

Office of Environmental Health Hazard Assessment



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Edmund G. Brown Jr.
Governor

June 26, 2017

Sent via E-mail and U.S Mail

Dr. Philip W. Miller
Vice President, Global Corporate Affairs
Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, Missouri 63167

RE: Petition for Reconsideration of the Proposition 65 Listing of Glyphosate Pursuant to the Labor Code Mechanism

Dear Dr. Miller:

Thank you for your letter of June 20, 2017, requesting that the Office of Environmental Health Hazard Assessment (OEHHA) reconsider the listing of the chemical glyphosate as known to the state to cause cancer. Proposition 65¹ requires the listing of certain chemicals and substances identified by reference to the California Labor Code.² On March 28, 2017, OEHHA announced that glyphosate would be listed as known to cause cancer for purposes of Proposition 65, based on its identification by the International Agency for Research on Cancer (IARC) as causing cancer.³ IARC indicated that the identification was based on "sufficient evidence" in animal studies and "limited evidence" in human (epidemiological) studies.⁴ Under the statute, case law and regulations, chemicals identified by IARC as carcinogens with sufficient evidence of carcinogenicity in humans or animals must be listed under Proposition 65. Specifically, Health and Safety Code section 25249.8(a) provides as follows:

"(a) On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter. *Such list shall include at a minimum those substances identified by reference in Labor*

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., commonly referred to as Proposition 65.

² See Health and Safety Code section 25249.8(a) and Title 27, Cal. Code of Regs., section 25904.

³ See <https://oehha.ca.gov/proposition-65/cmr/glyphosate-be-listed-under-proposition-65-known-state-cause-cancer>. The chemical has not been added to the list due to Monsanto's request for a stay in the Court of Appeal, which was summarily denied on June 16, 2017, and the Supreme Court, which summarily denied it on June 22, 2017.

⁴ See: <http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-10.pdf>.

California Environmental Protection Agency

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Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d)." (Emphasis added.)

Labor Code section 6382(b)(1) identifies the following chemicals and substances:

"(1) Substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)."

OEHHA's obligations under the Labor Code listing mechanism of Health and Safety Code section 25249.8, subdivision (a), which incorporates section 6382, subdivision (b)(1) of the Labor Code, was litigated in several cases, all of which found that OEHHA is required to list carcinogens identified by reference to the Labor Code.⁵ OEHHA has also adopted regulations setting out the criteria for listing chemicals via this mechanism and the required showing for a request for delisting or reconsideration. As stated in the regulations:⁶

"(a) Pursuant to Section 25249.8(a) of the Act, a chemical or substance shall be included on the list of chemicals known to the state to cause cancer if it is a chemical or substance identified by reference in Labor Code Section 6382(b)(1) as causing cancer.

(b) A chemical or substance shall be included on the list if it is classified by the International Agency for Research on Cancer (IARC) in its IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent edition), or in its list of Agents Classified by the IARC Monographs, as:

(1) Carcinogenic to humans (Group 1), or

(2) Probably carcinogenic to humans (Group 2A) with sufficient evidence of carcinogenicity in experimental animals, or

(3) Possibly carcinogenic to humans (Group 2B) with sufficient evidence of carcinogenicity in experimental animals. A chemical or substance for which there is less than sufficient evidence of carcinogenicity in experimental animals and classified by IARC in Group 2B shall not be included on the list...

