**STATE OF CALIFORNIA**
**OFFICE OF ADMINISTRATIVE LAW**

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| In re: | |
| OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT | DECISION OF DISAPPROVAL OF REGULATORY ACTION |
| REGULATORY ACTION: Title 22, California Code of Regulations | (Gov. Code, sec. 11349.3) |
| AMEND: 12805 | OAL File No. 05-1027-05 S |

**DECISION SUMMARY**

This action establishes the Proposition 65 Safe Drinking Water and Toxic Enforcement Act of 1986 "No Observable Effect Level" (NOEL) on reproductive toxicity for Di(2-ethylhexyl) phthalate (DEHP). This action sets the NOEL for intravenous exposure to DEHP for "adults", "infant boys", and "neonatal boys".

On December 13, 2005, the Office of Administrative Law ("OAL") disapproved the proposed amendment of the above-cited section in Title 22, California Code of Regulations ("CCR") for failing to comply with the "clarity" standard and for failing to follow the procedures required by the Administrative Procedure Act ("APA").

**DISCUSSION**

Regulations adopted by the Office of Environmental Health Hazard Assessment ("OEHHA") must be adopted pursuant to the APA. See Health and Safety Code section 25249.12. Any regulatory act a state agency adopts through the exercise of quasi-legislative power delegated to the agency by statute is subject to the APA unless a statute expressly exempts or excludes the act from the requirements of the APA. (Gov. Code section 11346.) No exemption or exclusion applies to the regulatory action here under review. Thus, before the instant regulatory action may become effective, OAL must review it for compliance with both the procedural requirements of the APA and certain substantive standards.

## 1. CLARITY

The APA requires regulations to be clear. The clarity standard is defined in section 11349(c) as "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them." This definition is made specific in Title 1 CCR section 16. Of particular relevance to this file is Title 1 CCR subsections 16(a)(1) and (a)(3), which provide that a regulation is presumptively unclear if:

> "(1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
>
> . . . .
>
> (3) the regulation uses terms which do not have meanings generally familiar to those 'directly affected' by the regulation, and those terms are defined neither in the regulation nor in the governing statute; or"

This regulation amends the existing Proposition 65 "No Observable Effect Level" on reproductive toxicity table by establishing the NOEL for Di(2-ethylhexyl)phthalate (DEHP). This action sets the NOEL for intravenous exposure for three age groups; "adults", "infant boys", and "neonatal boy" by quantifying the maximum allowable dose level (MADL) for the three ages. The MADL number multiplied by 1000 is NOEL for the three age groups for DEHP. DEHP is a plasticizer commonly used in intravenous bags and tubing. The proposed MADLs are shown in the regulation as follows:

"TITLE 22, CALIFORNIA CODE OF REGULATIONS
CHAPTER 3. SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
ARTICLE 8. NO OBSERVABLE EFFECT LEVELS

Section 12805. Specific Regulatory Levels: Chemicals Causing Reproductive Toxicity

Amend section 12805 (b) as follows:

| *(b) Chemical Name* | *Level (micrograms/day)* |
|---|---|
| Benzene | 24 (oral)<br>49 (inhalation) |
| Cadmium | 4.1 |
| 2,4-D butyric acid (2,4-DB, 2,4-dichlorophenoxybutyric acid) | 910 |
| 1,2-Dibromo-3-chloropropane | 4.3 (inhalation)<br>3.1 (oral) |
| Di(2-ethylhexyl)phthalate (DEHP) | 4200 (intravenous exposure of adults)<br>600 (intravenous exposure of infant boys) |

210 (intravenous exposure of neonatal boys)"

OEHHA provides no definition of either "infant boys" or "neonatal boys" either in the proposed amendments to section 12805 or in the definitions regulation (existing section 12102) for the entire Chapter 3 which implements the Proposition 65 Safe Drinking Water and Toxic Enforcement Act of 1986. Given the critical nature of both terms and the significantly different MADLs set, and the fact that unlike "adult", neither "neonatal" nor "infant" have a settled legal meaning, the lack of definition makes it impossible for those directly affected to know what age range is covered by either category. The lack of definitions of those age groups in the regulation or in the governing statute make this a presumed clarity violation under Title 1 CCR section 16(a)(3).

In addition, the lack of definition of both age ranges is also a clarity violation because the regulation can be read to apply two different MADLs to "neonatal boys".

