REQUEST FOR RECONSIDERATION OF DENIAL OF PETITION TO THE
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT (OEHHA)
CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

Pursuant to California Government Code section 11340.6

to amend California Code of Regulations, title 27, section 27001(c)
to add delayed onset of puberty in females as a reproductive toxic endpoint

for which lead is known to cause reproductive toxicity

Submitted November 10, 2016

by

Mateel Environmental Justice Foundation
Californians for Alternatives to Toxics
and
Ecological Rights Foundation
A. Introduction

On September 22, 2016 Mateel Environmental Justice Foundation, Californians for Alternatives to Toxics and Ecological Rights Foundation (collectively hereinafter, “Mateel”) petitioned the California Office of Environmental Health Hazard Assessment (“OEHHA”) to list lead and lead compounds as known to cause reproductive toxicity on the basis that lead has been found by both the U.S. EPA (“EPA”) and the National Toxicology Program (“NTP”) (both of which are authoritative bodies for purposes of Health & Safety Code Section 25249.8) to cause delayed onset of puberty in females. On October 28, 2016 OEHHA denied Mateel’s petition. Mateel hereby requests that OEHHA reconsider its October 28, 2016 denial of its petition.

B. Reasons OEHHA Should Reconsider its Denial

In its October 28, 2016 response to Mateel’s petition, OEHHA stated that, under the EPA’s nomenclature, the EPA labeled delayed puberty in females to be a form of developmental toxicity, that the EPA had found that it was concurrent blood lead levels in girls aged 6-18 that caused the delay in onset of puberty, and that OEHHA interprets Proposition 65 to mean that developmental effects relevant to Proposition 65 only if those effects were caused by pre-natal exposure. On this basis OEHHA denied Mateel’s petition.

1. OEHHA has Misconstrued the Basis for Mateel’s Petition

Mateel did not petition for the listing of lead as a reproductive toxin on the basis that it is a *per se* developmental toxin. Lead is already listed as a *per se* developmental toxin. Mateel petitioned OEHHA to make it clear that one of the reproductive effects for which lead is listed is the delayed onset of puberty in females. Although lead exposure to young women does impair their development as human beings, that impairment was not Mateel’s point. OEHHA considers delayed onset of puberty in females to be a form of female reproductive toxicity, even though delayed onset of puberty is a form of impaired development. Mateel’s point was that lead is a Proposition 65 reproductive toxin because it has been found by EPA to cause a condition that renders a young woman sterile during the time puberty has been delayed, even if the exposure that caused that impairment was post-natal.

2. The Actual Basis for Mateel’s Petition was, and is, that the EPA has Found Lead Exposure to Manifest Itself in a Way that OEHHA Considers to be a Form of Female Reproductive Toxicity Because Delayed Puberty – as a Form of Infertility – Impairs Women’s Reproductive Performance

Mateel’s point, and the actual basis for its petition, was and is that lead exposure to young women *impairs their ability to reproduce* by delaying the onset of puberty. Causing impaired female reproductive performance unquestionably IS a basis for listing a chemical as a female reproductive toxicant under Proposition 65. While it is true that lead exposure causes delays in the development of young women, the development delayed here is the onset of puberty. Delaying the onset of puberty impairs female reproductive performance by rendering the young...
woman temporarily sterile during the period that puberty has been delayed. For the past twenty-
three years, OEHHA has maintained and operated under a “longstanding interpretation” of
Proposition 65 that impaired female reproductive performance includes adverse effects on the
onset of puberty. (See, OEHHA’s (Nov. 1993) Criteria for Recommending Chemicals for
Listing as “Known to the State to Cause Reproductive Toxicity” at p. 2.) That document
unambiguously states that

‘Female reproductive toxicity’ is defined to include effects on the adult or, where
appropriate, developing female organism, including, but not limited to . . . .
[a]dverse effects observed in . . . onset of puberty.

The key word here is “onset,” which is a synonym for the word “development.” Adverse effects
in the onset of puberty are by definition effects on the developing organism. OEHHA has long
considered impaired development to be a form of female reproductive toxicity if that impaired
development impairs female reproductive performance. Because this form of developmental
toxicity impairs the ability of a woman to reproduce, post natal exposures are relevant for
Proposition 65 purposes – “Female reproductive toxicity is defined to include effects on the
adult . . . .”

