Health Consultation

Exposure Investigation Report

NORTH MORROW PERCHLORATE AREA

NORTH MORROW & UMATILLA COUNTIES, OREGON

APRIL 18, 2007

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

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HEALTH CONSULTATION

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Prepared by:

Oregon Public Health Division
Superfund Health Investigation and Education Program
Under Cooperative Agreement with the
Agency for Toxic Substances and Disease Registry

Table of Contents

Executive Summary

The purpose of this exposure investigation was to assess whether a more in-depth study was warranted to evaluate the potential public health impact from combined perchlorate exposure for sensitive subpopulations living in the Lower Umatilla Basin in northeastern Oregon, an area referred to as the North Morrow Perchlorate Area in this report. It was designed to address a data gap identified in the North Morrow Perchlorate Area Health Consultation released in December 2005 by the Oregon Superfund Health Investigation and Education (SHINE) Program. The health consultation concluded that, although perchlorate concentrations in drinking water in the area have not been detected at levels of concern, there was not enough information about exposure to non-drinking water sources, such as produce, in combination with exposure to perchlorate in drinking water. Data for other exposure routes was needed to evaluate the combined perchlorate exposure for sensitive populations in the area.

To help estimate combined perchlorate exposure in the North Morrow Perchlorate Area for sensitive subpopulations, SHINE, in cooperation with the Agency for Toxic Substances and Disease Registry (ATSDR), sampled locally available foods and dairy milk. These sampling data, along with drinking water data from the area collected between 2003 and 2005, were used to calculate combined perchlorate exposure estimates. Exposure estimates were compared with health protective guidelines to determine if there were estimated doses that exceeded these guidelines for the subpopulations assumed to be sensitive to potential effects from perchlorate - young children (less than six years old) and females of reproductive age (15 to 44 years old). These two populations are referred to as sensitive subpopulations. Females of reproductive age were used as surrogates for evaluating fetal risk posed by perchlorate exposure. Fetuses and preterm newborns are the subpopulations considered most sensitive to perchlorate exposure while infants and young children are also sensitive subpopulations.

Foods sampled included produce (watermelons, tomatoes, and corn) grown within the area of interest, locally-available produce that was grown outside the area of interest, and regionally-produced milk. Most of these commodities were purchased from farmers' stands, local grocery stores, and other commercial outlets in the North Morrow Perchlorate Area. In almost all cases, the levels of perchlorate found in the produce and milk sampled during this investigation were comparable to levels found in similar commodities from other parts of the United States. Drinking water data collected in the North Morrow Perchlorate Area from 2003-2005 were combined with milk and produce sampling results to calculate combined perchlorate exposure estimates. The exposure estimates for young children and females of reproductive age were all below the Minimal Risk Level (MRL) with one exception: the estimate for a maximally exposed one-year-old child slightly exceeded the MRL. This estimate was for a scenario that assumed a one-year-old would be exposed to the maximum perchlorate concentrations found in all drinking water and food tested from the area, which is not a likely scenario and is a highly protective estimate. Additionally the MRL is a health guideline designed to also be protective of health, so a slight exceedance would not be expected to result in adverse health effects, especially for a maximum exposure scenario.

This exposure investigation was intended as a screening project for assessing exposure in the North Morrow Perchlorate Area. Consequently, several limitations were encountered with the overall project design and the implementation of the investigation. Limitations associated with the sampling design included the small number of samples collected, the inability to sample all potential sources of perchlorate exposure, and the unknown level of background perchlorate exposure in the general population. A primary limitation associated with the implementation of the investigation was the inconsistency in three sampling results among the analytical laboratories, potentially due to an analytical problem or an undocumented lab-based error in processing those specific samples. Based on the results from this limited sampling of locally purchased milk and produce, along with the available drinking water data, the level of combined perchlorate exposure from these sources in the North Morrow Perchlorate Area is not likely to result in adverse health effects. However, the evolving science and standards related to perchlorate should be monitored, and the future need to revisit this stance should be considered in light of any new information. While this investigation confirmed that some produce and milk commercially available in the area do contain low levels of perchlorate, produce and dairy products contain many nutritional benefits and their consumption should not be restricted due the presence of low-level perchlorate contamination.

Objective

The purpose of this exposure investigation was to assess whether a more in-depth study was warranted to evaluate the potential public health impact from combined perchlorate exposure for sensitive subpopulations living within the North Morrow Perchlorate Area. Widespread perchlorate groundwater contamination has been documented in the Lower Umatilla Basin in northeastern Oregon, also referred to as the North Morrow Perchlorate Area. The area of contamination encompasses parts of Northwest Umatilla and North Morrow Counties and contains many rural communities as well as the cities of Boardman, Echo, Hermiston, Irrigon, Stanfield, and Umatilla (Figure 1).

Groundwater sampling in the area indicated low-level perchlorate contamination. Prior to this exposure investigation, the only available information about the community's potential perchlorate exposure was from the sampling of area drinking and irrigation wells. However, the Lower Umatilla Basin is an agricultural region and farmers potentially use perchlorate-contaminated groundwater to irrigate crops and to supply drinking water to dairy cattle. Perchlorate can be transferred from irrigation water into food crops and milk, leading to human exposure through consumption of these products. This exposure investigation was initiated to determine whether sensitive subpopulations living in the North Morrow Perchlorate Area were potentially exposed to enough perchlorate through multiple sources that it would pose a health risk. Exposure to a single contaminant through multiple sources, such as food and drinking water, is referred to as combined exposure. Limited sampling of locally available produce and dairy milk was conducted to address the identified data gap. These results, combined with previously gathered drinking water data, were used to estimate perchlorate exposure for sensitive subpopulations in the North Morrow Perchlorate Area.

Background

The North Morrow Perchlorate Area, located in northeastern Oregon, consists primarily of rural, agricultural communities. It has a semi-arid climate and is sparsely populated with the majority of people residing in the towns of Boardman, Echo, Irrigon, Stanfield, and Umatilla.

Groundwater sampling

The Oregon Department of Environmental Quality (DEQ) has monitored for nitrate in the area's groundwater since 1990. In 2003, the U.S. Environmental Protection Agency (EPA) and the DEQ analyzed for perchlorate in groundwater in addition to nitrate. At that time, perchlorate was detected in several wells, so EPA and DEQ have conducted several additional groundwater-sampling projects since then to monitor both contaminants.

Perchlorate was detected in many domestic drinking water wells (35%) tested in the North Morrow Perchlorate Area during previous investigations conducted between 2000 and 2005. The average concentration in drinking water wells was 3.5 parts-per-billion (ppb) among wells with quantifiable detections (Table 1). During DEQ sampling in 2003, perchlorate was detected in over half (54%, 72/133) of all of the groundwater wells tested in the area [1, 2]. This 2003 sampling event was one of approximately 14 different sampling events performed between 2000 and 2005 and samples were collected from drinking, irrigation, monitoring, stock water, industrial, and community wells. The highest perchlorate detection in a domestic drinking water well during all sampling events was 13.4 ppb [2]. This result is not consistent with other results from samples taken at this same well. A sample collected 14 months earlier had a perchlorate concentration of 1.21 ppb while one collected 10 months later was less than 4 ppb. The highest perchlorate detection in groundwater in the North Morrow Perchlorate Area was 29.2 ppb; however, this elevated sample was obtained from a monitoring well not available for public use.

Perchlorate

Perchlorate is a highly water-soluble anion and is a component of perchlorate salts, often in combination with ammonium, magnesium, or potassium [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].

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 formation or that it can form through geochemical processes [7-9]. Perchlorate has been detected in groundwater throughout the United States, with the highest levels found in Arkansas, California, Nevada, Texas, and Utah [10].

The primary perchlorate exposure route for humans is ingestion. There is a background of perchlorate exposure in the US population: perchlorate was found in the urine of all 2820 US residents studied as part of NHANES 2001–2002 [11]. The median background perchlorate exposure dose was estimated to be 0.07 µg/kg-day in US adults. The main health effect from perchlorate exposure is the inhibition of iodide uptake by the thyroid [12]. Iodide is important for thyroid hormone production. A prolonged reduction in iodide can cause a reduction in thyroid hormone levels, resulting in adult, infant, or fetal hypothyroidism. Environmental perchlorate exposure has been associated with decreased thyroid function in females with low iodine intake [13].

Prior to the completion of this investigation, the Oregon Department of Human Services' Superfund Health Investigation and Education (SHINE) program, in cooperation with the Agency for Toxic Substances and Disease Registry (ATSDR), prepared a health consultation to evaluate the public health impact posed by exposure to perchlorate in the North Morrow Perchlorate Area. This health consultation indicated that there was not enough information about exposure from sources other than drinking water to complete such an evaluation. Residents may be exposed to perchlorate from food sources in addition to drinking water. In particular, locally available produce and milk potentially containing perchlorate were identified as data gaps in the health consultation. This exposure investigation was initiated to assess whether a more in-depth study to address those data gaps was warranted.

Methods

A limited number of commercially available milk and produce samples were collected from the North Morrow Perchlorate Area for this investigation. Sampling of these food items garnered information on the extent of perchlorate contamination in some products potentially consumed by sensitive subpopulations. These data were then used to evaluate the public health impact of consuming commodities along with drinking perchlorate-contaminated drinking water.

Most produce sampled in this investigation was purchased from local markets and was grown in the North Morrow Perchlorate Area. However, produce sold in the area but grown outside of the area was also sampled.

Milk was sampled because cows are known to take up perchlorate into their milk from ingestion of contaminated alfalfa or contaminated drinking water. However, residents in the area generally do not purchase milk directly from dairies but, instead, purchase these products through typical routes including grocery stores, convenience stores, or other commercial outlets. The milk samples evaluated in this investigation were regional products that are composites from many different dairies covering a large geographic area throughout the western United States, primarily the Northwest, and these samples reflect the milk available for purchase in the area. Because milk represents a significant exposure source for young children, a subpopulation vulnerable to perchlorate exposure, it was important to include this product in the evaluation, regardless of its locality of origin.

Target Population

This exposure investigation targeted those most sensitive to perchlorate exposure in the North Morrow Perchlorate Area. Perchlorate inhibits iodide uptake by the thyroid gland, resulting in effects on thyroid hormones that are critical in fetal, infant, and young child development. The National Academy of Sciences (NAS) reported that fetuses and preterm newborns (and therefore pregnant women) are the subpopulations most sensitive to hypothyroidism, while infants and developing children are also considered sensitive subpopulations [14]. This investigation placed particular emphasis on generating exposure estimates for young children (less than six years old) and females of reproductive age (15 to 44 years old). Children ages six- to 15-years-old are assumed to be protected by health guidelines that protect younger children who are more sensitive to the potential effects of perchlorate so this age group was not evaluated in the investigation. For the purpose of this investigation, females of reproductive age were used as surrogates for evaluating fetal risk posed by perchlorate exposure. The inclusion of women of reproductive age in this investigation also ensures that other adults particularly sensitive to perchlorate due to health conditions such as hypothyroidism would also be covered by the results of this investigation.

Environmental Sampling Procedures

Prior to conducting sampling, SHINE submitted an exposure investigation protocol to ATSDR outlining the purpose of the investigation, sampling strategy, and data analysis approach. This protocol was approved in November of 2005 (Appendix A). The majority of the commodities collected were chosen because they satisfied the following requirements: they were commercially available within the area of investigation, were available at the time of sampling, were locally produced and had the potential to accumulate perchlorate from contaminated irrigation water, and were likely to be consumed by sensitive subpopulations. A few samples grown outside of the study area were selected for analysis because residents were expected to consume both locally- and regionally-generated produce and milk. The inclusion of both types of commodities in the investigation enabled the investigators to compare results from locally produced commodities with those produced outside the area of investigation.

Drinking Water

All drinking water data used in this analysis were collected prior to milk and produce sampling. The drinking water data were obtained during groundwater sampling projects by DEQ and EPA in the North Morrow Perchlorate Area between 2003 and 2005 (Table 1) [1, 2].