OEHHA discusses the levels set for infants and neonates in its revised supporting studies dated June 2005 (pp. 8-9) and suggests that "infant boys" are "0-2 years of age" for purposes of this regulation. OEHHA's study states, in pertinent part:

> "Therefore, MADLs specific to infant and neonates are developed as follows:
>
> For **infants 0-2 years of age**, the average body weight of 10 kg over this developmental period is used (Section 12703(a)(8); OEHHA, 2000; National Center for Health Statistics, 2005).
>
> Calculation of the NOEL for a 10 kg infant:
> 60 mg/kg-day x 10 kg = 600 mg/day
>
> **MADL** infant i.v. = 600 mg/day ÷ 1000 = 600 **µg/day**
>
> For neonates, the 50$^{th}$ percentile birthweight for boys of 3.5 kg is used (National Center for Health Statistics, 2005).
>
> Calculation of the NOEL for a 3.5 kg neonate:
> 60 mg/kg-day x 3.5 kg = 210 mg/day
>
> **MADL** neonate i.v. =210 mg/day ÷ 1000 = **210 µg/day**.
>
> All the MADLs derived above (4200 µg/day for adults, 600 µg/day for infant boys and 210 mg/day for neonatal boys) apply to exposure to DEHP by the i.v. route." [**Emphasis added**.]

No similar description of the age range for "neonatal boys" is included in OEHHA's supporting study. Given the dictionary definition of "neonatal" as "newborn", the use of "neonatal boys" in this regulation overlaps OEHHA's unspecified, but apparently intended, definition of "infant boys" as boys from zero to 2 years of age.

This obvious overlap violates the clarity standard because it results in two very different MADLs/NOELs for the same age. This is a presumed clarity violation under Title 1 CCR section 16(a)(1).

Last, the proposed table of MADLs shows no MADL level applicable to ages between "infant" or "adult". Persons directly affected have no way to determine what MADL, if any, is applicable to male children between 2 to 18 years of age. This seems illogical given the MADLs set for "infants" and "adults". The rulemaking record is silent on this issue.

**2. PROCEDURE**

The Department's rulemaking file fails to comply with the requirements of Government Code section 11347.3 because the rulemaking file fails to contain copies of all documents relied on and contains a copy of one document which has not been properly added to the rulemaking file. Government Code section 11347.3 lists the required contents of a rulemaking file. Subsection (b)(7) of section 11347.3 requires each rulemaking file to contain:

> "(7) All data and other factual information, technical, theoretical, and empirical studies or reports, if any, on which the agency is relying in the adoption, amendment, or repeal of a regulation, including any cost impact estimates as required by Section 11346.3."

OEHHA's revised second 15-day notice dated August 17, 2005 added 43 documents or other information relied on to this rulemaking file. Among the documents added was the following scientific paper:

> "Creasy DM (2003). Evaluation of testicular toxicology: a synopsis and discussion of the recommendations proposed by the Society of Toxicologic Pathology. *Birth Defects res Part B dev Reprod Toxicol* 68, 408-15."

A copy of this paper has not been included in this file in violation of the requirements of Government Code section 11347.3(b)(7). In addition, OEHHA has included an additional paper by Ms. Creasy which has not been properly added to the file by 15-day notice as required by Government Code section 11347.1. That unnoticed paper (rulemaking file pages 382-394) is: "Creasy DM (1997). Evaluation of testicular toxicity in Safety Evaluation Studies: The Appropriate Use of Spermatogenic Staging. Toxicology Pathology, Vol. 25, pp. 119-131." OEHHA, should provide additional 15-day notice to add this study to the rulemaking record if OEHHA intends to rely on it as well.

3. Additional Corrections.

While not reasons for disapproval, OAL recommends the following corrections to the file prior to resubmittal.

a. Add the chemical which is the subject of this action ("DEHP") to the OAL Form 400, Block B. 1a., "Subject of Regulations".

b. The first Title 1 CCR section 44 mailing statement (see Tab 12, p. 209) confirming OEHHA's compliance with the 15-day notice mailing requirements incorrectly refers to the notice as a 45-day notice. The title of the mailing statement is:

"STATEMENT OF 45-DAY NOTICE
OF AVAILABILITY OF MODIFIED TEXT
(Section 44 of Title 1 of the California Code of Regulations)"

While OEHHA in fact provided 45 days to comment during the first 15-day notice, the notice itself was not a 45-day notice. The notice was still a "15-day notice" (notice of changes to the original proposal) under the APA and the mailing statement and Table of Contents should be corrected accordingly.

**CONCLUSION**

For the reasons set forth above, OAL disapproves this amendment of section 12805 of Title 22 of the CCR. If you have any questions, please contact me at (916) 323-8915.

**Date:** 12/20/05

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Gordon R. Young
Senior Staff Counsel

For:

WILLIAM L. GAUSEWITZ
Director

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