

**Response to Comments Concerning the Notice of Intent to List
Tetrachlorvinphos, Parathion, and Malathion as Causing Cancer under
Proposition 65**

**Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
May 20, 2016**

On September 4, 2015, the Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Intent to List¹ tetrachlorvinphos, parathion, malathion, and glyphosate under Proposition 65² as chemicals known to the state to cause cancer. The September 4 notice initiated a 30-day public comment period that was scheduled to close on October 5, 2015. OEHHA extended the public comment period for parathion, malathion, and glyphosate to October 20, 2015 after receiving requests for an extension. This document responds to comments on tetrachlorvinphos, parathion and malathion. OEHHA is still reviewing public comments it received on glyphosate, and was recently sued³ to prevent its addition to the list. Therefore, the proposed listing of glyphosate will be addressed in a separate notice.

Effective October 1, 2015, the process by which OEHHA lists chemicals and substances via the Labor Code listing mechanism was adopted in regulation at Title 27, Cal. Code of Regs., section 25904⁴. Section 25904 outlines OEHHA's existing procedures for Labor Code listings and incorporates court decisions interpreting the Proposition 65 statute as it applies to Labor Code listings⁵. In accordance with OEHHA's longstanding practice and now required by that regulation, OEHHA provided an opportunity for the public to comment on whether the chemicals identified in the Notice of Intent to List (NOIL) meet the requirements for listing as causing cancer

¹ Notice of Intent to List Chemicals by the Labor Code mechanism: Tetrachlorvinphos, Parathion, Malathion, Glyphosate, available online at <http://www.oehha.ca.gov/proposition-65/crn/notice-intent-list-tetrachlorvinphos-parathion-malathion-glyphosate>

² The Safe Drinking Water and Toxic Enforcement Act of 1986 (codified at Health and Safety Code section 25249.5 *et seq.*) hereinafter referred to as Proposition 65 or the Act.

³ *Monsanto Company v Office of Environmental Health Hazard Assessment et al.*, Fresno County Superior Court case #16CECG00183.

⁴ All further references are to section of Title 27, Cal. Code of Regs unless otherwise stated.

⁵ Specifically, Section 25904 excludes from listing any chemicals or substances classified by the International Agency for Research on Cancer (IARC) as Group 2B based on limited evidence of carcinogenicity in experimental animals as required by *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment*, (2012) 210 Cal. App. 4th 1082. Additionally, in the Second Interim Order of the *Sierra Club v. Schwarzenegger (Brown)* case (Case No. RG07356881), the court ordered OEHHA to list chemicals when IARC concludes there is sufficient evidence of carcinogenicity in humans or animals, regardless of whether the final IARC Monograph on the substance or chemical has been published. See also, *California Chamber of Commerce v Schwarzenegger et al.*, (2011)196 Cal. App 4th, 233 clarifying that Labor Code listings are ministerial acts required by statute.

pursuant to Health and Safety Code section 25249.8(a) and Labor Code section 6382(b)(1).

OEHHA received 230 sets of comments on tetrachlorvinphos, parathion and malathion during the comment period. OEHHA has reviewed all of the submitted comments and accompanying materials on these chemicals in light of the statutory requirements, case law and regulations applicable to this listing mechanism. The majority of commenters simply stated their support or opposition to the listing of one or more of these chemicals. No response to those comments is required. Eight commenters addressed substantive issues regarding the proposed listing. These comments are responded to below.

Each of the three chemicals was identified by the International Agency for Research on Cancer (IARC) as having sufficient evidence of carcinogenicity in animals. Malathion was classified in Group 2A (probably carcinogenic to humans) and tetrachlorvinphos and parathion were classified in Group 2B (possibly carcinogenic to humans). Pursuant to Health and Safety Code section 25249.8(a), Section 25904(c) and in compliance with relevant case law, a chemical must be included on the Proposition 65 list if it is identified by IARC in the IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent edition), based on sufficient animal or human evidence, as probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B). The three chemicals meet this criterion for listing.

