Health Consultation

NORTH MORROW AND NORTHWEST UMATILLA
PERCHLORATE AREA

NORTHERN MORROW AND NORTHWESTERN COUNTIES,
OREGON

SEPTEMBER 30, 2006

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Agency for Toxic Substances and Disease Registry
Division of Health Assessment and Consultation
Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

An ATSDR health consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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HEALTH CONSULTATION

NORTH MORROW AND NORTHWEST UMATILLA PERCHLORATE AREA

NORTHERN MORROW AND NORTHWESTERN UMATILLA COUNTIES, OREGON

Prepared By:

Oregon Department of Health and Human Services
Superfund Health Investigation and Education Program
Under Cooperative Agreement with the
U.S. Department of Health and Human Services
Agency for Toxic Substances and Disease Registry

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Purpose and Health Issues

The Superfund Health Investigation and Education (SHINE) program evaluates the human health risks Oregonians face from exposures to environmental contaminants. SHINE is a part of the Oregon Department of Human Services (DHS), Public Health Division and was formed in 2001 as a cooperative agreement with the federal Agency for Toxic Substances and Disease Registry (ATSDR).

SHINE has prepared this Public Health Consultation to evaluate whether there is a public health impact from exposure to perchlorate in northern Morrow and northwestern Umatilla Counties. The area under investigation is known as the North Morrow and Northwest Umatilla Perchlorate Area. Perchlorate is a chemical that has been detected by the Oregon Department of Environmental Quality (DEQ) and U.S. Environmental Protection Agency (EPA) in groundwater wells at concentrations ranging from less than one to nearly 30 parts per billion (ppb). Of the 98 drinking water wells that have been tested, perchlorate was detected in 34 of the wells. The average concentration in the 34 wells with detectable perchlorate is 3.5 ppb. Manufactured perchlorate salts are commonly used as an oxidizer in rocket fuel, explosives, matches, and fireworks and perchlorate is also found in hypochlorite solutions used for water treatment. Perchlorate naturally exists is semi-arid climates, it is a known constituent of Chilean nitrate fertilizers, and there is evidence that it forms naturally through atmospheric processes. Perchlorate has been detected throughout the U.S. in groundwater and well as in food samples, dairy milk, and breast milk.

ATSDR was asked by the U.S. Environmental Protection Agency (EPA) to evaluate the health risks associated with ingestion of perchlorate in this area. Through a cooperative agreement with ATSDR, SHINE agreed to conduct this Public Health Consultation. Based on this evaluation, SHINE determined that perchlorate poses an *indeterminate public health hazard* in the North Morrow and Northwest Umatilla Perchlorate Area due to a lack of data about exposure to perchlorate from sources other than drinking water. In order to better assess other exposure sources, SHINE recommended sampling of foods available for purchase by residents in this area be tested for perchlorate.

Background

This section will provide background information about perchlorate, its current and historical uses, possible sources, and early agency response to the perchlorate detection in northeastern Oregon. Perchlorate is a contaminant that has been detected in groundwater throughout the United States, with the highest levels found in Arkansas, California, Nevada, Texas, and Utah [1]. Perchlorate was detected in groundwater at a site in California at levels as high as 1,100,000 ppb (not used for drinking water).

In the 1950s and 1960s, large doses (400-1000 mg/day) of perchlorate salts were used to treat hyperthyroidism (not to be confused with hypothyroidism, discussed below), although severe health problems related to treatment at high doses were identified, including agranulocytosis and aplastic anemia leading to death (Appendix A) [2]. The treatment for hyperthyroidism with perchlorate stopped in the mid 1960s due to the adverse affects described above as well as the availability of new alternative treatments.

Perchlorate is a highly water-soluble anion that is a component of perchlorate salt including ammonium, magnesium, potassium, and magnesium salts [3]. It is a mobile substance that moves easily from surface soils into groundwater, where it rapidly disperses. Perchlorate is stable in the environment and can persist in groundwater for decades [4]. Due to its low vapor pressure, it is not usually found in the vapor form at room temperature.

Ammonium perchlorate and perchloric acid contain chlorine in its highest oxidation state, which makes perchlorate a good oxidizer at elevated concentrations and temperatures. Because of its oxidation capabilities, ammonium perchlorate has been manufactured and used in solid rocket fuel, explosives, matches, and fireworks [5]. Perchlorate is also used to aid in the inflation of air bags [4]. It has been detected in hypochlorite solutions used for water and wastewater treatment and has also been measured in household bleach [6]. Natural deposits of Chilean nitrate fertilizers contain very small amounts of perchlorate [7]. There is also evidence that perchlorate exists naturally in semi-arid climates and can deposit onto land surfaces following atmospheric production or form through geochemical processes [7 & 8].

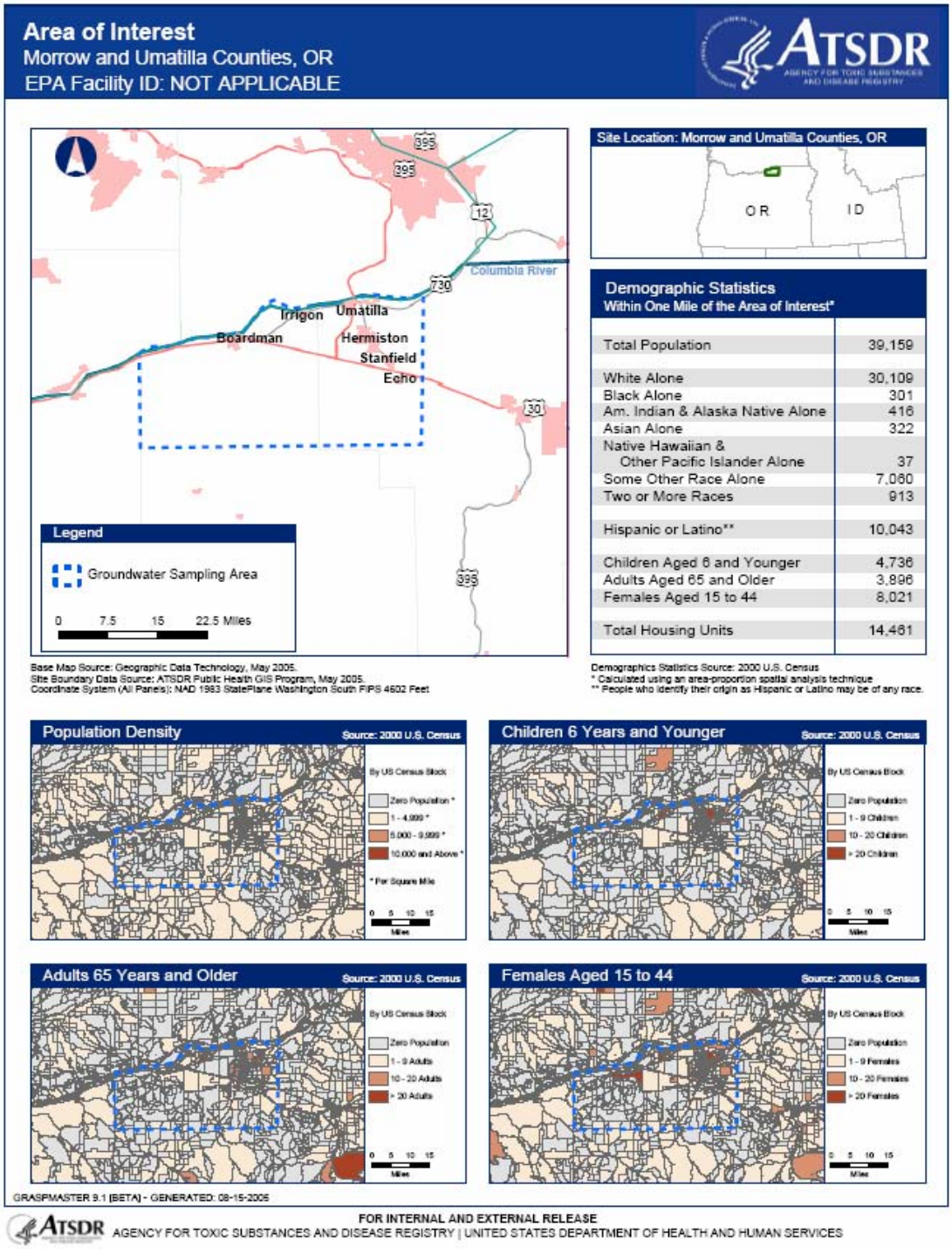
The Government Accountability Office (GAO) published a report in spring of 2005 about tracking perchlorate contamination in the U.S. They determined 65% of the groundwater perchlorate contamination found throughout the states is linked to defense and aerospace activities, such as rocket motor testing, bomb testing, or explosive disposal. The GAO estimated that 90% of perchlorate is produced for rocket propellant used by the military and NASA [1].

To date, the source, or sources, of perchlorate contamination has not been confirmed in northern Morrow and northwestern Umatilla Counties. There is a possibility that sources, such as hypochlorite solutions, or natural formation is the source of perchlorate in this area since the climate in Morrow and Umatilla Counties is semi-arid. The contaminated wells in the northern Morrow and northwestern Umatilla Counties are situated near sites historically used by the Navy and Air Force for bomb testing, by Boeing for engine testing, and the site of the Umatilla Ordnance Depot formerly known as the Weapons Depot which may also be a source of perchlorate in the area.

Since 1990, the DEQ has been assessing nitrate contamination of groundwater in the area. In 2003, the U.S. Environmental Protection Agency (EPA) assisted DEQ in a broad groundwater sampling effort that analyzed for perchlorate as well as nitrate. Since then, EPA and DEQ have conducted several additional sampling efforts to test for both perchlorate and nitrate. The area where sampling efforts were focused can be seen in

Figure 1. Most of this arid area is sparsely populated with most of the population density located in the towns of Boardman, Echo, Irrigon, Hermiston, Stanfield, and Umatilla.

Figure 1. Area of Interest



Perchlorate was detected in 34 of the 98 domestic drinking water wells tested between 2001 and 2005 with an average concentration for the wells with detections of 3.4 part per billion (ppb) (Table 1). One part per billion in water is equivalent to one microgram (one millionth of a gram) per liter (µg/L). During a joint EPA/DEQ sampling event in 2003, perchlorate was detected in over half of the one hundred thirty-three groundwater wells tested in the area [9 & 10]. The 2003 sampling event is only one of roughly 10 sampling events performed in the area between 2001 and 2005 that included monitoring drinking water, irrigation water, monitoring, and community groundwater wells. The highest detection in a domestic drinking water well to date within this area was 13.4 ppb [9]. The highest perchlorate detection in groundwater to date in Morrow and Umatilla Counties was 29.2 ppb, found in a monitoring well not available for public use.

Table 1. Summary of groundwater sampling results in the North Morrow and Northwest Umatilla Perchlorate Area – 2001 to 2005 [9 & 10]

Type of Well	Total Number of Wells Sampled	Number of Wells With Perchlorate Detections	Percent Of Wells With Detects	Average Concentration [ppb]	Minimum Concentration [ppb]	Maximum Concentration [ppb]
Irrigation	26	11	42%	2.3	< 1	4.23
Domestic/ Private	98	34	35%	3.45	<1	13.4
Community	10	2	20%	2.8	< 1	4.5
Monitoring	140	75	54%	7.6	< 1	29.2

Exposure Assessment and Toxicological Evaluation

Ingestion is the primary route of concern for human exposure to perchlorate. Perchlorate has been detected in drinking water, produce, and milk. Perchlorate has been shown to bioaccumulate in produce when perchlorate contaminated water is used to irrigate crops [11, 12, 13]. Perchlorate has also been detected in dairy milk and breast milk as a result of perchlorate ingestion by cows and pregnant or nursing women [14, 15].

For this consultation, five elements of an exposure pathway were evaluated to determine whether people are being exposed to perchlorate from the contaminated wells. If all the criteria are met for the five elements, then the exposure pathway is considered 'completed'. The five elements for a completed exposure pathway are listed below.

- *A contaminant source or release* – perchlorate was either released from military or other manufactured sources, released as hypochlorite, or formed naturally.
- *A way for the chemical to move through the environment to a point of exposure* – perchlorate moves easily from the surface, through the soil down into groundwater.
- *Exposure point or area* – perchlorate in domestic and irrigation water wells.
- *Route of exposure or a way for the contaminant to reach a population* – consumption of contaminated drinking water alone or possibly in combination with contaminated produce and milk, use of water from a contaminated well for bathing or other household uses.

- *A population that comes in contact with the contaminant* –residents who have contaminated wells, consume contaminated drinking water, or consume other food sources that have accumulated perchlorate.

SHINE determined that there is a completed exposure pathway for ingestion of perchlorate-contaminated drinking water. The exposed population includes residents that have had perchlorate detected in their domestic water wells. Although a completed exposure pathway exists for dermal exposure to groundwater through bathing or other household activities, it is unlikely that dermal absorption of perchlorate would pose a concern for human health and will not be considered in this consultation. Because perchlorate has a low vapor pressure, it is unlikely that people will breathe in dangerous levels of perchlorate so inhalation of the contaminant is not a completed exposure pathway and is not a concern.

There is also a potential pathway of exposure if milk and food items available to consumers in Morrow and Umatilla Counties are contaminated with perchlorate. However, at this time there is a lack of data to determine if perchlorate is present in these items. Because of this data gap, SHINE is unable to determine whether there are completed pathways of exposure for other sources. Therefore, we are unable to evaluate the relative risk of exposure from each individual source, beyond drinking water, since the cumulative risk from all sources combined remains to be determined.

A. Biological Effects and Health Effects

The main concern surrounding the effects of perchlorate exposure is the inhibition of iodide (a form of iodine, I^-) uptake into the thyroid. Maintaining proper iodide levels in the thyroid is important for thyroid hormone production. A prolonged reduction in iodide can cause a reduction in thyroid hormone levels, which can then lead to hypothyroidism in adults, infants, or a fetus.

Perchlorate has been shown to displace iodide at the sodium-iodide symporter (NIS) inhibiting iodide uptake into the thyroid [16]. The inhibition of iodide uptake does not necessarily result in any known health effects and can be remedied by increased intake of iodine-rich foods such as seafood, dairy foods, breads or cereals, and iodized salt [19]. An epidemiological study that exposed healthy men and women to various doses of perchlorate determined that radioiodide uptake inhibition was not a concern for the study population below 0.007 mg/kg/day [17]. The findings of the study were that there was a statistically significant difference in thyroid iodine uptake over a 14-day period at all administered doses except the lowest dose of 0.007 mg/kg/day. This was considered the no effect level (NOEL) and was the basis for the perchlorate health guidelines established by the EPA. This NOEL was based on an average of the group's response which is a common approach [18]. However, at the NOEL, four out of seven individual subjects did experience some decline in radio iodide uptake on day 14 of the study (see Figure 2d in the Greer et al. article).

Thyroid hormones are important for metabolism in children and adults. Maintaining iodide and thyroid hormone levels is essential for proper physical and mental development in fetuses, infants, and young children [5, 2, 19, 20].

When iodide inhibition does persist and thyroid hormone levels become too low, a person may develop hypothyroidism. However, the inhibition of iodide uptake does not automatically mean that a healthy adult will develop hypothyroidism. This is because adults have mechanisms in place to help compensate for iodide deficiency to maintain healthy thyroid hormone levels [2].

