

**Response to Comments Pertaining to the
Notice of Intent to Change the Basis for Listing for
1,2-Dibromo-3-Chloropropane (DBCP), Ethylene Oxide and Lead
to the Formally Required Listing Mechanism under Proposition 65**

**Office of Environmental Health Hazard Assessment
California Environmental Protection Agency**

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On September 20, 2013, the Office of Environmental Health Hazard Assessment (OEHHA) proposed to change the basis for listing for DBCP, ethylene oxide and lead from the Labor Code listing mechanism to the Formally Required listing mechanism. The proposal was based on specific warning and labeling requirements imposed by the federal Occupational Safety and Health Administration (OSHA) and U.S. Environmental Protection Agency (U.S. EPA) for the three chemicals. This document responds to the comments received on the Notice of Intent to Change the Basis for Listing.

Background: Health and Safety Code Section 25249.8(b), codified as part of Proposition 65, says, “A chemical is known to the state to cause cancer or reproductive toxicity....if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.”

Proposition 65’s implementing regulation, specifically Title 27, Code of California regulations, Section 25902(b), says:

- “[F]ormally required’ means that a mandatory instruction, order, condition, or similar command, has been issued in accordance with established policies and procedures of an agency of the state or federal government to a person or legal entity outside of the agency. The action of such agency may be directed at one or more persons or legal entities and may include formal requirements of general application;
- ‘[L]abeled’ means that a warning message about the carcinogenicity or reproductive toxicity of a chemical is printed, stamped, written, or in any other manner placed upon the container in which the chemical is present or its outer or inner packaging including any material inserted with, attached to, or otherwise accompanying such a chemical;
- ‘[I]dentified’ means that a required message about the carcinogenicity or reproductive toxicity of the chemical is to be disclosed in any manner to a person or legal entity other than the person or legal entity who is required to make such disclosure; and

- As causing reproductive toxicity means: "...the required label or identification uses any words or phrases intended to communicate a risk of reproductive harm to men or women or both, or a risk of birth defects or other developmental harm".

In response to its notice for lead, ethylene oxide and DBCP, OEHHA received one comment letter from APTCO, LLC. The commenter generally objects to the proposed change of basis for the listing of DBCP, ethylene oxide and lead as chemicals causing reproductive toxicity under Proposition 65¹, from the "Labor Code" mechanism to the "Formally Required to be Labeled or Identified" mechanism.² APTCO, LLC does not have specific objections to the listing of these three chemicals, however, it does have questions regarding the legality of the administrative process OEHHA is using to change the basis for the listings. The comments are summarized below, followed by OEHHA's responses.

Comment:

According to OEHHA's long-standing rule of general applicability, Formally Required to be Labeled or Identified listings are limited to prescription drugs regulated by the federal Food and Drug Administration (FDA). The three chemicals that are the subject of the notice are not drugs; therefore, all three chemicals have to be referred to the Developmental and Reproductive Toxicant Identification Committee (DART-IC) for consideration for listing.

Response:

Nothing in the statute, regulation or OEHHA's past practices limits the scope of chemical listings via the Formally Required mechanism to only those chemicals regulated by the federal Food and Drug

Health and Safety Code section 25249.8(b) provides in relevant part that "A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter...if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity."

According to Section 25902(b) of OEHHA's implementing regulations:

- "[F]ormally required' means that a mandatory instruction, order, condition, or similar command, has been issued in accordance with established policies and

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, initiative statute codified at California Health and Safety Code section 25249.5 *et seq.*, hereafter referred to as "Proposition 65" or "the Act".

² Title 27, Cal Code of Regulations, section 25902. All further references are to sections of Title 27, unless stated otherwise.

procedures of an agency of the state or federal government to a person or legal entity outside of the agency. The action of such agency may be directed at one or more persons or legal entities and may include formal requirements of general application;”

- “[L]abeled’ means that a warning message about the carcinogenicity or reproductive toxicity of a chemical is printed, stamped, written, or in any other manner placed upon the container in which the chemical is present or its outer or inner packaging including any material inserted with, attached to, or otherwise accompanying such a chemical;”
- “[I]dentified’ means that a required message about the carcinogenicity or reproductive toxicity of the chemical is to be disclosed in any manner to a person or legal entity other than the person or legal entity who is required to make such disclosure”; and
- As causing reproductive toxicity means: “...the required label or identification uses any words or phrases intended to communicate a risk of reproductive harm to men or women or both, or a risk of birth defects or other developmental harm.”

Further, according to the Final Statement of Reasons (FSOR) for the regulation, the language in the regulation is intended to be interpreted broadly to include any agency of the state or federal government because the regulation cannot change the “clear language of the statute”. (FSOR at page 4, available here: http://www.oehha.ca.gov/prop65/law/pdf_zip/12902%20FSOR%20March%201990.pdf.)

Lastly, the commenter is incorrect that OEHHA has only used the Formally Required mechanism to list prescription drugs that are regulated by the FDA. For example, the following chemicals were listed via this mechanism based on California Department of Pesticide Regulation, California Air Resources Board, federal OSHA and U.S. EPA labeling or identification requirements.