Milk

Seventeen (17) milk samples were purchased off-the-shelf from grocery stores and local markets in the North Morrow Perchlorate Area during January 2006. Milk samples represented most available brands from many area stores and included skim, 1%, 2%, and whole milk. The milk purchased was a composite of dairy milk gathered from different sources around the west coast and, as mentioned previously, were considered regional samples that were not necessarily produced within the North Morrow Perchlorate Area. Milk samples were shipped on dry ice within 24 hours of collection to a private contract lab for analysis where they were stored at –20°C until analyzed.

Produce

Investigators purchased watermelons (n=16), tomatoes (n=10), and corn (n=10) for perchlorate analysis. Most of these commodities were purchased from farmers' stands and from local grocery stores in the North Morrow Perchlorate Area during September 2005. Specifically, thirteen watermelon, eight tomato, and eight corn samples were purchased from retailers in the North Morrow Perchlorate Area. One watermelon produced in California was purchased within the investigation area and two other watermelons also from California were purchased in Portland, OR (all but one store within the area of investigation carried local watermelons). Of the eight corn samples purchased in the area, six were locally grown and the other two were grown in California. Of the eight tomato samples, six were locally grown and the other two were grown in Canada.

Sampling Preparation and Laboratory Analyses
Sampling and collection procedures are described in greater detail in the protocol (Appendix A). The produce samples were processed and prepared for analysis using methods described by FDA's Pesticide Data Program (Appendix B). FDA's procedure for cantaloupe was modified for watermelon because a method for watermelon was not listed. The rind was removed along with most watermelon seeds before processing. All samples were homogenized before storage. Samples were kept frozen in a -20ºC freezer until shipment to the private contract laboratory for analysis. Produce samples were shipped to the lab on dry ice by overnight express. The produce samples were received in good condition. The milk samples arrived at the lab with slight cracks in the glass containers holding the sample that occurred during shipping. However, the lab reported that the samples were not compromised by the cracks.

Milk and produce samples were initially analyzed by a private contract lab using EPA method 8321A (Appendix C). Detection limits using method 8321A are acceptably low for perchlorate analyses in milk and produce samples, with quantitation limits generally around 1 ppb.

Consumption Rates
Estimated consumption rates for water, milk, and each produce item were used in calculating combined exposure estimates. Consumption rates for each commodity were identified for the sensitive subpopulations. Consumption rates for females of reproductive age were derived using data from the EPA exposure factors handbook [15]. Consumption rates for young children were derived using data from the EPA child-specific exposure factors handbook [16].

Combined Exposure Estimates
Combined perchlorate exposure estimates were calculated for two target populations; children less than six years old and women ages 15-44. There are notable age-based differences in consumption rates among young children for some of the commodities sampled in this investigation. Therefore, exposure estimates were generated for two different age groups within this subpopulation. The two age categories used were a one-year old infant and a three-year old child. For estimation purposes, women were assumed to weigh 60 kilograms, one-year old infants 10 kilograms, and three-year old children 15 kilograms. Exposure estimates can be greatly influenced by body weight with a decreasing calculated exposure dose as weight increases.

Combined exposure estimates for perchlorate were calculated using the following equation:

Combined Exposure (mg perchlorate / kg body weight / day) =
*(Consumption Rate (g/day) * Perchlorate Concentration (µg/kg)) /*
*(Body Weight (kg)*1,000,000 [adjustment for units])*

mg/kg/day - milligrams (mg) of perchlorate per kilogram (kg) body weight per day
g - grams µg – micrograms kg - kilograms

Combined exposure estimates were generated based on both average and maximum concentrations of perchlorate found in drinking water and in individual commodities. Perchlorate concentrations were reported on a mass per mass wet weight basis, rather than a dry weight basis. The use of average and maximum concentrations for drinking water and each commodity provided a range of estimated exposures for target populations. If concentrations were reported by the lab to be less than the quantitation limit, then a concentration equal to half the quantitation limit was used for calculations.

In 2005, the NAS proposed a perchlorate health protective guideline of 0.0007 mg perchlorate/kg body weight/day based on ingestion by a pregnant woman intended to protect the fetus [14]. This recommended dose was adopted as the reference dose (RfD) for perchlorate by the EPA [17]. The health guideline was based on a "No Effect Level" (NOEL) of 0.007 mg perchlorate/kg body weight/day divided by a safety factor of 10, resulting in the RfD of 0.0007 mg perchlorate/kg body weight/day. Consequently, in late 2005, ATSDR also adopted a Minimum Risk Level (MRL) of 0.0007 mg perchlorate/kg body weight/day based on the NAS findings [18].

In this exposure investigation, the combined exposure estimates were compared to the MRL to determine if the estimated exposures were at levels that require greater in depth analysis. Sampling results were also compared to perchlorate concentrations found in similar food items throughout the U.S. to provide a context for the results found in this investigation.

Results

As described previously, milk and produce samples were collected from the North Morrow Perchlorate Area to evaluate perchlorate contamination in these commodities and their contribution to combined perchlorate exposure for the sensitive subpopulations. All sampling results for milk and produce are detailed in Tables 2 – 5.

Sampling Results

Most sampling results for milk and produce obtained during this investigation are reported in low parts-per-billion (ppb) concentrations. Nearly all of these results are consistent with other studies reporting perchlorate concentrations in milk and produce, including the U.S. Food and Drug Administration's (FDA) 2004 national market basket survey (Table 6).

All corn samples were less than 2 ppb (Table 2) and all tomato samples were less than 8 ppb (Table 3). The majority (88%, 14/16) of watermelon samples were less than 2 ppb (Table 4). Most milk samples (82%, 14/17) in the initial testing were less than 12 ppb (Table 5). While most results were low, the results for two milk samples and one watermelon sample were not in agreement with the other samples. These discrepancies and the agencies' approach to addressing them are described below.

The private laboratory contracted to analyze samples for this investigation initially reported extremely high perchlorate concentrations in two milk samples (8600 and 4500 ppb) and one watermelon sample (900 ppb). The reported perchlorate concentrations for these three samples were two to three orders of magnitude (i.e., 100 to 1000 times) higher than the concentrations in other similar samples from this investigation. The elevated concentrations of the two milk samples were well above any level ever reported for milk in the published literature. The two elevated milk samples were produced outside of the North Morrow Perchlorate Area but sold in the study area while the elevated watermelon sample was grown and sold within the study area.

Following the reporting of these initial sampling results from the contract lab, SHINE and ATSDR, in consultation with several state and federal agencies, determined that the findings should be validated prior to developing public health messages based on the data. Retesting was especially important to confirm the milk results because the two elevated results were well above any perchlorate concentrations found in milk tested in other studies. Also, the potential public health implications of commercially available, highly contaminated milk would a have national impact. SHINE and ATSDR recruited two reputable labs to reanalyze these samples and validate the initial results. The two labs—the Centers for Disease Control and Prevention's (CDC), National Center for Environmental Health lab and an FDA lab—received multiple samples for analysis that had been tested by the original contract lab. The CDC and FDA tested several other samples in addition to the samples with elevated perchlorate levels to provide a comparison between the initial lab results and retesting results. The CDC and FDA labs used an ion chromatography tandem mass spectrometry (IC/MS/MS) method also used by the original contract lab allowing for a direct comparison of the results between the three labs. The CDC and FDA labs were blinded to the initial results reported by the contract lab. The CDC lab analyzed a subset of milk samples while the FDA ran a subset of both milk and produce samples. The milk samples sent to CDC and FDA by the contract lab were split samples (i.e., a single sample divided in half).

The CDC and FDA reanalysis results were in agreement with each other for the split milk samples (Table 5). Perchlorate concentrations from this reanalysis were between five to 10 ppb for the two milk samples originally reported as 4500 and 8600 ppb by the contract lab. The retesting of the high watermelon sample by FDA indicated a significant difference in concentration, from 900 ppb initially reported by the contract lab to less than one ppb reported by the FDA upon reanalysis (Table 4). Retesting of corn and tomato samples by the FDA was in relatively good agreement with the initial contract lab results (Tables 2 and 3). The concentration of one tomato sample was lower upon retesting; however, it is not as large of a discrepancy as that found for the milk and watermelon samples. Following the retesting by CDC and FDA, the remaining portions of all samples were shipped back to the original contract lab. The contract lab conducted a final reanalysis in an attempt to replicate the FDA and CDC findings. The results from the final reanalysis by the contract lab were similar to results reported by CDC and FDA (Tables 4 and 5). These final measured values were used to estimate cumulative exposure to perchlorate.

Cumulative Exposure Estimates

There were specific assumptions used in generating combined exposure estimates for the sensitive subpopulations evaluated in this exposure investigation. All consumption rates for drinking water, milk, and produce were derived from EPA's exposure factors handbooks (Table 7) [15]. No modifications were made to these consumption rates to account for seasonality of crops and the subsequent potential for short-term spikes in consumption of some crops or, conversely, reduced consumption of crops that were not in season. Bodyweight assumptions for each age group were also obtained from the exposure factors handbooks.

Both average and maximum concentrations for each commodity as well as drinking water were used in the calculations to estimate perchlorate exposure for sensitive subpopulations. The average and maximum concentrations used in the combined exposure estimates were; 1.00 ppb and 1.68 ppb for corn, 3.07 ppb and 5.77 ppb for tomatoes, 0.78 ppb and 1.9 ppb for watermelon, and 7.42 ppb and 16.15 ppb for milk. The average concentration for drinking water used in the calculations was 3.4 ppb and the maximum concentration was 13.4 ppb. Values below the quantitation limits were replaced with a concentration equal to ½ the quantitation limit (0.5 ppb in all cases). No comparison samples grown outside the investigation area were included in calculating average and maximum perchlorate concentrations. Only the concentrations for locally produced watermelon, corn, and tomatoes were used to calculate the average and maximum concentrations. Three anomalous samples, two milk and one watermelon, were also excluded from all calculations since the discrepancies between the initial results and retest results could not be explained. For all other samples retested, initial results were replaced with an average between the initial concentration reported by the contract laboratory and all reported retest concentrations.

As mentioned in the target population section, the combined exposure estimates were calculated for the most sensitive subpopulations – young children and women of reproductive age (Tables 8 and 9). The estimates were calculated using both the average and maximum concentrations for each commodity. The average and maximum exposure calculations can be summarized as follows:

$$\text{Average exposure} = \frac{\text{Average Food \& Milk Concentrations} * \text{Food Consumption Rate}}{\text{Body Weight}}$$

$$\text{Maximum exposure} = \frac{\text{Maximum Food \& Milk Concentrations} * \text{Food Consumption Rate}}{\text{Body Weight}}$$

The combined perchlorate exposure estimates for women of reproductive age and three-year-old children did not exceed the MRL when using both mean and maximum concentrations of perchlorate in each commodity. The combined exposure estimate for one-year-old children was below the MRL when mean perchlorate concentrations were used in the calculations. The MRL was slightly exceeded for a one-year-old child when using the maximum perchlorate concentrations for each commodity in the calculations, but this is an unlikely exposure scenario, and the MRL is designed to be health protective.

Discussion

Environmental Sampling

Most of the milk and produce sampling results from this investigation were within the range of perchlorate concentrations found in similar food commodities sampled throughout the U.S. (Table 6). However, two of the milk samples initially tested much higher than other milk sample results from a national testing program. The one initially elevated watermelon sample result was also higher than other similar types of produce tested in several other sampling events listed in Table 6. Upon retesting, the concentrations in these three samples were significantly lower according to the two federal labs as well as the same contract lab. The concurrence among retesting results provided evidence that the initial high results were likely associated with an undocumented, lab-based error [19]. Perchlorate is an extremely stable compound at room temperature and it is not likely that it would have degraded significantly between testing events [20]. These three samples were excluded from the exposure calculations.