The thyroid hormones necessary for proper development in fetuses and infants are synthesized from iodide, and unlike adults, infants don't have an excess store of iodide [5]. There is concern that perchlorate exposure could cause a reduction in iodide levels in the thyroid below those required for proper development of fetuses and infants. However, there is no indication that infants and fetuses are at risk from exposure to perchlorate at the current levels detected in groundwater in north Morrow and northwestern Umatilla Counties.

Hypothyroidism is categorized into subclinical, overt, primary, or central hypothyroidism, which are based on health effects and severity of the condition [2]. Four to 8.5% of adults in the U.S. suffer from sub clinical hypothyroidism but show little or no sign of negative health effects. Subclinical hypothyroidism means that thyroid stimulating hormone (TSH) serum levels are high and serum T4 levels (a thyroid hormone referred to as thyroxine) are normal. Overt hypothyroidism is defined as high TSH serum levels and lowered serum T4 levels.

In adults, symptoms of hypothyroidism can include but are not limited to fatigue, altered metabolism, depression, weight gain, constipation, dry skin, and an enlarged thyroid (goiter). It has also been associated with unhealthy cholesterol levels, elevated blood pressure, impaired heart muscle contraction, and heart failure in people with existing heart disease [21]. Overt hypothyroidism is frequently treated with thyroid hormone medication. Doctors agree that pregnant and nursing women with subclinical hypothyroidism should be treated with thyroid hormone but there is a lack of agreement on how to treat other adults who have subclinical hypothyroidism.

Severe adverse developmental effects can result if fetuses or their mothers experienced significant iodide deficiency or hypothyroidism during pregnancy [2]. About 2.5% of pregnant women are diagnosed with subclinical hypothyroidism in the U.S. [22]. Subclinical hypothyroidism in pregnant mothers has been linked to adverse effects on neurological development, mental retardation in infants [19], placental abruption, and preterm births [20]. Hypothyroidism in infants and fetuses has been associated with lowered IQ, abnormal cognitive function, an impaired gait, impaired fine motor skills, and abnormal vision, hearing, and speech [23, 24]. These adverse effects have not been documented following low-level perchlorate exposure.

Because inadequate thyroid hormone production from causes other than perchlorate exposure is known to cause important health effects, concerns about the potential for perchlorate to have similar health effects have been raised. Although the health effects of hypothyroidism can be subtle and hard to measure, particularly when the extent of hypothyroidism is small, no studies reported in the literature have documented serious health effects from low-level perchlorate exposure similar to the exposure expected based on the water testing data alone from northern Morrow and northwestern Umatilla Counties [1, 2].

One limitation to our ability to use the information available from the research literature to assess risk for this Consultation is that potentially susceptible populations (described below) have not been well studied. For example, the Government Accountability Office reported that of the 90 perchlorate exposure studies they reviewed, none considered the fetus of a pregnant woman who is "nearly iodine-deficient" [1]. Maternal perchlorate exposure could adversely affect the development of an unborn child or a nursing infant, but there is a lack of information as to what level of exposure could cause harm.

Another limitation of the information obtained from the research literature is that several of the available studies are ecological. An ecological epidemiological study is designed to try and determine if an association exists between exposure to a contaminant and a health outcome when these are measured only at the population group (or "ecological") level. However, using only population level data can mask an association because an individual's exposure or health outcome may not be accurately reflected in the population group measurements used.

Since 1999, several ecological studies have evaluated the health impact of perchlorate exposure from ingestion of drinking water. The studies have evaluated exposure for school-aged children, newborns, and the general population. Many of the studies found no association between any adverse health effects from ingestion of perchlorate for newborns, infants, children, and adults [25, 26, 27, 28, 29]. Several of these have been criticized because they did not properly account for confounders [3]. A study conducted in California found a dose response of increased levels of TSH and decreased T4 levels in newborns with increasing perchlorate exposure [30]. Another study suggested that higher TSH levels in newborns were associated with perchlorate-contaminated drinking water [23]. However, the age of TSH screening for the exposed versus the control communities was different and may have been a confounder [3].

Thyroid cancer is another potential concern related to perchlorate exposure. However, it is unlikely that perchlorate causes thyroid cancer at a dose below that which causes a decline in thyroid hormone production [31]. Animal studies have shown that perchlorate does cause follicular cell tumors in the thyroid at very high doses similar to those that can result in an enlarged thyroid (goiter). Those doses are 1,000,000 times higher than the protective reference dose (the reference dose is defined below). There is not any epidemiological evidence to suggest that perchlorate causes thyroid cancer in humans at high doses.

B. Safe Exposure Levels

EPA uses a reference dose (RfD) as a health guideline to protect the most sensitive individuals. The RfD for perchlorate is the lifetime daily oral perchlorate dose determined to be protective of human health (including sensitive populations) for all sources of exposure [3]. Doses are commonly used to gauge the levels at which substances can cause various human health effects. Based on the recommendation from a National Research Council (NRC) report released in 2005, the EPA revised their perchlorate oral RfD. The current RfD for perchlorate is 0.0007 milligrams perchlorate/kilograms body weight/day (mg/kg/day) (Table 3) [31].

An RfD is usually based on a dose that causes no toxic effect. The current perchlorate RfD was derived from the Greer et al. human study where healthy adults ingested various doses of perchlorate to determine the dose that results in no biological effects [17]. A biological effect is different from a health effect. A biological effect is a precursor to a health effect that may or may not occur. The National Research Council chose to base the perchlorate RfD on the inhibition of iodide uptake because they said, "it is the event that precedes all thyroid-mediated effects of perchlorate exposure" [2]. Basing the RfD on a no effect level is considered to be an approach that is protective of human health.

An uncertainty factor of 10 is included in the RfD to provide added protection for sensitive populations (please see glossary in Appendix A). This means that the dose at which no effect was observed was divided by 10 and has the effect of reducing the acceptable daily dose to protect the most sensitive individuals, fetuses of pregnant women. The application of the uncertainty factor is summarized in Table 2. Uncertainty factors commonly range between 10 and 1000.

Table 3. Summary of how the NRC derived the RfD (Reference Dose).

Safe Perchlorate Dose That Had No Health Effect - NOEL (Greer et al, 2002)	Uncertainty Factor Added to NOEL– To Protect Sensitive Populations	NOEL/Uncertainty Factor = NRC RfD for Perchlorate
0.007 mg/kg/day	10	0.007mg/kg/day / 10 = 0.0007 mg/kg/day

Currently, there is no national or Oregon State standard for maximum acceptable perchlorate levels in drinking water. However, EPA's Office of Solid Waste and Emergency Response (OSWER) has set a drinking water equivalent level (DWEL) of 24.5 ppb. This is a preliminary remediation goal rather a drinking water standard, which is confusing to some people. The DWEL is based on the RfD and it will also be likely used in the establishment of a federal drinking water standard. The EPA RfD of 0.0007 mg/kg body weight/day translates to an equivalent concentration of 24.5 ppb in drinking water if the calculation assumes that 100% of adult exposure to perchlorate is from drinking water. This is the highest concentration of perchlorate in drinking water that is not expected to pose a significant risk to human health. If additional sources are also contributing to exposure and are considered when establishing a drinking water standard, the level of perchlorate in drinking water that could be considered 'safe' could be much lower.

All private domestic wells tested in Morrow and Umatilla Counties are below this concentration, however, a monitoring well in the area not available for human consumption contained perchlorate at 29.2 ppb. Although the perchlorate concentrations in almost all wells tested are below the maximum acceptable concentration of 24.5 ppb, with all drinking water wells below 14 ppb, it is important to note that the acceptable concentration in drinking water protective of health would be lower if food sources contribute to perchlorate exposure. For example, California has set a drinking water advisory of 6 ppb which includes an assumption that 60% of human perchlorate consumption comes from drinking water and the other 40% comes from other sources such as milk [32]. The drinking water advisory level for perchlorate is 2 ppb in Massachusetts [33]. It is largely based on the assumption that an uncertainty factor of 100 should be applied to the no effect level (NOEL) of 0.007 mg/kg/day found by Greer et al. instead of 10. The 100 is suggested because of the uncertainties about perchlorate toxicity and sources of exposure for sensitive individuals.

Sensitive Populations

Potentially sensitive populations to perchlorate exposure are pregnant and nursing mothers, fetuses, infants, young children, and people who have a severe iodine deficiency or have developed hypothyroidism. Infants and children are often considered a sensitive population for exposure to environmental contaminants. They are at greater risk from exposure to environmental contaminants, including perchlorate, because their organ systems are developing, and they consume more food on a per mass basis as compared with adults. Fetuses of pregnant women who may be iodine deficient or have hypothyroidism are considered to be the most sensitive individuals to perchlorate exposure according the National Research Council [2].

The thyroid hormones necessary for proper development in fetuses and infants are synthesized from iodide, and unlike adults, infants don't have an excess store of iodide [5]. Therefore exposure to perchlorate has the potential to reduce iodide below the level required for proper development of fetuses and infants. Perchlorate has been shown to both migrate into breast milk and may also cause a decrease of iodide levels in breast milk [15]. Therefore, a nursing infant may be exposed to perchlorate from breast milk and simultaneously receive less iodide from the milk because of the presence of perchlorate. Infants and young children that do not nurse could be exposed to perchlorate through ingestion of contaminated water, dairy milk, or produce. They could also be exposed when drinking formula mixed with contaminated groundwater. Growing children may consume large amounts of milk, and this could be an important source of their exposure.

Other people who may also be sensitive to perchlorate exposure include those with autoimmune thyroiditis (a common thyroid condition), pre-existing iodide deficiency, or who have conditions that result in lower thyroid hormone production. This group would be exposed to perchlorate through similar sources as non-breastfeeding infants and children.

There has been some concern expressed that EPA's Reference Dose (RfD) is based on a study of healthy adults and does not adequately account for risks posed to pregnant women, the population considered to be most sensitive to perchlorate exposure [5]. The RfD does have a built-in uncertainty or safety factor of 10 that is designed to be protective of sensitive populations (see part "D" of the Exposure Assessment and Toxicological Evaluation section for an explanation about the safety factor). However, it has been argued that the factor of 10 is not protective enough for sensitive populations and an uncertainty factor of 30 or 100 would be more appropriate [5, 33].

Discussion

Perchlorate is known to have the potential to inhibit thyroid hormone production. Although inadequate thyroid hormone production can cause serious health effects, these have not been documented from low levels of exposure to perchlorate. However, potentially susceptible populations have not been well-studied.

Based on the data available at this time, exposure to perchlorate in the drinking water alone in north Morrow and northwestern Umatilla Counties does not pose a public health threat to residents. However, SHINE is unable to evaluate the contribution of sources other than drinking water to the total exposure that residents in this area may have to perchlorate. More data are needed in order to evaluate the population's cumulative risk of exposure in that area and to make a comparison to EPA's RfD of 0.0007 mg/kg/day. Additional data could also be compared to national data for perchlorate in drinking water, milk, and produce. When more data are available, SHINE will evaluate the human health risk on the side of caution taking into full consideration the importance of protecting sensitive individuals.

The following items need to be sampled to gain a better understanding of perchlorate exposure in the North Morrow and Northwest Umatilla Perchlorate Area and determine if a more rigorous investigation is needed:

- Produce available to residents in the area that is locally grown as well as grown outside of Morrow and Umatilla Counties
- Dairy milk available to residents in the area

Community Health Concerns

In the summer of 2005, SHINE began to identify community concerns regarding the perchlorate issue by contacting the local health departments and the migrant health clinic to gauge the level of interest in the issue. SHINE also asked partner agencies about their knowledge of existing health concerns. In general, area residents that SHINE consulted with were unaware of the perchlorate contamination.

After the initial draft of this public health consultation was released, Morrow County officials requested a meeting with representatives from the involved agencies. Officials from Morrow and Umatilla Counties, local health department staff, representatives from the Navy, OSU Extension Office, Umatilla Army Depot, local business and concerned

community members attended the meeting held in Boardman at the Port of Morrow. Representatives of SHINE, others from the Oregon State Public Health Division, ATSDR, DEQ, EPA and ODA were on hand to answer questions and present information. Two overarching issues expressed by community members and officials included concerns that the map of the area included in the initial document could be damaging to the image of the community, and the impact the PHC process could have on agriculture and the local economy. Other frequent concerns that people had included:

- The lack of local participation in the PHC process
- The name of the area/site
- No documented relationship between perchlorate exposure and hypothyroidism
- Whether a window of safety exists with the uptake of perchlorate in produce
- The effectiveness of ionization treatment to remove perchlorate
- The perception of sampling of local crops to outsiders
- The length of time perchlorate remains in the body
- The large amount of food products (approximately 40%) that are imported to the area that would contribute to residents consumption of perchlorate
- The manner in which perchlorate is ingested, and whether another compound can metabolize into perchlorate
- Whether there is a correlation between where sensitive populations are and the presence of perchlorate
- The presence of symptoms among people consuming water contaminated with perchlorate
- The actions have been taken before definitive rules have been developed (relating to an MCL level set by the EPA).
- Risk communication should focus on sensitive populations and practitioners, not the entire community.
- The reliability of sampling in [particular retested] domestic well.
- Who will be the stakeholders for the review of the Exposure Investigation report

SHINE conducted one-on-one interviews with community leaders to learn about the perception of risk from perchlorate, the perception of the involved agencies, and what form of update on the progress of the perchlorate issue best serves interested members. The purpose of these interviews was to obtain information on remaining concerns from the community, as well as opinions on the best way to keep the community informed.

Document Release

SHINE released an initial draft of this public health consultation to introduce information about the potential health impact of perchlorate exposure on residents of northern Morrow and northwestern Umatilla Counties for public review and comment on December 1, 2005 until February 26, 2006. A press release was developed to notify the public of the document release and public comment period. SHINE staff developed a summary fact sheet and translated it into Spanish. Copies of the document and summary

fact sheet (see Appendix B) were made available at the presentations that were given in conjunction with staff from the DEQ, EPA, and ODA at a meeting held in Boardman at the end of January. The document was also available on the web at http://www.healthoregon.org/superfund. Comments on the draft version of the North Morrow and Northwest Umatilla Perchlorate Area Public Health Consultation were received and addressed in Appendix A.

Conclusions

1. The North Morrow and Northwest Umatilla Perchlorate Area poses an *indeterminate public health hazard*. The risk posed from consumption of drinking water alone does not appear to be a public health concern. However, the public health risk posed by exposure to perchlorate is indeterminate due to the absence of information about exposure from non-water sources when combined with drinking water as well as the potential of higher intake of these sources by children. Once data from other potential sources are available, exposure can be assessed for sensitive populations that currently ingest perchlorate from drinking water.

2. Perchlorate that has been detected in private groundwater wells that may be used for drinking water in the North Morrow and Northwest Umatilla Perchlorate Area at levels ranging from less than 1 to 13.4 ppb with an average in the wells with detections of 3.5 ppb. Perchlorate concentrations in irrigation wells in the area range from less than 1 to 4.23 ppb with an average of 2.3 ppb. The highest perchlorate detection in the area was 29.2 ppb in a monitoring well containing water that is not accessed by the public for drinking water.

3. A completed exposure pathway exists for exposure to perchlorate from ingestion of contaminated drinking water.

4. Fetuses, infants, young children, pregnant and nursing mothers, and people with severe iodine deficiency or hypothyroidism are considered to be populations that are sensitive to perchlorate exposure.

