturb” the 2015 or 2017 US EPA documents added to the administrative record by the OEHHA on June 28, 2022. The commenter states, “the Ninth Circuit recognized that “EPA could come to the same

human-health conclusion on remand,” if EPA provided an updated “explanation” for its conclusion in its Interim Decision that “glyphosate is not likely to be carcinogenic to humans.”

Response: OEHHA acknowledges the commenters statements regarding the status of the US EPA documents, and the Ninth Circuit opinion. US EPA has confirmed that its classification of glyphosate as “not likely to be carcinogenic to humans” remains in effect⁸⁷.

No changes to the rulemaking file or regulation were made based on these comments.

Comment 52 (Center for Food Safety): The commenter characterizes the two added documents as follows: “While these two cancer assessments that were undertaken in the context of OPP’s [US EPA Office of Pesticide Programs] registration review of glyphosate, which began in 2009, the motivation was to undermine IARC’s assessment.”

The 2015 report is characterized as “a highly biased and inaccurate rebuttal of IARC’s assessment”. The commenter critiques US EPA’s conclusions regarding the human, animal and mechanistic evidence leading to the IARC classification and the related data. The commenter notes the 2015 report used a review of animal studies co-authored by a Monsanto employee and “pesticide industry scientists and their consultants”, and that it relied on review of genotoxicity studies funded by Monsanto and a separate safety assessment “prepared in part by Monsanto officers.” The commenter discusses issues related to the Chair of the US EPA Cancer Assessment Review Committee (CARC) that prepared the 2015 review.

The commenter criticizes the 2017 report on a number of grounds including stating that a distinguished epidemiologist was removed from the external Science Advisory Panel, which peer reviewed the 2017 report, purportedly at the behest of CropLife. The commenter also objects to the inclusion of animal studies that the commenter, in a submission to US EPA, indicated were of low quality because of the nature of the test compound used (two studies) or that US EPA at an earlier time found invalid (one study). The commenter then critiques the US EPA OPP’s handling of studies with positive, treatment-related trends, and cancer findings at high dose levels, while also noting that the US EPA’s Office of Research and Development and the SAP raised significant concerns about the US EPA’s evaluation of the animal data. The commenter criticizes the US EPA’s approach to its hazard identification and risk assessment. The commenter then contrasts the US EPA approach to OEHHA’s when it derived the No Significant Risk Level (NSRL) for glyphosate under Proposition 65. The commenter

⁸⁷ See footnote 9.

concludes: “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 [US EPA Guidelines for Carcinogen Risk Assessment]. The proper procedure would have been low-dose linear extrapolation, as conducted by OEHHA.” The commenter then discusses OEHHA’s NSRL.

Response: OEHHA is relying on US EPA’s current classification of glyphosate as “not likely to be carcinogenic to humans” as set forth in US EPA documents⁸⁸. OEHHA is neither evaluating the underlying studies cited in the 2015 or 2017 documents, nor evaluating how US EPA reached its conclusions set forth in the documents. OEHHA notes that the commenter correctly characterizes the derivation of its NSRL for glyphosate.

The current version of the proposed warning accurately states US EPA’s carcinogenicity classification, and that classification remains US EPA’s current opinion.⁸⁹ Should EPA change its classification after reviewing the Interim Reregistration Decision, or at some other time in the future, OEHHA will propose an amendment to this regulation to align the warning with the changed classification.

No changes to the rulemaking file or regulation were made based on these comments.

Comment 53 (Center for Food Safety): The commenter states “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.*” ”

Response: The current version of the proposed warning accurately states US EPA’s carcinogenicity classification, and that classification remains US EPA’s current opinion.⁹⁰ By adding the two noticed documents to the administrative record, OEHHA is not analyzing the underlying scientific basis for the US EPA classification. The

⁸⁸ See pages 4 and 5.

⁸⁹ See page 4.

⁹⁰ See pages 4 and 5.

classification by US EPA is included in the proposed warning to show the divergence of opinion concerning the potential carcinogenicity of glyphosate to humans.

To the extent the comments address issues other than the addition of the 2015 and 2017 US EPA documents to the administrative record, they are irrelevant, and require no response.

