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## NOTE:

Dear Ms. Esther Barajas-Ochoa,

On behalf of the Joint Glyphosate Task Force, LLC, please find attached comments in response to California Environmental Protection Agency's Office of Environmental Health Hazard Assessment intent to include glyphosate on Proposition 65 listing.

These comments were also submitted via email on October 20, 2015.

Regards,  
Katie Miller  
Administrator - Joint Glyphosate Task Force, LLC

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October 20, 2015

Ms. Esther Barajas-Ochoa  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010, MS-19B  
Sacramento, California 95812-4010

**RE: California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) Intent to Include Glyphosate on Proposition 65 Listing**

Dear Ms. Barajas-Ochoa:

The Joint Glyphosate Task Force ("JGTF") appreciates the opportunity to submit these comments in response to the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) Notice of Intent to List glyphosate as a chemical known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"). The JGTF is a joint venture of 26 producers and distributors of glyphosate who have pooled resources to jointly develop health and safety data on glyphosate requested by both the U.S. Environmental Protection Agency ("EPA") and Canada's Pest Management Regulatory Agency ("PMRA"). The members of the JGTF that possess a glyphosate technical registration in the U.S. are listed in Attachment 1.

The JGTF opposes OEHHA's proposed listing of glyphosate under Proposition 65. The sole basis for OEHHA's intent to list glyphosate is the decision by the International Agency for Research on Cancer ("IARC") to classify glyphosate as a probable carcinogen. Numerous other regulatory agencies, including the EPA, PMRA and Germany's Federal Institute for Risk Assessment ("BfR"), have reviewed many of the same studies that formed the basis of the IARC determination and reached the opposite conclusion, i.e., that there is insufficient evidence of carcinogenicity. Importantly, in reaching this conclusion, these agencies also considered additional unpublished research which IARC, as a matter of policy, does not consider. OEHHA can and should consider such research, as well as the evaluations performed by these other agencies. Furthermore, OEHHA itself has reviewed the relevant science and concluded: "Based on the weight of evidence, glyphosate is judged unlikely to pose a cancer hazard to humans."<sup>1</sup> It would certainly be incongruous for OEHHA to list glyphosate as "known to the state to cause cancer" in light of its prior, independent contrary determination and thereby allow a group of hand-picked and unrepresentative individuals, convened overseas, to overrule the careful scientific review of California's health hazard assessment agency.

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<sup>1</sup> OEHHA, Public Health Goals for Chemicals in Drinking Water: Glyphosate (June 2007) ("OEHHA Assessment"), page 1, available at <http://oehha.ca.gov/water/phg/pdf/GlyPHG062907.pdf> (last visited October 2015). Notably, in this June 2007 OEHHA document, OEHHA considered the same data that IARC reviewed but OEHHA – unlike IARC -- concluded that glyphosate is not carcinogenic in rats and mice.

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In its September 4, 2015 Notice of Intent to List Glyphosate ("Notice"), OEHHA states that the glyphosate listing is being proposed pursuant to the "Labor Code" listing mechanism under Proposition 65. The Notice refers to the listings as "ministerial," and indicates that the scope of the agency's consideration of the merits of IARC's determination and receptiveness to public comments is limited:

Because these are ministerial listings, comments should be limited to whether IARC has identified the specific chemical or substance as a known or potential human or animal carcinogen. Under this listing mechanism, OEHHA cannot consider scientific arguments concerning the weight or quality of the evidence considered by IARC when it identified these chemicals and will not respond to such comments if they are submitted.

*Id.*

As discussed below, the JGTF believes that OEHHA's interpretation and use of the Labor Code Mechanism is incorrect, and as applied in this case will result in a denial of due process leading to an inappropriate listing of glyphosate under Proposition 65. In classifying glyphosate as a probable carcinogen, IARC selectively included and interpreted data, and used an approach that is very different from that used by regulatory agencies around the world. OEHHA has an obligation to examine the basis on which IARC's carcinogen classification rests, particularly when presented with evidence that the IARC classification is mistaken.

For more than 40 years, glyphosate has been a valuable tool for weed control in agriculture, industrial and turf use and around homes and gardens. The overall safety profile of glyphosate has contributed to the adoption of glyphosate-based herbicides in more than 160 countries around the world. Glyphosate is widely used throughout California and is especially important to the state's almond and grape industries and to counties and municipalities who need to control vegetation to fulfill their public functions.