Recommendations

1. SHINE recommends further collaboration with agencies to sample other potential sources of perchlorate exposure for residents in the North Morrow and Northwest Umatilla Perchlorate Area to fill the data gap. The data generated from this investigation should be compared to national data to provide context about the findings.
   - Test milk available to sensitive populations in northern Morrow and northwestern Umatilla Counties
   - Test produce available to sensitive populations potentially irrigated with perchlorate contaminated water

2. SHINE, in collaboration with ATSDR, recommends that they assess perchlorate exposure from food sources combined with drinking water. The estimated, cumulative exposure levels for residents in the North Morrow and Northwest Umatilla Perchlorate Area should be compared with the RfD of 0.0007 mg/kg body weight/day.

3. SHINE recommends working with other agencies and public health professionals to prepare risk messages for residents in the North Morrow and Northwest Umatilla Perchlorate Area as needed. These health messages must correspond to any health risks that sensitive populations in the area face from both individual sources and aggregate perchlorate exposure. If a health risk exists, the messages will include strategies that individuals can use to reduce the effects from exposure.

4. SHINE recommends that the EPA and DEQ continue working together to conduct further groundwater sampling to define the extent of perchlorate contamination in the North Morrow and Northwest Umatilla Perchlorate Area.

Public Health Action Plan

The Public Health Action Plan ensures that the public health consultation identifies public health risks along with providing a plan of action designed to reduce and prevent adverse health effects from exposure to hazardous substances in the environment. This plan includes a description of actions that will be taken by SHINE in collaboration with other agencies to pursue the implementation of the recommendations outlined in this document.

A. Past Actions

- SHINE reviewed existing groundwater sampling data collected by the DEQ and EPA in the North Morrow and Northwest Umatilla Perchlorate Area.
- SHINE attended the June 9th, 2005, inter-agency technical perchlorate meeting. The agencies and universities represented at the meeting were: ATSDR, EPA, Oregon Department of Agriculture (ODA), Oregon DEQ, Oregon DHS (SHINE program), and Oregon State University (OSU). The inter-agency group agreed that there is a need for the following actions:
  - Gather information so the EPA can better assess the relative source contribution that will involve sampling sources of perchlorate exposure such as milk and produce.
  - Possibly prepare an aggregate risk assessment to better characterize the public health implications for the population in the perchlorate area.
  - Determine the source of perchlorate contamination in the area.
  - Conduct additional sampling to further characterize the perchlorate contamination.
- SHINE collaborated with Oregon DEQ and the EPA to develop a conceptual site model to determine routes of human exposure to perchlorate.

- SHINE contacted key organizations serving sensitive populations to inform them about the release of the public comment health consultation
- A public meeting was held on January 26th, 2006 with Oregon DEQ, ODA, EPA, ATSDR, and SHINE and community leaders to discuss the health consultation and recommended sampling

B. Future and Ongoing Actions

- SHINE will continue to be involved with inter-agency activities for the North Morrow and Northwest Umatilla Perchlorate Area, primarily bi-weekly check-in calls to discuss sampling results, sample planning, issues surrounding the area, and any other updates.
- SHINE tested dairy milk and local produce available to North Morrow and Northwest Umatilla Perchlorate Area residents for perchlorate. The results and data analysis will presented in a separate document summarizing the perchlorate exposure investigation.
- SHINE is developing risk messages and creating a plan to communicate results of sampling investigations as needed.

*Note: Exposure investigation specific actions will be discusses in a separate document

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Certification

This North Morrow and Northwest Umatilla Perchlorate Area Health Consultation was prepared by the Oregon SHINE program under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR).). It was completed in accordance with approved methodology and procedures existing at the time the health consultation was initiated. Editorial review was completed by the Cooperative Agreement partner.

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The Division of Health Assessment and Consultation, ATSDR, has reviewed this public health consultation and concurs with the findings.

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APPENDIX A. Public comments and responses.

The public comment of the draft version of North Morrow and Northwest Umatilla Perchlorate Area Health Consultation was open from December 1, 2005 to February 24, 2006. SHINE received over 100 comments submitted by state and federal agencies, city and county governments, industry representatives, health advocacy groups, and researchers from academia. Comments only pertaining to this health consultation are addressed below. A follow-up document will be developed that addresses the results of the local food commodity sampling recommended in this health consultation. Unless otherwise noted, all pages referenced below refer to the public comment version of the document.

1. Concern about Figure 1 and "North Morrow and Northwest Umatilla Perchlorate Area" Name

Comment 1-1

On the map in the report, the entire Lower Umatilla Groundwater Management Area (LUBGWMA) was identified as a 'Hazardous Waste Site of Interest.' This is truly unfortunate as this appeared to be quite alarmist in its nature and would leave the general public deeply concerned about the public health implications when the data is insufficient to make this claim. Declaring a "Hazardous Waste Site of Interest," is a questionable call considering the fact that the US EPA has set no Maximum Contaminant Level (MCL) for perchlorate and there is significant debate at the national level concerning the health risk level of perchlorate and the EPA reference dose0.0007 mg/kg/day.

Response 1-1

SHINE agrees with your concern in regards to the ATSDR demographics map. The map has been changed and the boundary around the site is now referred to as the groundwater sampling area. The perchlorate area in Morrow and Umatilla Counties is not considered a hazardous waste site and was referenced incorrectly on this map. Please refer to the updated Figure 1 on page 4 of the final draft of the health consultation.

Comment 1-2

The Lower Umatilla Basin Groundwater Management Area is comprised of land within northern Morrow County and western Umatilla County; however, the study is referred to as the North Morrow Perchlorate Area. This is unfortunate as it would lead the public to believe it is only a problem in North Morrow County, when only approximately 25% of the projected population of the entire area lives in Morrow County. The inference that this is only a North Morrow County problem is further supported by the City of Boardman being the only city listed in the original map disseminated for public review.

Response 1-2

This point has been noted and an interagency workgroup is currently discussing a name change for the area. It was not the intention of any of the agencies to single out Morrow County. Again, the map in Figure 1 has been changed and now lists the cities of Boardman, Irrigon, Umatilla, Hermiston, Stanfield, and Echo within the site boundaries.

SHINE has referred to the area as North Morrow and Umatilla Perchlorate Area in the final version of this health consultation.

Comment 1-3
The focus on Morrow County through the name and the identifiers on the map that only call out the City of Boardman is of concern, although the area identified by SHINE includes western Umatilla County as well as north Morrow County.

Response 1-3
Based on the comments received for the public comment version of the health consultation , SHINE has changed the map in the final version of the public health consultation. Morrow County officials and interested parties have reviewed the new map to ensure that it more accurately represents the area.

Comment 1-4
The authors of the report have included a map (Figure 1) which shows the North Morrow and Northwest Umatilla Perchlorate Area circled in red and labeled a "Hazardous Waste Site of Interest" with no indication (or proof) of this in their "study." This statement was made with no concern or consideration of the potential economic impact to Morrow County, whose primary source of income is agriculture.

Response 1-4
The map has been changed and the site boundary is now referred to as the "groundwater sampling area."

2. Sources of Perchlorate
Comment 2-1
Many of the wells sampled in the LUBGWMA are constructed in the alluvial aquifer, which contain clay layers known as caliche. Caliche could be contributing to the natural occurrence of perchlorate or may cause lensing of perchlorate above the caliche.

Response 2-1
We appreciate your comment about potential natural deposits of perchlorate.

Comment 2-2
There is a need for soil column sampling to determine if perchlorate salt are tied up in the soil column rather than dissolved in groundwater. Reviewing the areas of higher concentration detections would seem to be the places where soil sampling would be beneficial and more consistent with a CERCLIS study to identify a specific contamination source.

Response 2-2
Soil column sampling is outside of the scope of the SHINE health consultation. SHINE is not in a position to sample other media at this time.

Comment 2-3

In addition to explosives, Chilean nitrates and naturally occurring, industrial perchloric acid usage such as hypochlorite (bleach) solutions may be another potential source worth noting. (see http://mass.gov/dep/cleanup/sites/percsour.pdf for more information).

Response 2-3

SHINE appreciates this comment. Language about hypochlorite and other bleach solutions as potential sources of perchlorate contamination have been added to the "Purpose and Health Issues" and well in the "Background" sections on pages one and two of the final document.

Comment 2-4

"Small amounts form naturally through atmospheric processes and deposit onto land surfaces." Because of the climatic similarities between eastern Oregon and west Texas, it may be worth noting that in arid environments i.e., west Texas, perchlorate is a naturally occurring precipitate.

Comment 2-5

It would be appropriate to include additional citation and discussion of natural sources of perchlorate in the environment. While the document acknowledges that perchlorate can occur naturally in the environment, there is a growing body of scientific literature that is addressing this topic and I think that it would be helpful to provide further discussion and references to non-anthropogenic sources of perchlorate in the environment.

Response 2-4 & 2-5

A brief discussion on the natural occurrence of perchlorate can be found in the first paragraph on page two of the final draft of the health consultation. This description is similar to the background information provided in several other publications about perchlorate.

Comment 2-6

Other than natural processes, point sources for perchlorate can include explosives, propellants, and fertilizers. Since this area of concern includes an Air Force and Navy bombing ranges at Boardman, and the Army's Chemical Weapons Depot at Umatilla, SHINE is assuming that point sources for the wide area of contamination may be present. While such a supposition is certainly in the realm of possibility, there is no evidence to date that would indicate that is certain or even probable.

Response 2-6

SHINE has not drawn any conclusions regarding the sources of perchlorate contamination in Morrow and Umatilla Counties and has only listed the potential sources. The inter-agency workgroup is discussing the opportunity for an outside group to perform isotopic analysis as a way to help identify the source of contamination but this is outside the scope of SHINE activities.

Comment 2-7
Land application of wastewater requires disinfection prior to application which includes the use of chlorine or sodium hypochlorite. Although the disinfection process could contribute to perchlorate in Morrow and Umatilla Counties, elimination of this process could result in additional public health concerns.

Response 2-7
Source contribution is not in the scope of SHINE's activities, but we will forward this comment to appropriate agencies.

3. Perchlorate Groundwater Concentrations in Morrow and Umatilla Counties
Comment 3-1
Page 1 states that the range of detected perchlorate concentrations is 0.5 to 30 ppb (paragraph 2, line 7). Page 2, 4th paragraph, states that the range is less than 1 to 24.5 ppb, and goes on to say that the highest concentration measured in a domestic well is 13.4 ppb and that 29.2 ppb was measured in a monitoring well that is not available for public use. The PHC should focus on the exposure medium of drinking water and should highlight results that are specific to drinking water sources, not measurements from non-drinking-water wells.

Response 3-1
It is important to include the concentrations in the different types of wells because that shows the potential range of concentrations that could exist in groundwater in the area. Concentration ranges in all types of wells will still be included in the report. However, language has been changed in the health consultation on pages one and two of the final document to clarify the perchlorate drinking water concentrations in the various well types.

The third sentence in the second paragraph on page one now reads, "Perchlorate is a chemical that has been detected by the Oregon Department of Environmental Quality (DEQ) and U.S. Environmental Protection Agency (EPA) in groundwater wells at concentrations ranging between 0.5 and 30 parts per billion (ppb)." The fifth paragraph on page two now reads, "Perchlorate was detected in 33 of the 98 domestic drinking water wells tested between 2003 and 2005 with an average concentration of 3.4 part per billion (ppb) (Table 1). One part per billion in water is equivalent to one microgram (one millionth of a gram) per liter (µg/L). During a DEQ sampling event in 2003, perchlorate was detected in over half of the one hundred thirty-three groundwater wells tested in the area [8 & 9]. The 2003 sampling event is only one of roughly 10 sampling events performed in the area between 2003 and 2005 that included monitoring drinking water, irrigation water, monitoring, and community groundwater wells. The highest detection in a domestic drinking water well to date within the North Morrow and Northwest Umatilla Perchlorate Area was 13.4 ppb [8]. The highest perchlorate detection in groundwater to date in Morrow and Umatilla Counties was 29.2 ppb, found in a monitoring well not available for public use."

Comment 3-2
It is apparent there is a need for more data to draw conclusions about public health risk in the LUBGWMA, however, it also appears that the area has been singled for review based upon the availability of an existing groundwater sampling network."

Although there is no disagreement, sampling results produce a picture of potential sources within the arbitrarily defined LUBGWMA, the sampling network does not allow for the true extent of the problem, nor define the areas of specific concern. Extended sampling of perchlorate in other groundwater management areas, i.e. the North Malheur County GWMA, would provide information as to whether the levels found in the LUBGWMA are unique or simply to be expected in other areas with similar agricultural or other land uses.

Response 3-2
SHINE agrees that it would be useful to determine the extent of perchlorate groundwater contamination eastern Oregon, however, this is beyond the scope of work done by the Superfund Health Investigation and Education (SHINE) Program. A lack of data from other areas in Oregon does not mean that public health risk posed by perchlorate in Morrow and Umatilla Counties should not be assessed. Any additional information about perchlorate in other areas of Oregon would provide helpful context for the perchlorate concentrations found in the two counties but it not required to assess exposure to perchlorate for residents in the area.

Comment 3-3
In the report, it did not clearly say that the small city communities of Boardman, Irrigon, and Umatilla, etc., found no or some trace discoveries of perchlorate in the city water drinking supplies.

Response 3-3
SHINE is not aware of perchlorate data for municipal water supplies in other communities in the area, besides Hermiston. This is because the Oregon Drinking Water Program does not mandate the monitoring of chemicals such as perchlorate in drinking water systems.

Comment 3-4
The report did not state anything about water samples taken or not taken from the industrial water wells of the Port of Morrow for the food processing industries in the Boardman area. This would relieve concern that our food processing industry was at risk.

Response 3-4
This point has been noted. SHINE did not provide the results for individual wells in the report because a detailed inventory for each well and the final water use is beyond the scope of this report.

4. Table 2

Comment 4-1

The 2004 FDA milk data in Table 2 should also be included.

Response 4-1

The FDA milk data has been added to table 2.

Comment 4-2

The results for lettuce are not applicable as lettuce is not locally grown, and the results for alfalfa are not useful because humans do not consume it. Thus, the lettuce and alfalfa information is not necessary and should not be included in the table.

Response 4-2

Theses items are included in the table to demonstrate that studies have shown that perchlorate can accumulate in food items grown in perchlorate contaminated irrigation water. Some people do consume alfalfa sprouts, however, it has been removed from the table.

Comment 4-3

Page 4, 1st paragraph and sentence: "The most common route of human exposure to perchlorate is through ingestion of contaminated drinking water, produce or milk (Table2)." However, Table 2 simply provides a brief (and incomplete) summary of perchlorate levels measured in various foods, and does not support that statement. It is probably more appropriate to describe how widespread perchlorate contamination is in the U.S.—e.g., 97% of milk samples collected by FDA in 2004 from areas across the country contained perchlorate.

Response 4-3

Table 2 was included to show that perchlorate can accumulate in milk and produce rather than provide a comprehensive summary of perchlorate in food commodities.

5. Inhibition of Iodide

Comment 5-1

How does iodine deficiency affect learning in students?

Response 5-1

Maternal iodine deficiency during pregnancy may adversely affect the child's brain development and reduce their ability to learn in school. It can result in a lower IQ, and it can also impair fine motor skills such as the ability to hold a pencil.

