



June 20, 2017

Via E-Mail and Federal Express

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

Dear Ms. Monahan-Cummings:

Monsanto Company (“Monsanto”) submits this petition pursuant to 27 Cal. Code Regs. § 25904(e) and Government Code § 11340.7 to request that the California Office of Environmental Health Hazard Assessment (“OEHHA”) refrain from adding glyphosate to the list of chemicals “known to the state to cause cancer” for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 (“Proposition 65”). As described herein, OEHHA originally proposed to list glyphosate based on a determination by the International Agency for Research on Cancer (“IARC”) that glyphosate is a “probable carcinogen.” It recently was revealed, however, that key scientific data were not disclosed to the IARC working group that considered glyphosate and that these data would have affected IARC’s analysis. This new information calls into question the validity of the IARC determination and, consequently, OEHHA’s reliance on that determination to list glyphosate under Proposition 65. Accordingly, Monsanto respectfully requests that OEHHA reconsider its decision to list glyphosate.

I. OEHHA’s Listing of Glyphosate Pursuant to the Labor Code Mechanism.

OEHHA’s decision to list glyphosate is based on the so-called Labor Code mechanism, which provides that the Proposition 65 “list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d).” Health & Safety Code § 25249.8(a). Section 6382(b)(1) of the Labor Code, in turn, identifies by reference “[s]ubstances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC).” OEHHA’s implementing regulations further provide that “[a] chemical or substance shall be included on the [Proposition 65] list if it is classified by [IARC] in its IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans . . . as: . . . (2) Probably carcinogenic to humans (Group 2A) with sufficient evidence of carcinogenicity in experimental animals. . . .” 27 Cal. Code Regs. § 25904(b).

On September 4, 2015, OEHHA provided notice of its intent to list glyphosate pursuant to the Labor Code mechanism.¹ OEHHA explained that glyphosate meets the criteria for listing because IARC classified glyphosate as Group 2A (“probably carcinogenic to humans”) and concluded that there was sufficient evidence of carcinogenicity in experimental animals. On March 28, 2017, OEHHA announced that it had determined that glyphosate would be added to the list of chemicals known to the state to cause cancer for purposes of Proposition 65 pursuant to the Labor Code mechanism.² OEHHA’s announcement stated that the effective date of the proposed listing “will be determined following a decision from the Court of Appeal regarding a request for a stay in the pending case *Monsanto v OEHHA*.” On June 15, 2017, the Court of Appeal denied the request for a stay, but the next day Monsanto filed a request for a stay with the California Supreme Court, which request is pending.

II. Recently Discovered Information Renders the IARC Determination Invalid.

New information has come to light that calls into question the validity of IARC’s determination that glyphosate is a “probable carcinogen.” In particular, Dr. Aaron Blair, Chair of the IARC working group that considered glyphosate, recently revealed in sworn deposition testimony that he failed to disclose to other working group members unpublished scientific data that showed no evidence of a link between glyphosate and cancer. *See Blair Depo. Tr. (Exhibit A) at pp. 172-183.* Dr. Blair admitted that the undisclosed data would have altered IARC’s analysis. *Id*; *see also Reuters, Cancer Agency Left in the Dark Over Glyphosate Evidence* (June 14, 2017) (attached as Exhibit B); *Mother Jones, A Scientist Didn’t Disclose Important Data — and Let Everyone Believe a Popular Weedkiller Causes Cancer* (June 15, 2017) (attached as Exhibit C). The data in question were developed as part of the Agricultural Health Study (“AHS”), one of the largest epidemiological studies to examine the effects of pesticide use on agricultural workers, farmers, and their families. A March 2013 draft of the study is attached as Exhibit D.

Specifically, in March 2017, Dr. Blair was deposed in connection with personal injury claims asserted against Monsanto related to allegations that Monsanto’s glyphosate-based products cause cancer. During the deposition, Dr. Blair testified under oath that:

1. The new AHS data found “no evidence of association between exposure to glyphosate and non-Hodgkin lymphoma,” Blair Depo. Tr. (Exhibit A) at 172:11-15;

¹ OEHHA, *Notice of Intent to List Chemicals By the Labor Code Mechanism Tetrachlorvinphos, Parathion, Malathion, Glyphosate* (Sept. 4, 2015), available at <https://oehha.ca.gov/proposition-65/cnr/notice-intent-list-tetrachlorvinphos-parathion-malathion-glyphosate>.