The JGTF encourages OEHHA to review the totality of the data on glyphosate. Based on the overwhelming weight of evidence, as well as the consensus of regulatory agencies around the world, the listing of glyphosate on Proposition 65 is scientifically unwarranted and unsound.

#### **I. Overview of the Labor Code Mechanism**

As noted above, OEHHA elected to use the Labor Code Mechanism to propose the listing of glyphosate under Proposition 65 as a "substance known to the state to cause cancer." The Labor Code Mechanism is set forth in Section 25249.8(a) of the Cal. Health & Safety Code. It specifies that a chemical shall be included on the list of chemicals known to the state to cause cancer or reproductive toxicity if it is a substance "identified by reference" in Labor Code 6382(b)(1) or (d) as causing cancer or reproductive toxicity.

Labor Code 6382 directs California to establish a list of hazardous substances. Under Subsection (b)(1) the list must include "substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)."

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OEHHA regulations implementing Cal. Health & Safety Code § 25249.8(a) state that “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.” Cal. Code of Reg. § 25904(a). Subsection (b) of this same regulation states that a chemical shall be included on the list if it is classified by IARC in its Monograph Series or in its list of Agents Classified by 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, for which there is less than sufficient evidence or carcinogenicity in experimental animals and classified by IARC in Group 2B shall not be included on the list.

Cal. Code of Reg. § 25904(b).

These same regulations specify that adding chemicals via the Labor Code Mechanism is subject to comment but that “comment is restricted to whether the identification of the chemical or substance meets the requirements of this section,” and that the Agency “shall not consider comments related to the underlying scientific basis for classification of a chemical by IARC as causing cancer.” *Id.* § 25904(c).

## **II. OEHHA’s Implementation of the Labor Code Mechanism Is Inappropriate**

OEHHA’s implementation of the Labor Code Mechanism, Cal. Health & Safety Code § 25249.8(a), is inappropriate for several reasons. First, the notion that OEHHA must reflexively list IARC-designated carcinogens under Proposition 65, subject only to “ministerial” confirmation that IARC’s designation was either a Group 1, Group 2A or Group 2B carcinogen, is not compelled by Cal. Health & Safety Code § 25249.8(a). The statutory language specifies that a chemical shall be included “by reference to” Labor Code 6382(b)(1) (which refers to substances listed by IARC as “human or animal carcinogens”). The statutory phrase “by reference to” gives OEHHA the freedom and discretion to consider and evaluate the basis for IARC listings. It does not mandate a reflexive adoption of IARC listings, as OEHHA seems to have concluded. Had the drafters of Proposition 65 intended such per force adoption of IARC carcinogen designations, they could have specified that the Proposition 65 list “shall include at a minimum those substances identified as human or animal carcinogens by IARC.”

Second, the manner in which OEHHA is using the Labor Code Mechanism effectively cedes its listing authority to an unelected, ad hoc group of individuals, chosen in a non-transparent manner by an organization in France, without even accepting public comments on – much less evaluating the soundness of – the decisions of this small cadre. This constitutes an improper delegation of the People’s authority to an entity without any safeguards for due process, public involvement, or control by the people’s representatives. This constitutes an unlawful declaration of power, in violation of the California Constitution. *See, e.g., Carson Mobilehome Park Owners’ Assn. v. City of Carson*, 35 Cal. 3d 184, 190 (1983) (“An unconstitutional delegation of authority occurs only when a legislative body (1) leaves the resolution of fundamental policy issues to others or (2) fails to provide adequate direction for the implementation of that policy”); *Bagley v. City of Manhattan Beach*, 18 Cal. 3d 22, 26-27 (1976)

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(employing non-delegation doctrine to invalidate voter initiative that would have allowed wages to be set by an arbitrator, and holding that “the city possessing no power under existing state statute to provide for arbitration of wage rates, such power cannot be created by local initiative”); *Int'l Assn. of Plumbing & Mech. Officials v. Cal. Bldg. Standards Comm'n*, 55 Cal. App. 4th 245, 253-54 (1997) (upholding delegation of authority to the California Building Standards Commission, a governmental entity, to adopt as law model codes prepared by private entities, but only because the Commission was vested with discretion subject to adequate safeguards and was not required to adopt the standards approved by a private entity).