Comment 5-2

I am concerned about children with a lower socio-economic status being disproportionately impacted by possible iodine deficiencies due to perchlorate exposure.

Response 5-2

Any health education efforts that SHINE undertakes will include activities to address this important population.

Comment 5-3
In the first paragraph of the inhibition of iodide study there is an apparent attempt to discredit the main body of scientific thought contained in the NRC report. The National Research Council debated the Greer study and ultimately decided that it was the best science upon which to base its recommendations. In fact, Greer is the principal supporting study used by the NRC Committee and subsequently the EPA, to establish the RFD for perchlorate in humans. The use of a public health consultation to debate these issues is inappropriate and irresponsible. If SHINE disagrees with the Greer study, the place to take up that debate is in the peer reviewed journals, not in a public process, which may lead to misunderstandings by consumers about the safety of their food and water.

Response 5-3
This section is intended to summarize the relevant information about what is known and what is not known about the inhibition of iodine uptake into the thyroid following ingestion of perchlorate. This is especially important for sensitive individuals. The discussion of the Greer et al. study was to emphasize that uncertainty exists for the evaluation of exposure to sensitive individuals such as pregnant women and infants.

Comment 5-4
Page 5, Section A. Perchlorate Health Effects and Toxicity. The entire paragraph is misleading and incorrect. The first sentence states that the "two main concerns" associated with perchlorate exposure are "inhibition of iodide uptake into the thyroid, and a decline in thyroid hormone production as a result of iodide inhibition." This is misleading, because these are not independent effects. It should be more clearly described that perchlorate inhibits iodide uptake by the thyroid, and that this biological activity can lead to changes in thyroid hormone production (production can also increase, not just decline).

Response 5-4
SHINE agrees that it is appropriate to state that iodide deficiency can lead to the decrease in thyroid hormone production and that the latter is not independent of the first effect. This is captured in the section of the health consultation referred to above and the language in section A on page five reads as follows in the final draft of the health consultation: "The main concerns surrounding the biological effects of perchlorate exposure are: the inhibition of iodide (a form of iodine, I^-) uptake into the thyroid, and a decline in thyroid hormone production as a result of iodide inhibition. A prolonged reduction in thyroid hormone levels can lead to hypothyroidism in adults, infants, or a fetus (see section C about hypothyroidism below)."

<u>6. Perchlorate Toxicity Mechanisms</u>
Comment 6-1
The role of sodium-iodide symporter (NIS) and how perchlorate interferes with this mechanism should be mentioned in the health effects and toxicity section.

Response 6-1
A brief mention of this mechanism has been added to the first sentence of the "Inhibition of Iodide Uptake" Section**.** The sentence now reads, "Perchlorate has been shown to displace iodide at the sodium-iodide symporter (NIS) inhibiting iodide uptake into the thyroid [18]."

7. Perchlorate Epidemiological Studies
Comment 7-1
The NRC report contains a number of "causal association" statements, including the one presented above, which was picked up in the GAO report, published in the spring of 2005. While no study of iodine deficient mothers was done, the NRC report has some very strong statements to make about the relationship between perchlorate exposure and possible fetal effects. This is what the NRC report actually says about potential fetal effects of perchlorate:

"Changes in thyroid function in newborns. The available epidemiological evidence is not consistent with a causal association between exposure during gestation to perchlorate in the drinking water at up to 120 ppb and changes in thyroid hormone and TSH production in normal-birth weight, full-term newborns. Most of the studies show neither significantly lower T4 production nor significantly higher TSH secretion in infants born in geographic areas in which the water supply had measurable perchlorate concentrations. However, no data are available on the association of perchlorate exposure with thyroid dysfunction in the groups of greatest concern, low-birth weight or preterm newborns, offspring of mothers who had iodide deficiency during gestation, or offspring of hypothyroid mothers."
(Summary, pg.9)

Additionally, the California Proposition 65 Developmental and Reproductive Toxicant Identification (DART) Committee conducted an extensive review of the data related to perchlorate effects to evaluate perchlorate as a reproductive toxicant, under the Prop. 65 regulations. The California Office of Environmental Health Hazard Assessment (OEHHA) reports the following on their public web site:

"*The DART committee decided in 2002 to consider the listing of perchlorate following formal requests by several environmental groups. OEHHA provided the committee with its 2004 assessment of perchlorate as a drinking water contaminant, which contains an extensive compilation of the scientific literature on perchlorate's health effects. OEHHA also provided the committee with the comprehensive January 2005 review of perchlorate published by the National Academy of Sciences, and several original studies of perchlorate. OEHHA does not make recommendations or take positions on the listing of chemicals under consideration by the committee."*

As a result of their three year investigation and review of the literature, the DART Committee decided that perchlorate could not be shown to be a reproductive toxicant and declined to list perchlorate as a Prop. 65 compound.

All of this additional data was available as SHINE prepared its health consultation. Yet, out of all the data that could have been used, SHINE chose to say that there were no studies on iodide deficient women who were pregnant.

Additionally on page 6, 1st full paragraph: "A study conducted in Arizona found that perchlorate contamination was associated with abnormal thyroid function in newborns" (Brechner et al. 2000). The PHC discusses only two of at least 11 community and occupational epidemiological studies that are available (Brechner and Crump YEAR?). This is not a balanced discussion of the available literature. Findings of the community studies are reasonably consistent, in that the incidence of congenital hypothyroidism was not increased among newborns or children in areas with perchlorate in the drinking-water supply, as compared to that in areas not affected by perchlorate contamination, when appropriately controlled for age, ethnicity, and birth weight.

Further, the information from the Brechner study that is presented in the PHC is misleading. When the Brechner data were restricted to the samples of TSH collected on the second day of life or thereafter—the appropriate biomarker for fetal hypothyroidism—there was no difference between newborn TSH levels in the Yuma and Flagstaff (exposed and control) populations. Further, the follow-up refinement of this study conducted by Lamm et al. (2003), which controlled for confounding factors, found no difference in TSH in the two Arizona communities. This study is not mentioned in the PHC.

Response 7-1
It is true that most epidemiology studies have not demonstrated an association between adverse health effects in sensitive individuals following environmental exposure to perchlorate. However, the epidemiological studies you mention above that have evaluated perchlorate exposure to date are ecological studies, which evaluate the association between exposure and current health outcome information at a population level. Ecological studies have some very notable limitations. Due to the nature of ecological studies, it is not appropriate to draw a causal association from the results. They are conducted to help shed light as to whether an association between exposure and health outcome might exist. Ecological epidemiological studies do not directly measure an individual's exposure and the resulting health effect following exposure. An ecological epidemiological study could suggest an association between a health outcome and chemical exposure does exist when in fact it doesn't, or vice versa.

SHINE recognizes that the general trend of the ecological studies to date show no adverse effects from maternal exposure to perchlorate. However, it is also true that to our knowledge, there are no epidemiology study that directly measures low-level, long-term perchlorate exposure from the environment (rather than medical treatment) in individual subjects most sensitive to perchlorate and the association of that exposure with potential adverse outcomes.

Comment 7-2
Another statement that is patently incorrect is the final sentence in the first paragraph of the "Perchlorate Health Effects and Toxicity" section (page 5): "Maternal perchlorate exposure can affect the development of an unborn child or a nursing infant, but there is a lack of information as to what level of exposure could cause harm." In fact, no study has shown any developmental effect on a fetus or nursing infant due to perchlorate exposure.

Response 7-2
See comment above for more information on ecological epidemiological studies.

SHINE agrees that it is unknown what level of perchlorate could cause adverse health outcomes such as developmental delays in a child whose mother was exposed to perchlorate during pregnancy, which is stated in the sentence. The sentence has been modified to say, "Maternal perchlorate exposure could affect the development of an unborn child or a nursing infant, but there is a lack of information as to what level of exposure could cause harm."

Comment 7-3
Page 6, 1st full paragraph. The last sentence states, "The high urinary levels [of iodide] indicate that their iodide intake was high and could have counteracted effects from perchlorate exposure[4]" (Hershman 2005). The PHC is citing a non-peer-reviewed "opinion" of one scientist as a basis for discrediting the findings of the Crump et al. (2000) study. However, the National Research Council of the National Academies of Science (NRC) carefully reviewed the Crump et al. study and found it to be particularly strong. They investigated each criticism of this study, and specifically investigated the potential for high iodide intake to interfere with the study's ability to detect the effects of perchlorate at exposures as high as 120 ppb, the level of exposure in the most highly exposed community, with an independent evaluation of competitive inhibition. The committee concluded that iodide intake did not mask or otherwise interfere with the effects of perchlorate exposure in this cohort, and that the data from the Crump et al. study could be considered in the evaluation of U.S. exposure to perchlorate in drinking water (NRC 2005, pp. 104–105).

Response 7-3
SHINE's intention was to include the discussion for a potential confounder of this study. The limitations of the perchlorate ecological studies are widely discussed in the literature.

Comment 7-4
Page 6, 2nd full paragraph. The final sentence states, "The epidemiological evidence is not strong enough to confirm whether perchlorate causes thyroid cancer in humans at high doses." This sentence suggests that perchlorate does cause cancer, but that the epidemiological evidence is insufficient to prove it. It should be removed or restated.

Response 7-4
Please note that the first sentence in this paragraph read: "It is unlikely that perchlorate causes thyroid cancer at a dose below that which causes a decline in thyroid hormone

production [14]." The last sentence in the paragraph will be changed in the final version of the document to read: "there is not any epidemiological evidence to suggest that perchlorate causes thyroid cancer in humans at high doses."

8. Hypothyroidism in Morrow and Umatilla Counties

Comment 8-1

Have greater amounts of people been determined to be affected with hypothyroid problems in Morrow and Umatilla Counties? Is there a higher rate compared with the general population of health problems associated with the thyroid?

Response 8-1

The incidence of hypothyroidism and thyroid illnesses among residents of Morrow and Umatilla Counties is not known at this time. The state public health lab does do newborn hypothyroid screening but there is limited information on hypothyroidism for children and adults in Oregon. SHINE felt it was important to get a better sense for perchlorate exposure before evaluating health outcome information.

9. Perchlorate Body Burden

Comment 9-1

There have been reports and also data that show a higher body burden of perchlorate even if the exposure media contains low concentrations. So, it would be very premature to conclude that the concentration in people will be within the no effects level.

Response 9-1

SHINE agrees with this statement and although we will not be performing biomonitoring at this time to evaluate the body burden from exposure to perchlorate, we are conducting additional sampling to examine cumulative exposure as an estimate for the dose received by sensitive individuals.

10. Perchlorate Reference Dose and Equivalent Drinking Water Concentrations

Comment 10-1

Section E- "Issues surrounding the Perchlorate Reference Dose" discusses concerns that have been posed regarding the EPA RfD of 0.0007 mg/kg-day. To the reader unfamiliar with these issues the discussion may be too cursory to understand the nature of the arguments. Therefore, it may be better to either simplify or omit these discussions for a lay audience, or to more fully develop the concepts. Alternatively, a technical appendix that fully develops the concepts may be appropriate.

Response 10-1

The section "Issues Surrounding the Perchlorate Reference Dose" has been deleted and a simplified paragraph of this discussion has been added at the end of the "Sensitive Populations" section. The paragraph now reads, "There has been some concern expressed that EPA's Reference Dose (RfD) is based on a study of healthy adults and does not adequately address the risks to fetuses, infants, children, and other sensitive populations [19]. The RfD does have a built-in uncertainty or safety factor of 10 that is designed to be protective of sensitive populations (see part "D" of the Exposure

Assessment and Toxicological Evaluation section for an explanation about the safety factor). However, it has been argued that the factor of 10 is not protective enough for sensitive populations and an uncertainty factor of 30 or 100 would be more appropriate [4, 28]."

Comment 10-2
The range of perchlorate detected in domestic wells in the Morrow & Umatilla Counties are well below the 24.5 ppb reference dose recommended by the National Academy of Sciences (NAS) as listed in the US Government Accountability Office (GAO) Report (GAO-05-462, page 1), and listed as well in SHINE's document (Table 3, page 8).

Response 10-2
This comment has been added to the consultation on page nine, paragraph one which has been changed to say, "The EPA RfD translates to an equivalent concentration of 24.5 ppb in drinking water if the calculation assumes that 100% of adult exposure to perchlorate is from drinking water. All private domestic wells tested in Morrow and Umatilla Counties are below this concentration, however, a monitoring well in the area not available for human consumption contained perchlorate at 29.2 ppb. The reference dose that you refer to in Table 3, page eight of the comment version of the health consultation, is the EPA reference dose (RfD) of 0.0007 mg/kg/day rather than the concentration of 24.5 ppb. These two numbers are related but are not interchangeable.

The equivalent concentration of 24.5 ppb in drinking water is commonly referred to because this is the equivalent drinking water concentration that would result in the dose of 0.0007 mg/kg/day if it is assumed that 100% of an adult's perchlorate exposure comes from consumption of drinking water when they drink two liters of water per day. However, the concentration considered to be "safe" in drinking water could be less than 24.5 ppb if only 20%, for example, of total exposure to perchlorate is from drinking water. Since perchlorate has been detected in produce, dairy, and other food items, it is likely that other sources contribute to a person's exposure to perchlorate in addition to drinking water.

Comment 10-3
Interpretation of the data in Table 1 is that the majority of domestic private and community wells had levels of perchlorate that were below the limit of detection. The average concentration of perchlorate in those wells where perchlorate was detectable was a value that is well below the equivalent EPA RfD of 24.5ppb in drinking water. The current document does not clearly communicate or interpret these observations. The interpretation of these values in the public health consultation (on page 11, just below table 3 {Safe Exposure Values}) seems to emphasize a single value (13.4 ppb, the highest concentration that was measured of all of the samples), and characterizes this value as being very similar to the EPA RfD in drinking water (24.5 ppb). This outlier value is not very similar to the RfD, and discussing a single data point is not appropriate when the majority of the data reflect that perchlorate levels in drinking water samples were below the limit of detection.

Response 10-3
We acknowledge that there are no domestic wells above the drinking water concentration of 24.5 ppb (see response 10-2). However, it has not been determined that this drinking water concentration (which assumes an adult is only exposed to perchlorate through ingestion of contaminated water) is an acceptable drinking water concentration for at risk people because it does not account for other potential sources of exposure. SHINE agrees that the 13.4 ppb is higher than those found in the majority of domestic wells tested, however, the maximum detection in a private well should be considered when evaluating potential exposures because others may have drinking water or irrigation wells with levels at this concentration or higher. It is especially important to take these higher levels into consideration for pregnant women, infants and young children who might drink this water or eat food from a garden irrigated with this water.

Comment 10-4
Page 6, Inhibition of Iodide, 1st full paragraph: "However, this study [Greer et al. 2002] has been criticized because the dose was based on an average of the group's response rather than the actual level where individual subjects experience zero response following perchlorate exposure." The PHC is citing a non-peer-reviewed "opinion" by one scientist to cast doubt on the RfD developed by the NRC and EPA.

Further, this comment demonstrates a lack of knowledge of how RfDs are set, because no-observed-adverse-effect levels (NOAELs) are typically set on the basis of group data, not individual data. Further, thyroid hormone levels typically fluctuate during the course of a day and week; therefore, defining "zero response" on an individual basis is not practical. Rather than discrediting the basis of the PHC toxicity assessment—the EPA RfD—the PHC should describe in greater detail the conservatism of the approach. The fact that the RfD is based on a non-adverse effect (biochemical changes in hormone levels) that precedes the adverse effect, and that this approach is very unusual for the Agency, ensures an added measure of health protection.

