Initial 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 23, 2021

California Environmental Protection Agency

Office of Environmental Health Hazard Assessment

Contents

Summary

The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65[1] and has the authority to promulgate and amend regulations to implement and further the purposes of the Act. OEHHA is proposing to adopt a new non-mandatory, safe harbor warning regulation to address the content of warnings for exposure to glyphosate from consumer products.

This proposed rulemaking would add Sections 25607.48 and 25607.49 to the Title 27, Article 6 Clear and Reasonable Warnings regulations. The proposed regulations would provide safe harbor guidance for businesses that cause consumer product exposures to glyphosate that require warning[2]. The new regulations would further the "right-to-know" purposes of the Act and provide warning language tailored for these exposures. Businesses who choose to provide the safe harbor warning language for such exposures would comply with the Act, because the content and methods provided in the regulation are deemed "clear and reasonable" by the lead agency for purposes of the Act. The warning is intended to provide balanced and understandable information to individuals who may be exposed to glyphosate at levels requiring warning.

The proposed regulation allows for the use of the signal words "Notice" or "Attention" on product labels to conform with existing safe harbor warning content for pesticides[3], including glyphosate, regulated by US Environmental Protection Agency (US EPA) and the California Department of Pesticide Regulation. This provision was adopted effective July 1, 2018, to avoid any conflict with standard signal words used on product labels for chemicals regulated by these authorities.

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[1] The Safe Drinking Water and Toxics Enforcement Act of 1986, codified at Health and Safety Code Section 25249.5 et seq., commonly known as Proposition 65, herein referred to as the "Act" or Proposition 65.

[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) of 1100 micrograms per day in Title 27, Cal. Code of Regs., section 25705. Exposures below this safe harbor level do not require warning.

[3] Subsection 25603(d): "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**".

Existing regulations[4] describe the safe harbor methods for providing consumer product warnings in cases where there are not tailored warnings. OEHHA is incorporating them by reference since no special methods are needed for these warnings.

Background and Problem to be Addressed by the Proposed Rulemaking

Basis for glyphosate Proposition 65 listing

Glyphosate is a registered herbicide used extensively in consumer products. It was listed in 2017 under Proposition 65 via the "Labor Code" listing mechanism[5] based on a finding by the World Health Organization's International Agency for Research on Cancer (IARC) that the chemical is "probably carcinogenic to humans" (Group 2A), and that there was "sufficient evidence" of carcinogenicity in experimental animals [6] [7]. In evaluating studies of cancer in humans, IARC concluded: "There is limited evidence in humans for the carcinogenicity of glyphosate. A positive association has been observed for non-Hodgkin lymphoma."

Cancer conclusions about glyphosate by other entities

The European Chemicals Agency (ECHA)[8] in its 2016 evaluation essentially agreed with IARC's conclusion regarding the human evidence:

> "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."

Regarding the animal data ECHA found inconsistencies within each of the three tumor types that had positive findings in multiple experiments in mice (malignant lymphoma,

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[4] Title 27, Cal. Code of Regs., section 25602.

[5] Title 27, Cal. Code of Regs., section 25904(b)(2).

[6] The listing of glyphosate as a carcinogen was upheld on appeal in *Monsanto Co. v. Office of Environmental Health Hazard Assessment*, 22 Cal. App. 5th 534 (Ct. App. 2018), review denied (Aug. 15, 2018).

[7] International Agency for Research on Cancer (IARC), Glyphosate Monograph in: Some Organophosphate Insecticides and Herbicides, IARC Monographs on the Evaluation of the Carcinogenic Risks to Humans, Volume 112. World Health Organization, IARC, available at: https://publications.iarc.fr/549.

[8] 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/10162/13626/clh_report_glyphosate_en.pdf.

renal tumors, haemangiosarcoma) and overall found that the data were insufficient to identify glyphosate as a carcinogen.

The French Agency for Food, Environmental and Occupational Health and Safety (ANSES) [9] determined that the evidence was insufficient for finding glyphosate to be a presumed carcinogen but that the substance could possibly be classified in Category 2 [suspected human carcinogen] but could not reach a decision absent a detailed analysis of the data. ANSES called on the European Chemicals Agency (ECHA) to rapidly review glyphosate.