² OEHHA, *Notice to Interested Parties, Chemical to Be Listed as Known to the State of California to Cause Cancer Glyphosate* (posted March 28, 2017), available at <https://oehha.ca.gov/proposition-65/cnr/glyphosate-be-listed-under-proposition-65-known-state-cause-cancer>.

2. At the time he was Chair of the IARC working group that considered glyphosate and a member of the epidemiology subgroup, Dr. Blair was aware of the AHS data from the 2013 study, which included four times as much data as a prior AHS study published in 2005, *id.* at 177:13-25;
3. He did not disclose the existence of the larger AHS dataset to other members of the glyphosate working group or epidemiology subgroup, *id.* at 178:1-7; and
4. If IARC had used the larger AHS dataset from 2013, it would have impacted IARC's analysis. In particular, Dr. Blair testified that "[t]he relative risk for the AHS study would have been lower," and the meta-analysis that the IARC working group found to be just barely statistically significant in March 2015 probably would not have shown an increased risk of cancer with exposure to glyphosate. *Id.* at 182:16-183:17.³

Separately, on May 3, 2017, the Chair of the IARC working group subgroup on animal toxicology, Dr. Charles Jameson, testified under oath that:

1. The initial assessment of his subgroup of experts in animal toxicology was that the animal data was "limited," Jameson Depo. Tr. (Exhibit E) at 206:1-20;
2. The IARC staff failed to make available to his subgroup a published paper containing tumor data from 14 glyphosate cancer bioassays, *id.* at 179:10-180:10; and
3. The full working group did not consider that data at the IARC meeting even when it was finally presented because "the amount of data in the tables was overwhelming," *id.* at 191:12-192:8.

This new information undermines the IARC working group's prior determination in March 2015 that glyphosate is a probable carcinogen. That finding was based on review of incomplete and inadequate epidemiological and animal data given the information (both published and unpublished) that was and/or should have been available to the working group at the time of its review. Accordingly, IARC's determination that glyphosate is a "probable carcinogen" is invalid and should not be relied upon by OEHHA to list glyphosate under Proposition 65.

III. At a Minimum, the Uncertainty Surrounding IARC's Classification of Glyphosate Should Cause OEHHA to Delay the Listing in Order to Avoid Unwarranted Consequences.

It has been reported that a draft paper analyzing the results of the larger AHS dataset should be submitted to an appropriate scientific publication later this year, with publication following that time. Furthermore, in response to these revelations, IARC has stated that "IARC

³ Four pages of Dr. Blair's deposition are deemed confidential pursuant to a protective order in the personal injury litigation and hence are removed from Exhibit A.

can re-evaluate substances when a significant body of new scientific data is published in the openly available scientific literature.” See IARC, *IARC Responds to Reuters Article of 14 June 2017*, available at http://governance.iarc.fr/ENG/Docs/IARC_responds_to_Reuters_15_June_2017.pdf (last visited June 20, 2017).

OEHHA is well aware of the significance of glyphosate and the adverse consequences that will ensue if glyphosate is listed incorrectly. Many of those consequences will persist even if glyphosate is removed from the list at a later date, whether by action of a court or OEHHA (including by OEHHA in response to an action by IARC). The Declarations of Drs. David Heering and David Stewart, attached hereto as Exhibits F and G, respectively, detail these potential consequences for Californians.

OEHHA need not agree that the IARC determination is invalid in order to reconsider its listing of glyphosate. There is significant uncertainty surrounding both the propriety of IARC’s classification and the scientific basis for it, as well as whether that classification will withstand scrutiny once the larger AHS study is published. To avoid the adverse consequences of listing glyphosate, OEHHA should at the very least delay its listing pending IARC’s reconsideration of this substance in light of the strong scientific evidence that was not made available to the IARC working group that improperly classified glyphosate as a probable human carcinogen.

IV. Conclusion

For these reasons, OEHHA should reconsider its decision to list glyphosate pursuant to the Labor Code mechanism and should not add glyphosate to the Proposition 65 list.

Respectfully,

Monsanto Company

By: 

Dr. Philip W. Miller

Vice President, Global Corporate Affairs

Enclosures