The perchlorate concentrations in local produce tested in this investigation were compared to the concentrations in produce samples generated outside the North Morrow Perchlorate Area. All but two of the non-local produce samples were purchased within the study area and were therefore considered locally available but not locally produced. Two watermelon samples were purchased in Portland because there were very few non-local watermelons available for purchase that could provide a comparison. The non-locally produced comparison samples are identified in Tables 2-4. The comparison samples were not used for calculating exposure estimates. The perchlorate concentrations in all produce samples that were locally grown, excluding the initially high watermelon sample, were comparable to the concentrations found in locally available produce grown outside the North Morrow Perchlorate Area. Since all of the milk samples were regional, rather than produced locally within the area of investigation, they were not differentiated by locality. The perchlorate concentrations found in the regional milk samples analyzed in this investigation were comparable to concentrations detected in milk samples analyzed in other studies conducted throughout the U.S. [7, 21].

Combined Exposure Estimates

Combined perchlorate exposure estimates indicated that females of reproductive age and three-year-old children were not at risk of exceeding the MRL through the consumption of contaminated drinking water and the local commodities tested. Neither of the target populations exceeded the MRL when using both the average and the maximum perchlorate concentrations for each commodity as well as drinking water (Tables 8 and 9). Similarly, cumulative perchlorate exposure estimates for a one-year-old infant indicated that this age group was not at risk of exceeding the MRL when considering average concentrations in each commodity as well as in drinking water (Table 8). When considering maximum concentrations in each commodity and in drinking water, the combined exposure estimates for one-year-old infants slightly exceeded the MRL (Table 9).

While the one-year-old age group exceeded the MRL when using maximum perchlorate levels in all commodities sampled as well as in drinking water, this is an unlikely exposure scenario. An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a lifetime of exposure. For this exposure scenario, the MRL is based on chronic (i.e. long term) exposures. In the one-year-old scenario, their exposure estimate would only be relevant for one year or less until they grow, rather than over an entire lifetime. Comparing the shorter duration exposure estimate for a one year old to the MRL is a health protective measure for developing children. Additionally, it is improbable that individuals in this age group would encounter maximum perchlorate contaminant levels in each of their drinking water, milk, and produce on a daily basis over an entire year. It would therefore be unlikely that their exposures would exceed the MRL on a daily basis. Based on this information, there is no indication that one-year-old infants in the North Morrow Perchlorate Area are exposed to perchlorate at levels that would result in adverse health effects.

The concentration of perchlorate that causes adverse health effects in humans is a subject of continuing scientific debate [22-25]. This uncertainty is reflected in the variability in perchlorate guidance values currently used by many state agencies. However, despite this uncertainty, the current MRL of 0.0007 mg/kg body weight/day adopted by ATSDR is designed to be protective for the most sensitive individuals. The MRL is an exposure dose allowable over a lifetime; a dose at or slightly above the MRL does not mean a health effect will result. Additional discussion about the MRL can be found in the North Morrow and Umatilla Perchlorate Health Consultation [26].

Although exposure to perchlorate near or just slightly above the MRL is not expected to result in health effects, a recent study released by Blount et al. provides evidence that low-level perchlorate exposure may be associated with altered thyroid function in women with low iodine levels [13]. The researchers evaluated the association between thyroid function and low-level perchlorate exposure for adolescent and adult men and women. They found that perchlorate was associated with lower thyroid hormone levels for women with urinary iodine levels less than 100 µg/L. Women with iodine levels less than 100 µg/L were considered to be a sensitive subpopulation in this study because low iodine levels indicated a person may be more sensitive to the effects of perchlorate. As mentioned in the background of the document, perchlorate can inhibit the uptake of iodine into the thyroid [12]. The Blount et al. study is the first of its kind to target and analyze low-level perchlorate exposure for women with low iodine levels in their urine who are considered a sensitive subpopulation. This study did not evaluate children less than six years of age. Reduced thyroid function was not associated with perchlorate levels for men or for women with urinary iodine levels greater than 100 µg/L. In light of this information, it should be taken into consideration that sensitive subpopulations with perchlorate in their drinking water in North Morrow and Umatilla Counties be educated about perchlorate and encouraged to work with their doctors to ensure they maintain adequate iodine intake.

Limitations

Limitations are inherent in a screening project such as an exposure investigation. For this project, limitations were related to two specific topics; the general approach used in exposure investigations (e.g. the sampling design and intentional biases introduced through targeted sampling) and the laboratory variability encountered during the analyses of food and milk samples.

Sampling Design

One limitation of this project's sampling design was the analysis of composite, off-the-shelf milk samples rather than milk from local dairies. Sampling milk from local dairies in the North Morrow Perchlorate Area would have evaluated the impact of perchlorate contamination from irrigation or private groundwater wells on the local milk supply. However, due to Oregon state laws regarding the selling of unpasteurized milk, milk from local dairies in the area are typically not directly available to consumers. Therefore, sampling milk directly from a dairy would not accurately reflect actual perchlorate exposure among area residents even though it is a more direct measure of site-specific impacts to the milk supply. Residents purchase their milk from local stores and these products are generally a composite of milk from different dairies that are processed and packaged by a regional distributor. While milk samples did not provide a direct measure of perchlorate's impact on the locally-produced milk supply, they did represent the locally available milk supply. Milk sampling from many regions in the U.S. has documented perchlorate contamination in dairy milk and this was an important potential source of exposure for the targeted population.

Another limitation of the study was that sampling did not represent a typical daily diet. If people eat several food items that contain perchlorate in a given day, then combined exposure estimates could be higher in some cases. However, a similar argument could be made that people only eat one or two food items containing perchlorate in a given day so the combined estimates in this investigation, which included three food sources in addition to milk, is an over estimate of perchlorate exposure.

Consumption estimates introduce additional limitations in this investigation. Consumption estimates obtained from EPA's exposure factors handbooks were the average consumption rates for each commodity, but may over or underestimate actual consumption rates depending on individual preferences. It appears that corn and watermelon rates in the handbook are higher and therefore overly protective because the EPA bases the consumption rate on the rates for similar foodstuffs combined (i.e., corn consumption rates include the consumption of green beans and lima beans while watermelon consumption rates also include other melons and berries). Also, due to the seasonality of some of the locally grown commodities sampled in this exposure investigation, residents' consumption of these commodities may vary significantly based on their availability (i.e. whether or not the commodity is in season).

Laboratory Analytical Variability

The inconsistent results reported from different labs analyzing the same homogeneous samples in this investigation imparted some uncertainty in the reliability and interpretation of this information. While the milk results from samples reanalyzed by FDA, CDC, and the contract lab are similar, the lack of agreement between these results and some of the initial results suggests that there was a lab error during the initial analysis, sample preparation, or resulting documentation. This is supported by the observation that the initial reported concentration of one watermelon sample was high yet, after retesting by the FDA and the same contract laboratory, the retest concentration was consistent between the two labs.

In September 2006, the EPA released a quality assurance (QA) report evaluating the reliability and usability of the sampling data obtained during this exposure investigation (Appendix D). The QA report was critical of all of the produce and milk sampling results and concluded that, “given the overall weaknesses and limitations of the data set as a whole, the data cannot be used by EPA in its assessment of perchlorate contamination in the North Morrow area.” While SHINE and ATSDR acknowledge the limitations and errors in the data set, we believe the data retain some utility for addressing combined exposure. The results are in agreement for all but three samples out of 53 samples total -- the two milk samples and one watermelon sample that were initially reported as elevated but had retest results several orders of magnitude lower. The lack of biological plausibility for the two extremely high initial milk results along with consistent retest results, led SHINE and ATSDR to conclude that these levels were probably the result of analytical problems or undocumented errors by the contract lab in the original analysis.

Much of EPA’s criticism of the sampling data revolved around errors or omissions in various forms of documentation such as project and sample processing notes, case narratives, and chain of custody forms. While it is unfortunate that these documents did not meet EPA’s guidelines, the public health agencies conducting the investigation used their own protocols rather than EPA’s quality assurance protocols (e.g. EPA’s Quality Assurance Project Plan). SHINE and ATSDR are independent agencies that generally follow their own protocols. Therefore, it is not necessary for these two agencies to rely upon EPA protocols as a metric for evaluating the reliability and usability of the data in making public health determinations.

It has been suggested that produce samples were compromised between initial testing and subsequent retesting, resulting in a breakdown of perchlorate in the sample. According to the contract laboratory, some of the produce samples were left out of the freezer for three days in late January or early February 2006 because the lab was preparing to dispose of them. The samples were returned to cold storage when the lab realized that SHINE requested that they be held in storage for possible retesting. According to multiple chemists involved in conducting the initial testing and retesting of the samples, the breakdown of perchlorate in these produce samples is unlikely [19, 20]. Perchlorate is chemically stable and typically does not breakdown easily or quickly at varying temperatures, including room temperature. Additionally, the initial and retesting results were in agreement for corn and tomato samples that were left out of cold storage for three days. The contract lab reported that the milk samples were never left out at room temperature and upon retesting the results for two milk samples were still several orders of magnitude lower than the initial results.

Interpretation

The impact of perchlorate in the food supply was an important consideration when evaluating combined perchlorate exposure in the North Morrow Perchlorate Area. Because combined exposure was the key measure used in conducting this evaluation, the threat posed by perchlorate-contaminated groundwater alone was not quantifiable in the absence of information on other sources of perchlorate exposure [21]. While there are limited data on perchlorate levels in the national food supply, it was not appropriate to generalize this very limited national data to the unique site and exposure characteristics for sensitive subpopulations living in the North Morrow Perchlorate Area.

Despite the limitations of the sampling data and the uncertainties regarding consumption rates, SHINE and ATSDR used protective approaches in calculating combined exposure estimates. The majority of the initial test results and all retest results suggest relatively low concentrations of perchlorate in each of the commodities sampled during this investigation. Based on this information from this investigation, there is no indication that perchlorate exposure will result in adverse health effects in the North Morrow Perchlorate Area. However, sensitive subpopulations that have perchlorate in their drinking water source are encouraged to work with their doctor to ensure they maintain adequate iodine levels to counter any potential effects from perchlorate found in drinking water or food items.

Evidence is mounting that human perchlorate exposure is widespread in the US **[**11**]**. Perchlorate has been detected in a variety of foods and beverages from around the U.S. and the world (Table 6) [7, 21, 27, 28]. There is an increasing body of data documenting perchlorate contamination in a variety of foods and beverages ranging from asparagus to apples to wine [27]. Perchlorate has even been detected in breast milk at concentrations up to 92 ppb [7]. Concentrations in food are generally in the low parts-per-billion range but some commodities have contained significant concentrations of perchlorate such as cantaloupe from Guatemala that contained perchlorate at an average concentration of 463 ppb [27].

Concentrations up to 11 ppb were detected in dairy milk by the FDA and Kirk et al. with an average ranging from two to five ppb [7, 21]. These values are consistent with the average and maximum concentrations from this investigation of 7.4 ppb and 13.9 ppb, respectively. Average tomato concentrations from this investigation were comparable to the concentrations measured by Aribi et al [27]. The maximum concentration found in tomatoes during this investigation was much lower than that found in some tomatoes grown in Mexico. There were no comparable concentrations identified for corn in any of the reviewed studies but the concentrations from this investigation suggest it only uptakes small amounts of perchlorate given the maximum concentration out of ten samples was less than two ppb. The majority of the results of the investigation suggest perchlorate uptake into watermelons sampled in this investigation was minimal (e.g., maximum concentration less than three ppb). There are limited data on perchlorate concentrations found in watermelon but a sample tested by Aribi et al. had a concentration of less than one ppb.

Conclusions

Recent discoveries of perchlorate's presence in a wide variety of foods and beverages from around the country emphasize the importance of evaluating combined perchlorate exposure when assessing the impact to sensitive subpopulations. This is especially important in regions where people are exposed to perchlorate through multiple sources including drinking water and food. The levels of perchlorate found in products sampled as part of this screening investigation were similar to levels reported by the FDA and other scientists around the country. Based on this limited sampling of locally purchased milk and produce, the available drinking water data, and the current knowledge regarding health risks from perchlorate, perchlorate exposure in the North Morrow Perchlorate Area is not likely to result in adverse health effects. Although this investigation confirmed that some produce and dairy milk do contain low levels of perchlorate, produce and dairy products contain many nutritional benefits and their consumption should not be limited due the presence of low-level perchlorate contamination. Sensitive subpopulations – women of childbearing age, children less than six years old, and people with iodine deficiency or hypothyroidism – who have perchlorate in their drinking water source are encouraged to work with their doctor to ensure they maintain adequate iodine levels to counter any potential effects from perchlorate found in drinking water or food items.