Some commenters analyzed IARC's scientific conclusions, disagreeing with IARC's classifications and providing their own scientific analyses and conclusions. Because listing under the Labor Code is a ministerial process, to be relevant to the listing, comments must be limited to whether IARC has identified the specific chemical or substance as a known or potential human or animal carcinogen in IARC groups 1, 2A or 2B, based on sufficient animal or human evidence. Pursuant to Health and Safety Code section 25249.8(a), Section 25904(c) and in compliance with relevant case law, OEHHA cannot refuse to list a chemical pursuant to the Labor Code listing mechanism if a commenter disagrees with IARC's scientific conclusions. Thus, substantive responses to comments on the underlying scientific evidence relied on by IARC to identify the chemicals are not provided here.

After careful consideration of all the public comments received, OEHHA has determined that tetrachlorvinphos, parathion, and malathion meet the requirements for listing as known to the state to cause cancer.

Substantive comments received are responded to below. The numbers in **bold** in the comments correspond to the commenter numbers in the table below. Comments from the individuals and groups listed in the table below are summarized, grouped and numbered by topic, and responses follow.

Commenters	
1	Agricultural Council of California & the California Farm Bureau Federation
2	The American Mosquito Control Association
3	Cheminova
4	Consumer Specialty Products Association
5	CropLife America
6	Ramboll Environ
7	The Scotts Company LLC
8	Western Plant Health Association

MALATHION

- 1. Comment (3, 8):** Section 6382(a) provides that the director [of the Department of Industrial Relations] shall not list a substance or form of the substance if the substance as present occupationally is not potentially hazardous to human health or there is no valid and substantial evidence that any adverse acute or chronic risk to human health may occur from exposure. Labor Code Section 6382(b) (1) provides that substances listed as human or animal carcinogens by the IARC shall be listed, subject to the exclusion provision contained in section 6382(a). Malathion fits these criteria for exemption. Commenter 3 lays out 5 reasons why malathion fits these criteria.

Response: Section 25249.8(a) of Proposition 65 states that “the list of chemicals 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)”. Proposition 65 only incorporates these two subsections of the Labor Code, not the entire section. Therefore, the exclusions in Section 6382(a) of the Labor Code do not apply to Proposition 65 listings.

- 2. Comment (1, 3):** It is not possible to construct a realistic scenario under which humans would be exposed to levels of malathion that are high enough to produce the kind of results that are seen in the animal studies used for the IARC decision. Animal studies were conducted at very high dose levels that exceeded the maximum tolerated dose for test animals. Such exposures are not relevant to humans when malathion products are used in accordance with government approved labels. Signs of toxicity occur only with exposures that are well above those to which humans may be exposed when using malathion in accordance with its government-approved labels.

Response: Considerations of the levels of actual human exposure to a chemical listed under Proposition 65 from a particular product, including determinations whether the exposure exceeds a level posing no significant risk, and hence requires a warning under Proposition 65, are dealt with in a later stage of the process⁶. Consideration of human exposure is not relevant to listing.⁷ OEHHA intends to provide compliance assistance for businesses subject to the warning requirements by proposing a safe harbor level for exposures to the chemical. Businesses may also request that OEHHA issue a Safe Use Determination for exposures to the chemical from specific products or uses pursuant to Title 27, Cal. Code of Regs., section 25204. A fact sheet outlining this process is available here: <http://www.oehha.ca.gov/media/downloads/cnr/sudfacts03112016.pdf>.

3. Comment (2, 3, 8): The review conducted by IARC was only a rudimentary assessment of hazard potential. It did not include exposure and risk assessment. It excluded consideration of hazard identification and human exposure. Without such an assessment, IARC's listing provides no justification that malathion presents a potential occupational human health hazard, or risk to the public.

