

October 21, 2013

**VIA EMAIL AND CERTIFIED MAIL**

George V. Alexeeff, Ph.D. ([P65PublicComments@oehha.ca.gov](mailto:P65PublicComments@oehha.ca.gov))  
Director  
c/o Cynthia Oshita  
Office of Environmental Health Hazard Assessment  
1001 I Street  
Sacramento, CA 95812

**Re: Formally Required-DBCP, Formally Required-Ethylene Oxide, Formally Required – Lead: APTCO, LLC’s Comments in Opposition to OEHHA’s Use of the Formally Required to be Labeled or Identified Listing Mechanism for Former Proposition 65 Labor Code Listings**

Dear Dr. Alexeeff:

These comments are submitted on behalf of APTCO, LLC, located in Delano, California, in opposition to the Office of Environmental Health Hazard Assessment’s (OEHHA) September 20, 2013 Notice of Intent to Change (NOIC) the basis of the above-referenced listings. APTCO’s objections are based solely on a concern that OEHHA is failing to follow proper legal and administrative procedures. These comments are not directed at issues related specifically to the three above-referenced chemicals, as APTCO does not use these chemicals in its manufacturing business. APTCO is concerned, however, that OEHHA’s administrative procedures be lawful.

Without providing public notice and an opportunity to comment and be heard, OEHHA has departed from its established and authorized practice of listing under Proposition 65 chemicals regulated by the FDA through the “Formally Required to be Labeled or Identified” (“Formally Required”) listing mechanism. OEHHA also is proposing to change the basis of these Labor Code listings by continuing to list them by reference to the federal Occupational Safety and Health Administration’s (OSHA) Toxic and Hazardous Substances Regulations, but OEHHA is no longer authorized to list these chemicals by reference to OSHA’s regulations. OEHHA should refer these chemicals instead to its Developmental and Reproductive Toxicant Identification Committee (DARTIC).

Agencies are subject to administrative procedure rules to protect the public from regulations which have been promulgated without effective and meaningful notice and opportunity to be

heard. Armistead v. State Personnel Bd., 22 Cal. 3d 198, 204 (1978). Rules which are made behind closed doors without public input are null and void. Kings Rehab. Ctr., Inc. v. Premo, 69 Cal. App. 4th 215, 217 (1999).

In addition, the California Supreme Court has invalidated regulations which “flatly contradict the position which the agency had enunciated at an earlier date. . . .” Henning v. Industrial Welfare Comm’n, 46 Cal. 3d 1262, 1270, 1278 (1988) (quoting General Electric v. Gilbert, 429 U.S. 125, 142 (1976)). Finally, an agency must always stay within the bounds of its statutory authority. SIRC v. OEHHA, 210 Cal. App. 4<sup>th</sup> 1082, 1099-100 (2012). See also Cal. Gov’t Code (“APA”) § 11342.1, .2; City of Arlington v. FCC, 569 U.S. \_\_\_, Slip Op. at 5 (2013).

The APA applies whenever an agency amends or revises a “standard of general application,” or any “rule” or “guideline” of general application. APA §§ 11346, 11342.600, 11340.5(a). OEHHA often maintains that it is not subject to the APA because the Safe Drinking Water and Toxic Enforcement Act of 1986 (“Proposition 65”), Health and Safety Code Section 25249.8(e), exempts from the APA when it “publishe[s] a list.” Section 25249.12(a) of Proposition 65, however, does not exempt OEHHA from the APA when it adopts or modifies regulations. The APA defines “regulation” as “every rule, regulation, order, or standard of general application.” APA § 11342.600; 11340.5(a).

OEHHA effectively has amended a long-standing rule of general application through its September 20, 2013 NOIC, as is explained below. Amending a rule, which is subject to the APA, in conjunction with changing a proposed listing, which may not be subject to the APA, however, does not mean OEHHA can escape the requirements of the APA. See APA §§ 11346, 11342.600, 11340.5(a).

OEHHA in fact has amended an established practice through its NOIC. In the past, OEHHA has explained to the public how it may list under the “Formally Required” mechanism. For example, it has explained on its website: “A third way for a chemical to be listed is if an agency of the state or federal government requires that it be labeled or identified as causing cancer or birth defects or reproductive harm. *Most chemicals listed in this manner are prescription drugs that are required by the U.S. FDA to contain warnings relating to cancer or birth defects or reproductive health.*” “Proposition 65 in Plain Language,” February 12, 2006, [www.oehha.org](http://www.oehha.org) (emphasis added). OEHHA’s 2013 “Proposition 65 in Plain Language” contains an identical statement of its practice under the “Formally Required” mechanism. See id.

OEHHA’s Chief Counsel, Carol Monahan-Cummings, also has consistently explained to the public that OEHHA may use this listing mechanism for chemicals regulated by the FDA. For example, she recently stated: “There’s another listing mechanism that we call, ‘Formally Required,’ and that really means that there’s a requirement, by generally it’s FDA, that a chemical be identified as causing cancer or reproductive toxicity. *And I say it’s FDA, because it’s been primarily used for the listing of prescription drugs, because of the labeling requirements - -*

*labeling inserts for drugs.”* February 25, 2013 OEHHA “CIC Proposition 65 Meeting,” Meeting Transcript at 21.