Response 10-4
The citation referred to in the comment above is from an article published in Environmental Health Perspectives, a peer reviewed journal (see reference #20), and refers to Figure 2d in the Greet et al. 2002 article. This statement was not included to discredit the NRC and EPA but it is an important consideration for perchlorate exposure for sensitive populations. Figure 2d shows four out of seven subjects experienced some effect on day 14 of exposure following the lowest administered dose of perchlorate. The lowest administered dose was considered to be the "No Effect Level" (NOEL) by Greer et al., despite the fact that four out of seven healthy adult subjects experienced some effect. It is important to make note of these issues because uncertainties still exist around perchlorate toxicity for sensitive individuals warranting conservative public health practice that targets those individuals.

Additionally, in the Massachusetts *Update to "Perchlorate Toxicological Profile and Health Assessment"* they consider the inhibition of iodide to be a potentially adverse effect, so disagreement may exist about how this effect should be classified.

Comment 10-5
Page 8, 1st full paragraph. EPA's definition of a RfD is, "An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime"[1]. The definition presented in the PHC is not accurate and should be modified. The RfD is not for "all routes of exposure" as stated in this paragraph.

Further, the paragraph continues on to state, "Doses are commonly used to evaluate how much of a substance is harmful to an individual." This statement is unclear and incorrect. If referring to the RfD with the word "doses," the RfD is generally used to assess what **is** not harmful, not what **is** harmful. Dose-response assessment or toxicity assessment is used to evaluate how much of a substance is harmful to individuals.

Response 10-5
The language describing the RfD has been changed to read, "the RfD for perchlorate is the lifetime daily oral perchlorate dose determined to be protective of human health (including sensitive populations) for all sources of exposure." All other language in this section will remain as stated.

Comment 10-6
Page 8, 4th paragraph. This paragraph is misleading and suggests that there is a risk to local residents, whereas the findings of this PHC indicate that the opposite is the case. Consider the statement, "24.5 ppb is slightly lower than the highest concentration of perchlorate detected in a monitoring well (29.2 ppb) tested in Morrow County. Although all the drinking water concentrations in the limited number of wells tested are below the equivalent RfD in water, there is a strong possibility that residents are exposed to perchlorate from sources other than drinking water." This statement implies that drinking-water exposures are just below the level considered to be harmful, and because residents are also exposed to perchlorate in food, they are likely at risk. This is highly misleading and irresponsible. The RfD equivalent drinking-water concentration should be compared to the average concentrations of perchlorate in private and community wells—3.4 and 2.8 ppb, respectively (Table 1 of the PHC). The comparison provided in this discussion is misleading, because it refers to the highest concentration measured in a monitoring well that is not used as a drinking-water source.

The perchlorate exposures via drinking-water sources are only 14% and 11% of the RfD drinking-water equivalent in private and community wells, respectively.
Further, the perchlorate groundwater concentration data were collected from more than 200 wells, 107 of which supply drinking water. If this is a "limited" sampling, then these limitations should be described in detail in the Background section.

[1] http://www.epa.gov/iris/gloss8.htm

Response 10-6
A summary of the data is described in the background section. The authors feel that the language is clear in the health consultation that all drinking water wells are below 24.5 ppb. Some changes have been made to language referring to the limited number of wells tested. The paragraph 9 now reads, "Although the perchlorate concentrations in almost all wells tested are below 24.5 ppb, it is important to note that the acceptable concentration in drinking water protective of health would be lower if additional food sources contribute to perchlorate exposure were taken into consideration. For example, California has set a drinking water advisory of 6 ppb which includes an assumption that 60% of human perchlorate consumption comes from drinking water and the other 40% comes from other sources such as milk [27]. The drinking water advisory level for perchlorate is 2 ppb in Massachusetts [28]. It is largely based on the assumption that an uncertainty factor of 100 should be applied no effect level (NOEL) of 0.007 mg/kg/day found by Greer et al. instead of 10. The factor of 100 is suggested because of the uncertainties about perchlorate toxicity and sources of exposure for sensitive individuals."

Comment 10-7
Page 9, first full paragraph. "So the new RfD is higher than the old one, and some concern has been expressed that it was raised following the NRC recommendation without consideration of normal review processes." The amount of scientific review conducted by EPA, and EPA's extensive interaction with NRC during the review process exceeds, by far, the level of review that virtually every other RfD receives. This discussion is not helpful to the lay reader—its extreme brevity renders it confusing and alarming. If it is necessary to describe the difference between the provisional RfD and the new final RfD, then the most important difference between the two values should be stated clearly.

Response 10-7
SHINE agrees that referring to EPA's old provisional RfD is not helpful for the public. Language about the old provisional RfD has been removed from the health consultation.

11. Perchlorate Reference Dose Safety Factor
Comment 11-1
EPA did not introduce the safety factor of 10. Rather the NAS participating scientist decided to incorporate this safety factor, with one descent from a participant, on the grounds that he wanted an additional safety factor of 3 added to the factor of 10 for a total safety factor of 30. This participant was overruled and the factor of 10 was the ONLY safety factor added to the RfD.

Comment 11-2
Page 8, 3rd paragraph. The text states, "The EPA added a safety factor of 10 to the RfD to provide added protection for sensitive populations." This statement is not accurate and should be changed to state that, in developing the RfD, EPA and NRC divided the NOAEL for inhibition of iodide uptake by an uncertainty factor of 10 to provide added protection for sensitive populations such as children.

Response 11-1 & 11-2:
SHINE appreciates these comments. The language in the first sentence of this paragraph has been changed to read, "A safety factor of 10 is included in the RfD to provide added protection for sensitive populations."

Comment 11-3
SHINE's discussion of the perchlorate RfD is misleading. The RfD for perchlorate is far more protective than one based on a standard Lowest Observable Adverse Effect Level (LOAEL). In fact, the perchlorate RfD was controversial because the NRC committee agreed not to use the standard risk assessment methodology, and set their recommended RfD at a level based the "No Observable Effect Level". The .007mg./kg./day level was based on an exposure level that caused no observable iodide uptake interference. It is well noted in the NRC study and in the scientific literature that iodide uptake interference is not an "adverse" health effect, but simply a precursor effect that in and of itself has no adverse effect on the health of the subject. It was an extremely conservative view that was adopted by the NRC and the EPA when they agreed to use the NOEL to set the RfD.

Additionally, since there was, and continues to be, uncertainty over effects in the most sensitive sub-populations, a full 10X uncertainty factor was applied to the NOEL. This is how the .0007 mg./kg/day RfD was set.

The authors of the PHC also discount the use of the 10x safety factor, by stating, "…there are people in the scientific community who feel that the factor of 10 does not provide enough protection. Then they go on to say, *"Usually an RfD is based on a negative health effect rather than a biochemical event."* (pg. 9, paragraph 1)

A 10X factor is the maximum factor used by EPA to ensure safety in a risk assessment. EPA has the latitude to assess lower levels, but in this case, they chose to be maximally conservative and used the 10x factor. Additionally, there are also many in the scientific community that believe no risk factor was warranted, as the underlying assumptions are so conservative that even the most sensitive sub-populations are protected. What one or two scientists on either side of the issue believe is not pertinent to a public health consultation. SHINE is obligated by their commitment to the public interest to use the best science available and that science is contained in the NRC Report.

Response 11-3
Ten is not the maximum safety factor that can be applied by the EPA to ensure safety in a risk assessment. A safety factor of 10 to 1000 is commonly used to account for uncertainties in studies or data including but not limited to variability in human susceptibility to chemicals, limitations in epidemiological studies, insufficient data on reproductive or developmental outcomes, and uncertainty about the effect level of a chemical. The Massachusetts *Update to "Perchlorate Toxicological Profile and Health Assessment"* recommended a safety factor of 100 be added to the Greer NOEL of 0.007 mg/kg/day which results in a health guideline of 0.00007 mg/kg/day, 10 times lower than EPA's RfD (p. xi).

Comment 11-4
Following the discussion on the safety factor, the authors then propose that the *"old provisional RfD of .0001-.0005 mg./kg/day may be more appropriate."*

The arguments of the SHINE authors presented in the consultation, are biased and inappropriate for a public health consultation. If the SHINE program has issues with the methodology used by the NRC, EPA's subsequent adoption of the RfD, or any other issue related to the science, they should address them through the scientific, peer review process.

Response 11-4
It is important to note that SHINE did not state in the draft version of the health consultation document that the old provisional RfD of 0.0001 to 0.0005 mg/kg/day was more appropriate than the adopted EPA RfD of 0.0007 mg/kg/day. SHINE has omitted any discussion about EPA's old provisional RfD in the final document.

12. OSWER Drinking Water Equivalent Level
Comment 12-1
EPA Office of Solid Waste and Emergency Response (OSWER) has just issued a guidance on how the drinking water equivalent level (DWEL) of 24.5 ppb should be applied. Please see OSWER memo of Jan 26, 2006 for details.

Response 12-1
Thank you for this comment. We have added language that OSWER has issued this guidance in the final health consultation document on page nine. The final draft version of the health consultation reads: "However, EPA's Office of Solid Waste and Emergency Response (OSWER) has set a drinking water equivalent level (DWEL) of 24.5 ppb." We would also like to add that although EPA has issued this interim guidance level, EPA has not set a maximum contaminant level (MCL) for perchlorate in drinking water that is considered safe for drinking.

13. At Risk Populations for Exposure to Perchlorate
Comment 13-1
The sub-populations of higher risk from exposure to perchlorate is similar to the higher risk sub-populations for nitrates so efforts to bring messages to these individuals will likely be similar to efforts already in existence due to the LUBGWMA.

Response 13-1
Thank you for mentioning this point. SHINE will work with local health departments and existing organizations to disseminate appropriate health education messages to at-risk populations based on the investigation results to better characterize exposure to perchlorate exposure.

Comment 13-2
There may be a greater health threat for community members that are non-English speaking or migrant workers, and this may contribute to higher congenital hypothyroidism rates among the Hispanic population.

Response 13-2
Preventing the potential for adverse health effects in non-English speaking and migrant communities exposed to environmental hazards is a priority for us. SHINE's health education action plan will include activities to address this important population. If future findings indicate that there is a public health concern, we will work with local health department staff to develop a plan to educate sensitive populations on how they can prevent or reduce exposure.

14. Community Concerns
Comment 14-1
The community concerns section clearly states SHINES intention to use this PHC as an activist tool. Without an established standard in water or food, SHINE cannot responsibly deliver public health impact messages to the community. The implication in these statements is that residents are mistaken if they feel that the 24.5 ppb level is protective, yet SHINE has no supportable data to say otherwise. They also imply that concern over the impact to agriculture and the local economy is misplaced, that the Iowa perspective of no safe level is the more appropriate perspective. This bias is in direct contradiction to the body of opinion on this topic and is an irresponsible public health message to this or any other community.

Response 14-1
The community concerns section is a standard section in all health consultation and assessments and the information presented in this section only identified some concerns expressed by community members in other states whose drinking water contained perchlorate. The reference to the community in Iowa has been deleted.

Comment 14-2
It is irresponsible to alarm consumers in Morrow and Umatilla Counties that a potential exposure pathway exists from their milk and produce supply as is done in the fourth paragraph of page five in the Exposure Assessment and Toxicological Evaluation section.

Response 14-2
No conclusions were drawn in this report about the presence of perchlorate in milk or food items and it was not our intention to alarm consumers. To date, SHINE and other health department staff have not heard from any community members indicating that they are alarmed. This paragraph addresses the possibility that perchlorate may be found in milk and food items, in addition to drinking water in Morrow and Umatilla Counties.

15. Public Health Consultation Conclusions, Recommendations, and Planned Actions
Comment 15-1

Conclusion 1: I think the data we have shows that the highest concentration detected in one of the MW is above the "screening level" of 24.5 ppb. The detected levels in the DW wells are below the screening level, however, from a risk standpoint, since perchlorate bioconcentrates, the drinking water route may still be an issue.

Response 15-1
SHINE agrees with this comment.

Comment 15-2
Conclusion 3: Levels in domestic wells were as high as 13 ppb. These could constitute a potential health threat if individuals are also being exposed through pathways other than drinking water. At a maximum concentration of 13 ppb in domestic wells, I will assume that consuming water contaminated at this level will constitute a potential health threat.

Response 15-2
SHINE will not draw conclusions about safe levels of perchlorate in drinking water for residents in Morrow and Umatilla Counties because at this time, there is not enough information to draw such a conclusion.

Comment 15-3
Under planned actions: We need to have a better handle on the nature and extent of the contamination, including additional sources of exposure, to better assess the risk to the population. So, we need to have additional samples collected and analyzed to reach this goal.

Response 15-3
SHINE agrees with this statement and is the reason addition sampling was conducted.

Comment 15-4
We believe the assumptions, conclusions and recommendations of the PHC are misleading, uninformed and needlessly frightening to the consuming public about the food supply in the area.

Response 15-4
The public health consultation does not draw any conclusions about perchlorate in the food supply in the area. It presents the possibility that perchlorate can accumulate in milk and produce and that this is something that needs to be investigated in the North Morrow and Northwest Umatilla Perchlorate Area. It is very important to SHINE that messages about potential exposure to perchlorate are given context and target those most sensitive to exposure.

Comment 15-5
How can intelligent risk messages [recommendation #3 from the draft health consultation] be prepared when only an *indeterminate public health hazard* has been determined? This would be a waste of funds and time if the proper scientific work is not performed which includes clear goals and standards.

Response 15-5
No messages were developed based on this initial health consultation because the site was declared an *indeterminate public health hazard*. Risk messages will be prepared for sensitive populations as needed once more information has been gathered about exposure. SHINE recommended further sampling because of the need for more information. Exposure investigations are designed to fill data gaps so that we can better assess the public health impact of a contaminant.

Comment 15-6
Regarding conclusion #1, "The North Morrow and Northwest Umatilla Perchlorate Area poses an indeterminate public health hazard," I understand we cannot quantify exposure and hence potential risk from all sources, and therefore public health hazard is indeterminate. However, it is reasonable to add a conclusion that the maximum concentration measured in groundwater (Table 1) is below the DWEL, and average concentrations are well below the DWEL. Thus, risks from drinking water are not apparent, however, risk is indeterminate due to absence of information about exposure from non-water sources and potentially higher intakes to children. Stating the conclusion in this slightly modified way conveys a somewhat different meaning that conveys what we do know. That is, while do not see any clear risks from drinking water, we but further investigation of the perchlorate contribution from foods.

Response 15-6
SHINE agrees that additional language could be added to the conclusion section while emphasizing that other sources of exposure may exist and these must be evaluated in combination with drinking water. Conclusion #1 now reads, "The North Morrow and Northwest Umatilla Perchlorate Area poses an *indeterminate public health hazard*. Risks of exposure to perchlorate from drinking water are not apparent, however, risk is indeterminate due to absence of information about exposure from non-water sources and potentially higher intakes to children. Once data from other sources are available, the exposure of sensitive populations that currently have contaminated drinking water can be assessed."

