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# OEHHA

## Office of Environmental Health Hazard Assessment

Public Information - Fact Sheets

### Public Health Goal for Perchlorate Questions and Answers Office of Environmental Health Hazard Assessment April 2005

#### A Fact Sheet

[04/01/05]

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#### 1. What is California's public health goal (PHG) for perchlorate in drinking water?

A. In March 2004, Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA) published a PHG of 6 parts per billion (ppb) for perchlorate in drinking water. OEHHA has identified 6 ppb as the level of perchlorate in drinking water that does not cause or contribute to adverse health effects. Prior to publication, OEHHA's PHG and perchlorate assessment underwent two rounds of independent peer reviews by University of California scientists, as well as several public comment periods.

#### 2. Is this a draft or interim PHG?

A. No. The PHG was final when it was published in March 2004, and has been in effect since that time.

#### 3. Why did OEHHA recently conduct a review of perchlorate?

A. When OEHHA published the PHG in 2004, OEHHA made a commitment to review the much-anticipated National Academy of Sciences (NAS) report on perchlorate upon its completion, and, if necessary, to revise the PHG. The NAS released its report in January 2005.

#### 4. Why did the NAS prepare a report on perchlorate?

A. Four federal agencies – the U.S. Environmental Protection Agency (U.S. EPA), the Department of Defense, the Department of Energy, and the National Aeronautics and Space Administration – asked the NAS to review U.S. EPA's 2002 draft risk assessment of perchlorate and to independently assess the adverse effects of perchlorate ingestion. Although it

 
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was not a review of OEHHA's PHG for perchlorate, the NAS report investigated scientific questions that are relevant to the PHG.

**5. Will OEHHA revise the PHG for perchlorate at this time?**

**A.** No. The NAS findings are consistent with and support the approach that OEHHA took in developing the PHG. OEHHA carefully reviewed the NAS report and concluded that no revisions to the PHG are necessary. The NAS report shows that OEHHA scientists are in agreement with national experts on perchlorate regarding the fundamental steps needed to assess the chemical's health effects and develop health-protective goals and standards for drinking water.

**6. Why did OEHHA conclude that the NAS findings support the approach OEHHA took in developing the PHG?**

**A.** The NAS report made four general findings that are in agreement with OEHHA's PHG assessment for perchlorate. These findings are:

1. • The health effects of perchlorate should be assessed using data from clinical studies involving humans, rather than laboratory animals. The NAS specifically recommended the use of a well-regarded 2002 study in which healthy volunteers were administered perchlorate. OEHHA used that same study to assess perchlorate's health effects and develop the PHG.
2. • The perchlorate health effect of primary concern is the reduction of the uptake of iodide, an essential nutrient, by the thyroid gland (a butterfly-shaped gland in the throat). While not harmful by itself, inadequate iodide uptake may lead to the harmful disruption of proper thyroid function. The NAS report said that the reduction of iodide uptake "is the key event that precedes all thyroid-mediated effects of perchlorate exposure," and that focusing on the reduction of iodide uptake "is the most health protective and scientifically valid approach." OEHHA's perchlorate assessment similarly focused on the reduction of iodide uptake as the critical health effect.
3. • The fetuses of pregnant women are "the most sensitive population" to perchlorate's health effects, the NAS report said. OEHHA similarly concluded that pregnant women and fetuses are most sensitive to perchlorate after evaluating the chemical's health effects on adults, infants and lactating women, as well as pregnant women and fetuses.
4. • To ensure that a perchlorate assessment does not underestimate the chemical's effects on pregnant women and fetuses, the NAS recommended the same approach that OEHHA used in developing its PHG. This involved the use of a "margin of safety" to account for the likelihood that fetuses are more sensitive than adults to perchlorate. Margins of safety are discussed in the "Frequently Asked Questions" fact sheet on OEHHA's Web site.