These public statements reflect OEHHA’s practice dating back many years of using the “Formally Required” mechanism for listing prescription drugs based on FDA requirements. See e.g., August 22, 1997 “Chemicals under Consideration For Possible Listing Via Administrative Mechanisms: Request For Relevant Information” at 2; October 29, 1999 “Notice of Intent to List Chemicals . . . Simvastatin and Pravastatin,” at 1-2.

More importantly, OEHHA’s past practice reflects its listing authority under Proposition 65 to list only those chemicals which have been identified, classified or determined to cause cancer or reproductive toxicity by an authoritative body or by OEHHA’s qualified experts. See Health and Safety Code Section 25249.8(a)-(b). The public has justifiably relied on OEHHA’s authorized interpretation of the “Formally Required” mechanism, yet OEHHA abruptly tried to amend this interpretation by proposing to change the listings of chemicals that are not prescription drugs with required FDA warnings from Labor Code listings to “Formally Required” listings.

OEHHA rightfully informed the public that it is no longer authorized to list these chemicals by reference to the Labor Code Section 6382(d)’s reference to OSHA’s 2012 Hazard Communication Standard, which is incorporated into OSHA’s Toxic and Hazardous Substances Regulations. But OEHHA failed to inform the public that it has departed from its authorized and established practice under the “Formally Required” mechanism, and that it is not authorized to continue to list these chemicals by reference to OSHA’s regulations.

It is clear to the public that OEHHA has not proposed to list prescription drugs or chemicals by reference to FDA required labels or identifications, but OEHHA did not explain in the NOIC why it is permitted to list these chemicals based on safety and hazard “language” (as opposed to mandatory classifications) in OSHA’s Hazardous Substances Regulations. Without providing the public with the reasons for and the information relevant to this change in policy, OEHHA’s NOIC appears to be a routine and authorized “Formally Required” listing proposal rather than an abrupt and unauthorized change in practice.

Because OSHA no longer formally requires these chemicals to be labeled, identified or classified as reproductive toxicants, as OEHHA admits in its NOIC, and because there are no provisions in Proposition 65 which authorize OEHHA instead to list them based solely on required “language” or hazard warnings in the OSHA regulations, OEHHA cannot regain its authority to list them by reference to the OSHA regulations merely by using the “Formally Required” mechanism.<sup>1</sup>

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<sup>1</sup> See APTCO, LLC’s July 31, 2013 “Comments in Opposition to the Proposed Regulatory Concept for Section 25904, Title 27, California Code of Regulations: Chemical Listings by Reference to the California Labor Code” for a general discussion and analysis of OEHHA’s authority to list chemicals by reference to OSHA’s 2012 regulations.

George V. Alexeeff

October 21, 2013

Page 4

FDA mandated drug labels or inserts are based on required FDA chemical classifications or identifications. See generally 21 C.F.R. Part 200 et seq. (2013). See also 21 C.F.R. § 201.80 (specific label requirements, including relating to pregnancy and breast feeding). OSHA required language and hazard warnings are not based on OSHA mandated reproductive toxicant identifications or classifications. See 29 C.F.R. 1910 Subpart Z (2012). The OSHA “information” relating to the three NOIC chemicals is safety and hazard information-not mandatory chemical classifications or identifications. OEHHA is not authorized under any of the Proposition 65 listing mechanisms to list chemicals based solely on hazard information. See n.1. Moreover, OEHHA recognizes the FDA as an authoritative body for identification of chemicals causing cancer or reproductive toxicity, but it does not recognize OSHA as an authoritative body for this purpose. See Cal. Code Regs. § 25306 (l).

OEHHA has foreclosed all opportunity for public comment on and participation in this new and unauthorized procedure by limiting the substance of public comments. The NOIC provides: “Because these are ministerial listings, comments should be limited to whether OSHA requires that DBCP, ethylene oxide or lead be labeled to communicate a risk of reproductive harm.” NOIC at 3.

The courts will not support an agency’s action which is unauthorized and contradicts its established practice without compliance with the APA. Sirc v. OEHHA, 210 Cal. App. 4<sup>th</sup> at 1099. See Armistead, 22 Cal. 3d 198; Henning, 46 Cal. 3d 1262. The California Court of Appeal recently ruled against OEHHA in SIRC v. OEHHA, 210 Cal. App. 4<sup>th</sup> at 1099, in part because of OEHHA’s “vacillating practice” of adopting a new interpretation that contradicts a prior interpretation and enlarging the scope of its power.

Before OEHHA amends its “Formally Required” listing procedure, and before it proposes to list chemicals by reference to language in OSHA’s Hazardous Substances Regulations under the “Formally Required” mechanism, it must formally notify the public of its intentions and rationale and provide the public with a meaningful opportunity to comment and be heard. For these reasons, APTCO objects to OEHHA’s 9/20/2013 NOIC.

Sincerely,



Harry Edward Grant

of

RIDDELL WILLIAMS P.S.

cc: Mathew Rodriquez, Agency Secretary ([SectyRodriquez@calepa.ca.gov](mailto:SectyRodriquez@calepa.ca.gov))

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