Response: In classifying malathion in Group 2A, IARC made the hazard identification that malathion is probably carcinogenic to humans, based on sufficient evidence of carcinogenicity in animals and limited evidence from human studies and supportive information from other relevant data. While consideration of human exposure and risk is not relevant to listing, OEHHA notes that the IARC Monograph has a section discussing human exposure. OEHHA acknowledges that a full risk assessment for Malathion was not performed by IARC. Listing malathion under Proposition 65 based on IARC's identification is not a finding by OEHHA that malathion presents a potential occupational human health hazard, or a human health risk when used according to the label. Under Proposition 65, risk evaluation and a determination of the need to warn about exposures for given uses takes place at later phases in the process, and not during the listing phase⁸. Thus, after a chemical is listed, if a business is sued and can establish that the exposure it causes will not cause more than one excess cancer per 100,000 exposed individuals, it need not provide the warning required by the statute.

4. Comment (1, 2, 3, 8). Commenters cited organizations (e.g., US Environmental Protection Agency (US EPA), California Department of Pesticide Regulation (DPR), Canada Pest Management Regulatory Agency, European Union) that

⁶ Health and Safety Code section 25249.10(c), Title 27, Cal Code of Regs Section 25701 *et seq.*

⁷ *Exxon Mobil Corporation v. OEHHA* 169 Cal. App. 4th 1264

⁸ *Exxon Mobil Corporation v. OEHHA* 169 Cal. App. 4th 1264

have reviewed toxicological studies on malathion and have determined there is no substantial evidence that any adverse acute or chronic risk to human health will occur from exposures when products containing malathion are used in accordance with their approved labels. One commenter noted that, as found by US EPA and DPR, there is a clear threshold for carcinogenic exposures below which no tumors form. Some commented that various agencies have continued to allow the use of malathion in agriculture.

Response: Proposition 65 does not limit or restrict the use of malathion products. It simply requires a warning for exposures to the chemical in certain circumstances. The IARC finding of carcinogenic hazard (“sufficient evidence in experimental animals for the carcinogenicity of malathion”) is based on considerations of hazard and not based on conclusions regarding overall risk, such as may be made by regulatory authorities. The addition of a chemical to the Proposition 65 list is based on the hazard finding of IARC. As indicated above, under Proposition 65, considerations of exposure assessment and dose response analyses that contribute to determinations about whether or not a given exposure exceeds the no significant risk level and therefore requires a warning are dealt with in later phases of the process.

5. Comment (6, 7): Although OEHHA is correct in noting that this designation [for malathion] already appears on IARC’s website, publication of the basis for the designation has yet to be released to the public in a comprehensive, transparent source consistent with the norms of scientific communications; e.g. an IARC monograph. OEHHA’s listing is premature.

Response: Under Proposition 65, chemicals are to be added to the list based on Section 6382(b)(1) of the Labor Code, which identifies “substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC).” OEHHA is required by court order to list chemicals based on the IARC designation, and to not wait until the Monograph has been published:

“Under *AFL-CIO v. Deukmejian* (1989) 212 Cal. App. 3d 425, OEHHA has a mandatory duty to list any chemical for which IARC has concluded there is “sufficient” evidence of cancer in humans or animals. This includes those agents added to the IARC list, *whether or not the final monograph has been published* ...”⁹

⁹ (*Sierra Club, et al. v. Schwarzenegger*, Alameda County Superior Court case number RG07356881) (Attachment A) (Emphasis added)

Nonetheless, OEHHA notes that since the time OEHHA published its Notice of Intent to List Malathion, IARC has published the Monograph and made it available on its website.¹⁰

6. Comment (3): US EPA has approved many malathion labels under FIFRA, and continues to do so. Therefore, these labels comply with the FIFRA requirement that malathion does not pose an unreasonable risk to human health.

Response: This comment is not directly relevant to the listing of malathion under Proposition 65. As noted above, the evaluation of risk comes at a later phase in the Proposition 65 process.

