October 20, 2015

Lauren Zeise, Ph.D., Acting Director
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, California 95812-4010

RE: *Notice of Intent to List Tetrachlorvinphos, Parathion, Malathion and Glyphosate Under Labor Code Listing Mechanism*

Dear Dr. Zeise:

On behalf of CropLife America ("CLA") and Responsible Industry for a Sound Environment ("RISE") (hereinafter, collectively, "CLA") thank you for the opportunity to comment on the California Office of Health Hazard Assessment ("OEHHA")'s September 4, 2015 Notice of Intent to List Tetrachlorvinphos, Parathion, Malathion, and Glyphosate as chemicals "known to the state to cause cancer" for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") ("Notice"). CLA is the national trade association representing developers, manufacturers, formulators and distributors of crop protection chemicals and other plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all of the crop protection and biotechnology products used by American farmers. CLA represents the interests of its member companies by, among other things, monitoring legislation, federal and state agency regulations, and other actions and litigation that impact the crop protection and pest control industries, and participating in such actions when appropriate. RISE is a national not-for-profit trade association representing more than 220 producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the United States, including a wide range of products used on lawns, gardens, sport fields, golf courses, and to protect public health.

CLA opposes the proposed listing of the Noticed Chemicals.[1] The sole basis for the proposal is the recent decision by the International Agency for Research on Cancer ("IARC") to classify these four pesticidal substances as carcinogens, specifically, glyphosate and malathion in Category 2A ("Probably Carcinogenic to Humans") and tetrachlorvinphos and parathion in Category 2B ("Possibly Carcinogenic in Humans") in the Agency's classification system. Indeed, with respect to glyphosate, numerous other regulatory agencies, including the U.S. Environmental Protection Agency ("EPA"), Canada's Pest Management Regulatory Agency ("PMRA") and, for at least one chemical, even OEHHA itself, have reviewed the same studies that formed the basis of the IARC review, and found 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.

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[1] CLA's reasons are the same for opposing the listing of all four chemicals. Accordingly, we refer to the "Noticed Chemicals" without distinction.

Background. The September 4, 2015 Notice states that the listings are being proposed pursuant to the "Labor Code" listing mechanism. 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.

As discussed below, CLA believes that OEHHA's interpretation and use of the Labor Code Mechanism to list these substances without considering whether there is a scientific basis for doing so is inappropriate. Because IARC limits the scope of its review to studies that are published, that agency obviously and deliberately omits from its consideration some of the most extensive and highest quality studies conducted according to government protocols and submitted to government agencies for review in connection with pesticide registrations pursuant the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") in the United States and similar laws in other countries.[2] CLA urges OEHHA not to list the chemicals under Proposition 65 without recognizing this anomaly.

The "Labor Code Listing Mechanism." The Labor Code Listing Mechanism is described in Section 25249.8(a) of the Cal. Health & Safety Code. It provides 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). Section 6382 directs California to establish a list of "hazardous substances," which must include, among other things, "substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)." *See* Cal. Labor Code §§ 6382(b)(1) and (d).

The OEHHA regulation implementing the Labor Code Listing Mechanism begins by repeating the statutory text, stating 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., *tit.* 27, § 25904(a). Subsection (b) of the 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),

(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 or carcinogenicity in experimental animals and classified by IARC in Group 2B shall not be included on the list.

Cal. Code Regs., *tit.* 27, § 25904(b).

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[2] *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").

Discussion. OEHHA's implementation of the Labor Code Mechanism is inappropriate for several reasons.

First, the notion that OEHHA must reflexively list substances designated in the above-referenced IARC categories subject only to "ministerial" confirmation of their classification is not compelled by Cal. Health & Safety Code § 25249.8(a). Although 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"), that phrase ("by reference to") need not be interpreted as a shackle that requires OEHHA to make decisions unwarranted by the weight of the scientific evidence. Beyond reciting that requirement, OEHHA never explains why it believes that no interpretive safeguards are appropriate.

Second, the manner in which OEHHA is using the Labor Code Listing Mechanism constitutes an improper delegation of the state's authority to an entity without any safeguards for due process, public involvement, or control. In this regard, it is well-recognized that the authors of the IARC Monograph series are selected in an *ad hoc* and non-transparent manner by persons themselves not elected or otherwise selected in an impartial manner by governmental authorities, that does not even allow for public input. This uncritical reliance on IARC results in an unlawful delegation 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) (delegation of authority violates the California Constitution when a legislative body "leaves the resolution of fundamental policy issues to others" or "fails to provide adequate direction for the implementation of that policy"); *Bagley v. City of Manhattan Beach*, 18 Cal. 3d 22, 26-27 (1976) (employing non-delegation doctrine to invalidate voter initiative that would have allowed wages to be set by an arbitrator, and holding that because the city has 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) (California Building Standards Commission, a governmental entity, may adopt as law model codes prepared by private entities, but only because the Commission could, as a matter of discretion, decide not to adopt the model codes).

This improper delegation of authority is particularly troubling where a chemical that is a candidate for listing is a proprietary substance or a regulated pharmaceutical product or a registered pesticide, because IARC's rules for designating scientists for the panel reviewing a candidate chemical categorically exclude scientists from industry who have conducted studies for regulatory purposes, and thus are likely to have the greatest knowledge of the candidate chemical.[3] In fact, in its Preamble, IARC explicitly disavows any policy or rule-making authority and makes "no recommendation . . . with regard

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[3] 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.)

to regulation or legislation."[4] Beyond its admittedly limited scope, IARC can also selectively choose pieces of available data to include in its evaluation.

For example, the case of glyphosate clearly illustrates this flaw. There, IARC relied on only four of the fourteen available animal health studies and selectively interpreted data from the studies it considered. Further, as noted above, the IARC process also overlooked the conclusions of regulatory agencies globally. If OEHHA moves forward with an intention to list based solely on the IARC classification, it will do so as a result of incomplete and misinterpreted data. Moreover, OEHHA would be making a decision to list without the benefit of the sound, science-based assessment by competent regulators, including the EPA. As discussed above, an IARC classification alone is neither a sound nor sufficient basis for a Proposition 65 listing. We urge OEHHA to consider the limitations of the IARC classification process as the agency makes listing decisions, especially for substances that are highly regulated and carefully reviewed by other competent authorities.

CLA takes the safety and stewardship of pesticides extremely seriously. In the United States, Canada, the European Union and most countries worldwide, no pesticide can be used until it has been thoroughly reviewed and approved for its intended use. This robust regulatory process should give pesticide applicators and users, public health authorities, and the general public confidence that pesticide products can be used safely and effectively when label directions are followed.

CLA, therefore, asks OEHHA to consider the overwhelming weight of evidence as it considers the listing of tetrachlorvinphos, parathion, malathion, and glyphosate. Decisions about public health and safety should be made on sound science and all available data. CLA appreciates the opportunity to submit these comments. If you have any questions or concerns, please do not hesitate to contact Rachel Lattimore at rlattimore@croplifeamerica.org or 202.872.3895.

Sincerely,

Rachel Lattimore
Senior Vice-President, General Counsel & Secretary
CropLife America

Aaron Hobbs
President
RISE, Responsible Industry for a Sound Environment

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[4] IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble (emphasis added), page 3, (2006), available at http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf (last visited October 2015).

cc: Ms. Esther Barajas-Ochoa
Ms. Carol Monahan Cummings, Chief Counsel