... (e) Any person may petition the lead agency to consider removing a chemical or substance from the list pursuant to this section. The petition shall identify the chemical or substance in question *and the reasons why the provisions of subsections (a) and (b) are not met.*" (Emphasis added)

⁵ *California Chamber of Commerce v. Brown, et al.* (2011) 196 Cal. App. 4th, 233; *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal. App. 4th 1082 ; *Sierra Club v Brown* (2013) Alam

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Pursuant to Section 25904, subdivision (e) of the regulations, the only legal basis for a request for reconsideration of a chemical's placement on the Proposition 65 list would be that the provisions of subsections (a) and/or (b) are not met. Monsanto has not made such a showing, having provided no evidence that IARC has changed its classification of glyphosate as a carcinogen, or its finding that animal studies provided sufficient evidence of carcinogenicity. Instead, Monsanto complains that IARC, pursuant to its own rules, only considered published, peer-reviewed studies when making the glyphosate determination in 2015, and contends that the IARC finding was erroneous because it did not consider certain unpublished data. It appears that Monsanto has already brought the issue to IARC's attention and they have provided a reasonable response stating that they can re-evaluate a substance when a significant body of new scientific data is published in the openly available scientific literature.⁷

In the event IARC were to change its classification of glyphosate, resulting in subdivisions (a) and/or (b) of Title 27, California Code of Regulations section 25904 no longer being met, Monsanto would at that time be able to petition OEHHA to reconsider the listing. If OEHHA were to determine at that time that glyphosate no longer meets the listing criteria in the regulation, OEHHA would then determine whether the chemical met the criteria for listing via another listing mechanism, and if not, refer the chemical to the Carcinogen Identification Committee for consideration for potential delisting as provided in the regulation.⁸ Unless and until IARC changes its classification of glyphosate, this request for OEHHA to reconsider its listing decision is premature. Monsanto's request is denied. However, Monsanto may re-submit the request in the event IARC changes its determinations regarding this chemical.

If you have questions regarding this letter, please feel free to contact me at (916) 322-6325.

Best Regards,



Allan Hirsch
Chief Deputy Director

Enclosure

⁷ See attached statement from IARC, available on its website at http://governance.iarc.fr/ENG/Docs/IARC_responds_to_Reuters_15_June_2017.pdf

⁸ Title 27, Cal. Code of Regs., section 25904(f)

IARC responds to Reuters article of 14 June 2017

The International Agency for Research on Cancer (IARC) has noted the recent article from Reuters (published on 14 June 2017) on the subject of the carcinogenicity of glyphosate and the related contentious legal and regulatory context.

The IARC Secretariat was not informed about unpublished results from the Agricultural Health Study (AHS) about glyphosate. The IARC Working Group for Monographs Volume 112, which met in March 2015, did not consider unpublished results from the AHS, or from any other study.

In the section on [Data for the Monographs](#), the [Preamble](#) to the IARC Monographs notes, *“With regard to epidemiological studies, cancer bioassays, and mechanistic and other relevant data, only reports that have been published or accepted for publication in the openly available scientific literature are reviewed.”* The Preamble also states that *“Data from government agency reports that are publicly available are also considered.”* Consequently, the IARC Monograph on glyphosate only included studies and data meeting these criteria. As reported in the Reuters article, the update of the AHS analysis is still under way.

The IARC Monographs Programme does not base its evaluations on opinions presented in media reports. Instead, the Programme conducts evaluations of carcinogenicity based on the systematic assembly and review of all publicly available and pertinent scientific studies, by independent experts, free from vested interests.

The journal article by Tarone referenced in the Reuters article acknowledges that the author consulted with a lawyer representing Monsanto and that payment was received for that consultation. IARC scientists took note of the article and submitted a Letter to the Editor of that journal in December 2016. To date, this letter has not been published. However, the journal’s editors have indicated, most recently in correspondence dated 17 May 2017, that the article by Tarone will be corrected to report the author’s paid consultation with Monsanto as a conflict of interest. In addition, the journal editor indicated that the text of the published article itself will be changed and that the revised article will be characterized as an “opinion paper” rather than a “research paper”.

Further information about the IARC Monographs, including the correct classifications of glyphosate (Group 2A), red meat (Group 2A), and coffee (Group 3), can be found at monographs.iarc.fr.

IARC can re-evaluate substances when a significant body of new scientific data is published in the openly available scientific literature.