This improper delegation is particularly troubling in the case of IARC because IARC's rules for designating panelists reviewing a candidate chemical (1) exclude the scientists with the greatest knowledge of the candidate chemical, namely, scientists from industry who have actually presided over studies involving the chemical, and (2) permits inclusion of scientists affiliated with public interest groups that often have an anti-industry bias.<sup>2</sup>

Third, by limiting its focus under the Labor Code Mechanism to the “ministerial” task of verifying that IARC has designated a substance as either a Group 1, Group 2A or Group 2B carcinogen, OEHHA affords no meaningful opportunity for public comment or analytical role for the state in connection with listings based on IARC carcinogenicity decisions. Stated another way, OEHHA's implementation of the Labor Code Mechanism is devoid of any procedural protections. Those procedural protections are vital for IARC designations of pesticides, however, because as a matter of policy IARC panels do not review unpublished studies.<sup>3</sup> In the case of glyphosate, registrants have submitted numerous carcinogenicity studies to regulatory authorities around the world. Many of those studies were unpublished and thus were disregarded by IARC. Notably, regulatory agencies (including the recent reviews by Germany, on behalf of the EU reevaluation, and PMRA) have consistently concluded that there is insufficient evidence of carcinogenicity after evaluating all of the available data on glyphosate (including unpublished glyphosate data). OEHHA can and should review this unpublished data rather than blindly adopt IARC's cancer designations – or at a minimum, take into consideration the scientific opinion of EPA, PMRA and other agencies on the question of whether glyphosate is a carcinogen.

We urge OEHHA to invite and accept comments on IARC's scientific basis for deeming glyphosate a probable carcinogen. The IARC cancer classification of glyphosate overlooked decades of thorough and robust analysis by regulatory agencies, including a multi-year assessment just completed by Germany on behalf of the regulatory authority in the European Union, as well as the reregistration review that Canada's PMRA recently completed. EPA, having previously determined that there is insufficient

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<sup>2</sup> IARC is part of the World Health Organization (“WHO”), and follows WHO procedures with respect to declarations of interests by participants in its meetings (WHO 2004). Each potential participant in an IARC panel must declare “any interests that could constitute a real, potential or apparent conflict of interest, with respect to his/her involvement in the meeting or work, between (a) commercial entities and the participant personally, and (b) commercial entities and the administrative unit with which the participant has an employment relationship.” The WHO defines conflict of interest to mean “the expert or his/her partner, or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject matter being considered.” Any apparent conflict of interest exists when “an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others.” (WHO 2004.)

<sup>3</sup> See *Preamble to the IARC Monographs* (2006) at 4 (“only reports that have been published or accepted for publication in the openly available scientific literature are reviewed”).

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evidence of carcinogenicity, is in the process of completing its own registration review of glyphosate. Much of the data reviewed by these agencies were excluded from IARC's review, and the animal studies cited by IARC as "sufficient evidence in experimental animals" were previously considered in OEHHA's 2007 evaluation in which the Agency concluded that glyphosate is not carcinogenic in rats or mice.

In the event that OEHHA invites comments on IARC's scientific basis for deeming glyphosate a probable carcinogen, we intend to submit a much more comprehensive discussion.

The JGTF appreciates the opportunity to submit these comments, and hopes OEHHA will accept comments on the range of issues described above.

Sincerely,



Katie D. Miller  
Administrator – Joint Glyphosate Task Force, LLC

**Attachment 1:****List of Member Companies of the Joint Glyphosate Task Force, LLC with U.S. Registrations**

Company Name	EPA Company Number
Aceto Agricultural Chemicals Corp.	2749
Agan Chemical Manufacturing, Ltd.	11603
AgroMarketing Co., Inc.	87845
AgSaver II, LLC	85806
Albaugh, LLC <sup>1</sup>	42750
BASF Sparks LLC	51036
Cheminova A/S	4787
Cinmax International LLC	87659
Consus Chemical, LLC	86828
Dow AgroSciences, LLC	62719
Farmway Inc.	86277
Gly-Peak	89996
Glysorttech, LLC	89117
Helm Agro US, Inc.	74530
MEY Corporation	80967
Monsanto Company	524
NewAgco Inc.	86794
Nufarm Limited	35935
Ragan and Massey, Inc.	84009
Repar-Glypho, LLC	86004
Sharda Worldwide Exports P.Ltd.	82633
Syngenta Crop Protection, Inc.	100
Tacoma Ag	83520
Tide International USA	84229
United Phosphorus, Inc.	70506

<sup>1</sup> Atanor SA (EPA Co. No. 46146) is a subsidiary of Albaugh and holds glyphosate technical registrations.