**7. Did the NAS report disagree with OEHHA's PHG assessment in any way?**

**A.** The NAS did not review the OEHHA PHG. OEHHA carefully reviewed the NAS report and did not find any statements that conflicted with OEHHA's approach in developing the PHG. However, there are two important areas of difference between the NAS report and OEHHA's assessment. These differences are:

1. The NAS report did not calculate a safe level of perchlorate in drinking water, as this was outside the request made to the NAS. Additional calculations not addressed in the NAS report are necessary to develop a PHG, such as accounting for an individual's exposure to perchlorate from food and other sources besides drinking water.
2. The NAS report calculated a "reference dose" after first identifying a "No Observable Effect Level," or NOEL (a generic number identifying a level of perchlorate exposure from any source that would not cause a health effect). OEHHA used a statistical method called the "benchmark dose" to identify a level of perchlorate exposure that would not cause a health effect. A PHG can be calculated from either a NOEL or benchmark dose, and both numbers in this case were obtained using data from the same 2002 perchlorate study. The benchmark dose approach is preferred when the number of subjects in a study is relatively small, as in the 2002 study. The NAS report said the benchmark dose "can be an improvement" over other approaches, but used the NOEL approach rather than choose between several methods for calculating a benchmark dose.

**8. Industry representatives say that OEHHA and the NAS broke with standard risk assessment practices by selecting a non-adverse health effect (the inhibition of iodide uptake by the thyroid gland) rather than an adverse health effect (the harmful disruption of proper thyroid function) as the focus of their perchlorate assessments. What is OEHHA's response?**

**A.** U.S. EPA since 1987 has published at least 23 reference doses, and OEHHA has published other PHGs (for barium, aluminum, copper, fluoride and thallium), based on health effects that are not traditionally considered to be "adverse". The PHG for perchlorate did not set any precedents or vary from accepted risk assessment practices in this regard.

OEHHA identified the inhibition of iodide uptake as the critical health effect for perchlorate in part because there is adequate data to show perchlorate's effect on iodide uptake. There is no data at present to determine the precise levels of perchlorate exposure that can cause thyroid disruptions in the pregnant woman and her fetus. Given this uncertainty, OEHHA felt the PHG should be set to prevent the inhibition of iodide uptake, thereby protecting against all harmful health effects from perchlorate.

The NAS report said that a focus on the reduction of iodide uptake "is the most health protective and scientifically valid approach." The report also said, "Inhibition of iodide uptake is a more reliable and valid measure, it has been unequivocally demonstrated in humans exposed to perchlorate, and it is the key event that precedes all thyroid-mediated effects of perchlorate exposure."

Basing the PHG on harmful thyroid disruption, as suggested by some industry groups, would be in direct conflict with these NAS findings.

**9. In arguing for a PHG of 236 ppb, the Perchlorate Study Group and other industry groups say that in order to comply with California law, OEHHA must set the PHG just below the level that causes harmful thyroid disruption. What is OEHHA's response?**

A. The PHG for perchlorate fully complies with state law. Health and Safety Code Section 116365 requires OEHHA to set the PHG for a given contaminant at "the level of the contaminant in drinking water that is not anticipated to cause *or contribute to* adverse health effects" (emphasis added). OEHHA and the NAS agree that inhibition of iodide uptake is the key event that precedes thyroid disruptions and other harmful health effects from perchlorate exposure.

Section 116365 also says that if there is inadequate data to determine the level of exposure that causes adverse health effects, OEHHA must set the PHG "at a level that is protective of public health, with an adequate margin of safety." There currently is inadequate data to determine the level of perchlorate exposure that causes thyroid disruption that can harm the fetus, considered by both OEHHA and the NAS to be the most sensitive to perchlorate. The PHG is calculated to prevent the inhibition of iodide uptake that can lead to harmful dysfunction of the thyroid gland, thereby protecting public health, including the health of fetuses.