On the other hand, the US Environmental Protection Agency (US EPA) has concluded that glyphosate is "Not likely to be carcinogenic to humans"[10], and some other governmental agencies that regulate pesticides reached similar conclusions.[11]

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. The standard Proposition 65 safe harbor warning language – which includes the phrase "known to cause cancer" – is not the best fit in this situation. Therefore, OEHHA is proposing tailored language for warnings for glyphosate that presents a balanced description of the likelihood that glyphosate can cause human cancer.

Proposition 65 safe harbor warning for glyphosate in consumer products

Proposition 65 requires a warning for significant exposures to listed carcinogens. A warning is not required when the person responsible for the exposure can show that it

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[9] 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.

[10] 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-reg-review-decision-case-num-0178.pdf.

[11] Canada: "glyphosate is unlikely to pose a human cancer risk". Government of Canada, Pesticide Management Regulatory Agency, Summary, Re-evaluation Decision RVD 2017-01, Glyphosate, April 2017. Available at: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2017/glyphosate-rvd-2017-01.html; New Zealand: glyphosate is "unlikely to be genotoxic or carcinogenic to humans." NZ Environmental Protection Authority, Review of the Evidence Relating to Glyphosate and Carcinogenicity. Prepared by W Temple, August 2016. See also Douwes et al. Carcinogenicity of glyphosate: why is New Zealand's EPA lost in the weeds? NZ Med Assoc, 131 (1472): 82-89, 2018. Available at: https://assets-global.website-files.com/5e332a62c703f653182faf47/5e332a62c703f6a2202fcb30_Douwes%20FINAL.pdf.

poses no significant risk assuming lifetime exposure at the level in question[12]. Effective July 1, 2018, OEHHA adopted a No Significant Risk Level (NSRL)[13] for glyphosate of 1100 micrograms per day. 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[14]. Where products result in exposures to consumers above the NSRL, a safe harbor warning can be used[15]. 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.[16]

Additional application of Proposition 65 consumer product warning

Proposition 65 applies to businesses with ten or more employees. For these businesses existing Proposition 65 safe harbor regulations provide guidance for providing warning to consumers and workers for exposures above a level posing no significant risk[17]. The business does not need to provide an additional warning where the warning being given for the chemical and endpoint fully complies with the: Federal Hazard Communications Standard, or for pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

In this case, US EPA, which implements FIFRA, has determined no cancer warning is required for glyphosate on the product label. Since occupational exposures can occur through use of consumer products and labeling under FIFRA does not include a cancer warning, a business subject to Proposition 65 may choose to provide a Proposition 65 warning using the consumer product warning provisions of the safe harbor

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[12] Health and Safety Code section 25249.10.

[13] No Significant Risk Levels are adopted by OEHHA as guidance for businesses and enforcers concerning when a warning is required for a given exposure (Title 27, Cal. Code of Regs., section 25701 et seq.).

[14] For example, exposure to a user that spills the product on the palmer surface of one hand could be estimated to be approximately 110 µg glyphosate via the dermal route, every time the product is used, and the product is not used every day by a typical home user.

[15] Title 27 Cal. Code of Regs., section 25601 et seq.

[16] For example, a Safety Data Sheet for one product implicitly notes the possibility of high exposure. “Handling: Avoid contact with eyes, skin or clothing. Avoid breathing spray mist. Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.” https://alligare.com/wp-content/uploads/2019/06/glyphosate-5.4-sds-v3.1.pdf.

[17] Title 27, Cal. Code of Regs., section 25606.

regulations.[18] Adopting a tailored warning for glyphosate would facilitate occupational warnings for exposures that occur through use of consumer products that contain glyphosate.