3. Whether EPA Called Delayed Onset of Puberty to be a Form of
Developmental or Female Reproductive Toxicity is Beside the Point;
What is Relevant is that OEHHA Considers Delayed Onset of Puberty
to be a Form of Female Reproductive Toxicity

The only above-ground regulation that defines “reproductive toxicity” simply says that
there are valid studies in humans or experimental animals that “indicate that there is a causal
relationship between the chemical and reproductive toxicity.” (See, Cal. Code Regs., tit. 27,
section 25306, subdivision (g) (“section 25306(g”).) Under section 25306, an authoritative body
need only find a causal relationship between exposure to the chemical and “reproductive
toxicity.” The authoritative body need not specify the Proposition 65-relevant category –
developmental, male reproductive or female reproductive – upon which it based its finding of
reproductive toxicity. Whether EPA nomenclature pigeonholes “delayed onset of puberty in
females” as “developmental toxicity” or “female reproductive toxicity” is beside the point. The
point is what OEHHA considers delayed onset of puberty to be. Here the EPA found that lead
exposure causes a condition that OEHHA has long defined to be a form of female reproductive
toxicity.

OEHHA has always taken the position that it does not just base its evaluation of an
authoritative body’s assessment on the simple words the authoritative body used in its finding.
OEHHA has always taken the position that it “looks under the hood” of an authoritative body
finding to determine for itself whether what the authoritative body found actually fits the
definition of “reproductive toxicity” under the Act. That is the whole purpose of sections
25306(h) and (i).

Courts have taken a similar approach to OEHHA’s role in considering an authoritative
body’s finding for purposes of listing a chemical as a Proposition 65 reproductive toxin. It is what the authoritative body actually found – and the science it used – that matters, not the particular words the authoritative body used to describe its finding. OEHHA is not a prisoner of a different agency’s nomenclature, nor should it be. For example, in *Western Crop Protection Association v. Davis* (2000) 80 Cal.App.4th 741, 745-47, a trade association sought to block OEHHA from putting chemicals on the Proposition 65 list on the basis of their being placed in the federal EPA’s Toxic Release Inventory (“TRI”). The legal basis for inclusion in the TRI was broader than that required for Proposition 65 listing of a chemical as known to cause reproductive toxicity. (*Id. at 745.*) The EPA criterion for putting a chemical in the TRI was that the chemical was “reasonably anticipated” to cause reproductive toxicity. The trade association argued that Proposition 65 could not be interpreted to mean that a chemical could be listed if it was only “reasonably anticipated to cause reproductive toxicity,” that the Proposition 65 criterions was limited to chemicals “known” to cause reproductive toxicity. The *Western Crop* court ruled that in spite of the broader (“reasonably anticipated” instead of “known”) criterion for TRI inclusion, the chemicals at issue could still qualify for the Proposition 65 list, provided the record demonstrated that EPA had actually put them on the TRI because they were “known,” rather than “reasonably anticipated” to be reproductive toxicants. (*Id. at 751-53.*)

The record, here, clearly shows that what the EPA found was that lead causes a condition that OEHHA considers to be a form of female reproductive toxicity, a condition that would qualify lead as a Proposition 65 reproductive toxin. A simple look at what the EPA found in its Integrated Science Assessment shows that EPA’s finding is encompassed by OEHHA’s longstanding definition of “female reproductive toxicity.” OEHHA should therefore reconsider its denial of Mateel’s petition and, upon reconsideration, grant Mateel’s petition.

4. **OEHHA’s Interpretation of Proposition 65 to Mean that Developmental Toxicity is only Relevant if it Results Entirely or Primarily from Prenatal Exposure is an Underground Regulation**

In its October 28, 2016 Response to Mateel’s petition, OEHHA stated that OEHHA has a long standing interpretation of Proposition 65 that only developmental effects resulting entirely or predominantly from prenatal exposure to the chemical are relevant to listing chemicals under Proposition 65. This longstanding interpretation is nowhere to be found in any above-ground regulation that has passed Administrative Procedures Act muster. It is therefore an underground regulation and invalid.