**10. The NAS report said their calculation of a NOEL and a reference dose is a "reasonable and transparent approach" in conducting a perchlorate assessment. Why does OEHHA feel it should use the benchmark dose that it developed?**

A. The benchmark dose method is widely considered to be more reliable than the method used by NAS when the number of subjects in a study is small. OEHHA and the NAS agree that a single, well-regarded 2002 study contains the best data for assessing perchlorate's health risks, but the study had only 37 human subjects. The statistical analysis used in calculating the benchmark dose reduces the uncertainties inherent in using a study with a small number of subjects. The University of California scientists who peer reviewed OEHHA's perchlorate assessment recommended the use of the benchmark dose. The NAS report said the benchmark dose "can be an improvement" over other approaches and did not object to its use. The use of the benchmark dose does not conflict with the NAS findings.

**11. The Perchlorate Study Group also suggests an alternate PHG of 16 ppb if OEHHA cannot accept a PHG of 236 ppb. What is OEHHA's response to the suggested PHG of 16 ppb?**

A. In calculating this suggested PHG, the Perchlorate Study Group accounted for exposures to perchlorate from sources besides drinking water by using a new method that has not been peer reviewed by independent scientists. This method uses data from a small-scale study of perchlorate levels in urine conducted in Atlanta, and presumes that this study

adequately represents the exposure of Californians to perchlorate in food and other sources besides drinking water. While this new method may show promise, OEHHA believes it is important to use established methods of accounting for non-drinking water exposures that have been peer reviewed by independent scientists.

**12. Several environmental groups have urged OEHHA to lower the PHG to 1 ppb. What is OEHHA's response?**

**A.** The request by the environmental groups asserts that a PHG of 1 ppb is needed to protect infants. This is based on calculations of the PHG using an infant's body weight and fluid consumption rate. In evaluating the effects of perchlorate on infants, OEHHA considered U.S. EPA data showing that the high rate of fluid ingestion by infants is likely to be compensated for by the correspondingly high rate at which infants excrete wastes. In other words, perchlorate ingested by infants through drinking water is eliminated relatively quickly through urination. The NAS report did not provide any evidence that contradicts the U.S. EPA data. Documentation submitted to OEHHA by the environmental groups did not acknowledge this fast rate of elimination by infants, thereby overestimating the risk that perchlorate poses to infants.

The request by the environmental groups also implies that infants, rather than pregnant women and their fetuses, are the most sensitive population to perchlorate's health effects. While there is general agreement that infants are more sensitive to perchlorate than adults, OEHHA does not have a basis at this time for diverging from the NAS findings by concluding that infants are more sensitive than fetuses to perchlorate. OEHHA agrees with the NAS that pregnant women and their fetuses have the greatest sensitivity to perchlorate. The PHG fully protects infants as well as pregnant women and fetuses.

**13. Does a new law, AB 2342, apply retroactively to the perchlorate PHG and other PHGs?**

**A.** The request by the environmental groups to lower the PHG contains several references to AB 2342, a bill pertaining to PHGs that Governor Schwarzenegger signed in September 2004, and which took effect in January 2005. OEHHA is looking forward to implementing the bill and believes it will benefit the PHG program in the long term. However, the bill was not in effect when OEHHA published the PHG for perchlorate in March 2004, and it does not require OEHHA to retroactively revise any existing PHG. More importantly, it is premature at this time to speculate how AB 2342 might be applied to the perchlorate PHG and other PHGs.

AB 2342 requires OEHHA, when developing PHGs, to conduct certain evaluations of the effects of drinking water contaminants on infants and children if sufficient information is available. The bill does not specify how OEHHA should use the results of these evaluations in developing PHGs. OEHHA is currently securing resources to develop guidelines concerning when and how such evaluations should be performed, and how they should be incorporated into the development of PHGs. OEHHA expects to solicit and consider public comments before finalizing these guidelines. Until the guidelines are finalized, it is not possible to determine exactly how the bill's requirements can be applied to any individual PHG.