No changes to the rulemaking file or regulation were made based on these comments.

Comment 54 (Anon5, Anon13, BlascoN, Cara, Center for Food Safety, CharleboisS, CrawfordN, DobroslawaD, DoeringD, HigginsM, HouseD, KhoeC, Martin, MoserJ, MullenT, MurphyL, NgD, PesiniR, PfisterJ, PovillJ, SchachtT, SmithM, SternR, TaylorT, TreffryN): Commenters state that based on the recent Ninth Circuit Court of Appeals ruling, US EPA must “vacate” its finding on the human health risks of glyphosate. Thus, US EPA will likely change its classification of glyphosate to align with the IARC classification. The proposed California warning for glyphosate-based herbicides is therefore inaccurate.

Response: The Ninth Circuit ruling vacated the US EPA Interim Registration Review Decision and required US EPA to re-evaluate the human health risk assessment portion of that decision. Nonetheless “not likely to be carcinogenic to humans” was the classification in prior related documents and remains the US EPA classification for glyphosate⁹¹. Should EPA change its classification after reviewing the Interim Reregistration Decision, or at some other time in the future, OEHHA will propose an amendment to this regulation to align the warning with the changed classification.

No changes to the rulemaking file or regulation were made based on these comments.

Comment 55 (Moms Across America): The commenter states it is submitting the comment for consideration regarding the “Glyphosate papers” and EPA’s assessment compared to IARC’s. The commenter states that many claim glyphosate is safe and is an essential tool; US EPA continues to claim the science shows it is not a carcinogen. IARC has found it to be a carcinogen. The commenter states that the scientist Charles Benbrook analysis finds the difference is due to the heavy reliance by US EPA on industry commissioned studies compared to the peer reviewed studies relied on by IARC. The commenter describes a relationship between Monsanto and a US EPA scientist and states certain studies were ghostwritten by a Monsanto toxicologist. The commenter states OEHHA has a duty to Californians to review and include independent science, and mountains of data showing glyphosate is carcinogenic.

⁹¹ See pages 4 and 5.

Response: Glyphosate has been listed under Proposition 65 as a carcinogen since 2017. The addition of the documents to the record was not part of a hazard identification process, or review of the evidence of carcinogenicity by OEHHA. The determination that glyphosate should be listed under Proposition 65 as a carcinogen has already been made.

No changes to the rulemaking file or regulation were made based on these comments.

Comment 56 (Commenters identified below): Several commenters make statements concerning glyphosate that are not comments on the documents added to the administrative record. These include:

- Glyphosate harms microorganisms in the body and thereby harms human health. It also harms the soil, water, various insects, plants, and animals. Glyphosate should be banned and/or no longer used. (Anon1, Anon3, Anon4, Anon6, Anon7, Anon9, EstesD, HamannK, KLaura, KhoeC, MPR, VerDuinM) Glyphosate is harmful and should be banned. (HoodS, LangfordJ) Glyphosate should be banned (SmithR) Glyphosate must/should be phased out. (CrawfordN, Moms Across America)
- Glyphosate should have been banned years ago but has not been because of financial pressure from the manufacturer. (LandressJ)
- Glyphosate is not safe for use in any manner, contamination is widespread and is ineffective. Over 37 weeds are resistant. It is destroying the soil and impairing crops and yields and affects livestock. Sows fed glyphosate sprayed grains lose their litters. Manure from animals eating glyphosate sprayed grains results in antibiotic resistant bacteria. Immune systems of humans, animals, soil, plants are weakened by the chemical. The solution for farmers is regenerative organic farming. Glyphosate products should be labeled as carcinogenic and as a “reproductive effector” (Moms Across America)
- The US EPA decision flies in the face of science. (Anon2)
- Do not allow removal of the carcinogenic warning label for glyphosate, or reconsider the label proposed in regulation. (Anon8, Anon10, CostamagnaM, NaimanK, OchoaC).
- Glyphosate is carcinogenic. Everyone deserves to know. Its use is destroying microbial life and making our food less nutritious as a result of the weakened soil biome. (SommaD)