Recommendations

- Residents in the North Morrow Perchlorate Area should continue to eat a balanced diet, choosing a variety of foods including high-fiber grains, fruits and vegetables.

- Residents in the North Morrow Perchlorate Area should continue to be educated about the presence of perchlorate in groundwater, ways to reduce exposure if they are concerned, and methods for testing their drinking water wells if they so desire.

- Specific outreach should be targeted by SHINE to sensitive subpopulations (i.e., young children and women of reproductive age) about the findings of this investigation. If perchlorate is present in their water source, they will be encouraged to work with their doctor to ensure that adequate iodine intake and proper thyroid function are maintained.

- The evolving standards and scientific understanding related to perchlorate should be monitored, and in the future the results of this investigation may be re-evaluated in light of any new information.

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Certification

The Superfund Health Investigation and Education Program of the Oregon Department of Human Services prepared this Exposure Investigation under a cooperative agreement with the Agency for Toxic Substances and Disease Registry. This document is in accordance with approved methodology and procedures.

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I have reviewed this health consultation, as the designated representative of the Agency for Toxic Substances and Disease Registry and concur with its findings.

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Tables

Table 1. Groundwater Sampling Results in the North Morrow Perchlorate Area; 2003–2005[2]

Type of Well	Wells Sampled	Wells With Perchlorate Detections	Percent Of Wells With Detects	Average Concentration in Wells with Detects [ppb]	Minimum Concentration [ppb]	Maximum Concentration [ppb]
Irrigation	26	11	42%	2.3	< 1	4.23
Domestic/ Private	98	34	35%	3.5	<1	13.4
Community	10	2	20%	2.8	< 1	4.5
Monitoring	140	75	54%	7.6	< 1	29.2

Table 2. Corn Sampling Results

Matrix	Contract Lab [ppb]	FDA Retest 1 [ppb]	FDA Retest 2 [ppb]	Average [ppb]	Values Used for Calculations [ppb]
Corn	0.5				0.5
Corn	1.4	1.27	1.47	1.38	1.38
Corn	1.3				1.3
Corn	1.7	1.62	1.71	1.68	1.68
Corn	0.5				0.5
Corn	1.6				1.6
Corn	0.5				0.5
Corn	0.5				0.5
Corn*	0.5				-
Corn*	0.5				-
Average	0.9			**Average**	1.00
				Maximum	1.68
				n	8

* Comparison sample produced outside the North Morrow Perchlorate Area and not used in exposure calculations

Notes: Values <1 ppb were calculated to be 1/2 the Quantitation Limit (QL equal to 1 ppb in most cases)

Table 3. Tomato Sampling Results

Matrix	Contract Lab [ppb]	FDA Retest 1 [ppb]	FDA Retest 2 [ppb]	Average [ppb]	Values Used for Calculations [ppb]
Tomato	2.8				2.8
Tomato	1.9				1.9
Tomato	4.6				4.6
Tomato	3.8				3.8
Tomato	5.1	7.01	5.2	5.77	5.77
Tomato	3.6				3.6
Tomato	1.6				1.6
Tomato	0.5				0.5
Tomato*	6.3	0.5		3.4	-
Tomato*	0.5				-
Average	3.07			**Average**	3.07
				Maximum	5.77
				n	8

* Comparison sample produced outside the North Morrow Perchlorate Area and not used in exposure calculations

Notes: Values <1 ppb were calculated to be 1/2 the Quantitation Limit (QL equal to 1 ppb in most cases)

Table 4. Watermelon Sampling Results

Matrix	Contract Lab [ppb]	FDA Retest 1 [ppb]	FDA Retest 2 [ppb]	Contract Lab Retest [ppb]	Average [ppb]	Values Used for Calculations [ppb]
Watermelon	0.5	0.5			0.5	0.5
Watermelon	0.5					0.5
Watermelon	0.5					0.5
Watermelon	1.6	0.5			1.05	1.05
Watermelon	0.5					0.5
Watermelon	1.9					1.9
Watermelon	0.5	0.5			0.5	0.5
Watermelon	1.1					1.1
Watermelon	1.1					1.1
Watermelon	0.5					0.5
Watermelon	0.5					0.5
Watermelon	0.7					0.7
Watermelon†	900	0.5	0.5	0.5	225.38	-
Watermelon*	2.4	0.5			1.45	-
Watermelon*	0.5	0.5			0.5	-
Watermelon*	0.5					-
Average	57.08				**Average**	0.78
					Maximum	1.9
					n	12

* Comparison sample produced outside the North Morrow Perchlorate Area and not used in exposure calculations

† Value not used in exposure calculations due to discrepancies in analytic results

Notes: Values <1 ppb were calculated to be 1/2 the Quantitation Limit (QL equal to 1 ppb in most cases)

Table 5. Milk Sampling Results

Matrix	Contract Lab [ppb]	FDA Retest [ppb]	CDC Retest [ppb]	Contract Lab Retest (CDC returned samples) [ppb]	Contract Lab Retest (FDA returned samples) [ppb]	Average [ppb]	Values Used for Calculations [ppb]
Milk	8.8						8.8
Milk	4.9						4.9
Milk	4.8						4.8
Milk	10	12				11.00	11
Milk	4.7	4.91	4.37	5.4		4.85	4.85
Milk	6						6
Milk	24	13.9	11.7	15		16.15	16.15
Milk	11						11
Milk	5	6.53				5.77	5.77
Milk	5.6						5.6
Milk	5.4						5.4
Milk	6.2						6.2
Milk	6.6						6.6
Milk	8						8
Milk	6.2						6.2
Milk†	4500	7.63	5.17	6.2	5	904.80	-
Milk†	8600	10.3	8.06	12	8.1	1727.69	-
Average (All Samples)	777.48					**Average**	7.42
Average (Excluding 2 High Samples)	7.81					**Maximum**	16.15
						n	15

† Values not used in exposure calculations due to conflicting analytic results

Note: Values <1 ppb were calculated to be 1/2 * Quantitation Limit (QL equal to 1 ppb in most cases)

Table 6. Perchlorate Concentrations in Various Commodities and Milk; U.S. and Worldwide

Commodity	Average Concentration [ug/kg] = [ppb]	Max Concentration [ug/kg] = [ppb]	Country of Origin	Study
Food Commodities				
Green Apples	0.31	-	Canada	Aribi et al., 2006 *
Fuji Apples	0.08	-	China	Aribi et al., 2006 *
Red Apples	0.09	-	Canada	Aribi et al., 2006 *
Red Delicious Apples	0.12	-	USA	Aribi et al., 2006 *
Bananas	2.43	-	Columbia	Aribi et al., 2006 *
Bananas	0.30	-	Ecuador	Aribi et al., 2006 *
Blueberries (Baby Food)	0.11	-	Canada	Aribi et al., 2006 *
Blueberries	0.22	-	Canada	Aribi et al., 2006 *
Cantaloupe	151.65	-	Costa Rica	Aribi et al., 2006 *
Cantaloupe	463.50	-	Guatemala	Aribi et al., 2006 *
Cantaloupe	308.16	-	Guatemala	Aribi et al., 2006 *
Green Grapes	21.98	-	Chile	Aribi et al., 2006 *
Green Grapes	19.29	-	USA	Aribi et al., 2006 *
Grapefruit	3.30	-	USA	Sanchez et al., 2006
Green Leaf Lettuce	10.70	27.40	USA	FDA, 2004
Iceberg Lettuce	7.76	71.60	USA	FDA, 2004
Red Leaf Lettuce	11.60	52.00	USA	FDA, 2004
Romaine Lettuce	11.90	129.00	USA	FDA, 2004
Oranges	0.08	-	Cyprus	Aribi et al., 2006 *
Oranges	9.99	-	USA	Aribi et al., 2006 *
Oranges	7.40	-	USA	Sanchez et al., 2006
Pineapple	1.02	-	Costa Rica	Aribi et al., 2006 *
Red Tomato	0.33	-	Canada	Aribi et al., 2006 *
Red Tomato	62.80	-	Mexico	Aribi et al., 2006 *
Red Tomato	0.26	-	USA	Aribi et al., 2006*
Watermelon	0.24	-	USA	Aribi et al., 2006*
Milk				
Dairy Milk	2.00	11.00	USA	Kirk et al., 2005
Dairy Milk	5.76	11.30	USA	FDA, 2004
Breast Milk	10.50	92.20	USA	Kirk et al., 2005

* A single sample was analyzed by IC-ESI-MS/MS and a single value was reported with a standard deviation based on duplicate or triplicate readings

Table 7. Consumption Rates for Populations of Concern; EPA Exposure Factors Handbooks (adult and child-specific)

	1 year old child (10 kg)	3 year old child (15 kg)	15-44 year old women (60 kg)
Watermelon [g/day]	8	13	4.8
Corn [g/day]	9	11	10
Tomato [g/day]	7	13	51
Milk [mL/day]	475	347	158
Water [mL/day]	313	313	2000

Table 8. Combined Dose Estimates Based on the Average Perchlorate Concentrations in Each Commodity and Drinking Water

	1 year old child	3 year old child	15-44 year old women
Drinking water [ppb]		3.4	
Watermelon [ppb]		0.78	
Corn [ppb]		1.0	
Tomato [ppb]		3.1	
Milk [ppb]		7.4	
Combined Dose [mg/kg/day]	0.00046	0.00025	0.00014

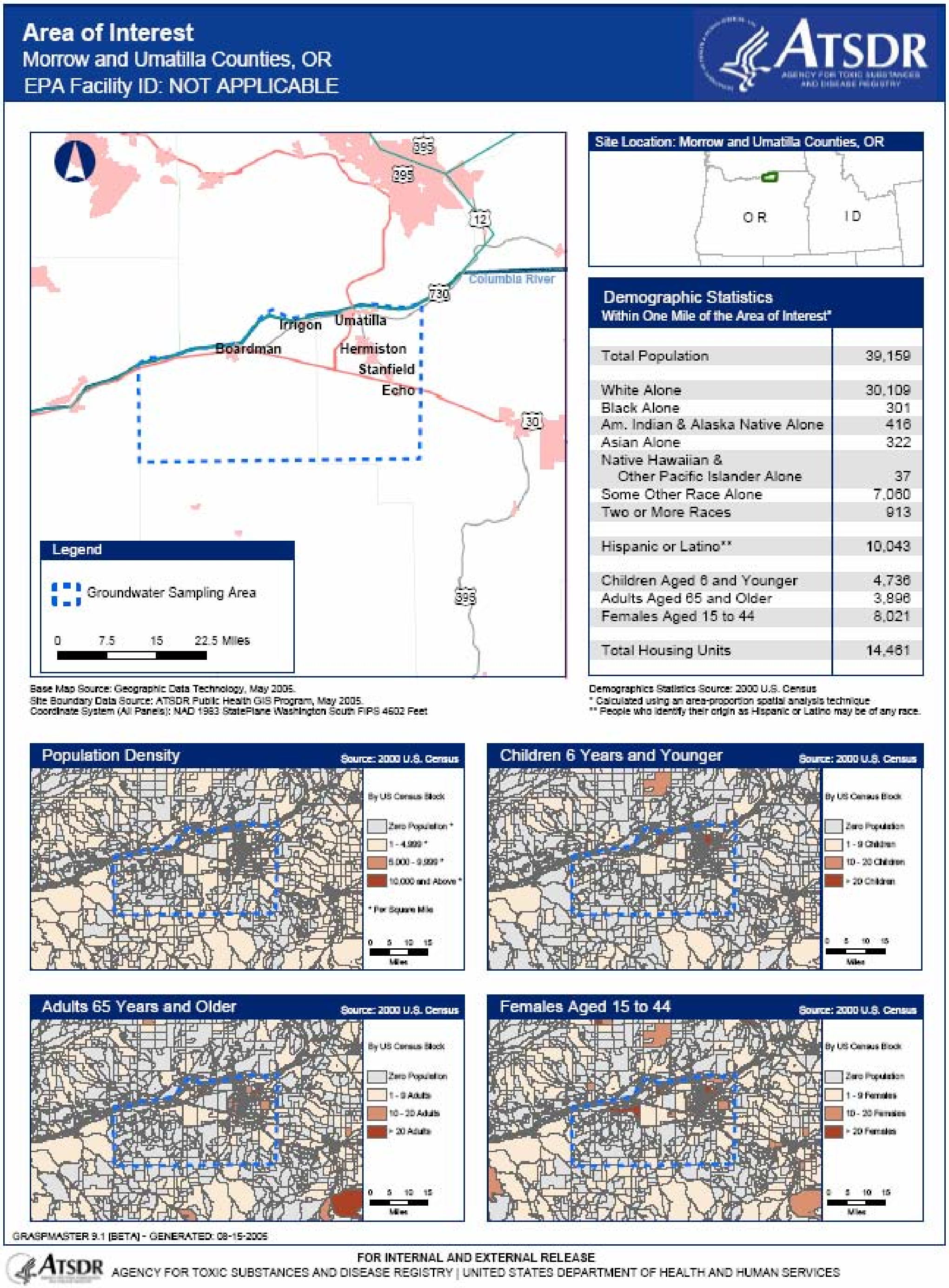
Table 9. Combined Dose Estimates Based on the Maximum Perchlorate Concentration in Each Commodity and Drinking Water

