

# Executive Summary

## Position Paper of the Perchlorate Study Group<sup>1</sup> Concerning Revision of the Perchlorate Public Health Goal to Adopt Scientific Findings of the National Academy of Sciences

Upon issuing its public health goal (PHG) for perchlorate in March of 2004, the Office of Environmental Health Hazard Assessment (OEHHA) acknowledged the comprehensive review of perchlorate health effects that was underway at the National Academy of Sciences (NAS), and the potential importance of that review to OEHHA's PHG. OEHHA further committed to "carefully review the NAS conclusions" and to "revise the PHG as necessary".

The NAS report was issued on January 10, 2005. It reflects the combined input of 15 of the nation's foremost experts in the many scientific disciplines relevant to perchlorate health effects and risk assessment. The report agrees with many of the findings and conclusions in OEHHA's PHG, disagrees with others, and eliminates areas of scientific uncertainty identified by OEHHA in its March, 2004 document - issues that directly impact the setting of the PHG. Chief among the latter is the identification of a "no observed adverse effect level" (NOAEL), which for the first time allows OEHHA to gauge the margin of safety implicit in the current PHG. Moreover, this finding brings into focus OEHHA's mandate under state law to set the PHG at the "safe dose response threshold". In this context, a review of the NAS report leads to the conclusion that OEHHA must revise the current PHG.

The key findings from the NAS report include the following:

- In adults, "sustained exposure" (*i.e.*, several months or longer) to ***more*** than 0.4 milligrams per kilogram (mg/kg) of perchlorate per day is required before any harm could occur. This value is, effectively, the NOAEL. Using standard default U.S. EPA and OEHHA exposure factors for converting a health-based dose level to a drinking water concentration (70 kg for body weight and 2 liters per day for drinking water consumption), this is equivalent to more than 14,000 ppb, to which additional uncertainty factors could be applied to account for data limitations and contributions from non-drinking water sources.
- A dose of 0.007 mg/kg per day has no effect at all on the human body. Using the same standard default exposure factors, this is equivalent to 245 ppb in drinking water. A value with no effect on a person is called a No Observed Effect Level or NOEL.

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<sup>1</sup> Participating in this position paper are the member companies of the Perchlorate Study Group, with the exception of Lockheed Martin Corporation.

- All drinking water standards in California and at the federal level are based on the NOAEL. The NAS Committee took the highly unusual step of using the more conservative NOEL, rather than the NOAEL, as its point of departure. The difference between these values represents a 57-fold margin of safety. This recommendation constitutes a major policy shift – a drinking water standard based on the NOEL would be unprecedented.
- To account for variations in the population (*i.e.*, the fetus of a woman with hypothyroidism or iodine deficiency), the NAS Committee took the further step of adding a 10-fold safety factor to the NOEL to derive a reference dose of .0007 mg/kg per day. This dose incorporates a composite 570-fold margin of safety. Using the standard default exposure factors, this dose converts to a drinking water concentration of 25 ppb. The NAS Committee repeatedly acknowledges the conservatism of its reference dose, citing both the NOEL-based point of departure and the 10-fold uncertainty factor, and states that this level “should protect the health of even the most sensitive populations.”

These findings clarify OEHHA’s statutory obligations in setting a PHG. Health and Safety Code Section 116365 states “if adequate scientific evidence demonstrates that a safe dose response threshold for a contaminant exists, then the public health goal should be set at that threshold.” By defining the NOAEL, and finding that the point of departure – the NOEL – is based on a non-adverse effect (inhibition of iodide uptake by the thyroid), the NAS Committee has arguably established a floor for the “safe dose response threshold” at the NOEL. Given the large margin of safety between the NOAEL and the NOEL, and in recognition of regulatory precedent, this dose should be converted to a drinking water concentration using default exposure factors for body weight and water consumption (70kg and 2L/day, respectively), not the more conservative factors for pregnant women used by OEHHA in its March, 2004 PHG. The corresponding drinking water concentration is 245 ppb. Further adjustment to account for exposures from food and other sources (“relative source contribution”) would also be consistent with regulatory precedent in California, and data is now available from the Centers for Disease Control that can be used to derive a quantitative value for relative source contribution. This analysis leads to a net reduction of 9 ppb. Thus, OEHHA is required, as a matter of state law and regulatory precedent, to set the PHG at 236 ppb.

OEHHA takes the position in its March, 2004 PHG that the point of departure must be adjusted for body weight and water consumption rates for the most sensitive subpopulation. These adjustments are neither scientifically nor legally supported, given the very conservative basis for the 236 ppb PHG. Nevertheless, if OEHHA maintains this position, it has two options for calculating the PHG:

1. Use the NAS NOEL as the point of departure and then adjust for a pregnant woman's body weight and water consumption rate, resulting in a PHG of 176 ppb. Both OEHHA and the NAS Committee agree that this subpopulation is the most sensitive to perchlorate exposure. An additional adjustment for relative source contribution (a net reduction of 9 ppb) would result in a PHG of 167 ppb.
2. Use the NAS NOEL as the point of departure and apply a 10-fold safety factor, as the NAS Committee did, to account for variations in the population. Converting the NAS reference dose to a drinking water concentration using standard default exposure factors would yield a PHG of 25 ppb, and further adjustment for relative source contribution, as noted above, reduces the PHG to 16 ppb. Further adjustments to account for variations in the population would be double-counting, since these variations are more than accommodated by the extremely conservative point of departure and the 10-fold uncertainty factor.

It is important to note that these calculations borrow from assumptions traditionally applied to a NOAEL. In light of the new information in the NAS report that clearly establishes the extreme conservatism of the NOEL, and the requirements of California law, there is no scientific or legal basis for making these adjustments.

As OEHHA anticipated in March of 2004, the NAS report provides valuable input into OEHHA's efforts to establish a PHG for perchlorate. Other scientific work published subsequent to the March, 2004 PHG provides further clarity on issues central to the setting of the PHG. With this accumulated scientific knowledge, we can now identify the "safe dose response threshold" using "the most current principles, practices and methods" employed by experts in the field, as state law requires.

A PHG set below the safe dose response threshold does nothing to advance public health — it ignores the expert conclusions of the NAS as well as much of the work in OEHHA's analytical document; it flies in the face of precedent by adopting an approach that could produce serious practical, economic and even adverse health consequences with respect to other PHGs that OEHHA will have no principled basis for distinguishing from perchlorate; and it diverts both private and public resources away from much more pressing public needs.

With this in mind we urge OEHHA to recognize the work of its own scientists, the NAS's authoritative report, and the requirements of its statute, and revise the PHG to 236 ppb.