7. Comment (1, 2): Malathion is a critical component to public health programs designed to combat vector-transmitted diseases such as malaria, dengue fever, chikungunya, West Nile virus, and encephalitis. Malathion plays an important role in integrated pest management programs designed to offset the growing resistance of insects to the pyrethroid class of chemicals used in agriculture and in public health protection programs. It is certainly not inconceivable that, based on this listing, malathion would eventually be removed from vector control inventories due to public pressure arising from its listing. Ironically, the public health of California's citizenry would thus be placed at higher risk from a measure ostensibly deemed to eliminate a possible, but vanishingly small, risk. It is in the public's interest that this be fully taken into account in OEHHA policy contexts.

Response: The listing of malathion under Proposition 65 does not restrict or ban the use of the product. Further, public agencies are exempt from the provisions of Proposition 65 (Health and Safety Code section 25249.11(b)), and therefore a Proposition 65 listing would impose no restrictions or even warning requirements on public agencies that use malathion.

As previously stated, the listing of malathion by OEHHA is a ministerial duty based on its identification as a carcinogen by IARC. OEHHA is not allowed by law to consider a chemical's uses, however merited, when making a listing decision. OEHHA intends to provide assistance by proposing a safe harbor level that identifies a level of malathion exposure that does not pose a significant cancer risk. Businesses may also request that OEHHA issue a Safe Use Determination for exposures to the chemical from specific products or uses pursuant to Title 27, Cal. Code of Regs., section 25204. A fact sheet outlining this process is available here: <http://www.oehha.ca.gov/media/downloads/cnr/sudfacts03112016.pdf>.

¹⁰ <http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-07.pdf>

TETRACHLORVINPHOS, MALATHION AND PARATHION

1. **Comment (5):** OEHHA does not explain why it interprets the statutory language that states a chemical shall be included “by reference to” Labor Code 6382(b)(1) as an obligation to list with no interpretive safeguards.

Response: The level of discretion (interpretive safeguards) that the commenter reads into this section of the Labor Code is incorrect. OEHHA is required by statute to list the chemical based on IARC’s identification¹¹ as long as IARC has classified the chemical as having adequate animal or human evidence.¹² OEHHA cannot decline to list a chemical that meets the criteria for listing, simply based on comments that disagree with IARC’s scientific evaluation.

2. **Comment (4, 5):** OEHHA is effectively deferring its authority to a quasi-governmental international body without any safeguards for due process and public involvement that are the hallmark of the United States and California Constitutions. Listing via the Labor Code mechanism significantly limits or precludes public involvement, as IARC will not consider public comments nor is IARC subject to any review or appeal. Consequently, there are no safeguards or transparency with the Labor Code process that are required for each listing mechanism.

Response: The comments challenge the constitutionality of the Labor Code listing provision of Proposition 65, to the extent that it relies on IARC classifications.¹³ OEHHA’s interpretation of the provision is based on relevant statutory and case law, which makes clear that the scientific review of the evidence for these listings is conducted by IARC, not OEHHA. Proposition 65, through its incorporation of the relevant subsection of the Labor Code, has designated IARC as a scientific authority for the identification of carcinogenic chemicals for purposes of Proposition 65.

- In *AFL-CIO v. Deukmejian*¹⁴, the court held that OEHHA has a mandatory duty to list any chemical for which IARC has concluded there is sufficient evidence of cancer in humans or animals¹⁵.
- In *California Chamber of Commerce v. Brown*¹⁶, the court held that “the absence of independent evaluation by OEHHA or the state’s experts does not

¹¹ *California Chamber of Commerce v. Brown* Cal. App. 4th 233 (2011)

¹² *SIRC v OEHHA* (2012) 210 Cal.App.4th 1082

¹³These allegations have been raised by Monsanto in its pending litigation against OEHHA *Monsanto v OEHHA* (Fresno County Superior Court case number 16CECG00183 (January, 21, 2016). That case has not yet been decided.)

¹⁴ *AFL-CIO v. Deukmejian* (1989) 212 Cal. App 3rd., 425

¹⁵ See also *SIRC v OEHHA* (2012) 210 Cal.App.4th 1082

¹⁶ *California Chamber of Commerce v. Brown* (2011) 196 Cal. App. 4th 233, at 260

render the Labor Code reference method set forth in subdivision (a) an anomaly within the statutory scheme.”