State law requires OEHHA to periodically review and, if necessary, revise each PHG. OEHHA expects to use the future AB 2342 guidelines when it next reviews the PHG for perchlorate. In developing the current PHG, OEHHA considered all relevant and available information on infants and fetuses. The information indicates that a PHG of 6 ppb for perchlorate protects all human populations, including fetuses and infants.

**14. What is the role of the Department of Health Services (DHS) in protecting drinking water from threats posed by perchlorate?**

**A.** DHS regulates public drinking water suppliers and sets California's regulatory drinking water standards, officially known as Maximum Contaminant Levels (MCLs). State law requires DHS to set each MCL as close to the corresponding PHG as is economically and technically feasible, placing primary emphasis on the protection of public health. DHS can set the MCL above the level of the PHG if it determines that the economic impact on water suppliers or consumers of reducing a contaminant to the PHG level would be excessive compared to the reduction in estimated health risk, or if current testing or treatment technologies are not adequate to ensure drinking water contamination levels would be at or below the PHG.

DHS began development of an MCL for perchlorate shortly after publication of the PHG in 2004. DHS will be releasing the draft MCL for public comment and review soon.

**15. Is water dangerous to drink if it contains contaminant levels that exceed the PHG?**

**A.** A PHG represents a health-protective level for a contaminant that DHS and California's public water systems should strive to achieve if it is feasible to do so. However, a PHG is not a boundary line between a "safe" and "dangerous" level of a contaminant, and drinking water can still be considered acceptable for public consumption even if it contains contaminants at levels exceeding the PHG. As long as drinking water complies with all MCLs, it is considered safe to drink, even if some contaminants exceed PHG levels.

**16. In February, the U.S. EPA announced a "Drinking Water Equivalent Level" for perchlorate of 24.5 ppb, which it calculated from the NAS reference dose. Is OEHHA's PHG in conflict with the new U.S. EPA number?**

**A.** No. A federal Drinking Water Equivalent Level (DWEL) is not equivalent to a PHG. The primary difference is that the DWEL assumes all exposure to a contaminant comes from drinking water, while the PHG by law must account for exposures to a contaminant from sources besides drinking water, such as food. For this reason, a PHG for a given contaminant often will be lower than the corresponding DWEL. The next step for U.S. EPA would be to reduce the DWEL by a factor that accounts for human exposure to perchlorate from food and other sources. This number would be the Maximum Contaminant Level Goal (MCLG), which is the federal equivalent of a PHG.

**17. Do the results of a recent study of perchlorate levels in human breast milk suggest that OEHHA's PHG should be lowered?**

A. The breast milk study, while important, did not provide sufficient information to justify any revisions to the PHG. The study, published in February 2005, was conducted by three researchers at Texas Tech University who measured levels of perchlorate in both dairy milk and human breast milk samples from throughout the United States, including California. Average perchlorate levels in the breast milk samples were 10.5 ppb, compared to average levels of 2.0 ppb in dairy milk. There is no evidence that drinking water was the source of the perchlorate detected in the breast milk samples, as the researchers did not find any correlation between perchlorate levels in the breast milk and drinking water of the study participants. The sources of the perchlorate in the breast milk samples remain unclear. OEHHA would need additional data on the sources of the perchlorate before it could review or revise its PHG calculations that account for perchlorate exposures from food and other non-drinking water sources.

**18. Can the PHG be used to determine if foods containing perchlorate are safe to eat?**

A. No. The PHG serves as a goal for drinking water only. It is calculated using data on the amount of drinking water that humans consume, and therefore it cannot be applied to food. By law, the PHG must account for exposures to a contaminant from food and other non-water sources. Thus, the PHG indicates that 6 ppb of perchlorate in drinking water would not pose a health risk even if a person were also ingesting perchlorate in lettuce, milk and other foods where perchlorate has been detected. However, the PHG does not suggest a safe level of perchlorate in food.

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