**PUBLIC NOTICE**
**Initiation of Risk Assessments for Chemicals in Drinking Water**
**July 2008**

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A. Requirements

The Calderon-Sher California Safe Drinking Water Act of 1996 requires the Office of Environmental Health Hazard Assessment (OEHHA) to post notices on its Web site of water contaminants for which it is initiating development of public health goals (PHGs) for the chemicals in drinking water. The law also describes the intent and general context of the PHGs. PHGs are concentrations of chemicals in drinking water that are not anticipated to produce adverse health effects following long-term exposures. OEHHA is required to consider potential adverse effects on members of subgroups that comprise a meaningful proportion of the population, including but not limited to infants, children, pregnant women, the elderly, and individuals with a history of serious illness. The public health goals are non-regulatory in nature but are to be used as the health basis to update the state's primary drinking water standards (maximum contaminant levels, or MCLs) established by the California Department of Public Health (DPH) for chemicals subject to regulation.

The act requires PHGs to be developed for the approximately 88 chemicals for which state or federal MCLs are provided, and review and update the risk assessments that form the basis for the PHGs as appropriate at least every five years. Other chemicals may be added to the list by legislative or interdepartmental request. Opportunities for public comment and peer review are provided.

B. Implementation

OEHHA has published 81 PHGs as of July 2008. Two MCLs, for gross alpha and gross beta radionuclides, represent screening levels for contaminants rather than specific regulatory standards; for these, OEHHA has provided risk assessments and guidance memoranda. In addition, re-evaluations of the original PHG have been completed for nine chemicals. OEHHA concluded that no new information was available on some of these that would require significant changes to the PHG document. The re-reviews of several other chemicals required more extensive efforts, for which complete updated documents have been published. The supporting documents are available at http://www.oehha.ca.gov/water/phg/index.html.

PHG review documents for all the other chemicals that have state MCLs are currently in preparation, as well as updates of the PHG for several chemicals. Drafts for public comment on eight of these chemicals (bromate, chlorite, 2,4-dichlorophenoxyacetic acid, lead, oxamyl, pentachlorophenol, styrene, and trichloroethylene) are currently posted on the OEHHA Web site. PHGs for several more chemicals should be released this year. At the initial posting, a 45-day public comment period is provided, followed by a public

workshop. All comments received are considered in the preparation of a second draft, which is then posted for a 30-day public comment period. After consideration of comments, the final PHG is then published on the OEHHA Web site for public reference and use by DPH in developing California MCLs.

Evaluation is now being initiated for two more chemicals for which PHGs were developed earlier (see Section D), which are now being re-reviewed as part of the ongoing PHG update process. Information relevant to the development of PHGs is requested on each of these chemicals.

C. PHGs to be released for public review

Draft documents for five other chemicals (antimony, hexavalent chromium, selenium, 1,2,3-trichloropropane, and trihalomethanes) are nearing completion, and are planned for release for public review as soon as possible.

Risk assessments are currently in progress for several other chemicals for which initiation of review has previously been announced. Workload considerations and in a few cases, complicated and difficult toxicological interpretations, do not allow us to project completion schedules for these draft updates:

- Alachlor
- Atrazine/Simazine
- Bentazon
- Benzo(a)pyrene
- Cyanide
- Dalapon
- Dibromochloropropane (DBCP)
- 1,2-Dichlorobenzene
- 1,4-Dichlorobenzene
- 1,1-Dichloroethylene
- 1,2-Dichloropropane
- Dinoseb
- Dioxin (TCDD)
- Endothall
- Endrin
- Fluoride
- Haloacetic acids
- Hexachlorocyclopentadiene
- Methoxychlor
- Nitrate/nitrite
- Picloram
- 1,2,4-Trichlorobenzene
- Trichlorofluoromethane (Freon 11)
- Trichlorotrifluoroethane (Freon 113)

D. Initiation of risk assessments

Risk assessment is being initiated for the following chemicals for which PHGs have already been released, but are being updated after prioritization on the basis of availability of new data, concern about environmental exposures, and potential significance as drinking water contaminants:

- Diethylhexylphthalate
- Perchlorate

A brief description of these chemicals is provided below. This announcement solicits the submission of pertinent information on these contaminants that could assist our office in preparing or updating the risk assessment and deriving a PHG.