	1 year old child	3 year old child	15-44 year old women
Drinking water [ppb]		13.4	
Watermelon [ppb]		1.9	
Corn [ppb]		1.7	
Tomato [ppb]		7.0	
Milk [ppb]		16.5	
Combined Dose [mg/kg/day]	**0.00109***	0.00061	0.00049

* Exceeds MRL of 0.0007 mg/kg/day

Figures

Figure 1. Demographics for the North Morrow Perchlorate Area



Appendices

Appendix A. Exposure Investigation Protocol

Exposure Investigation Protocol

Lower Umatilla Basin

August 2005

Prepared by

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Table of Contents

I. Project Overview

a. Summary

Groundwater perchlorate contamination is widespread in the Lower Umatilla Basin in northeastern Oregon. The area with groundwater contamination is commonly referred to as the North Morrow Perchlorate Area. The Oregon DEQ and the U.S. EPA conducted sampling in 2003 and 2004 at 133 groundwater wells in the North Morrow Perchlorate Study Area to characterize perchlorate contamination. Perchlorate was detected in over half of the 133 wells tested. Through a cooperative agreement with ATSDR, the Superfund Health Investigation and Education (SHINE) program became involved in the North Morrow Perchlorate Area to evaluate the risk of residents' exposure to perchlorate.

Residents in the study area who use well water as a drinking water source are at risk of exposure to perchlorate through ingestion of drinking water. There is evidence to suggest that milk and produce also contribute to their risk of exposure. Recent studies have shown that perchlorate can bioaccumulate in produce and crops irrigated with contaminated water [1 & 2]. Additionally, perchlorate has been detected in dairy milk and breast milk samples in areas where perchlorate has been measured in groundwater [3]. It is currently unknown whether perchlorate in the groundwater has affected food and milk produced in the North Morrow Perchlorate Area.

The purpose of this exposure investigation is to fill a data gap to address the exposure to perchlorate faced by residents in the North Morrow Perchlorate Study Area who have perchlorate contaminated drinking water. SHINE is currently unable to estimate the risk of exposure from perchlorate ingestion because there is a lack of information about the contribution from sources other than drinking water. To fill this data gap, SHINE plans to sample locally available produce and milk that residents in the study area could consume to estimate Combined exposure to perchlorate.

b. Investigators and Collaborators

The SHINE program in the Oregon Department of Human Services will be responsible for sample collection, data analysis, data analysis, exposure estimation, and report writing. This will be done in collaboration with ATSDR region 10. The Oregon DEQ laboratory will process and freeze-dry samples to prepare them for analysis. Severn Trent Laboratories (STL) in Denver will perform the sample analysis.

II. Introduction

a. Background

Perchlorate was detected in over half of the wells tested in the North Morrow Perchlorate Area, which included monitoring, irrigation, and domestic wells. The concentrations in the wells with detections ranged from 1 to 25 ppb. Of the 54 domestic drinking water wells tested in 2003, 25 contained perchlorate, seven of which had concentrations above

4 ppb (Table 1). The one community well tested in 2003 did contain perchlorate at 1.14 ppb.

Table 1. Summary of 2003 groundwater sampling results in the North Morrow Perchlorate Area.

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	12	9	75%	2.24	1.01	4.23
Domestic/ Household	54	25	46%	2.95	1.06	6.92
Community	1	1	100%	-	1.14	1.14
Total	67	35	52%	-	-	

The perchlorate anion, a dissolution product of perchlorate salt, is a commonly used ingredient in explosives and rocket fuel. Perchlorate is also found in small amounts (0.03%) as an inert ingredient in nitrate fertilizer from Chile, and it has been shown to form naturally through atmospheric processes. Contaminated wells in Umatilla and Morrow Counties are situated near sites historically used by the Navy and Air Force for bomb testing, by Boeing for engine testing, and still used by the Umatilla Army Depot. A GAO report published in May, 2005, cites that 65% of the known groundwater perchlorate detections found throughout the U.S. can be linked to defense and aerospace activities, such as rocket motor testing, bomb testing, or explosives disposal [4].

Humans are exposed to perchlorate through ingestion. A known source of exposure is contaminated drinking water. Additionally, milk and produce may be important sources of exposure. Recent studies have shown that perchlorate can bioconcentrate in produce and crops irrigated with contaminated water [1 & 2]. Additionally, perchlorate has been detected in dairy milk and breast milk samples in areas where perchlorate has been measured in groundwater [3].

Perchlorate inhibits iodide (I^-) uptake into the thyroid. Sufficient iodide intake is necessary for thyroid hormone production. Maintaining proper levels of thyroid hormones is particularly important for fetuses, infants, and young children for skeletal and neurological development. Unlike adults, fetuses do not have an excess thyroid hormone supply; this results in a very high hormone turn-over rate so fetuses are very dependent on the maternal supply of iodide, especially in the first trimester [5]. In adults and older children, thyroid hormones help regulate metabolism.

EPA's perchlorate reference dose is 0.0007 mg/kg/day [6]. The RfD is based on an epidemiological study that measured the radioactive iodide uptake inhibition in healthy adults following perchlorate exposure. There is concern that the RfD is based on a study of healthy adults and does not adequately address the risks of perchlorate exposure for fetuses, infants, children, and other sensitive populations [7]. A recent report published by scientists from ATSDR recommended further investigation to evaluate the risk of perchlorate exposure to sensitive populations [8].

Populations of concern for exposure to perchlorate include pregnant and nursing mothers, fetuses and small children, and people with severe iodide deficiency or have hypothyroidism. The health implications of perchlorate exposure could be serious for populations of concern.

b. Justification for Exposure Investigation

The RfD of 0.0007 mg/kg/day translates to a concentration of 24.5 ppb if one assumes that a 70 kg adult is only exposed to perchlorate through consumption of 2 L of drinking water per day. The current levels of perchlorate measured in drinking water in the North Morrow Perchlorate Study Area are below the RfD when only drinking water is considered as a source of exposure. However, since perchlorate has been detected in dairy milk tested and is known to bioconcentrate in produce grown with contaminated irrigation water, additional sources may contain perchlorate and residents could be exposed to these other sources in addition to drinking water. More data is needed to determine whether other potential sources of perchlorate, such as milk, combined with drinking water, results in exposure to unacceptable levels of perchlorate for populations of concern within the study area.

c. Objectives

The primary objective of this investigation is to gather additional data to better address perchlorate exposure in the North Morrow Perchlorate Study Area. Sampling local produce that has been grown within the study area and dairy milk from cows that may have been exposed to perchlorate will allow SHINE to better estimate resident's combined exposure. The combined exposure estimate will be calculated for people of different ages with a focus on young children under the age of 6 and women ages 15-44 since they are populations of concern. The sampling results will be compared to perchlorate concentrations found in food items tested in national studies. Exposure estimates will be compared to the RfD of 0.0007 mg/kg/day to determine if exposure is nearing levels of concern for sensitive populations. Appropriate risk messages will be developed for the community according to sampling results.

III. Methods

a. Design

The design of this exposure investigation is to test milk and produce from the North Morrow Perchlorate Area. There is a need to balance collection of food items realistically consumed by residents in the perchlorate study area while obtaining local commodities that may be impacted by perchlorate contaminated irrigation water. All milk and food items will be collected within the bounds of the area where ground water has been found contain perchlorate. Produce samples will be both locally grown as well as from outside the area, referred to as control samples. Control samples will provide additional information, on top of national data, that can be compared to the results of analyzed samples grown within the perchlorate area.

SHINE will purchase milk from stores in the perchlorate area for perchlorate analysis. This milk is largely regionally produced milk which maintains a sense of locality but it very well could come from states other than Oregon. There are dairy farms in the area but it is unlikely that residents consume milk purchased directly from a single dairy farmer because this service does not appear to be available. Residents are much more likely to buy and consume milk from grocery and convenience stores which are composites of milk from several dairies. It only takes one dairy to contribute milk to the composite from cows whose milk contains perchlorate that contaminates the off-the-shelf product. If perchlorate is detected in the composite, off-the-shelf milk samples, the concentration will be lower than what would be found if the single source were tested but will be a more accurate representation of exposure for residents living in the area.

It is plausible that people in the area frequently consume locally grown produce. Residents within the area are not likely to limit their diets only to local produce but they may consume several local items at a given time that have been grown in the area with perchlorate contaminated irrigation water. To best account for impacts of contaminated groundwater on local produce, SHINE will collect produce grown in the North Morrow Perchlorate Area that has to the potential to be irrigated with water containing perchlorate. At this stage of the exposure investigation, the field where they were grown will not be determined at the time of sampling.

b. Investigation Population

Sampling will be focused on produce and milk. No participants will be needed for this exposure investigation.

c. Data Collection/Sampling Procedures

Milk

12-16 milk samples will be purchased off-the-shelf from grocery stores and local markets within the North Morrow Perchlorate Area. Milk collected will be any brand available from the store whether it is from the region or from California alone. The samples will represent what is available to the residents and will include skim, 1%, 2%, and whole milk. Milk samples will be shipped on dry ice to STL for analysis within 24 hours of collection. They will be stored at – 20°C until they are analyzed.

The following information will be documented at the time of sample collection:

- Store Name
- Store Location
- Milk Brand
- Dairy Name and Location (if available)
- Fat Content
- Lot number
- Expiration/Use-By Date

Produce

Watermelon, tomatoes, and corn will be purchased largely from farmer's stands and from local grocery stores within the North Morrow Perchlorate Study Area. The specific commodities collected will be modified depending on what local produce is available at the time of sampling and that are likely to uptake perchlorate from contaminated groundwater. SHINE will try to select items that are locally grown and consumed by sensitive populations. SHINE will analyze 12-16 watermelon samples, 6-8 corn samples, and 6-8 tomato samples. The number of corn and potato samples analyzed is dependent on the amount of funding available. A few watermelon control sample grown outside of the study area (i.e. from California) will be collected for comparison to locally grown produce. Control samples for other produce items will be collected if funding permits.

The following information will be documented at the time of sample collection:

- Commodity type
- Name of grocery store of farm stand
- Name of farm where commodity was grown
- Location of farm where commodity was grown
- Number of commodity purchased at a given location
- Lot number if applicable

If produce is purchased at a grocery store or larger market, rather than from a local farmer's market stand, produce labels will be inspected and produce department personnel will be consulted to ensure the produce was grown locally.