The US Occupational Safety and Health Administration oversees the federal Hazard Communication Standard noted above, which requires covered manufacturers, distributors, or importers to provide a Safety Data Sheet (SDS), and among other things, such as training to employees who can be exposed to hazardous chemicals. Employers must make the SDS available for review by their employees. The SDS is thus used "to communicate information to employees on hazardous chemical products."[19] OEHHA has found SDS's for some glyphosate products that state the IARC finding along with findings by other agencies, including the US EPA, but some do not [20]. Below is an example of the type of information that may be included in one SDS:

> "Carcinogenicity / Chronic Health Effects: Prolonged overexposure to glyphosate may cause effects to the liver. EPA has given glyphosate a Group E classification (evidence of non-carcinogenicity in humans). Canada PMRA has classified glyphosate as non-carcinogenic. In 2015 IARC classified glyphosate as a probable human carcinogen Group 2A based on limited human evidence and some evidence in animals." [21]

As noted, where no warning is being given for an exposure to a chemical listed under Proposition 65 that is covered by the provisions of Section 25606(a), a business may use the consumer product, environmental or other tailored exposure warning methods

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[18] Title 27, Cal. Code of Regs., section 25606(b): "For occupational exposures to chemicals not covered by subsection (a), warnings may be provided consistent with Sections 25601, 25602, 25603, 25604, 25605 and 25607 et seq. of this Subarticle."

[19] Occupational Safety and Health Administration (OSHA) Hazard Communication Safety Data Sheets. Available at: https://www.osha.gov/sites/default/files/publications/OSHA3493QuickCardSafetyDataSheet.pdf.

[20] For example, the Bayer SDS for Roundup Promax® Herbicide SDS dated 9/24/2020 states under the header "Assessment carcinogenicity", "Potassium salt of glyphosate: Based on available data, the classification criteria are not met. Important comment to IARC Listing: Our expert opinion is that classification as a carcinogen is not warranted."

[21] Safety Data Sheet for "Buccaneer 5 Herbicide" available online at: http://www.cdms.net/LDat/mp83M009.pdf. Note that IARC found "sufficient evidence" of carcinogenicity in experimental animals, not "some evidence."

and content provided in the safe harbor regulations, as appropriate. (Section 25606(a)).[22] [23] [24] [25]

Public health importance of clear and informative warning for glyphosate

Avoiding significant exposures to glyphosate is important from a public health perspective. IARC concluded that "data from all studies combined show a statistically significant association between non-Hodgkin lymphoma and exposure to glyphosate."[26] While US EPA ultimately reached a different conclusion, many experts on the US EPA's FIFRA[27] Scientific Advisory Panel (FIFRA SAP) found the Agency did not follow its own

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[22] Section 25606(b): For occupational exposures to chemicals not covered by subsection (a), warnings may be provided consistent with Sections 25601, 25602, 25603, 25604, 25605 and 25607 et seq. of this subarticle.

[23] California Labor Federation v. California Occupational Safety and Health Standards Board, 221 Cal.App.3d 1547, (Ct. App. 1990) "Nevertheless, it is undisputed that several million California workers are entitled to Proposition 65 warnings in the workplace if the proposition is not preempted by Fed/OSHA. Under these circumstances, we cannot accept the premise that Proposition 65 is not a state law governing occupational safety and health within the meaning of Proposition 97 simply because it also applies outside the workplace and exempts certain employers from its requirements." (at page 1557)

"… at oral argument counsel for the Board conceded that there are situations in which Proposition 65 applies but the HCS does not, either in terms of chemicals covered or levels of exposure triggering warning requirements. For example, petitioners have alleged in the petition, and the Board has admitted, the highly relevant fact that incorporation of Proposition 65 in the present state plan will result in regulation of an additional 66 carcinogens and 18 reproductive toxins not currently so regulated. In our view, the state plan is not consistent with Proposition 65 unless it includes all of the protections afforded by the proposition. That Proposition 65 and the HCS both generally relate to the provision of warnings to employees regarding hazardous substances is simply not sufficient to render the state plan consistent with the proposition." (Page 1558)

