

# Risk Assessment of Perchlorate for Development of the Public Health Goal

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# Topics to be covered:

- The federal risk assessment and regulatory process – RfDs, DWELs, MCLs, MCLGs
- The state process – PHGs, MCLs, ALs
- Perchlorate scientific issues
- Status of perchlorate standards

# Federal Water Standards

Defined by U.S. EPA, regulated under  
the Safe Drinking Water Act

- RfD – Reference Dose, estimated safe daily dose, to within an order of magnitude
- DWEL – Drinking water equivalent level, derived from RfD using standard parameters (70 kg bw, 2 L/day)
- MCLG – Maximum Contaminant Level Goal, desirable level in water, set at zero for carcinogens
- MCL – Maximum Contaminant Level, maximum level allowed, considering technical and economic feasibility

# California Water Standards

Defined by DHS and OEHHA, regulated under the California Safe Drinking Water Act

- PHG – Public Health Goal, estimated safe level, including *de minimis* cancer risk level (OEHHA)
- MCL – Maximum Contaminant Level, maximum level allowed, considering technical and economic feasibility (DHS)
- Action Level – “Advisory” level for otherwise non-regulated chemicals (DHS and OEHHA)

# U.S. EPA

# California

RfD/MCLG = PHG

MCL = MCL

MCLs must be set as close as feasible to the health goals under both statutes; California MCL must be equal to or lower than federal MCL

# Perchlorate Risk Assessment

- PHG requested by DHS, and underway in OEHHA for about three years
- Extensive literature review and analysis
- Lengthy internal and external scientific and public review process

# Thyroid gland

- Supports metabolism and cell growth
- Thyroid takes up iodine and forms thyroid hormones T3/T4, which are released after stimulation by TSH
- Deficiency causes goiter and growth retardation
- Overactivity causes Graves Disease

# Perchlorate Effects

- Inhibition of iodine uptake into thyroid
- Decreased thyroid function, decreased growth and cell metabolism
- Potentially cause goiter in pregnant women and developmental effects including decreased IQ in offspring
- Thyroid tumors in rodents and aplastic anemia in humans (high doses)

# Critical endpoint chosen by OEHHA

- Inhibition of thyroid uptake of iodide
  - The first event in the chain of anti-thyroid effects of perchlorate
  - Reversible inhibition of sodium iodide symporter (NIS)
  - Treated as an adverse effect for the risk assessment

# Critical endpoints chosen by U.S. EPA

- Multiple low-dose effects in rat studies
  - Changes in rat brain development
  - Behavioral changes
  - Immunological effects

# Why not choose changes in serum T4 as the endpoint?

- Variable threshold for T4 depression, affected by many factors:
  - Dietary iodide intake level
  - Exposure duration and amount of iodide stored in thyroid
  - Variability in thyroid hormone regulation
  - Other environmental and behavioral influences on thyroid function

# Why not choose changes in serum T4 as the endpoint?

- It does not consider effects of NIS inhibition in other extra-thyroidal tissues (e.g., mammary glands)
  - Breast milk is the sole source of iodine for some infants
  - An adequate supply of iodine is required for normal growth

# Perchlorate Scientific Issues

- Use of human versus animal data, with corresponding UFs (30 or 300)
- Identification of iodine uptake inhibition as the critical effect
- Evidence for/against sensitive populations
- Adequacy of UF, considering data limitations

# Exposure Calculations

- Drinking water considered primary exposure route
- Uptake into plants from irrigation water an important consideration
- Perchlorate contribution from food not yet calculable
- “Relative source contribution” not clear

# At environmental concentrations, could perchlorate cause?

- Goiter in pregnant women
- Adverse neurological development in fetuses and infants
- Reduction of IQ in offspring
- Additional stress on patients suffering from hypothyroidism

# Status of Perchlorate Standards - Federal

- U.S. EPA proposed an RfD of 0.00003 mg/kg-day in 2002, with a DWEL of 1 ppb
- RfD document under review by NAS, report will take several months
- MCL will take 2-3 years after RfD finalized

# Status of Perchlorate Standards - California

- DHS set Action Level of 4 ppb in 2002
- OEHHA proposed PHG in the range of 2-6 ppb in 2002
- SB1822 (HSC 116293) required OEHHA to adopt a PHG on Jan 1, 2003, and DHS to adopt an MCL on or before Jan 1, 2004

# Status of Perchlorate Standards - California

- Industry sued to require 2nd peer review of PHG, and won
- Draft PHG now submitted for 2nd UC peer review
- PHG delayed for several months
- MCL finalization date unknown

# Meanwhile....

- Crop analyses continuing
- More perchlorate–contaminated wells being discovered
- Current bills in the U.S. Senate (Boxer) and Assembly (Capps) direct U.S. EPA to finalize an MCL in 2004.

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## **Useful websites:**

OEHHA: [www.oehha.ca.gov](http://www.oehha.ca.gov)

DHS: [www.dhs.ca.gov/ps/ddwem/chemicals/chemindex.htm](http://www.dhs.ca.gov/ps/ddwem/chemicals/chemindex.htm)

U.S. EPA: [www.epa.gov/safewater/mcl.html](http://www.epa.gov/safewater/mcl.html)

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