- Acrylonitrile
- Anabolic steroids
- Benzidine-based dyes
- Bromoxynil
- Cyanazine
- Cycloheximide
- Cyhexatin
- 1,2-Dibromo-3-chloropropane (cancer)
- Dinocap
- Dinoseb
- Ethylene dibromide
- Ethylene oxide (cancer)

- Methyl bromide, as a structural fumigant
- 4,4'-Methylene bis (2-chloroaniline)
- Polychlorinated dibenzo-p-dioxins
- Polychlorinated dibenzofurans

Thus it is clear that the statute, OEHHA's regulations and general past practices of the agency do not support the commenter's contention that the proposed action is beyond the scope of OEHHA's authority under the regulation.

Comment:

Using the Formally Required mechanism for listings based on OSHA and U.S. EPA warning requirements exceeds the scope of the regulation because OEHHA's past practice has been to only list chemicals in prescription drugs regulated by FDA. The proposed change of basis for listing the three chemicals is therefore an unlawful amendment of the regulation because the public was not provided with an opportunity to comment as required by the California Administrative Procedure Act.

Response:

As explained in the response to comment number one, the action being proposed by OEHHA is not beyond the scope of OEHHA's authority under the statute or regulation. It is also not contrary to past practice. Further, even if it had been OEHHA's practice to rely only on the FDA requirements for prescription drug labeling, which is not the case here, such a practice cannot modify the clear effect of the law, which requires broader application of the Formally Required Listing Mechanism³.

The commenter argues that OEHHA must amend Section 25902 before it may lawfully use that regulation as a basis for listing any chemical that is not a prescription drug regulated by the federal FDA. While the commenter is correct that amendments to a regulation must be accomplished in compliance with the California Administrative Procedure Act, no such amendment is necessary here. The regulation reflects the clear meaning of the statutory requirement that chemicals formally required by a state or federal agency to be labeled or identified as causing cancer or reproductive toxicity be listed under Proposition 65. There is no express or implied limitation in the statute or regulation that supports the commenter's argument.

Comment:

OEHHA's established practice to use the Formally Required mechanism for prescription drugs is evidenced by statements in an OEHHA fact sheet and by OEHHA's Chief Counsel at a recent public meeting that the mechanism has been mostly used to list prescription drugs.

³ *California Chamber of Commerce v Brown* (2011) 196 Cal.App.4th233, 253-255

Response:

The fact sheet and the Chief Counsel simply made general informational statements that many of the listings made under the Formally Required mechanism have been for prescription drugs. Neither the fact sheet nor the Chief Counsel said the Formally Required mechanism can *only* be used for prescription drugs or that OEHHA has only used the mechanism to list prescription drugs. As stated above, OEHHA has used the Formally Required mechanism to list at least 16 chemicals that are not prescription drugs.

Comment:

OEHHA is not authorized to list the three chemicals by reference to the OSHA regulations.

Response:

The proposed changes in the basis for listing of the three chemicals at issue here easily meet the criteria in both the statute and the regulation. Specifically, as stated in the "Notice of Intent to Change the Basis for Listing," the chemicals are required to be labeled or identified as causing reproductive toxicity by federal OSHA or U.S. EPA, or both.

"DBCP, ethylene oxide and lead are required to be identified or labeled to communicate a risk of reproductive toxicity by OSHA regulations. In addition, the US Environmental Protection Agency (US EPA) also requires labels to communicate a risk of reproductive toxicity for ethylene oxide.

Language from the OSHA regulations and US EPA warning requirements which meets the requirements of Section 25902 is quoted below for each of these three chemicals.

1,2-Dibromo-3-chloropropane (DBCP)

'1910.1044(n)(1)(ii)

The employer shall assure that each employee is informed of the following:

'...1910.1044(n)(1)(ii)(a)

The information contained in Appendix A...'

Appendix A, under "II. Health Hazard Data", states:

'...2. Chronic exposure. Prolonged or repeated exposure to DBCP has been shown to cause sterility in humans. It also has been shown to produce cancer

and sterility in laboratory animals and has been determined to constitute an increased risk of cancer in man.’⁴

Ethylene oxide

‘1910.1047(j)(2)(i)(A)

The employer shall post and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas that bear the following legend:

“DANGER
ETHYLENE OXIDE
MAY CAUSE CANCER
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE
REQUIRED IN THIS AREA
AUTHORIZED PERSONNEL ONLY”

‘...1910.1047(j)(2)(i)(B)

Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(2)(i)(A) of this section:

“DANGER
ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE
WORN IN THIS AREA”

‘...1910.1047(j)(2)(ii)(A)

The employer shall ensure that labels are affixed to all containers of EtO [ethylene oxide] whose contents are capable of causing employee exposure at or above the action level or whose contents may reasonably be foreseen to cause employee exposure above the excursion limit, and that the labels remain affixed when the containers of EtO leave the workplace. For the purposes of this paragraph (j)(2)(ii), reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers.’