[24] See Chemical Specialties Manufacturers Association v. Allenby, 958 F.2d 941 (9th Cir. 1992) "Manufacturers only become liable for misbranding when their labels are insufficient, not for posting additional warning signs as dictated by state law. If manufacturer awareness of new product risks is triggered by the State of California's list of chemicals known to cause cancer or reproductive toxicity, then the list of chemicals merely uncovers hazards that should have been uncovered by the manufacturers. The more likely scenario is that the hazards of a chemical are already known to both the manufacturer and the EPA, but that neither believes that cancer or reproductive toxicity is a likely danger. In this scenario, it seems contradictory to assert that the EPA will prosecute a company for satisfying the standards developed by the EPA but deemed insufficient by the State of California." (Page 947)

[25] See also, Title 8, Cal. Code of Regs., section 5194 (b)(6) which incorporates Proposition 65 into the California Hazard Communication Standards.

[26] IARC, March 1, 2016. Q&A on Glyphosate, available at: https://www.iarc.who.int/wp-content/uploads/2018/11/QA_Glyphosate.pdf.

[27] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §136 et seq.

Guidelines for Carcinogen Risk Assessment in reaching this conclusion and found the evidence of carcinogenicity suggestive[28].

> "Many Panel members believe that the EPA did not provide convincing evidence of a lack of carcinogenic effects. These Panelists agreed that the four findings listed above are adequate to reject the Issue Paper's conclusion of "not likely to be carcinogenic to humans" and support a conclusion of "suggestive evidence of carcinogenic potential" under these Guidelines." [29]

Furthermore, the FIFRA SAP[30] as a whole pointed out that the available epidemiology studies evaluated by the US EPA did not include studies of "potentially more highly exposed workers, such as those who manufacture, formulate, or are involved in the wholesale handling or selling of glyphosate", and characterized that absence as resulting in a "critical data-gap."

Since the IARC and US EPA evaluations, several researchers have published additional scientific evidence in the peer-reviewed literature that supports the concern that high occupational exposure to glyphosate can lead to non-Hodgkin lymphoma including epidemiologic findings in highly exposed individuals[31,32], findings of non-Hodgkin

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[28] FIFRA Scientific Advisory Panel (FIFRA SAP), SAP Minutes and Final Report No. 2017-01. A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: EPA's Evaluation of the Carcinogenic Potential of Glyphosate. December 13-16, 2016. FIFRA Scientific Advisory Panel Meeting. And March 16, 2017, Transmittal Memorandum. From Steven Knott, Acting Executive Secretary FIFRA SAP Staff, to Rick Keigwin Acting Director, US EPA Office of Pesticide Programs. Available at: https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf.

[29] Ibid, see pages 88-89.

[30] Ibid, see pages 15, 20, and 21.

[31] Weisenburger DD, 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, 2021 online: https://www.sciencedirect.com/science/article/pii/S2152265021001518. Epidemiologic evidence reviewed in this paper included three meta-analyses of epidemiology studies, two pooled analyses of epidemiologic data, and one update of a large prospective cohort study. Each of these studies were published in the peer-reviewed literature since the IARC review.

[32] Meloni F, Satta G, Padoan M et al. Occupational exposure to glyphosate and risk of lymphoma: results of an Italian multicenter case-control study. Environ Health. 2021 Apr 28;20(1):49.

lymphoma in multiple studies in mice exposed to glyphosate[33,34], and emerging evidence on mechanisms of glyphosate induction of non-Hodgkin lymphoma.[35]

Proposition 65 was enacted to fill gaps[36] 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[37] that are based on the allegation that exposures to glyphosate caused individuals' non-Hodgkin lymphoma. Some of these cases have yielded multi-million-dollar verdicts that have survived appellate review, though some have had the jury-awarded damages reduced. [38] 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.

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[33] Weisenburger (2021), Ibid.

[34] Portier CJ, A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies, Environmental Health, 19:18, 2020, including supplementary information provided on the journal site. Available at: https://ehjournal.biomedcentral.com/articles/10.1186/s12940-020-00574-1.

