PUBLIC NOTICE
Initiation of Risk Assessments for Chemicals in Drinking Water
July 2010

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 90 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 85 PHGs as of July 2010. 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 18 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 (antimony, benzo(a)pyrene, hexavalent chromium, methoxychlor, selenium, styrene, TCDD (dioxin) and trihalomethanes) are currently posted on the OEHHA web site. Draft PHG documents 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). These 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 updated PHGs for three chemicals (alachlor, fluoride, and
perchlorate) are nearing completion, and second postings for methoxychlor,
selenium, and trihalomethanes are also being finalized.

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:

- Atrazine/Simazine
- Cyanide
- Diethylhexylphthalate
- Dibromochloropropane (DBCP)
- 1,4-Dichlorobenzene
- 1,1-Dichloroethylene
- 1,2-Dichloropropane
- Endothall
- Haloacetic acids
- Hexachlorocyclopentadiene
- 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:
• Ethylbenzene
• Xylene

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 updating the risk assessment and deriving a revised 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, 2010 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:

ETHYLBENZENE

Ethylbenzene (CAS Registry Number: 100-41-4) is a volatile aromatic hydrocarbon derived from petroleum. Ethylbenzene is a natural constituent of crude petroleum and is a standard component of gasoline and diesel fuels. It is also used as a chemical intermediate, primarily in the production of styrene. Ethylbenzene may contaminate drinking water from both natural (oil seeps) and human sources (petroleum spills, waste sites, gasoline storage tank leaks, etc.). Ethylbenzene enters the atmosphere from emissions from industrial facilities and other localized sources, and from evaporation of gasoline in refueling and other activities.

Ethylbenzene was classified as Group 2B (possibly carcinogenic to humans) by the International Agency for Research on Cancer in 2000. The classification of ethylbenzene as a carcinogen was based upon studies by the National Toxicology Program (NTP, 1999) which found clear evidence of a carcinogenic effect in male rats, and some evidence of a carcinogenic effect in female rats and male and female mice. These data were judged appropriate for a satisfactory cancer risk assessment. Ethylbenzene was listed under Proposition 65 as a chemical known to the State of California to cause cancer in 2004. Ethylbenzene
was identified as a Toxic Air Contaminant (TAC) by OEHHA (2007) as a result of its listing as a U.S. Hazardous Air Pollutant.

OEHHA adopted a unit risk value for ethylbenzene of $2.5 \times 10^{-6} \text{ (μg/m}^3\text{)}^{-1}$ and an inhalation cancer potency value of 0.0087 (mg/kg-d)$^{-1}$ (OEHHA, 2007). These values are based on the incidence of kidney cancer (renal tubule adenoma or carcinoma) in male rats. They are used in the OEHHA Air Toxics Hot Spots program for estimating the cancer risk associated with inhalation exposures to ethylbenzene. An oral cancer potency value of 0.011 (mg/kg-d)$^{-1}$ has also been adopted. The support document that describes the derivation of these values has undergone public and peer review and was approved by the Scientific Review Panel for Toxic Air Contaminants. For assessment of non-cancer effects, the OEHHA Air Toxics Program also adopted a Chronic Reference Exposure Level for ethylbenzene of 0.4 ppm in air in 2000, based upon renal, pituitary, and liver effects in both rats and mice (NTP, 1999). Other effects such as hearing loss are also observed (Cappaert et al., 1999; Fechter et al., 2007).

A Proposition 65 “no significant risk level” (NSRL) for ethylbenzene was developed by OEHHA in 2008. A NSRL is defined in regulation as the daily intake level posing a $10^{-5}$ lifetime risk of cancer. The inhalation and oral human cancer potency estimates for ethylbenzene were estimated as 0.013 and 0.017 (mg/kg-day)$^{-1}$, respectively, resulting in corresponding NSRLs of 54 and 41 μg/day for the two exposure routes (OEHHA, 2008).

Soil screening levels for chemicals are also developed by OEHHA for risk assessments of properties for school sites. A draft has been released on ethylbenzene for this purpose (OEHHA, 2009), based on carcinogenicity and an inhalation cancer potency value of 0.0087 (mg/kg-d)$^{-1}$ from the OEHHA (2007) evaluation.

The update of the risk assessment for the ethylbenzene PHG will include an evaluation of the studies on which these recent OEHHA risk assessments were based, as well as a broader review of the relevant literature since publication of the original PHG in 1997. A few additional studies, noted below, have been published since the recent OEHHA reviews. This evaluation will be used to estimate appropriate health-protective levels for ethylbenzene in drinking water, with an adequate margin of safety, for all exposed populations.

**Selected References**


OEHHA (2007). Notice of Adoption of Unit Risk Value for Ethylbenzene. Attachment: Long-Term Health Effects of Exposure to Ethylbenzene. Air


**XYLENE**

Xylene is an organic solvent consisting of a benzene ring with two attached methyl groups. The methyl groups can be in different relative positions on the six-carbon benzene ring, resulting in three slightly different forms, or isomers. Xylene is commonly utilized as a mixture of the three isomers, called ortho-, meta- and para-xylene (o-, m- and p-xylene), which have similar properties and are thus isolated together from their mixed hydrocarbon sources. Xylene is found in small proportions in petroleum and coal tar and also can be formed by the catalytic processes used in a petroleum refinery. Technical grade xylene consists of the three isomers in the proportions of 45 to 55% m-xylene and about 20% of each of the o- and p-isomers, with the remainder being ethylbenzene.

Xylene is one of the most widely used chemicals, with a United States production of several billion pounds per year. It is used in paint thinners, varnishes, as a rubber solvent in the tire industry, in printing and paper manufacturing, as a solvent in the plastic industry and as a component of gasoline and fuel oils. The individual isomers are used in the manufacture of plastics. This widespread use results in great opportunities for spills, leaks and process losses (such as in the drying of paints), as well as potential occupational and residential exposures.

Xylene is volatile and can be rapidly absorbed following both inhalation and oral exposure. Once absorbed, it is relatively rapidly metabolized in the body, mostly in the liver. Its lipophilicity results in uptake into fat and the brain. Exposure to the vapors can cause irritation to eyes, nose, and throat, and sedation at high doses. Xylene does not appear to be carcinogenic in animals or humans. The 1997 OEHHA risk assessment for the PHG estimates a health-protective level based on behavioral effects with chronic human exposures to xylene.

In animal studies, toxic effects have not been remarkable. The U.S. EPA reference dose (RfD) of 0.2 mg/kg-day (with a 1000-fold uncertainty factor) is based on decreased body weight and increased mortality in a chronic study in rats, with a No Observed Adverse Effect Level (NOAEL) of 250 mg/kg-day (U.S. EPA, 2003). Xylene exposure can cause ototoxicity (hearing loss) with relatively high exposures (Crofton et al., 1994; Maguin et al., 2006; Gagnaire et al., 2007). A large number of new studies have been published since the earlier PHG review; a selection of these is listed below.
Selected References