Sample Processing – Produce

Produce samples will be prepared and homogenized using method: USDA SOP: PDP-LABOP-03 (Appendix A). There is a method for corn, tomatoes, and watermelon. Seeds will be removed from the watermelons. Deionized water will be used to wash the produce and clean the food processor and utensils.

After processing, all produce samples will be kept frozen at – 20°C until they are analyzed. Samples will be shipped to the laboratory for analysis in coolers with dry ice to keep samples frozen.

Sample Analysis

Samples will be analyzed by STL in Denver using EPA method 8321A. Please see Appendix B for more details regarding this method.

Detection limits are very low for perchlorate analysis in milk and produce samples. Detection limits for method 8321A fall in the parts per trillion range so there is not a concern about all of the perchlorate detections falling below the MDL.

d. Fieldwork Coordination

Fieldwork for this project will be coordinated by SHINE and will involve visiting the North Morrow Perchlorate Study Area to obtain milk and produce samples. Following collection, samples will be kept on ice in a cooler for transport back to Portland, with the exception of watermelons, they will be kept cool until processing, and will be processed within a 2-3 days of collection before they spoil.

e. Data Analysis
There will be enough milk and watermelon samples to calculate average concentrations and evaluate the variability of the data. Statistical analysis for corn and potatoes will be dependent on the number of samples collected.

If perchlorate is detected in any of the commodities analyzed, SHINE will derive a combined exposure estimate. Combined exposure estimates will be compared to the RfD. Combined exposure will be calculated using both the mean (arithmetic or geometric depending on distribution) and the maximum concentrations found in each commodity and will then be combined with exposure to the mean and maximum (approximately 3.4 and 13 ppb) concentration respectively found by DEQ and EPA in private drinking water wells. Exposure estimates will also be calculated for individual sources only if concentrations are high enough to warrant concern. Consumption rates for water, milk, and produce will be obtained from EPA's Exposure Factors Handbook. Exposure estimates will be calculated for various age groups and will target sensitive populations. The exposure estimates will be just that, an estimate, and are not intended to encompass potential exposure from all food items that an individual may consume. The data analysis is not intended to provide a complete characterization of health risks.

Results of the EI will be compared to data from other studies that tested food and milk samples for perchlorate from around the U.S. This information will provide a useful reference to evaluate whether commodities in the North Morrow Perchlorate Study are more or less impacted by the presence of perchlorate in groundwater than in California or Arizona, for example.

If Combined Exposure is Less than RfD
If the estimates are below the RfD, then it will be likely that residents are not exposed to perchlorate at unacceptable levels from ingestion of store bought milk, local produce, and private drinking water within the North Morrow Perchlorate Study Area. SHINE is aware that residents could still be exposed from other sources, such as produce from California, or produce not tested, which would be important information to relay to residents.

If Combined Exposure is at or Near RfD
If the contribution to estimated perchlorate exposure from milk and food analyzed for the EI in combination with drinking water is found to be a public health risk (at or near the RfD), the risk messages will focus on enabling the sensitive populations to make informed decisions to lower their own risk. Further investigation will be recommended to better characterize sources of contamination (i.e. locating irrigation wells of concern or cow feed) if certain commodities from an area appear to contribute substantially to exposure.

f. Impact of EI Results on Public Health Decisions
The results of this EI will be targeted towards the residents in the North Morrow Perchlorate Study Area with contaminated drinking water who are also considered to be at risk from exposure to perchlorate. If perchlorate is found at appreciable concentrations in produce and dairy in addition to what has already been measured in the drinking water, SHINE would be better equipped to evaluate the combined risk from ingestion for residents in the Lower Umatilla Basin. When only considering drinking water concentrations of perchlorate in the Lower Umatilla Basin area, it does not appear that there is a public health risk. However, the risk could change significantly with additional data. Knowing the relative source contribution of perchlorate exposure and whether residents are being exposed to perchlorate at concentrations of concern will allow us to assess risk and to properly direct risk messages to protect the public's health.

If results suggest that residents are at risk from exposure to perchlorate, SHINE would educate the affected residents on how to reduce and prevent exposure to perchlorate. For example, pregnant or breastfeeding mothers would be encouraged to find a multi-vitamin that contains iodine because many prenatal vitamins do not. For developing children, parents would be encouraged to continue feeding developing children a balanced, nutritious diet containing a variety of foods while adding in some food items rich in iodine or that have been iodized. Foods known to contain high levels of iodine include: baked goods, seafood, and iodized salt. Parents could also provide the children with vitamins that contain iodine. If other data warrant, SHINE can recommend that at risk populations find an alternate source of drinking water or use a reverse osmosis treatment system to remove the drinking water pathway of exposure. However, this may be a burdensome, costly recommendation and would have to be weighed carefully. An important risk communication strategy will be to prepare messages that minimize impacts of EI results on the local agricultural economy.

IV. Community Involvement

Exposure investigation objectives have been shared with state and federal inter-agency team that includes: DEQ, EPA, ODA, and OSU. They have provided questions and comments about SHINE's sampling objectives some of which have been incorporated into this protocol. SHINE will communicate results of the exposure investigation to community members in Morrow and Umatilla Counties in collaboration with local health department officials, community leaders, and members of the inter-agency team.

V. Estimated Time Frame
(This timeframe was developed in August, 2005. The timeframe has shifted. Please see the summary of SHINE's approach to the exposure investigation titled, *North Morrow Perchlorate Exposure Investigation, 12/05, Oregon DHS, SHINE Program*.)

2005

August: Sampling protocol development

September:	Sample collection Sample processing/freeze drying
October:	Sample analysis
November:	Sample analysis
December:	Data analysis and combined exposure estimation
Jan/February:	Data analysis and combined exposure estimation cont. EI report writing

VI. Projected Budget and Source of Funding

(This budget may exclude some of the total expenses and will be updated upon completion of the exposure investigation)
Funding for this exposure investigation will come from the carry-over 1043 fund. The projected cost of the project is $10,451.

Cost of food items:	Milk	16 cartons * $2.75	=$44.00
	Melons	16 * $6.00	= $96.00
	Tomatoes	8 * $0.50	=$4.00
	Corn	8 * $0.25	=$2.00
	Subtotal		**=$146.00**
Sample Processing & Shipping:	Ice For Coolers		=$5.00
	Sample Shipping	To & Frm Lab	=$400.00
	Subtotal		**=$405.00**
Sample Analysis:	$200/sample		
	Subtotal	48 samples * $200.00	**=$9600**
Travel for Sampling:	Car Rental		=$100.00
	Gas		=$75.00
	Food	2 people, 2 days	=$125.00
	Subtotal		**=$300.00**
	TOTAL COSTS		**=$10,451**

VII. References

[1] Jackson WA, Joseph P, Laxman P et al. 2005. Perchlorate accumulation in forage and edible vegetation. *Journal of Agricultural and Food Chemistry*; 53:369-373.

[2] The Institute of Environmental and Human Health, Texas Tech University. 2001. A Final Report Entitled: Uptake of the perchlorate anion in to various plant species.

[3] Kirk AB, Martinelango PK, Tian K et al. 2005. Perchlorate and iodine in dairy and breast milk. *Environmental Science & Technology*; 39(7):2011-2017.

[4] United States Government Accountability Office (GAO). 2005. PERCHLORATE: A system to track sampling and cleanup results as needed. Report to the Chairman, Subcommittee, on Environment and Hazardous Materials, Committee on Energy and Commerce, House of Representatives. GAO-05-462 Perchlorate. Washington, D.C., May, 2005.

[5] Hershman JM. 2005. In My View…Perchlorate and thyroid function: What are the environmental issues? *Thyroid*; 15(5):427-431.

[6] United States Environmental Protection Agency (EPA). 2005. Reference dose for chronic oral exposure to perchlorate and perchlorate salts. Washington, D.C.: U.S. Environmental Protection Agency, Integrated Risk Information System; 2005.

[7] Ginsberg G, Rice D. 2005. The NAS perchlorate review: Questions remain about the perchlorate RfD. *Environmental Health Perspectives* [Online]; [doi:10.1289/ehp.8252]:2-15. URL: http://dx.doi.org/.

[8] Scinicariello F, Murray HE, Smith L. 2005. Genetic factors that might lead to different responses in individual's exposure to perchlorate. *Environmental Health Perspectives* [Online]; [doi:10.1289/ehp.8076]:1-39. URL: http://dx.doi.org/.

Appendix B. USDA Method PDP-LABOP-03 For Produce Sample Processing

United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Pesticide Data Program

SOP No.: PDP-LABOP-03 Page 1 of 16
Title: Sample Preparation for Fresh Fruit and Vegetable, Grain, and Processed Commodities
Revision: 13 Replaces: 07/01/03 Effective: 10/01/04

1. Purpose:

To provide standard procedures for the preparation of USDA/AMS Pesticide Data Program
(PDP) fresh fruit and vegetable, grain, and processed commodities.

2. Scope:

This standard operating procedure (SOP) shall be followed by all laboratories conducting residue studies for PDP, including support laboratories conducting stability or other types of
studies that may impact the program.

3. Outline of Procedures:

5.1 Preparation and Homogenization of Fresh Fruit and Vegetable Commodities

a. Apples
b. Asparagus
c. Bananas
d. Broccoli
e. Cabbage
f. Cantaloupes
g. Carrots
h. Cauliflower
i. Celery
j. Corn
k. Cucumbers
l. Eggplant
m. Grapes
n. Green Beans
o. Head Lettuce
p. Honeydew Melons
q. Leaf Lettuce
r. Mushrooms
s. Onions
t. Oranges/Grapefruit
u. Peaches/Nectarines
v. Pears
w. Peas
x. Pineapples
y. Plums

z. Potatoes
aa. Spinach
ab. Strawberries
ac. Summer Squash
ad. Sweet Cherries
ae. Sweet Peppers
af. Sweet Potatoes
ag. Tomatoes
ah. Watermelon
ai. Winter Squash

j. Corn
Remove husk and silk from each ear. Wash each ear under cold running tap water for approximately 15-20 seconds to assure that all surfaces are rinsed. Allow to drain for at least 2 minutes on paper towels on a flat surface. Using a clean dry knife or other appropriate utensil, remove kernels from cob. Mechanically chop just until a visually homogeneous mixture is attained.

ag. Tomatoes
Wash each tomato under cold running tap water for approximately 15-20 seconds to assure that all surfaces of the tomato are rinsed. Allow to drain for at least 2 minutes on paper towels on a flat surface. Do not peel. Using a clean, dry knife, cut the tomato around the stem area. Remove any stem, being careful to remove as little of the meat as possible. The tomatoes may be quartered prior to homogenization. Mechanically chop just until a visually homogeneous mixture is attained.

ah. Watermelon
Wash each melon under cold running tap water for approximately 15-20 seconds to assure that all surfaces are rinsed. Allow to drain for at least 2 minutes on paper towels on a flat surface. Using a clean, dry knife, cut each watermelon into quarters, and remove the rind. For large watermelons take alternate quarters of each fruit and mechanically chop just until a visually homogeneous mixture is attained. For small watermelons, take the entire sample and mechanically chop just until a visually homogeneous mixture is attained.

Appendix C. Method SW8321A - Used by STL Denver for Perchlorate Analysis

STL-DENVER

LOW LEVEL PERCHLORATE ANALYSIS BY IC/MS/MS

Method SW-8321A

The low-level analysis of perchlorate is performed by ion chromatography with electrospray ionization tandem mass spectrometry (IC/MS/MS). This is distinct from STL Denver's LC/MS/MS configuration for perchlorate analysis in the use of a larger injection volume, a more efficient ion exchange column, electrolytic eluent generation, and ion suppression technology. This IC provides three times greater separation of perchlorate from potential interfering substances than is achieved by LC. The procedure can be performed directly on water samples with TDS > 20,000 mg/L with no off-line clean up steps. The MS/MS detector system is the same.