- In *Sierra Club, et al. v. Schwarzenegger*,¹⁷ the court ordered OEHHA to list chemicals that IARC concluded have sufficient evidence of cancer in humans or animals, and that fall in IARC groups 1, 2A or 2B.

Health and Safety Code section 25249.8 expressly states that the Proposition 65 list must contain “at a minimum” those substances identified by reference in Labor Code sections 6382, subsections (b)(1) and (d). This provision has been part of Proposition 65 since it was approved by California voters in 1986. The Labor Code section cited in the statute specifically identifies IARC by name.

To the extent that the comments challenge the constitutionality of the Labor Code listing provision as it has been interpreted by the Courts, this issue will be decided in the pending litigation. OEHHA provides the following brief response without waiving any further response that it may raise in the litigation. No governmental function was delegated to IARC through this statutory provision. Instead, the law identifies IARC as an authoritative source for identifying chemicals that cause cancer. “[W]hile the legislative body cannot delegate its power to make a law, it can make a law to delegate a power to determine some fact or state of things upon which the law makes or intends to make its own action depend.”¹⁸ In this instance, California citizens in enacting Proposition 65, and the Legislature in enacting the Labor Code, are relying on an internationally recognized scientific body to identify known carcinogens. In turn, that identification triggers other provisions of the law. OEHHA is the agency that adds to the Proposition 65 list the substances identified as carcinogens by IARC pursuant to Health and Safety Code section 25249.8(a) and the referenced Labor Code provisions. Relying on IARC’s scientific findings for purposes of listing substances known to cause cancer fits the definition of a “delegation of power to determine a fact or state of things upon which the law depends”¹⁹ (i.e., the identification of substances that are known to cause cancer that are subject to the warning requirements and discharge prohibitions of the law).

3. Comment (5): 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 to the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”) in the United States and similar laws in

¹⁷ *Sierra Club, et al. v. Schwarzenegger*, (Alameda County Superior Court case number RG07356881 (Attachment A),

¹⁸ *Kugler v Yocum* (1968) 71 Cal. Rptr. 687, 690

¹⁹ *Kugler v Yocum* (1968) 71 Cal. Rptr. 687, 690; *Wheeler v Gregg* (1949) 90 Cal. App. 2d. 348, 363

other countries. CLA urges OEHHA not to list the chemicals under Proposition 65 without recognizing this anomaly.

Response: In describing data covered by its reviews IARC notes that “only reports that have been published or accepted for publication in the openly available scientific literature are reviewed. ... Data from government agency reports that are publicly available are also considered.”²⁰ For example, in the case of malathion, IARC reviewed US EPA documents that described in detail the relevant aspects of study design and presented in detail study data and findings from the chronic studies of malathion conducted in male and female mice by the International Research and Development Corporation, and the two-year chronic feeding studies of malathion conducted in male and female rats by Huntingdon Life Sciences. These studies were submitted to US EPA under the FIFRA program. The citations of these reports from the IARC Monograph are as follows:

EPA (1994). Malathion: 18-month carcinogenicity study in mice, International Research and Development Corporation. MRID 43407201. HED Doc No. 011455. Slauter RW, author. Peer reviewed by EPA. Washington (DC): Office of Pesticides and Toxic Substances, United States Environmental Protection Agency. Available from: <https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/057701/057701-004.pdf>, accessed 21 March 2016.

EPA (1996). Malathion: 2-year chronic feeding/carcinogenicity study in Fischer 344 rats. Huntingdon Life Sciences. 1996. MRID 43942901. Washington (DC): Office of Pesticides and Toxic Substances, United States Environmental Protection Agency. Available from: <http://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/057701/057701-114.pdf>, accessed 9 December 2015.

²⁰ International Agency for Research on Cancer (2006), IARC Monographs on the Evaluations of Carcinogenic Risks to Humans, Preamble, World Health Organization, IARC, Lyon, France.