[35] Weisenburger (2021), Ibid. Mechanistic evidence reviewed in this paper included two genotoxicity studies in human lymphocytes, three genotoxicity and/or epigenetic studies in human peripheral blood mononuclear cells, and one study showing development of plasma cell neoplasms in mice which resembled a subtype of human non-Hodgkin lymphoma. Each of these studies were published in the peer-reviewed literature since the IARC review.

[36] "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).

[37] E.g., Sara Randazzo and Jacob Bunge, Inside the Mass-Tort Machine That Powers Thousands of Roundup Lawsuits, W.S.J., November 25, 2019 (noting that more than 42,700 farmers, landscapers and home gardeners had sued Bayer AG for failing to warn of Roundup's cancer risks), https://www.wsj.com/articles/inside-the-mass-tort-machine-that-powers-thousands-of-roundup-lawsuits-11574700480.

[38] See for example, In re Roundup Prod. Liab. Litgation, No. 16-CV-0525-VC, 2019 WL 3219360, (N.D. Cal., July 12, 2019); In re Roundup Products Liability Litigation, MDL No. 2741, No. 3:19-cv-02224 (N.D. Cal., Feb. 3, 2021; Johnson v. Monsanto Co.,52 Cal. App. 5th 434 (2020).

OEHHA is aware of the District Court decision in the National Association of Wheat Growers[39] case in which the Plaintiffs challenged a potential Proposition 65 warning for glyphosate. That court found that, as applied to glyphosate, the standard safe harbor warning was false and misleading under standard First Amendment analysis because it failed to address the situation presented in the case where one respected authoritative body comes to conclusions with which other authorities disagree, including the US EPA. It similarly found that alternative warnings offered by the Attorney General also would violate the First Amendment rights of the plaintiff businesses not to be compelled to provide information about their products that they believed was false and misleading. The District Court enjoined enforcement of the warning requirement, but businesses were not enjoined from providing a warning if they choose to do so. Thus, OEHHA has developed the proposed regulation taking into account the concerns expressed in the District Court decision in that case. OEHHA's safe harbor regulations are non-mandatory guidance. OEHHA does not have enforcement authority under Proposition 65 and thus cannot require warnings to be given for an exposure to any listed chemical, including glyphosate. The injunction in the National Wheat Growers case is still in effect. Therefore, no enforcement actions can be taken against businesses who do not provide warnings for significant exposures to this chemical. OEHHA does not intend to suggest otherwise by proposing this regulatory action.

The proposed warning would be adopted into the safe harbor regulations which identify warnings specifically determined to be "clear and reasonable" for purposes of Proposition 65. It presents a balanced description of the conflict between IARC's conclusion and those of other regulatory agencies, including US EPA. It also provides the clear message that an individual's personal risk of cancer from use of these products is a function of level and duration of exposure to the chemical. In other words, not everyone who uses the product is in danger of contracting cancer.[40] Each of the statements in the proposed warning is factual.

Proposed Amendments

Where use of a product is anticipated to result in exposures that exceed the NSRL, OEHHA is proposing that businesses can provide a tailored safe harbor Proposition 65 warning that includes information allowing the consumer to make an informed choice

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[39] National Association of Wheat Growers et al. v. Becerra et al., United States District Court, Eastern District, Judge William B. Shubb. Currently on appeal to the 9th Circuit Court of Appeals (case # 20-16758).

[40] Historically the pesticide label has not given much direction to users, and it did not tell users to take any specific precautions. A newer label (2015) for Roundup Ready can be found at https://images.thdstatic.com/catalog/pdfImages/be/be69d124-d76e-481a-83dc-5775e25c0468.pdf. This label includes the following precautions:

> "7.1. Precautions for safe handling: Avoid contact with eyes. Avoid breathing vapour or mist. When using do not eat, drink or smoke. Wash hands thoroughly after handling or contact. Wash contaminated clothing before re-use. Thoroughly clean equipment after use. Do not contaminate drains, sewers and water ways when disposing of equipment rinse water."

concerning their use of the product. The warning may also encourage consumers to follow label directions more carefully, thus reducing exposures. The specific language for the proposed regulation is discussed below.

Section 25607.48 Warnings for Exposures to Glyphosate from Consumer Products– Methods of Transmission.