Comment 15-7
The first conclusion of the PHC states, "The North Morrow and Northwest Umatilla Perchlorate Area poses an *indeterminate public health hazard*." This statement implies that a public health hazard exists, but that its magnitude is indeterminate. This statement is inappropriately alarming, inconsistent with the findings of the analysis, and inconsistent with the approach applied by the Agency for Toxic Substances and Disease Registry (ATSDR) at other sites where data is limited regarding particular sources of site-related exposure.

Response 15-7
ATSDR and SHINE use standard categories to characterize the public health impact of environmental contaminants at a site. Please refer to the glossary in Appendix B for the definition of *indeterminate public health hazard*. When a data gap exists for an exposure pathway, as it does in this case for ingestion of perchlorate, then a ranking of

'indeterminate' is most appropriate until more information is gathered and evaluated for the ingestion pathway. This ranking states that there is not enough information to assess the public health impact from exposure for one or more pathways, and is consistent with ATSDR's application of this hazard category.

Comment 15-8
We contend that if SHINE continues with the analysis of food for perchlorate content and releases results without a context in which to discuss them, consumers will potentially alter their diets and those of their children in an attempt to avoid exposure. Given the current science on perchlorate exposure, these diet changes are likely to do more harm than good to the public health in the Morrow County area and beyond.

Response 15-8
We have noted your concern and agree that people in Morrow and Umatilla Counties should maintain a well-balanced and nutritious diet, and we have not recommended any diet changes to the public.

16. Public Health Education and Outreach
Comment 16-1
ODHS should utilize the local health offices in Morrow and Umatilla Counties to coordinate with the Oregon Departments of Environmental Quality, Agriculture, and other appropriate agencies to develop and deliver accepted education messages to the residents about the nature of risk from perchlorate in food products.

Response 16-1
SHINE appreciates the recommendation. We have been working with these agencies, in addition to others, on a regular basis and plan to coordinate efforts with local officials to distribute messages to the local community.

17. Release of SHINE's Perchlorate Health Consultation
Comment 17-1
It was my understanding that DEQ and EPA were working together on the occurrence of perchlorate in the LUB GWMA to identify the source, determine acceptable levels and address other concerns. However, the report released by the Oregon Department of Human Services came as a complete surprise.

Response 17-1
The public health consultation document was prepared as a way of informing all members of the community about the potential public health impacts from exposure to perchlorate. SHINE regrets that community residents and officials did not feel adequately informed about our activities on the perchlorate issue and will make it a priority to keep affected and interested parties informed in the future.

Comment 17-2
Public scare tactics and irresponsible publication of poorly done studies that draw faulty conclusions which could potentially undermine the economic viability of Morrow

County, or any other area in Oregon where perchlorate might be found, are unnecessary and definitely unwelcome. This flawed document should be discarded immediately and a proper study with testing of perchlorate should be conducted based on firm scientific principles and adherence to longstanding rules, including peer review.

Response 17-2
SHINE would like to reiterate that this document is not intended to be a study. It is an assessment of the public health impact of exposure to perchlorate. Because of the lack of data for sources other than drinking water, SHINE made the recommendation to conduct an investigation to gather more data including information on produce and milk to better characterize exposure potential. Both produce and milk have the potential to accumulate perchlorate and are commonly consumed by sensitive populations.

18. Concern about SHINE's Health Consultation Approach
Comment 18-1
There is a belief that it requires more than a minimum of research to draw the types of conclusions presented in this document. When developing conclusions of this nature, activities should include objective review, presentation, and peer review. The report appears to be little more than a thinly veiled 'scare campaign' aimed at frightening the public into clamoring for both SHINE and Oregon DHS to access the 'DOD's Superfund' for their research program.

Response 18-1
The health consultation is solely designed to introduce the potential public health impact of exposure to perchlorate and to outline the need for additional information to assess this impact. SHINE extensively reviewed the relevant literature to prepare the public health consultation document, but this document is not intended to provide a full literature review. The report is a beginning step in the process to investigate perchlorate exposures for at-risk populations in North Morrow and Northwest Umatilla Counties. The SHINE program is not a research program; it is a public health, cooperative agreement program funded by the federal Agency for Toxic Substances and Disease Registry (ATSDR) designed to address the public health impacts from exposure to environmental contamination.

Comment 18-2
A PHC is defined by ATSDR as, "A review of available information or collection of new data to respond to a specific health question or request for information about a potential environmental hazard. Health consultations are focused on a specific exposure issue. Obviously, this PHC extended beyond the typical bounds of a PHC as defined by ATSDR. SHINE's own definition of a PHC is similar to that offered by ATSDR and is inconsistent with the PHC prepared for the North Morrow and Northwest Umatilla Perchlorate Area. Specifically, PHCs are described as, "similar to PHAs. . . , but they usually focus on one specific, site-related public health question.

Response 18-2
This health consultation was within typical bounds of a PHC to address one question of public health significance. It addressed only the ingestion pathway of perchlorate and

determined there was not enough information to assess the contribution of all sources to that pathway. The explanation of why other pathways don't contribute to exposure and why they were not addressed in this PHC is explained in the Exposure Assessment & Toxicological Evaluation section.

Comment 18-3
The specific exposure issue is defined in the PHC as (page 1), "the potential health concerns posed by the contamination of perchlorate in groundwater wells throughout northwestern Umatilla and northern Morrow Counties." Thus, the PHC should provide conclusions regarding exposure to perchlorate in groundwater wells, consistent with the stated purpose of the analysis, based on the information available, which is limited at this point to data on drinking water.

Response 18-3
Addressing the impact from groundwater not only includes evaluating drinking water but also includes food sources that may be impacted by the groundwater such as produce and milk. The recommendation for further sampling is only a first step to evaluate whether the contaminated groundwater is having an impact on food crops potentially grown with that water.

Comment 18-4
It is outside the objectives of the PHC to attempt to quantify exposure to perchlorate in produce or milk that may or may not originate from the study area. The primary conclusion of this PHC should be that exposure to perchlorate in drinking water poses "No Apparent Public Health Hazard," because drinking-water perchlorate concentrations are far less than (<15%) the U.S. Environmental Protection Agency (EPA) reference dose (RfD)-equivalent drinking-water exposure level.

It is acknowledged that some site-related perchlorate exposure may occur due to the consumption of locally- or home-grown produce, or locally produced milk, affected by perchlorate from the site. However, this expousre pathway should be evaluated separately from drinking-water exposure and described as a Potential/Indeterminate Public Health Hazard (ATSDR Category 3), which is defineds as a site "for which no conclusions about public health hazard can be made because data are lacking."[2]

Response 18-4
SHINE believes that all major potential sources of perchlorate ingestion should be considered cumulatively, because EPA's reference dose of 0.0007 mg/kg/day considers cumulative lifetime daily dose. There is a guideline for clean-up set at 24.5 ppb but this is different than a health guideline for drinking water. In other states, such as California and Massachusetts, the drinking advisories have been set much lower than 24.5 ppb (6 ppb and 2 ppb respectively). In California they used a smaller lowest effect level observed in the Greer et al. 2002 study and they considered that sensitive populations are exposed to perchlorate from other sources in addition to drinking water. In

[2] http://www.atsdr.cdc.gov/COM/hazcat.html

Massachusetts they used a safety factor of 100 instead of 10 to account for the uncertainties around perchlorate exposure and toxicity.

Comment 18-5
The PHC would be more informative to the public, as well as consistent with other PHCs prepared by ATSDR if it would distinguish the potential exposures that can be evaluated; provide a description for those exposures that can be quantified, differentiate from those that cannot be evaluated due to the lack of data; and specify that the potential risk due to the latter is indeterminate due to a lack of data.

Response 18-5
Please refer to the first four paragraphs under the Exposure Assessment and Toxicological Evaluation section. SHINE feels this explanation is sufficient.

Comment 18-6
We recommend that the PHC be completely re-written to be a drinking water consultation.

Response 18-6
This document will remain as written to address all sources of ingestion to perchlorate since that is the original question we were requested to address.

Comment 18-7
The following paragraph is clearly intended to support the need for more data. The logical implication to a reader, by the way this statement is presented, is that SHINE believes that residents of Morrow and Umatilla County are at risk, even though the actual data does not support such an implied assumption. NWFPA asked Shine if they intended to give consumers advice that is contrary to the FDA's perchlorate message. They said they did not intend to, but this paragraph clearly states their intent to assign a level of harm in advance of the science on exposure effects.

"The Government Accounting Office reported that of the 90 perchlorate exposure *studies they reviewed, none considered the fetus of a pregnant woman who is "nearly iodine-deficient" [5]. Maternal perchlorate exposure can affect the development of an unborn child or a nursing infant, but there is a lack of information as to what level of exposure could cause harm."* (A. Perchlorate Health Effects & Toxicity, pg. 6, PHC)

Response 18-7
SHINE has not concluded that there is a public health risk to residents or to sensitive populations in the North Morrow and Northwest Umatilla Perchlorate Area. This statement only acknowledges a widely documented and discussed data gap about what levels of perchlorate exposure are a concern for sensitive populations.

<u>19. Community Review of Public Health Consultation before Public Release</u>
Comment 19-1

I am concerned that no initial agency or peer review was done concerning this document prior to its release for public review.

Response 19-1
There is an interagency working group that addresses issues relating to the perchlorate contamination in Morrow and Umatilla Counties. Representatives from EPA, DEQ, DHS Drinking Water Program, ATSDR, ODA, and DHS SHINE, meet regularly to discuss perchlorate in the affected counties. Members of the interagency group reviewed the document before the public comment release. Additionally, the public comment version of a document serves as an opportunity for the public to comment on SHINE's findings and proposed activities contained in the draft document. The comments submitted during the comment period can then be incorporated into the final version of a document as appropriate.

Comment 19-2
There is a group of individuals, the LUB GWMA Advisory Committee that should have served as a peer review group for the DHS SHINE report. By working with this group the concerns could have been reduced or eliminated.

Response 19-2
SHINE collaborated with the federal, state, and local health and environmental agencies during the initial investigation, and made contacts with migrant health clinics and area residents to learn about and address the community health concerns around this issue. The working group mentioned above has a variety of representatives collaborating on this issue. The working group served as reviewers for the development of the public health consultation document, as well as the protocol for the exposure investigation.

Comment 19-3
To better facilitate communication and sharing of information we request to be included in any future DHS SHINE distribution of information. This would include any analysis of sampling, reports or modeling.

Response 19-3
Your request has been noted and we have added you to our list of stakeholders.

Comment 19-4
We request information concerning SHINE's mission and objectives concerning this particular project.

Response 19-4
SHINE's mission is to determine the public health impact of human exposure to environmental contaminants for communities throughout Oregon and ultimately to reduce exposures to hazardous substances and mitigate potential adverse human health effects from such exposures. The SHINE goals that support this mission in Morrow and Umatilla Counties and their specific objectives are:

1. Respond to requests to conduct public health consultations and exposure investigation activities.
    - Evaluate the health risks associated with consuming perchlorate from drinking water, and potentially other sources, for the special populations that live in the communities of Morrow and Umatilla Counties.
    - Fill an important data gap by conducting an exposure investigation to better understand components of exposure for sensitive populations to sources of perchlorate that could lead to an increased risk of adverse health effects. The scope of this investigation is not intended to provide a complete characterization of health risks; rather it is to help SHINE better evaluate exposure to perchlorate from a combination of potential sources.
2. Initiate and support health promotion and community involvement activities by educating sensitive populations on ways to reduce the effects of exposure
    - Develop and implement site-specific community involvement and health education action plans
    - Build the capacity of community-based organizations, community groups, and local health departments to carry out site-specific health education activities
3. Strengthen external collaboration
    - Collaborate with local, state and federal agencies, organizations and residents living in the affected areas on SHINE program activities
    - Inform interested parties about SHINE's sites-specific capabilities and limitations

Comment 19-5
Morrow County should have real concerns and insist on having primary involvement in the public health education process, given the real impacts such a consultation and public notice would have in relation to the county's economy, especially in the areas of agriculture and tourism. In essence, the proposed activities appear aggressive, and not adequately funded to reach such conclusions in the time proposed by SHINE.

Response 19-5
SHINE agrees that it would be useful to work in collaboration with local agencies and community leaders. The proposed activities for sampling in this health consultation are a first step in looking at other sources that could be contributing to the perchlorate exposure for sensitive populations in the area.

Comment 19-6
We make the following recommendations for the county's involvement as the PRIMARY stakeholder in this process. First, given the fact that the EPA has not established a maximum contaminant level (MCL) for perchlorate, the long term exposure effects of perchlorate are not known, and that the local findings do not for the most part exceed the interim long term exposure guidance of 24.5 ppb, and public notification at this time in not justified and could be extremely damaging to the economy of the county.

Response 19-6
SHINE's next steps and the approach to health education in the community are still in development and dependent on the exposure investigation results. We will involve the input from local health departments, programs that serve the sensitive populations, and community leaders.

20. SHINE Exposure Investigation

Comment 20-1
I commend your group for including perchlorate concentrations in food sources in your assessment.

Response 20-1
SHINE appreciates your comment. We are committed to performing an evaluation of exposure to perchlorate and the implications for potential public health impacts from exposure in Morrow and Umatilla Counties.

Comment 20-2
I hope you will include Prickly Pear Cactus in your sampling based on the study, *Plants as bioaccumulators of* perchlorate, as prickly pear cactus plantations provide fruit and juice for a large number of food beverage and nutrition products in the US.

Response 20-2
The recommendation to test prickly pear cactus is noted, as it has been shown to concentrate perchlorate at concentrations over 1000 ppb. However, at this time, SHINE is restricted to conducting limited sampling of produce and milk to determine if they are important sources of exposure for sensitive populations, which will not include prickly pear cactus. This additional data will allow SHINE to better characterize cumulative exposure, inform health education activities needed in the area, and to help determine whether further investigation is needed.

Comment 20-3
There is agreement with the need for assessing aggregate exposure to perchlorate, and considering sources other than drinking water. I am unclear, however, as to the rationale behind proposing that these risks be assessed specifically upon data on perchlorate in food items grown in the area under investigation. If residents were exclusively consuming food items that are grown in the North Morrow and Northwest Umatilla Perchlorate Area, I could understand this rationale. However, it would seem to me that many individuals obtain their food from retail supermarkets or other sources, where the origin of the food may be from areas far away from the North Morrow area.

Response 20-3
SHINE is in agreement with this statement. The approach of the exposure investigation is to test both produce grown in Morrow and Umatilla areas that could be impacted by contaminated irrigation water as well as to test produce from areas outside the region. Testing food from elsewhere was intended to provide a sense for possible ranges of concentrations for food available to the residents in the area, not just grown in the area.

The selected produce items are ones that at-risk, sensitive populations are likely to consume, as well as those that are likely to accumulate perchlorate through irrigation with contaminated water. The testing is not intended to be a full characterization of the food items a sensitive individual might consume. Instead, it is designed to provide more information about whether there is a potential risk of exposure to perchlorate for sensitive individuals in the study area and to help determine whether further investigation would be warranted.

Comment 20-4
To date there has been no information presented by SHINE about adverse effects being experienced or observed in the local medical community (especially in maternity and family care cases). I have the impression that SHINE is not convinced either that a health hazard exists but they can't rule potential health risks posed by exposure to perchlorate. It would be tragic if even one baby, toddler, or family suffered permanent (or even temporary) damages of the type that perchlorate apparently can cause. So I feel that you need to complete your research until you can issue a "clean bill of health." It seems to me that this is SHINE's job, and that is what is needed for you to discharge from your duties.