‘... 1910.1047(j)(2)(ii)(B)

Prior to June 1, 2015, employers may include the following information on containers of EtO in lieu of the labeling requirements in paragraph (j)(1)(i) of this section:

⁴ The OSHA regulation for DBCP quoted above can be accessed online at:
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10061

“1910.1047(j)(2)(ii)(B)(1)
DANGER
CONTAINS ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD;”

‘...1910.1047(j)(2)(ii)(B)(2)
A warning statement against breathing airborne concentrations of EtO.’

‘...1910.1047(j)(2)(ii)(C)
The labeling requirements under this section do not apply where EtO is used as a pesticide, as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when it is labeled pursuant to that Act and regulations issued under that Act by the Environmental Protection Agency.’⁵

The US EPA 2013 required precautionary statements on the conditional registration and use label for ethylene oxide (registration number 89514-1) reads:

‘DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD

...

‘OTHER POSSIBLE DELAYED HEALTH EFFECTS:

“May cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic changes, and cancer.”

...

‘DO NOT REMOVE THIS LABEL.’

Lead

‘1910.1025(g)(2)(vii)(A)
The employer shall ensure that labels of bags or containers of contaminated protective clothing and equipment include the following information:

“DANGER: CLOTHING AND EQUIPMENT CONTAMINATED WITH LEAD. MAY DAMAGE FERTILITY OR THE UNBORN CHILD. CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM. DO NOT EAT, DRINK OR SMOKE WHEN HANDLING. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.”

⁵ The OSHA regulation for ethylene oxide quoted above can be accessed online at:
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10070

'1910.1025(l)(1)(i)

Each employer who has a workplace in which there is a potential exposure to airborne lead at any level shall inform employees of the content of Appendices A and B of this regulation.'

Appendix A under 'II. Health Hazard Data' states:

'(2) Long-term (chronic) overexposure. Chronic overexposure to lead may result in severe damage to your blood-forming, nervous, urinary and reproductive systems...'

'Chronic overexposure to lead impairs the reproductive systems of both men and women. Overexposure to lead may result in decreased sex drive, impotence and sterility in men. Lead can alter the structure of sperm cells raising the risk of birth defects. There is evidence of miscarriage and stillbirth in women whose husbands were exposed to lead or who were exposed to lead themselves. Lead exposure also may result in decreased fertility, and abnormal menstrual cycles in women. The course of pregnancy may be adversely affected by exposure to lead since lead crosses the placental barrier and poses risks to developing fetuses. Children born of parents either one of whom were exposed to excess lead levels are more likely to have birth defects, mental retardation, behavioral disorders or die during the first year of childhood.'

Appendix B in 'XI. SIGNS - PARAGRAPH (M)' states:

'The standard requires that the following warning sign be posted in the work areas when the exposure to lead exceeds the PEL [Permissible Exposure Limit]:

"DANGER
LEAD MAY DAMAGE FERTILITY OR THE UNBORN CHILD
CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM
DO NOT EAT, DRINK OR SMOKE IN THIS AREA"

'However, prior to June 1, 2016, employers may use the following legend in lieu of that specified above:

"WARNING
LEAD WORK AREA
POISON
NO SMOKING OR EATING""⁶

⁶ The OSHA regulation on lead quoted above can be accessed online at:
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10030

Even a cursory review of the above OSHA and U.S. EPA labeling and identification requirements shows that all three chemicals at issue here meet the criteria for listing contained in the statute and the regulation.

Comment:

OEHHA cannot rely on federal OSHA warning requirements as a basis for a Formally Required listing because federal OSHA is not designated as an authoritative body under Section 25306(l).

Response:

The statute sets out four separate and distinct methods for adding chemicals to the Proposition 65 list⁷. The chemicals at issue here are not being proposed for listing via the Authoritative Bodies listing mechanism described in Section 25306. On the contrary, the chemicals are being proposed under the Formally Required mechanism described in Section 25902, which requires listing where a chemical is required to be labeled or identified as causing cancer or reproductive toxicity by *any* federal or state agency. As discussed earlier in the responses to comments 1 and 2, the Formally Required regulation is intentionally broad, because the statutory provision it is interpreting is very broad. In fact, the FSOR for the regulation specifically discussed objections to the regulation that related to using federal OSHA warning and labeling requirements as a basis for listing. The agency rejected that contention and specifically cited Department of Pesticide Regulation Pesticide Safety Information Sheets (PSIS) and the OSHA requirements for Material Safety Data Sheets (MSDS) as sufficient basis for listing chemicals under this mechanism:

“...an MSDS and a PSIS are among the types of material which the Agency intended to include within the definition of ‘labeled.’ Since these two documents are a primary method of communicating safety and health information to potentially affected individuals, including these documents within the scope of the regulation is well within the scope of the statute as either a required label, required identification, or both.” (FSOR, page 7)

Whether or not federal OSHA or any other state or federal agency that requires a chemical to be labeled or identified as causing cancer or reproductive toxicity is considered an “authoritative body” for purposes of the separate listing mechanism described in Section 25306 is irrelevant. Each of the listing mechanisms is separate and distinct from each other⁸.

⁷ Health and Safety Code section 25249.8

⁸ *Exxon Mobil Corp. v Office of Environmental Health Hazard Assessment* (2009) 169 Cal.App.4th 1264, 1269-1270