Proposed new Section 25607.48 would establish safe harbor warning methods for exposures to glyphosate. The warning methods in this Section would allow a business to provide a safe harbor warning using the existing methods for consumer product warnings described in Section 25602.

Section 25607.49 Warnings for Exposure to Glyphosate from Consumer Products – Content

Proposed new Section 25607.49 would establish safe harbor warning content for exposures to glyphosate. The warning language for exposures to glyphosate being proposed in subsection (a) is as follows:

> ⚠ **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 US EPA, have determined that glyphosate is unlikely to cause cancer, or that the evidence is inconclusive. A wide variety of factors affect your personal cancer risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate.

The proposed warning includes several elements of existing safe harbor warnings adopted by OEHHA, including the warning symbol, signal word, the name of the chemical and the URL where users can access more information about the chemical, including ways to reduce exposure[41].

This warning includes information on why the chemical is considered a carcinogen (in part because it is classified as “probably carcinogenic to humans” by IARC), and a statement that the level and duration of exposures affect a person’s cancer risk.

[41] See, Section 25602*, supra* note *5.*

Each of these statements is based on purely factual information contained in the listing record for glyphosate[42] or the supporting scientific information for the NSRL[43].The statements regarding carcinogenicity also reflect the range of opinion, described above.[44] US EPA and some governmental bodies found glyphosate is unlikely to be a human carcinogen, while other bodies noted the evidence of effects in epidemiology studies and certain findings from animal studies, but concluded this evidence is insufficient for assigning a cancer category.

Consistent with safe harbor warning content for other pesticides given in subsection 25603(d), subsection (b) provides that the signal words "**ATTENTION**" or "**NOTICE**" in capital letters and in bold may be substituted for the words "**CALIFORNIA PROPOSITION 65 WARNING".** This provision was adopted to avoid any conflict with standard signal words used on product labels for chemicals regulated by the US EPA or California authorities. As stated in the ISOR for that rulemaking:

> "In proposing this regulatory action, OEHHA intends to provide a narrow exception to the safe harbor provisions as they relate to the content of pesticide exposure warnings on product labels. OEHHA is only allowing use of an alternate signal word in the narrow circumstance where the US EPA and DPR signal word and the Proposition 65 signal word conflict. This regulatory amendment will help businesses provide information that is useful to Californians about their potential exposures to listed pesticides and provide more guidance to affected businesses, thereby furthering the purposes of the Act."[45]

Necessity

Under the Act, unless covered by one of the exceptions specified by the Proposition 65, if a business causes a significant exposure to a chemical listed as a carcinogen it must provide a warning. Glyphosate is listed as a carcinogen based on IARC's conclusions. As discussed above, however, other bodies have reached different conclusions. Industry groups have argued in litigation against the Attorney General that, because the IARC findings diverge from those of regulatory bodies, the warning requirement as

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[42] https://oehha.ca.gov/proposition-65/crnr/glyphosate-be-listed-under-proposition-65-known-state-cause-cancer; https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer.

[43] OEHHA (2017) Initial Statement of Reasons, Proposed Amendment to Section 25705(b) Specific Regulatory Levels Posing No Significant Risk, https://oehha.ca.gov/media/glyphosate032917isor.pdf ; OEHHA (2018) Final Statement of Reasons, Section 25705(b) Specific Regulatory Levels Posing No Significant Risk, No Significant Risk Level: Glyphosate, available at: https://oehha.ca.gov/media/downloads/crnr/glyphosatensrlfsor041018.pdf.

[44] See section above: "Cancer conclusions about glyphosate by other entities."

[45] Initial Statement of Reasons, Title 27, California Code of Regulations, Proposed Amendments to Article 6 Clear and Reasonable Warnings Amendment to Section 25603 Consumer Product Exposure Warnings - Content: Signal Words for FIFRA-Regulated Pesticide Exposure Warning Labels, at 5 (2018).

applied to glyphosate would not comply with First Amendment protections for commercial speech.