The procedure applies to water, soil, and vegetation samples. The routine reporting limit is 0.010 ug/L in water and 0.10 ug/kg in soil and vegetation.

SEVERN TRENT LABORATORIES, INC. TERMS AND CONDITIONS OF SALE (Short Form)

Where a purchaser (Client) places an order for laboratory, consulting or sampling services from Severn Trent Laboratories, Inc. (STL), a Delaware corporation, STL shall provide the ordered services pursuant to these Terms and Conditions, and the related Quotation or Price Schedule, or as agreed in a negotiated contract. In the absence of a written agreement to the contrary, the Order constitutes an acceptance by the Client of STL's offer to do business under these Terms and Conditions, and an agreement to be bound by these Terms and Conditions. No contrary or additional terms and conditions expressed in a Client's document shall be deemed to become a part of the contract created upon acceptance of these Terms and Conditions, unless accepted by STL in writing.

1. ORDERS AND RECEIPT OF SAMPLES

1.1 The Client may place the Order (i.e., specify a Scope of Work) either by submitting a purchase order to STL in writing or by telephone subsequently confirmed in writing, or by negotiated contract. Whichever option the Client selects for placing the Order, the Order shall not be valid unless it contains sufficient specification to enable STL to carry out the Client's requirements. In particular, samples must be accompanied by: a) adequate instruction on type of analysis requested, and b) complete written disclosure of the known or suspected presence of any hazardous substances, as defined by applicable federal or state law. Where any samples which were not accompanied by the required disclosure, cause interruptions in the lab's ability to process work due to contamination of instruments or work areas, the Client will be responsible for the costs of clean up and recovery.

1.2 The Client shall provide one week's advance notice of the sample delivery schedule, or any changes to the schedule, whenever possible. Upon timely delivery of samples, STL will use its best efforts to meet mutually agreed turnaround times. All turnaround times will be calculated from the point in time when STL has determined that it can proceed with defined work following receipt, inspection of samples, and resolution of any discrepancies in Chain-of-Custody forms and project guidance regarding work to be done (Sample Delivery Acceptance). In the event of any changes in the sample delivery schedule by the Client, prior to Sample Delivery Acceptance, STL reserves the right to modify its turnaround time commitment, to change the date upon which STL will accept samples, or refuse Sample Delivery Acceptance for the affected samples.

1.3 STL reserves the right, exercisable at any time, to refuse or revoke Sample Delivery Acceptance for any sample which in the sole judgment of STL: a) is of unsuitable volume; b) may pose a risk or become unsuitable for handling, transport, or processing for any health, safety, environmental or other reason, whether or not due to the presence in the sample of any hazardous substance and whether or not such presence has been disclosed to STL by the Client; or c) holding times cannot be met, due to passage of more than 48 hours from the time of sampling or 1/2 the holding time for the requested test, whichever is less.

1.4 Prior to Sample Delivery Acceptance, the entire risk of loss or damage to samples remains with the Client, except where STL provides courier services. In no event will STL have any responsibility or liability for the action or inaction of any carrier shipping or delivering any sample to or from STL's premises. Client is responsible to assure that any sample containing any hazardous substance which is to be delivered to STL's premises will be packaged, labeled, transported and delivered properly and in accordance with applicable laws.

2. PAYMENT TERMS

2.1 Services performed by STL will be in accordance with prices quoted and later confirmed in writing or as stated in the Price Schedule. Quoted prices do not include sales tax. Applicable sales tax will be added to invoices where required by law. Invoices may be submitted to Client upon completion of any sample delivery group. Payment in advance is required for all Clients except those whose credit has been established with STL. For Clients with approved credit, payment terms are net 30 days from the date of invoice by STL. All overdue payments are subject to an additional interest and service charge of one and one-half percent (1.5%) (or the maximum rate permissible by law, whichever is lesser) per month or portion thereof from the due date until the date of payment. All fees are charged or billed directly to the Client. The billing of a third party will not be accepted without a statement, signed by the third party, that acknowledges and accepts payment responsibility. STL may suspend work and withhold delivery of data under this order at any time in the event Client fails to make timely payment of its invoices. Client shall be responsible for all costs and expenses of collection including reasonable attorney's fees. STL reserves the right to refuse to proceed with work at any time based upon an unfavorable Client credit report.

3. CHANGE ORDERS, TERMINATION

3.1 Changes to the Scope of Work, price, or result delivery date may be initiated by STL after Sample Delivery Acceptance due to any condition which conflicts with analytical, QA or other protocols warranted in these Terms and Conditions. STL will not proceed with such changes until an agreement with the Client is reached on the amount of any cost, schedule change or technical change to the Scope of Work, and such agreement is documented in writing.

3.2 Changes to the Scope of Work, including but not limited to increasing or decreasing the work, changing test and analysis specification, or acceleration in the performance of the work may be initiated by the Client after sample delivery acceptance. Such a change will be documented in writing and may result in a change in cost and turnaround time commitment. STL's acceptance of such changes is contingent upon technical feasibility and operational capacity.

3.3 Suspension or termination of all or any part of the work may be initiated by the Client. STL will be compensated consistent with Section 2 of these Terms and Conditions. STL will complete all work in progress and be paid in full for all work completed.

4. WARRANTIES AND LIABILITY

4.1 Where applicable, STL will use analytical methodologies which are in substantial conformity with published test methods. STL has implemented these methods in its Laboratory Quality Manuals and referenced Standard Operating Procedures and where the nature or composition of the sample requires it, STL reserves the right to deviate from these methodologies as necessary or appropriate, based on the reasonable judgment of STL, which deviations, if any, will be made on a basis consistent with recognized standards of the industry and/or STL's Laboratory Quality Manuals. Client may request that STL perform according to a mutually agreed Quality Assurance Project Plan (QAPP). In the event that samples arrive prior to agreement on a QAPP, STL will proceed with analyses under its standard Quality Manuals then in effect, and STL will not be responsible for any resampling or other charges if work must be repeated to comply with a subsequently finalized QAPP.

4.2 STL shall start preparation and/or analysis within holding times provided that Sample Delivery Acceptance occurs within 48 hours of sampling or 1/2 of the holding time for the test, whichever is less. Where resolution of inconsistencies leading to Sample Delivery Acceptance does not occur within this period, STL will use its best efforts to meet holding times and will proceed with the work provided that, in STL's judgment, the chain-of-custody or definition of the Scope of Work provide sufficient guidance. Reanalysis of samples to comply with STL's Quality Manuals will be deemed to have met holding times provided the initial analysis was performed within the applicable holding time. Where reanalysis demonstrates that sample matrix interference is the cause of failure to meet any Quality Manual requirements, the warranty will be deemed to have been met.

4.3 STL warrants that it possesses and maintains all licenses and certifications which are required to perform services under these Terms and Conditions provided that such requirements are specified in writing to STL prior to Sample Delivery Acceptance. STL will notify the Client in writing of any decertification or revocation of any license, or notice of either, which affects work in progress.

4.4 The warranty obligations set forth in Sections 4.1, 4.2 and 4.3 are the sole and exclusive warranties given by STL in connection with any services performed by STL or any Results generated from such services, and STL gives and makes NO OTHER REPRESENTATION

OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED. No representative of STL is authorized to give or make any other representation or warranty or modify this warranty in any way.

4.5 Client's sole and exclusive remedy for the breach of warranty in connection with any services performed by STL, will be limited to repeating any services performed, contingent on the Client's providing, at the request of STL and at the Client's expense, additional sample(s) if necessary. Any reanalysis requested by the Client generating Results consistent with the original Results will be at the Client's expense. If resampling is necessary, STL's liability for resampling costs will be limited to actual cost or one hundred and fifty dollars ($150) per sample, whichever is less.

4.6 STL's liability for any and all causes of action arising hereunder, whether based in contract, tort, warranty, negligence or otherwise, shall be limited to the lesser amount of compensation for the services performed or $100,000. All claims, including those for negligence, shall be deemed waived unless suit thereon is filed within one year after STL's completion of the services. Under no circumstances, whether arising in contract, tort (including negligence), or otherwise, shall STL be responsible for loss of use, loss of profits, or for any special, indirect, incidental or consequential damages occasioned by the services performed or by application or use of the reports prepared.

4.7 In no event shall STL have any responsibility or liability to the Client for any failure or delay in performance by STL which results, directly or indirectly, in whole or in part, from any cause or circumstance beyond the reasonable control of STL. Such causes and circumstances shall include, but not be limited to, acts of God, acts of Client, acts or orders of any governmental authority, strikes or other labor disputes, natural disasters, accidents, wars, civil disturbances, equipment breakdown, matrix interference or unknown highly contaminated samples that impact instrument operation, unavailability of supplies from usual suppliers, difficulties or delays in transportation, mail or delivery services, or any other cause beyond STL's reasonable control.

5. RESULTS, WORK PRODUCT

5.1 Data or information provided to STL or generated by services performed under this agreement shall only become the property of the Client upon receipt in full by STL of payment for the whole Order. Ownership of any analytical method, QA/QC protocols, software programs or equipment developed by STL for performance of work will be retained by STL, and Client shall not disclose such information to any third party.

5.2 Data and sample materials provided by Client or at Client's request, and the result obtained by STL shall be held in confidence (unless such information is generally available to the public or is in the public domain or Client has failed to pay STL for all services rendered or is otherwise in breach of these Terms and Conditions), subject to any disclosure required by law or legal process.

5.3 Should the Results delivered by STL be used by the Client or Client's client, even though subsequently determined not to meet the warranties described in these Terms and Conditions, then the compensation will be adjusted based upon mutual agreement. In no case shall the Client unreasonably withhold STL's right to independently defend its data.

5.4 STL reserves the right to perform the services at any laboratory in the STL network, unless the Client has specified a particular location for the work. In addition, STL reserves the right to subcontract services ordered by the Client to another laboratory or laboratories, if, in STL's sole judgment, it is reasonably necessary, appropriate or advisable to do so. STL will in no way be liable for any subcontracted services (outside the STL network) except for work performed at laboratories which have been audited and approved by STL.

5.5 STL shall dispose of the Client's samples 30 days after the analytical report is issued, unless instructed to store them for an alternate period of time or to return such samples to the Client, in a manner consistent with U.S. Environmental Protection Agency regulations or other applicable federal, state or local requirements. Any samples for projects that are canceled or not accepted, or for which return was requested, will be returned to the Client at his own expense. STL reserves the right to return to the Client any sample or unused portion of a sample that is not within STL's permitted capability or the capabilities of STL's designated waste disposal vendor(s). ALL DIOXIN, MIXED WASTE, AND RADIOACTIVE SAMPLES WILL BE RETURNED TO THE CLIENT, unless prior arrangements for disposal are made.

5.6 Unless a different time period is agreed to in any order under these Terms and Conditions, STL agrees to retain all records for five (5) years.

5.7 In the event that STL is required to respond to legal process related to services for Client, Client agrees to reimburse STL for hourly charges for personnel involved in the response and attorney fees reasonably incurred in obtaining advice concerning the response, preparation to testify, and appearances related to the legal process, travel and all reasonable expenses associated with the litigation.

6. INSURANCE

6.1 STL shall maintain in force during the performance of services under these Terms and Conditions. Workers' Compensation and Employer's Liability Insurance in accordance with the laws of the states having jurisdiction over STL's employees who are engaged in the performance of the work. STL shall also maintain during such period, Comprehensive General and Contractual Liability (limit of $2,000,000 per occurrence/ aggregate), Comprehensive Automobile Liability, owned and hired, ($1,000,000 combined single limit), and Professional/Pollution Liability Insurance (limit of $5,000,000 per occurrence/aggregate).

7. AUDIT

7.1 Upon prior notice to STL, the Client may audit and inspect STL's records and accounts covering reimbursable costs related to work done for the Client, for a period of two (2) years after completion of the work. The purpose of any such audit shall be only for verification of such costs, and STL shall not be required to provide access to cost records where prices are expressed as fixed fees or published unit prices.