I suspect that Oregon State Public Health's conclusion will be "no health hazard." But, unless you can say that now, in good conscience, you need to finish the job. People can understand that if the symptomatic conditions appear, they won't understand why you didn't finish the investigation. We are aware that you feel it is important not to raise any undue premature alarms.

Response 20-4
SHINE appreciates your comments. We believe it is essential to investigate exposure to environmental contaminants and try to rule out the possibility of adverse public health impacts before providing messages to the community.

<u>21. Produce Sampling</u>
Comment 21-1
When evaluating exposure to perchlorate, food, dairy, and drinking water commodities produced outside of the identified area should be sampled.

Response 21-1
This a valid point and produce and milk grown locally as well as from outside of the area have been collected and are being analyzed.

Comment 21-2
While we agree it is important to understand what the perchlorate levels of locally grown crops will be, consumer exposure from foods is normally from foods from many sources around the country and world. I don't see how data only on locally grown corn, tomatoes, and melons can give a good picture of perchlorate exposure, particularly when perchlorate is found in other foods, such as leafy vegetables. I would think sampling a wider variety of foods, grown locally and from other areas, that are being consumed by the susceptible population in this area is more appropriate.

Response 21-2
Given the available resources, produce samples were collected for both items grown locally and from outside the area depending on availability at the time of sampling. Additional information about the reasoning and approach for the follow-up sampling of locally available, not just locally grown, produce is outside the scope of this document. More detail about the sampling will be discussed in a follow-up document summarizing the exposure investigation efforts and results.

Comment 21-3
We believe that SHINE is unable to evaluate risk to residents in North Morrow County, or anywhere in Oregon for that matter, until a total diet study has been completed by the FDA and the federal agency finalizes its risk assessment model. That data is currently being developed by FDA. The FDA is the expert agency on this issue and is conducting a scientifically valid and responsible risk assessment on perchlorate in the food supply. When their assessment is complete, the FDA and Oregon Department of Agriculture will have authority to enforce regulations or guidelines, if established, in food. SHINE has no singular role in this.

We challenge SHINE's statement, *"When more data are available, SHINE will evaluate the human health risk on the side of caution in order to protect sensitive populations."* The Food and Drug Administration is considered the premier science-based food safety agency in the world today. This agency has access to the world's foremost experts in the field. The FDA has conducted market basket assessments for decades and has the expertise and resources to do the perchlorate project.

Comment 21-4
We also are concerned that the recommendations in the PHC for produce testing are not well founded and go beyond what is appropriate at the state level when in fact the Food and Drug Administration is conducting comprehensive studies, with adequate budgets and acknowledged perchlorate and food testing experts. While we agree with the critical importance of understanding sources of perchlorate in food, we strongly disagree that SHINE should undertake a study of the local food supply at this point because the FDA is actively studying this issue (as discussed above).

Response 21-3 & 21-4
Market basket research conducted by the FDA is very different than site-specific evaluations of the public health impacts from contaminants present in a variety of media at that site. All pathways of exposure must be considered when evaluating the impact of contaminants at each unique site. This is not accomplished by sampling through a market basket survey that only considers food items. SHINE and ATSDR are appropriate health agencies for evaluating site-specific impacts from contaminants present in a variety of media.

Comment 21-5
SHINE must operate within the national context of perchlorate study. The PHC shows that SHINE is uninformed about the current national efforts to assess the human health impacts in the food supply. In addition, SHINE is not qualified to participate in this work

due to their lack of understanding about the food supply, how it is produced and distributed to the consumer.

Response 21-5
SHINE is aware of the national perchlorate efforts. This health consultation was reviewed by several federal agencies including the FDA. SHINE and ATSDR work on a site-by-site basis and while considering the national context of perchlorate is a priority for us, our primary responsibility is to address public health impacts from exposure to perchlorate in the North Morrow and Northwest Umatilla Perchlorate Area.

Comment 21-6
The presence of anions other than perchlorate, including nitrate, can interfere with analysis for perchlorate in food. Nitrate-based fertilizers are likely to be used in fields and the area is already under investigation for nitrate contamination (as noted on page 2 of the PHC); therefore, it is imperative that any sampling of local produce and milk be performed using analytical methods that control for potential anion interference. Both FDA and EPA have developed methods that control for anion interference. The FDA method is described in a very recent publication (Krynitski et al. 2006), which is available from FDA, and should be followed for any future investigations.

Response 21-6
The comment has been noted; however, this is outside the scope of a public health consultation.

Comment 21-7
SHINE has not demonstrated that at the completion of this investigation, that they can address these key questions:

1) Can an exposed population be identified?
2) Does a data gap exist that effects the ability to interpret whether a public health issues exists?
3) Can the data analysis identify point sources of contamination?
4) Can the data gaps be addressed by an exposure investigation?
5) How would the current information result in effective public health decision making?

Response 21-7
The questions raised in this comment will be addressed in a follow-up document that summarizes exposure investigation efforts and results.

<u>22. Background Perchlorate Concentrations</u>
Comment 22-1
The PHC recommends that the background exposure to perchlorate in food be combined with exposure to perchlorate from water sources to estimate a cumulative exposure that should be compared to EPA's reference dose. However, it should be noted that EPA's RfD is based on an intentional human dosing study (Greer et al, 2002), wherein individuals were administered perchlorate in drinking water and also consumed a normal

diet. Because perchlorate in food from background sources is now recognized to be widespread, the participants in the Greer study were consuming perchlorate in their diet in addition to the perchlorate administered in water. Thus, background perchlorate in food has already been taken into account and is intrinsically considered in the RfD. For this reason, it should not be necessary to add the exposure via background sources in food to the exposures via drinking water. Only in the case where food grown and consumed locally contains more perchlorate than background food would exposure via this pathway be of potential health significance relative to this PHC and this site.

Response 22-1
SHINE does not refer to the perchlorate levels in food items considered in the cumulative exposure estimate as background levels. There is not enough information at this time to determine what perchlorate concentrations in food are considered to be background. Additionally, the Greer et al. study included a small number of adult participants and their potential exposure to perchlorate from food items can't be assumed to be background and generalized to a different population in a different part of the country. This is especially true for a generalization made to infants and children who have very different consumption rates than adults and consume more food on a per mass basis than adults.

Comment 22-2
Any potential exposure that may be present in Morrow and Umatilla Counties would also exist in Multnomah, Washington, Marion, Jackson or any of the 36 counties in the State of Oregon. In fact, because most food is sold interstate, exposure is not contained within the borders of this state and could be expected in Washington State, as well. NWFPA believes that SHINE does not understand the food distribution system in the United States if they believe that milk and produce produced in Morrow and Umatilla County is necessarily sold in those counties or that local milk and produce are the only products available in these counties. This paragraph incorrectly leads to conclusions that are not supported by facts and illustrates SHINE's lack of capacity to study the food supply. SHINE should confine its study to its assigned task of reviewing the data on water and leaving the food component to the experts in the field.

Response 22-2
SHINE did not state that food grown in Morrow and Umatilla Counties is only consumed in those counties nor was there reference that local milk and produce are the only products available in those counties. SHINE recommended that milk and produce - available (not just local) to consumers that live in the area be sampled. These are the items most known to uptake perchlorate and to be consumed by sensitive populations. This will be addressed in more detail in the follow-up document that will summarize the sampling efforts and results. In past consultations, SHINE and ATSDR have evaluated contaminants in a variety of media that could potentially lead to exposure for residents at affected sites.

Comment 22-3
SHINE's evaluation of non-site-related background exposures is outside the constructs of both a PHC and a PHA.

The PHC recommends sampling milk and produce from the North Morrow area—regardless of whether it is produced locally, and potentially affected by site-related perchlorate, or not. We believe it is more important to develop an understanding of the risks perchlorate may pose in food generally in the US, and an attempt to characterization of the potential hazard in one location, without a comprehensive description of "background," is not possible and will be misleading.

Response 22-3
The North Morrow area is considered a site by SHINE, and we are looking at site-related exposures. ATSDR and SHINE often evaluate the impact of environmental contamination in areas referred to as a site but may not be defined as a hazardous waste site. The purpose of this health consultation was to evaluate sensitive population's exposure to perchlorate regardless of background within the North Morrow and Northwest Umatilla Perchlorate Area.

Comment 22-4
At least 97% of commercially available milk samples collected and analyzed by FDA in 2004 from 13 states across the country contained perchlorate. If sampling of any one location (North Morrow or anywhere else in the US) yielded these results without the background context of what exists across the US, an alarming and inappropriate conclusion could be immediately reached that there is a serious problem in that one area, and that steps to address the public health concern must be undertaken. However, in this example case the public would be unnecessarily alarmed and no site-specific action would benefit the community.

Response 22-4
This comment has been noted.

23. Perchlorate Bioconcentration
Comment 23-1
Based on the information presented in the current PHC regarding perchlorate in irrigation water (page 4, Table 1, Summary of groundwater sampling results), one would not expect locally grown produce to be highly contaminated. The table notes that the mean concentration of perchlorate in irrigation waster is only 2.3 ppb, with a maximum of 4.23 ppb. Rather than sampling locally available produce, a more appropriate first step would be to conduct a screening analysis to estimate exposures via locally grown produce. Such an analysis would use available bioconcentration factors for the produce grown locally (or that for similar produce), ingestion rate information for locally-grown produce and concentrations of perchlorate in irrigation water. This assessment might provide sufficient information to determine whether perchlorate from groundwater used as irrigation water is a potential health concern and warrants further study.

Response 23-1
SHINE uses site-specific information to draw conclusions about exposure rather than estimating concentrations in media from general, non site-specific data. The approach to

estimating cumulative exposure will be discussed in the follow-up exposure investigation document.

Comment 23-2
The concentration of perchlorate in irrigation water or laboratory/greenhouse conditions that generated these concentrations in produced or concentration factors should be presented to put into context the concentrations measured in irrigation water in the study area.

Response 23-2
This is outside the scope of this health consultation.

24. Testing of Breast Milk for Perchlorate
Comment 24-1
I hope your team will consider tests of human breast milk from exposed women.

Response 24-1
Although biomonitoring (testing of blood, urine or breast milk) may provide us with a measurement of potential exposure to perchlorate, SHINE is not planning to conduct biomonitoring at this time. Moreover, biomonitoring would not contribute to the development of health education messages on steps vulnerable people can take to reduce or prevent exposure, because it will not define which sources contribute to an individual's perchlorate burden.

25. Perchlorate Biomonitoring
Comment 25-1
In light of the recent CDC testing by Dr. Ben Blount, which demonstrated high levels of perchlorate in human urine in populations nationwide without perchlorate tainted drinking water, the low level detected in some of your wells should not be discounted for sensitive people.

Response 25-1
Thank you for your comment and your reference to the work performed by Dr. Blount and his team. SHINE's exposure investigation considers cumulative exposure to perchlorate from several sources, including produce, milk and drinking water. The work by Dr. Blount and the National Center for Environmental Health is important in understanding internal doses of perchlorate throughout the United States. However, at this time, it is difficult to conclude that the levels detected in urine of individuals tested to date are high until more comprehensive sampling throughout the U.S. has been conducted. This work is currently being conducted by Dr. Blount and his colleagues through the CDC National Health and Nutrition Examination Survey (NHANES).

26. Concerns about Refusal to Retest Groundwater for Perchlorate
Comment 26-1
Perchlorate levels in an aquifer may vary widely with time depending on rainfall and other factors. Farmers, property owners, and renters have been known to refuse retesting

their wells for perchlorate after a low level was detected, for fear of devaluing their property.

Response 26-1
This is a valid community concern. Environmental contamination has been shown to negatively impact property value. This is a primary reason SHINE's activities in Morrow and Umatilla Counties follow a well established health assessment process, and consider comments and recommendations by other state and federal agencies.

27. FDA Messages
Comment 27-1
The PHC should strive for similar simple answers as those developed by the FDA to responds to obvious questions that the public will have (http://www.cfsan.fda.gov/~dms/clo4qa.html).

Response 27-1
SHINE is committed to providing simple and straightforward answers to difficult questions in every community where we are involved. SHINE did not have enough information to answer questions about the exposure for sensitive populations in the North Morrow and Northwest Umatilla Perchlorate Area at the time the draft version of this PHC was released which is the reason that further sampling was recommended.

28. Therapeutic Uses of Perchlorate
Comment 28-1
The PHC is an activist document that attempts to flaunt sound science. The study of perchlorate in the environment and the public health impacts of that have been under study on a national level for several years. The PHC contains a number of statements that attempt to discredit the NRC report and other mainstream scientific organizations on the accepted science of perchlorate and human health impacts. Here are some examples:

1. "In the 1950's and 1960's, large doses (400-1000 mg./day) of perchlorate salts were used to treat hyperthyroidism …, until severe health problems related to this treatment were identified, including agranulocytosis and aplastic anemia leading to death (Appendix A) [5]." Background, pg.2

The statement above, while not false, is clearly intended to lead the reader to draw a conclusion that is not supported by the NRC study.

Here is what the NRC study actually says.
"Treatment of hyperthyroid patients with potassium perchlorate typically caused few side effects, although some patients had nausea, vomiting, rashes, fever, lymph node enlargement, or kidney dysfunction. The frequency of side effects was dose-dependent. Thirteen patients who had taken 400-1,000 mg of potassium perchlorate per day for 2-20 weeks developed aplastic anemia (cessation of production of red blood cells) or agranulocytosis (cessation of production of white blood cells), and seven of them died. Because of those events and the development of better antithyroid drugs, the use of

perchlorate to treat hyperthyroid patients largely ceased by the late 1960s. "A study of long-term administration of potassium perchlorate reported in 1984, however, provides useful data. Eighteen people who had hyperthyroidism caused by Graves disease were treated initially with 900 mg per day. The dose of potassium perchlorate was reduced over a 12-month period to an average of 93 mg per day as thyroid function returned to normal. The patients then received 40-120 mg per day for 12 months. During that period, all the patients had normal serum T4 and T3 concentrations, and most patients no longer had high serum concentrations of TSH-receptor stimulating antibodies, which are the cause of hyperthyroidism in patients who have Graves disease. Absence of the antibodies indicated that the patients no longer had Graves disease. Thus, one could consider treatment in the latter 12 months to be equivalent to administration of perchlorate to healthy people. Therefore, the results provide evidence that moderately high doses of perchlorate given chronically to people with a history of hyperthyroidism do not cause hypothyroidism.

"Overall, there have been no reports of the appearance of new thyroid disorders, thyroid nodules, or thyroid carcinomas in patients treated with potassium perchlorate for hyperthyroidism." (NRC – Heath Implications of Perchlorate Ingestion. Executive Summary, 2005, pg. 3, 4)

The PHC would have you believe perchlorate treatment was accompanied by "severe health problems" when the NRC committee actually concludes that not only is perchlorate treatment dose-dependent, but acute high levels have no long term effects. The PHC takes the observations of the NRC committee out of context, presumably to support a pre-determined argument.

Response 28-1
A full review of the historical use of perchlorate is outside the bounds of this health consultation. The reference to the use of high doses of perchlorate to treat Graves Disease was only included in the report to acknowledge that it had historical therapeutic use and to show that adverse affects were observed following administration of those high doses. There is no predetermined argument made in the PHC. It is a discussion of the relevant science for perchlorate and evaluation of information available for the health assessment process.