OEHHA has determined that a tailored safe harbor warning for significant glyphosate exposures from consumer products can provide clear and factual and information for the benefit of those who could be exposed. As discussed above, where no consumer product warning is being given under FIFRA for significant exposures to glyphosate, the safe harbor language provides content and methods that businesses can use to provide a warning if they choose to do so. Also, under OEHHA's implementing regulations, a business that determines it must provide a warning for a worker exposure that is not required under FIFRA may use the proposed consumer product safe harbor content and methods to provide the warning, if appropriate. (Section 25606(a)).

Avoiding significant exposures to carcinogens is very important from a public health perspective and is precisely the reason Proposition 65 requires warnings about them. Since such warnings may not be required under Occupational Safety and Health Administration (OSHA), California OSHA (Cal/OSHA), or US EPA requirements, it is even more important that warning language and methods be provided for significant exposures to listed chemicals. This will facilitate the provision of warning to individuals who have a right to receive information that can help them make informed decisions about their exposures to listed chemicals. To facilitate glyphosate warnings in a manner that avoids the First Amendment concerns that have been raised about the standard consumer product warnings when used in the context of glyphosate, OEHHA proposes to adopt a tailored warning.

Economic Impact Assessment Required by Government Code Section 11346.3(b)

In compliance with Government Code Section 11346.3, OEHHA has assessed all the elements pursuant to Sections 11346.3(b)(1)(A) through (D).

Creation or elimination of jobs within the State of California

This regulatory action will not impact the creation or elimination of jobs within the State of California. The proposed regulation will help businesses comply with the warning requirements of Proposition 65 by providing specific safe harbor content for warnings for exposures to glyphosate.

Creation of new businesses or elimination of existing businesses within the State of California

This regulatory action will not impact the creation of new businesses or the elimination of existing businesses within the State of California. The proposed regulation will help businesses comply with the requirements of Proposition 65 by providing specific safe harbor methods and content for consumer product warnings for exposure to glyphosate.

Expansion of businesses currently doing business within the State of California

This regulatory action will not impact the expansion of businesses within the State of California. The proposed regulation will provide specific safe harbor methods and content for consumer product warnings for exposure to glyphosate.

Benefits of the proposed regulation to the health and welfare of California residents, worker safety, and the state's environment

OEHHA has concluded that the public would benefit from the proposed amendments because businesses will understand how to comply with the warning requirements such that warnings considered to be clear and reasonable are provided to Californians using consistent and uniform content and methods. The action furthers the right-to-know purposes of the statute and therefore promotes public and worker health and safety.

Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon

Citations to documents relied on for this proposal are cited in this document. Copies of these documents will be included in the regulatory file for this action and are available from OEHHA upon request.

No other technical, theoretical, or empirical material was relied upon by OEHHA in proposing the adoption of this regulation.

Benefits of the Proposed Regulation

Regulated businesses that choose to follow the safe harbor provisions of the clear and reasonable warning regulations when providing warnings for exposures to glyphosate will likely benefit from the proposed amendments because the amendments provide guidance and safe harbor protection for businesses causing exposures to glyphosate from consumer products.

Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has determined there are no reasonable alternatives to the proposed regulatory action that would carry out the purposes of the Act. The proposed action provides specificity to the regulations concerning how safe harbor warnings can be provided and what the warning message should include for exposures to glyphosate.

Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has initially determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the proposed action, or would be as effective and less burdensome to small business, or would be more cost-effective and equally effective in implementing the statutory policy or other provision of law to small business. The current proposal furthers the purposes of Proposition 65 by providing specific safe harbor methods and content for consumer product warnings for exposure to glyphosate.

Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

OEHHA does not anticipate that the regulation will have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed action will provide specific safe harbor methods and content for consumer product warnings for exposure to glyphosate.

Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues

Proposition 65 is a California law that has no federal counterpart. OEHHA has determined that the regulation does not duplicate and will not conflict with federal law or regulations, including FIFRA.[46]

[46] As noted previously, existing regulations concerning the use of alternative signal words for pesticide warnings are designed to avoid any conflict with standard signal words under FIFRA and the warning need not be provided on the product label.