- Glyphosate is harmful to endangered species and humans. “Investigations into the producers of glyphosate manipulated scientific literature, journalists, media, researchers and data” (Anon11)
- Glyphosate is harmful to the environment and humans and creates resistant species. (BrandtV, MarlinL) Foods with glyphosate damage the microbiome. (RivoireC)
- “Exposures to Glyphosate are proven Dangerous. This must be reflected in your policies and actions!” (LeeP)
- “Glyphosate is a poison. Stop pretending that it's not.” (FutrellS)
- Oppose the use of man-made chemicals that poison creatures that nurture life. Stop the use of herbicides and pesticides. (Anon 12)
- Stop using animals in toxicity studies. (CrumJ)
- “80% of people have this terrible chemical in their bodies. It causes cancer.” (Dane) CDC just released data showing 80% of urine sample of people from 2013-2014 contain glyphosate, showing glyphosate is widespread in food and the environment. Children are more exposed than adults. Glyphosate’s probable link has been known for years. Hundreds of millions of pounds are dumped on American farmlands each year. (KrissE)
- “Why are there STILL one too many [expletive] with contempt for our planet, who are content with poisoning it?” (DougheryD)
- Given the exceptional leniency shown toward and overwhelming subsidization of industries that create and perpetuate environmental emergencies affecting everyone’s health and livelihood, any failure on your part to directly address and act upon these issues can only be seen as complicity in extinction and a clearly genocidal agenda. (Anon14)
- Glyphosate testing should be done by an independent third party. US EPA should not ignore SAP findings. If procedures were correctly followed, US EPA’s findings would mirror IARC’s. It should not be used. (GalP) Self-provided data from those who are supposed to be regulated will inevitably go only one way. Current labeling as “noncarcinogenic” is nonsense in light of data. (StradtmanG)
- Reassess the carcinogenicity and risk of glyphosate. (JarvisM)
- “I have the cancer, non Hodgkins Lymphoma, directly linked to exposure to Glyphosate (Roundup). I was heavily exposed while working on a documentary

about this toxic weed killer in California. the state of California has classified Glyphosate as carcinogenic and we know that butterfly populations have been profoundly harmed by this toxic weed killer. Please follow the science and get this cancer causing herbicide out of our food and environment. here's the award winning short film I made about this issue: www.roundupwine.org" (ScottC)

Response: Commenters' public health and environmental concerns and personal stories are acknowledged. However, the comments do not address the two documents added to the administrative record and require no response.

No changes to the rulemaking file or regulation were made based on these comments.

Local Mandate Determination

OEHHA has determined this regulatory action will not impose a mandate on local agencies or school districts and will not require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. Local agencies and school districts are exempt from Proposition 65. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action.

Alternatives that Would Lessen the Adverse Economic Impact on Small Business Determination

There were no alternatives proposed that would lessen any adverse economic impact on small businesses as defined in Government Code Section 11342.610 that were rejected by OEHHA.

The proposed regulatory amendments do not affect small businesses as defined in Government Code Section 11342.610. Proposition 65, by its terms, does not apply to small businesses with less than 10 employees. Further, this regulatory action does not require any business to use the proposed warning. Instead, the proposed regulation provides non-mandatory, safe harbor methods and content for consumer product warnings for exposures to glyphosate.

Alternatives Determination

While several commenters proposed different warning language or requested that OEHHA withdraw the proposed warning,⁹² OEHHA has determined that no alternative it considered or that was otherwise identified and brought to its attention would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the proposed regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. OEHHA also considered taking no action but finds that taking no action is inconsistent with the intent of the Act and its existing implementing regulations and would not address the District Court's expressed concerns with the general consumer product safe harbor warning language in Section 25603⁹³.

Non-duplication Statement

Proposition 65 is a California law that has no federal or state counterpart. OEHHA has determined that the regulation does not duplicate and will not conflict with federal law or regulations, including FIFRA. OEHHA has further determined that the regulation does not serve the same purpose as a state or federal statute or another regulation.

⁹² See comments numbered 1-7 and 27-31 and responses to them.

⁹³ *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (E.D. Cal. 2020)