8. MISCELLANEOUS PROVISIONS

8.1 These Terms and Conditions, together with any additions or revisions which may be agreed to in writing by STL, embody the whole agreement of the parties and provide the only remedies available. There are no promises, terms, conditions, understandings, obligations or agreements other than those contained herein, and these Terms and Conditions shall supersede all previous communications, representations, or agreements, either verbal or written, between the Client and STL. These Terms and Conditions, and any transactions or agreements to which they apply, shall be governed both as to interpretation and performance by the laws of the state where STL's services are performed.

8.2 The invalidity or unenforceability, in whole or in part of any provision, term or condition hereof shall not affect in any way the validity or enforceability of the remainder to these Terms and Conditions, the intent of the parties being that the provisions be severable. The section headings of these Terms and Conditions are intended solely for convenient reference and shall not define, limit or affect in any way these Terms and Conditions or their interpretations. No waiver by either party of any provision, term or condition hereof or of any obligation of the other party hereunder shall constitute a waiver of any subsequent breach or other obligation.

8.3 The obligations, liabilities, and remedies of the parties, as provided herein, are exclusive and in lieu of any others available at law or in equity. Indemnifications, releases from liability and limitations of liability shall apply, notwithstanding the fault, negligence or strict liability of the party to be indemnified, released, or whose liability is limited, except to the extent of sole negligence or willful misconduct.

Appendix D. EPA QA review

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue
Seattle, Washington 98101

August 17, 2006

Reply To
Attn of: MGREPOGR
OEA-095

MEMORANDUM

Subject: Data Assessment of Perchlorate Analysis of Produce and Milk Products Purchased from the Local Stores in the Lower Umatilla Basin and the vicinity of North Morrow Site

FROM: for Ginna Grepo-Grove, Chemist
Quality Assurance Office

To: Daniel D. Opalski, Director
Office of Environmental Cleanup

Christine Kelly, Project Manager
USEPA

cc: Sylvia Kawabata, Unit Manager
Site Assessment and Cleanup Unit 2
Office of Environmental Cleanup

Ken Marcy, Site Assessment Manager
Office of Environmental Cleanup

The quality assurance (QA) review of the perchlorate analysis of 17 milk and 47 produce samples purchased from different local stores located from the above referenced site has been completed. The perchlorate data was generated by an exposure study conducted by the Oregon Department of Human Services (ODHS) Superfund Health Investigation and Education (SHINE) program in the North Morrow perchlorate area funded through a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR).

Since the goal of this review is to determine the quality of the perchlorate data generated by the exposure study for EPA's possible use during PA/SI and other site-related Superfund investigation activities, the reviewer based the data evaluation on the specifications of the OMB's Data Quality Guidelines (*66 Federal Register 49718 and 49719, September 28, 2001*), EPA's QA Order 5360A.2 and

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General Conclusion:

The perchlorate data generated by this study do not meet the data quality procedures and measures set forth by the EPA's Information Quality Guidance. The study commenced without an EPA required Quality Assurance Project Plan. Although the exposure study was conducted with a work plan entitled "Exposure Investigation Protocol for Lower Umatilla Basin", the work plan failed to sufficiently address EPA's essential QA planning elements, such as data quality objectives and sample collection conceptual design and rationale, analytical measurement objectives and the project-required field and laboratory documentation and data deliverables. The initial analyses of the samples were performed by Severn-Trent Lab located in Denver, CO and some of the samples were sent to CDC and FDA labs for confirmatory analyses due to high levels of perchlorate reported by STL. Proper sample control and transfer of sample custody from one lab to another was not adequately documented. The situation was made more complicated by the significant variability of the perchlorate values reported by three different labs for some of the samples (some of them differ by 3 orders of magnitude) and thus, further rendered the integrity of the samples and the data suspect. Analytical results reported and the available supporting documentation may not withstand public and/or legal scrutiny.

Given the overall weaknesses and limitations of the data set as a whole, the data cannot be used by EPA in its assessment of perchlorate contamination in the North Morrow area.

Specific comments:

1. There were no documented discrepancies noted during the initial analysis of milk and produce samples performed by STL on January 28, 2006 and December 24, 2005, respectively. The retention times of an isotopically labeled perchlorate compound was used for compound identification and the response of the labeled compound was also used for quantitation. The perchlorate identification and quantitation are correct. There were no transcription errors observed between the raw data and the reported results. The calibrations were acceptable and the instrument remained stable throughout the course of the analytical sequences. There were no QC samples (matrix spike and matrix spike duplicate samples) analyzed with the milk products; however, the lab control sample and duplicate (LCS/LCSD) results were good. LCS/LCSD recoveries and reproducibility were acceptable.

   There were trace levels of perchlorate in the method blanks associated with the samples. However, since the perchlorate concentrations detected in all of the samples are greater than 10x the values in the blanks, therefore, the blank contamination does not appear to have affected the quality of the data reported.

   Based on all of the information provided for this review, there is no clear sample analysis or data integrity reason to reject the original STL data as faulty data.

2. The high concentration levels of perchlorate reported from the 2 milk samples and 1 watermelon sample may seem improbable and may suggest the potential for lab contamination during STL's initial analyses. However, other than the lower results from the re-analyses done by CDC, FDA and STL (again), there's no real evidence in the raw data to support contamination. At this time, it will be very difficult to assess any lab contamination because the sample analyses were performed quite sometime ago.

Based on all of the information provided for this review, there is no clear indication of lab contamination that would lead EPA to reject the original STL data as faulty data.

3. The integrity of the produce samples shipped to FDA and the subsequent perchlorate results are suspect because the samples were left out of the cold storage for 3 days (unfrozen). This happened after the original STL analyses and prior to shipment of samples to the FDA lab.

4. No actual chain-of-custody (COC) documentation and sample control of samples sent to CDC and FDA by STL was provided to EPA for this review. EPA was only provided with a re-constructed and incomplete chain of custody for this portion of the review. In addition the chain-of-custody documentation was incomplete for the original sample collection, storage, and shipment by ODHS, and the original processing by STL. Original documentation of maintenance of sample integrity while samples are collected, in-transit, in process and in storage is required by EPA's quality system to ensure that the resulting data are based on reliable samples.

   Without adequate original chain-of-custody documentation, the integrity of the samples could be suspect.

5. Overall, the project documentation was inadequate to support EPA's use. There are a lot of unaccounted for erasures and inconsistencies between the hand-written notes, the re-constructed COCs, project and sample processing notes and the lab's Case Narratives. These inconsistencies are sufficient to cast additional doubt on the integrity of the samples and the results. For example: The total number of milk vials shipped to STL per sample was not documented. There is no documentation of sample control. STL indicated in the Case narrative that spike and spike duplicate analyses were not performed in milk due to insufficient amount of samples, but after STL's initial analysis, the left over milk samples were sent to CDC and FDA for analysis then sent back to STL for re-analysis – documentation is really not clear where did the milk samples come from for 3 more re-analyses.

   The overall poor documentation for these samples creates further questions about sample and data integrity.

6. Note that assessment of the CDC and FDA generated data was not performed. The analytical data and supporting documentation from CDC and FDA labs were not available at the time of this review.

Appendix A

Background Information:

The following samples were initially analyzed for perchlorate by Severn & Trent Laboratories, Inc (STL) of Denver, CO following the modified SW846 Method 8321A, "*Perchlorate by Ion Chromatography With Electrospray Ionization Tandem Mass Spectrometry (IC/MS/MS)*":

Milk Samples: Purchased on 01/18/06; Verified Time of Sample Receipt (VTSR) at STL on 01/20/06; Analyzed by STL on 01/28/06

M-01-0102	M-01-0202	M-02-0101	M-03-0101	M-04-0102	M-04-0202
M-05-0101	M-06-0102	M-06-0202	M-07-0104	M-07-0204	M-07-0304
M-07-0404	M-08-0103	M-08-0203	M-08-0303	M-09-0101	

Watermelon Samples: Purchased 9/7/05; Processed on 9/8-9/05; 9/12-13/05; VTSR at STL-12/6/05; Analyzed by STL on 12/24/05

W-01-0102	W-01-0202	W-02-0102	W-02-0202	W-03-0101	W-04-0101
W-05-0101R	W-06-0101	W-07-0102	W-07-0202	W-08-0102	W-08-0202
W-09-0102	W-09-0202	W-10-0101R	W-11-0101R		

Corn Samples: Purchased 9/7/05; Processed on 9/8-9/05; 9/12-13/05; VTSR at STL-12/6/05; Analyzed by STL on 12/24/05

C-01-0104	C-010204	C-010304	C-01-0404	C-03-0104
C-03-0204	C-03-0304	C-03-0404	C-05-0103R	C-05-0203R
C-05-0303R	C-08-0104	C-08-0204	C-08-0304	C-08-0404

Tomato Samples: Purchased 9/7/05; Processed on 9/8-9/05; 9/12-13/05; VTSR at STL-12/6/05; Analyzed by STL on 12/24/05

T-02-0104	T-02-0204	T-02-0304	T-02-0404
T-04-0102R	T-04-0202R	T-05-0102R	T-05-0202R
T-06-0104	T-06-0204	T-06-0304	T-06-0404
T-08-0104	T-08-0204	T-08-0304	T-08-0404

The technical holding time (40 CFR 136 water criteria) for perchlorate was exceeded by the produce samples even before shipment to STL lab. However, since the homogenized produce samples were kept frozen at -20C while in storage and during shipment, the data associated was likely not compromised based on holding times.

Due to the elevated levels of perchlorate in some of the samples during initial analysis by STL, some of the samples were shipped to Center for Disease Control (CDC) and Food and Drug Administration (FDA) labs for confirmatory analyses. A reconstructed chain of custody (COC) record for these samples shipped by STL to CDC and FDA labs were prepared by ODHS SHINE after all analyses were completed and was submitted to EPA. However, the actual COC records and sample control documentation from STL to the FDA or CDC labs were not available at the time of this review.

List of samples (16 samples) shipped by STL to FDA lab for confirmatory perchlorate analysis following the FDA Method, "*Rapid determination of perchlorate Anion in Foods by Ion Chromatography-Tandem Mass Spectrometry*", *revision 2, April 12, 2005:* Date of sample shipment and receipt at FDA: undocumented (most probably - the same shipment date as CDC – 2/8/06).

Milk samples:

M-03-0101 M-04-0102 M-05-0101 M-06-0202 M-07-0404 M-08-0303

Watermelon Samples:

W-01-0102 W-02-0102 W-03-0101 W-05-0101R W-07-0101 W-10-0101R

Tomato Samples:

T-04-0102R T-06-0304

Corn Samples:

C-03-0104 C-01-0204

List of Samples Shipped on 02/08/06 by STL to CDC lab for analysis (4 milk samples- CDC used 675 mls for each sample):

M-04-0102 M-04-0102 M-05-0101 M-07-0404 M-08-0303

List of produce samples that were removed from cold storage, kept outside for 3 days prior to shipment to FDA for re-analysis (based on e-mail communication from STL to ODHS dated 2/2/06): Note that the integrity of these samples and results was likely compromised due to improper sample storage.

W-01-0202	W-02-0102	W-03-0101	W-05-0101R	W-07-0102	W-10-0101R
C-01-0104	C-03-0104	T-04-0102R	T-06-0304		

Left-over samples after analysis at FDA and CDC labs were shipped back to STL on February 27, 2006.

The following samples were re-extracted and re-analyzed by STL using SW846 Method 6890, "*Perchlorate by Electrospray Ionization Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS)*", due to discrepancy of results with the FDA and CDC labs:

Milk Samples:

M-04-0102 M-08-0303 M-08-0303dup M-05-0101 M-07-0404 M-07-0404dup

Watermelon Samples:

W- 02-0102 (result suspect – preservation & holding times)

STL's re-extraction and re-analysis results were comparable with the perchlorate values generated by CDC and FDA. Note, however, that the analytical method used by STL during the initial analysis by STL of milk and produce samples is different from the re-analysis (Method 8321A vs. Method 6890).