Information submitted to OEHHA in response to this request should not be proprietary in nature, because all information submitted is a matter of public record. Information should be submitted by September 1, 2008 to:

Michael Baes
PHG Project
Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment
1515 Clay St., 16th floor
Oakland, California 94612

All data submitted will be considered in the development of the PHG for these chemicals. If substantive revisions to the original PHG documents are required, the draft documents will be available for discussion in a public workshop and public comment will be solicited as described above in Section B. The final risk assessments will be utilized by DPH for potential revisions to the MCLs for the chemical in drinking water, as described in more detail on the DPH Web site at http://www.cdph.ca.gov/certlic/drinkingwater/Pages/MCLsandPHGs.aspx.

E. Descriptions of chemicals or substances for review initiation:

## DIETHYLHEXYLPHTHALATE

Diethylhexyl phthalate (DEHP) is a phthalic acid ester used primarily as a plasticizer in polyvinyl chloride resins. It is a very high production volume chemical, and its widespread use in plastics means there is a high potential for environmental release and human exposure. Typical environmental levels are quite low because DEHP has low water solubility and volatility, and binds strongly to soil and sediment. DEHP is biodegradable, so its half-life in water is relatively short (ca. 1 month); its half-life in soil can be much longer because of the tight binding to soil particles. Bioconcentration in environmental organisms and in humans has been demonstrated. Human exposure to DEHP is mostly through food.

Estimates of oral absorption have varied over a wide range, possibly due to biliary excretion and binding to food constituents. DEHP is metabolized in the intestine to monoethylhexyl phthalate (MEHP) and 2-ethylhexanol. The ethylhexyl side chain of MEHP can be metabolized by α- or β-oxidation. These products tend to be conjugated and excreted in the urine and feces with relatively short half-lives (a few hours to a few days).

DEHP has very low acute toxicity, with oral LD50 values ranging from 26 to greater than 34 g/kg in a variety of species. Liver and testes are the principal target organs for toxic effects. DEHP causes adverse reproductive and developmental effects in laboratory animals, and is an antiandrogen that causes a syndrome called "testicular dysgenesis." It is listed under Proposition 65 as a chemical known to cause both reproductive toxicity and cancer. Chronic oral administration of DEHP causes a dose-dependent increase in liver tumors in both mice and rats. In the previous PHG document, OEHHA based its assessment on concerns regarding the carcinogenicity of DEHP, citing the evidence of tumors in experimental animals, and basing the PHG value on an extrapolation of risk from the rodent tumor data. A large number of recent scientific studies have attempted to clarify the possible mechanisms by which DEHP may cause cancer in animals, and establish whether those mechanisms are relevant to human carcinogenic risk. Much of this work has focused on whether specific receptors mediate the carcinogenic response and whether modes of action such as oxidative stress and other DNA-damaging events have a role in the process. As OEHHA moves forward in revising this document, comments on these factors are welcomed.

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## PERCHLORATE

Perchlorate, or $ClO_4^-$, is a stable anion that is widespread in the environment at very low concentrations. It is apparently formed by lightning in the atmosphere by an energetic reaction between chloride and oxygen, and may accumulate in soil and groundwater in

very dry locations. Perchlorate is used as an oxidizer in rocket fuel, fireworks, and road flares, and is also present in nitrate fertilizer from Chile, which has been widely used in the U.S. Perchlorate is taken up by plants from groundwater or irrigation water, and can be concentrated by certain plant species, especially in hot dry environments. Exposure to perchlorate is mostly through food, but it can also occur at significant concentrations in drinking water, either from natural or manmade sources.

Perchlorate is well absorbed by the oral route. It is not metabolized in experimental animals or humans, and is quickly excreted. Because of its similarity in molecular size and charge to iodine, perchlorate can compete with iodine for uptake into the thyroid gland. This provides a mechanism for toxicity, which can be especially relevant when there is a low availability and/or high physiological demand for iodine. Rodents have a rapid turnover of iodine in their thyroid glands, and thus appear to be more sensitive to the iodine-inhibitory effects of perchlorate than humans. However, pregnant women and their fetuses could be somewhat more sensitive than other humans to the iodine-inhibitory effect because of increased iodine demand, and, in the case of neonates, low iodine storage in their thyroids.

A recent population-based study by the National Health and Nutrition Examination Survey (NHANES) reported that blood levels of thyroid hormones were related to perchlorate exposure among women who had low urinary iodide excretion. OEHHA reanalyzed the same data, and found that women who consume low iodine in their diets and smoke during pregnancy appear to be a particularly susceptible subpopulation. Other recent studies have failed to demonstrate any actual health effects on mothers, their fetuses, or neonates from exposures to environmental levels of perchlorate. The update of the risk assessment will include a reexamination of these issues in the context of subclinical thyroid disease to estimate appropriate health-protective levels for perchlorate in drinking water, with an adequate margin of safety, for all exposed populations.

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