29. Water Treatment Systems
Comment 29-1
Due to the existing nitrate issue in the LUBGWMA, several individuals with private wells have installed reverse osmosis units.

Response 29-1
Reverse osmosis units and anion exchange resins are effective in removing perchlorate from groundwater in addition to treating nitrate. The use of a treatment system is highly recommended for residents who use groundwater wells in the LUBGWMA (north Morrow and northwestern Umatilla Counties as outlined in Figure 1). It is important to

note that installation and maintenance of these units is costly and may not be feasible for some households that have private groundwater wells contaminated with perchlorate.

More information about treating water for perchlorate contamination can be found at the following link:
http://www.clu-in.org/contaminantfocus/default.focus/sec/perchlorate/cat/Treatment_Technologies/

30. Economic Impact of Investigation

Comment 30-1

If the sampling results adversely impact the economy and job loss occurs, this could pose a greater health risk than the one that exists for perchlorate.

Response 30-1

Thank you for making this point. This is an important consideration that SHINE agrees with. The messages based on the outcome of the limited sampling were developed carefully with potential adverse outcome in mind.

Comment 30-2

The area where the future raceway is intended to be situated in the west Boardman area did not have wells noted in the study, however it is in the boundaries of the perchlorate study area. This places a gray cloud over future development of that intended area of real estate.

Response 30-2

The extent of the sampling site boundary is defined by the boundaries of the Lower Umatilla Basin Groundwater Management Area (LUBGWMA). Questions or comments about specific groundwater sampling locations falls outside of SHINE's work at this site and can be addressed by DEQ.

APPENDIX B. ATSDR glossary of environmental health terms.

The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency with headquarters in Atlanta, Georgia, and 10 regional offices in the United States. ATSDR serves the public by using the best science to take responsive public health actions and provides trusted health information to prevent harmful exposures and diseases related to toxic substances. ATSDR is not a regulatory agency, unlike the U.S. Environmental Protection Agency (EPA), which is the federal agency that develops and enforces environmental laws to protect the environment and human health.

This glossary defines words used by ATSDR in communications with the public. It is not a complete dictionary of environmental health terms. If you have questions or comments, call ATSDR's toll-free telephone number, 1-888-42-ATSDR (1-888-422-8737).

Absorption
For a person or animal, absorption is the process through which a substance enters the body through the eyes, skin, stomach, intestines, or lungs.

Acute
Occurring over a short time [compare with **chronic**].

Acute exposure
Contact with a substance that occurs once or for only a short time (up to 14 days) [compare with **intermediate duration exposure** and **chronic exposure]**.

Adverse health effect
A change in body function or cell structure that might lead to disease or health problems.

Agranulocytosis
An acute disease marked by high fever and a sharp drop in circulating granular white blood cells.

Aplastic Anemia
A form of anemia in which the capacity of the bone marrow to generate red blood cells is defective and red blood cell production ceases.

Background level
An average or expected amount of a substance or radioactive material in a specific environment, or typical amounts of substances that occur naturally in an environment.

Biologic uptake
The transfer of substances from the environment to plants, animals, and humans.

Cancer
Any one of a group of diseases that occurs when cells in the body become abnormal and grow or multiply out of control.

Cancer risk
A theoretical risk for developing cancer if exposed to a substance every day for 70 years (a lifetime exposure). The true risk might be lower.

Carcinogen
A substance that causes cancer.

CAS registry number
A unique number assigned to a substance or mixture by the American Chemical Society Abstracts Service.

CERCLA [see **Comprehensive Environmental Response, Compensation, and Liability Act of 1980**]

Chronic
Occurring over a long time (more than 1 year) [compare with **acute**].

Chronic exposure
Contact with a substance that occurs over a long time (more than 1 year) [compare with **acute exposure** and **intermediate duration exposure**].

Completed exposure pathway [see **exposure pathway**].

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)
CERCLA, also known as **Superfund**, is the federal law that concerns the removal or cleanup of hazardous substances in the environment and at hazardous waste sites. ATSDR, which was created by CERCLA, is responsible for assessing health issues and supporting public health activities related to hazardous waste sites or other environmental releases of hazardous substances.

Concentration
The amount of a substance present in a certain amount of soil, water, air, food, blood, hair, urine, breath, or any other media.

Contaminant
A substance that is either present in an environment where it does not belong or is present at levels that might cause harmful (adverse) health effects.

Dermal
Referring to the skin. For example, dermal absorption means passing through the skin.

Dermal contact
Contact with (touching) the skin [see **route of exposure**].

Detection limit
The lowest concentration of a chemical that can reliably be distinguished from a zero concentration.

Disease prevention
Measures used to prevent a disease or reduce its severity.

Disease registry
A system of ongoing registration of all cases of a particular disease or health condition in a defined population.

DOD
United States Department of Defense.

Dose (for chemicals that are not radioactive)
The amount of a substance to which a person is exposed over some time period. Dose is a measurement of exposure. Dose is often expressed as milligram (amount) per kilogram (a measure of body weight) per day (a measure of time) when people eat or drink contaminated water, food, or soil. In general, the greater the dose, the greater the likelihood of an effect. An exposure dose is how much of a substance is encountered in the environment. An absorbed dose is the amount of a substance that actually got into the body through the eyes, skin, stomach, intestines, or lungs.

Dose-response relationship
The relationship between the amount of exposure [**dose**] to a substance and the resulting changes in body function or health (response).

Environmental media
Soil, water, air, **biota** (plants and animals), or any other parts of the environment that can contain contaminants.

Environmental media and transport mechanism
Environmental media include water, air, soil, and **biota** (plants and animals). Transport mechanisms move contaminants from the source to points where human exposure can occur. The **environmental media and transport mechanism** is the second part of an **exposure pathway**.

EPA
United States Environmental Protection Agency.

Epidemiologic surveillance
The ongoing, systematic collection, analysis, and interpretation of health data. This activity also involves timely dissemination of the data and use for public health programs.

Epidemiology
The study of the distribution and determinants of disease or health status in a population; the study of the occurrence and causes of health effects in humans.

Exposure
Contact with a substance by swallowing, breathing, or touching the skin or eyes. Exposure may be short-term [**acute exposure**], of intermediate duration, or long-term [**chronic exposure**].

Exposure assessment
The process of finding out how people come into contact with a hazardous substance, how often and for how long they are in contact with the substance, and how much of the substance they are in contact with.

Exposure-dose reconstruction
A method of estimating the amount of people's past exposure to hazardous substances. Computer and approximation methods are used when past information is limited, not available, or missing.

Exposure investigation
The collection and analysis of site-specific information and biologic tests (when appropriate) to determine whether people have been exposed to hazardous substances.

Exposure pathway
The route a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it. An exposure pathway has five parts: a **source of contamination** (such as an abandoned business); an **environmental media and transport mechanism** (such as movement through groundwater); a **point of exposure** (such as a private well); a **route of exposure** (eating, drinking, breathing, or touching); and a **receptor population** (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a **completed exposure pathway**.

Groundwater
Water beneath the earth's surface in the spaces between soil particles and between rock surfaces [compare with **surface water**].

Hazard
A source of potential harm from past, current, or future exposures.

Hazardous waste
Potentially harmful substances that have been released or discarded into the environment.

Health consultation
A review of available information or collection of new data to respond to a specific health question or request for information about a potential environmental hazard. Health consultations are focused on a specific exposure issue. Health consultations are therefore more limited than a public health assessment, which reviews the exposure potential of each pathway and chemical [compare with **public health assessment**].

Health education
Programs designed with a community to help it know about health risks and how to reduce these risks.

Health investigation
The collection and evaluation of information about the health of community residents. This information is used to describe or count the occurrence of a disease, symptom, or clinical measure and to estimate the possible association between the occurrence and exposure to hazardous substances.

Health promotion
The process of enabling people to increase control over, and to improve, their health.

Indeterminate public health hazard
The category used in ATSDR's public health assessment documents when a professional judgment about the level of health hazard cannot be made because information critical to such a decision is lacking.

Incidence
The number of new cases of disease in a defined population over a specific time period [contrast with **prevalence**].

Ingestion
The act of swallowing something through eating, drinking, or mouthing objects. A hazardous substance can enter the body this way [see **route of exposure**].

Inhalation
The act of breathing. A hazardous substance can enter the body this way [see **route of exposure**].

Lowest-observed-adverse-effect level (LOAEL)
The lowest tested dose of a substance that has been reported to cause harmful (adverse) health effects in people or animals.

mg/kg
Milligram per kilogram.

mg/cm^2
Milligram per square centimeter (of a surface).

mg/m^3
Milligram per cubic meter; a measure of the concentration of a chemical in a known volume (a cubic meter) of air, soil, or water.

Migration
Moving from one location to another.

No apparent public health hazard
A category used in ATSDR's public health assessments for sites where human exposure to contaminated media might be occurring, might have occurred in the past, or might occur in the future, but where the exposure is not expected to cause any harmful health effects.

No-observed-adverse-effect level (NOAEL)
The highest tested dose of a substance that has been reported to have no harmful (adverse) health effects on people or animals.

No public health hazard
A category used in ATSDR's public health assessment documents for sites where people have never and will never come into contact with harmful amounts of site-related substances.

Oxidation
The combination of a substance with oxygen or a reaction in which the atoms in an element lose electrons and the valence of the element is correspondingly increased.

Plume
A volume of a substance that moves from its source to places farther away from the source. Plumes can be described by the volume of air or water they occupy and the direction they move. For example, a plume can be a column of smoke from a chimney or a substance moving with groundwater.

Point of exposure
The place where someone can come into contact with a substance present in the environment [see **exposure pathway**].

Population
A group or number of people living within a specified area or sharing similar characteristics (such as occupation or age).

ppb
Parts per billion.

ppm
Parts per million.

Prevalence
The number of existing disease cases in a defined population during a specific period [contrast with **incidence**].

Prevalence survey
The measure of the current level of disease(s) or symptoms and exposures through a questionnaire that collects self-reported information from a defined population.

Prevention
Actions that reduce exposure or other risks, keep people from getting sick, or keep disease from getting worse.

Public comment period
An opportunity for the public to comment on agency findings or proposed activities contained in draft reports or documents. The public comment period is a limited time period during which comments will be accepted.

Public availability session
An informal, drop-by meeting at which community members can meet one-on-one with ATSDR staff members to discuss health and site-related concerns.

Public health action
A list of steps to protect public health.

Public health advisory
A statement made by ATSDR to EPA or a state regulatory agency that a release of hazardous substances poses an immediate threat to human health. The advisory includes recommended measures to reduce exposure and reduce the threat to human health.

Public health assessment (PHA)
An ATSDR document that examines hazardous substances, health outcomes, and community concerns at a hazardous waste site to determine whether people could be harmed from coming into contact with those substances. The PHA also lists actions that need to be taken to protect public health [compare with **health consultation**].

Public health hazard
A category used in ATSDR's public health assessments for sites that pose a public health hazard because of long-term exposures (greater than 1 year) to sufficiently high levels of hazardous substances or **radionuclides** that could result in harmful health effects.

Public health hazard categories
Public health hazard categories are statements about whether people could be harmed by conditions present at the site in the past, present, or future. One or more hazard categories might be appropriate for each site. The five public health hazard categories are **no public health hazard**, **no apparent public health hazard**, **indeterminate public health hazard**, **public health hazard**, and **urgent public health hazard**.

Public health statement
The first chapter of an ATSDR **toxicological profile**. The public health statement is a summary written in words that are easy to understand. The public health statement explains how people might be exposed to a specific substance and describes the known health effects of that substance.

Public meeting
A public forum with community members for communication about a site.

Reference dose (RfD)
An EPA estimate, with uncertainty or safety factors built in, of the daily lifetime dose of a substance that is unlikely to cause harm in humans.

Registry
A systematic collection of information on persons exposed to a specific substance or having specific diseases [see **exposure registry** and **disease registry**].

RFA
RCRA Facility Assessment. An assessment required by RCRA to identify potential and actual releases of hazardous chemicals.

RfD
See **reference dose**.

Risk
The probability that something will cause injury or harm.

Risk reduction
Actions that can decrease the likelihood that individuals, groups, or communities will experience disease or other health conditions.

Risk communication
The exchange of information to increase understanding of health risks.

Route of exposure
The way people come into contact with a hazardous substance. Three routes of exposure are breathing [**inhalation**], eating or drinking [**ingestion**], or contact with the skin [**dermal contact**].

Safety factor [see **uncertainty factor]**

Sample
A portion or piece of a whole. A selected subset of a population or subset of whatever is being studied. For example, in a study of people the sample is a number of people chosen from a larger population [see **population**]. An environmental sample (for example, a

small amount of soil or water) might be collected to measure contamination in the environment at a specific location.

Source of contamination
The place where a hazardous substance comes from, such as a landfill, waste pond, incinerator, storage tank, or drum. A source of contamination is the first part of an **exposure pathway**.

Special populations
People who might be more sensitive or susceptible to exposure to hazardous substances because of factors such as age, occupation, sex, or behaviors (for example, cigarette smoking). Children, pregnant women, and older people are often considered special populations.

Substance
A chemical.

Superfund Amendments and Reauthorization Act (SARA)
In 1986, SARA amended CERCLA and expanded the health-related responsibilities of ATSDR. CERCLA and SARA direct ATSDR to look into the health effects from substance exposures at hazardous waste sites and to perform activities including health education, health studies, surveillance, health consultations, and toxicological profiles.

Surface water
Water on the surface of the earth, such as in lakes, rivers, streams, ponds, and springs [compare with **groundwater**].

Toxic agent
Chemical or physical (for example, radiation, heat, cold, microwaves) agents that, under certain circumstances of exposure, can cause harmful effects to living organisms.

Toxicology
The study of the harmful effects of substances on humans or animals.

Tumor
An abnormal mass of tissue that results from excessive cell division that is uncontrolled and progressive. Tumors perform no useful body function. Tumors can be either benign (not cancer) or malignant (cancer).

Uncertainty factor
Mathematical adjustments for reasons of safety when knowledge is incomplete. For example, factors used in the calculation of doses that are not harmful (adverse) to people. These factors are applied to the lowest-observed-adverse-effect-level (LOAEL) or the no-observed-adverse-effect-level (NOAEL) to derive a minimal risk level (MRL). Uncertainty factors are used to account for variations in people's sensitivity, for differences between animals and humans, and for differences between a LOAEL and a

NOAEL. Scientists use uncertainty factors when they have some, but not all, the information from animal or human studies to decide whether an exposure will cause harm to people [also sometimes called a **safety factor**].

Urgent public health hazard
A category used in ATSDR's public health assessments for sites where short-term exposures (less than 1 year) to hazardous substances or conditions could result in harmful health effects that require rapid intervention.

Volatile organic compounds (VOCs)
Organic compounds that evaporate readily into the air. VOCs include substances such as benzene, toluene, methylene chloride, and methyl chloroform.

Other Glossaries and Dictionaries
Environmental Protection Agency - http://www.epa.gov/OCEPAterms/
National Center for Environmental Health (CDC) - http://www.cdc.gov/nceh/dls/report/glossary.htm
National Library of Medicine (NIH) - http://www.nlm.nih.gov/medlineplus/mplusdictionary.html