Health Consultation

Responses to Public Comments

CHELATED METALS IN GROUNDWATER

STURGIS, ST. JOSEPH COUNTY, MICHIGAN

EPA FACILITY ID: MID005174339

NOVEMBER 26, 2007

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

Health Consultation: A Note of Explanation

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

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

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STURGIS, ST. JOSEPH COUNTY, MICHIGAN

EPA FACILITY ID: MID005174339

Prepared By:

Michigan Department of Community Health
Under Cooperative Agreement with the
U.S. Department of Health and Human Services
Agency for Toxic Substances and Disease Registry

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Acronyms and Abbreviations

µg	microgram
Abbott	Abbott Laboratories (Ross Products Division)
ATSDR	Agency for Toxic Substances and Disease Registry
BLL	blood lead level
BOD	biological oxygen demand
dl	deciliter
DRI	Dietary Reference Intake
DWC	Drinking Water Criteria
EDTA	ethylene diamine tetraacetic acid
EPA	U.S. Environmental Protection Agency
ERM	Environmental Resources Management
FDA	Food and Drug Administration
FS	Feasibility Study
GI	gastrointestinal
GPD	gallons per day
IEUBK	Integrated Exposure Uptake and Biokinetic
IOM	Institute of Medicine
kg	kilogram
L	liter
MDCH	Michigan Department of Community Health
MDEQ	Michigan Department of Environmental Quality
mg	milligram
NAS	National Academy of Sciences
NPDES	National Pollution Discharge Elimination System
ppb	parts per billion
ppm	parts per million
RI	Remedial Investigation
RMEG	Reference Dose Media Evaluation Guide
UL	Tolerable Upper Intake Level
VAS	vertical aquifer sampling
WHO	World Health Organization

Summary

Abbott Laboratories, Ross Products Division, of Sturgis, St. Joseph County, Michigan uses a cleaning product containing the chelator, ethylene diamine tetraacetic acid (EDTA), to remove residual product from processing tanks and equipment. The wastewater from this process is released to a land application site. As the EDTA-containing wastewater enters the groundwater, it causes, through a series of chemical reactions, naturally-occurring iron, manganese, and other common metals to dissociate from the soil and enter the groundwater, chelated to the EDTA. As the groundwater migrates, the EDTA releases these metals and instead chelates other naturally-occurring, more “exotic” metals, such as cobalt and nickel. Some metals have been detected in down-gradient monitoring or drinking water wells at concentrations exceeding drinking water criteria. Water softening does not appear to remove all of these metals. Several drinking water wells have been plugged, and new wells have been drilled into a deeper aquifer.

Chelated cobalt in drinking water is not expected to be bioavailable and poses no public health hazard. Chelated iron and other metals, which exceeded their respective criteria by up to almost eight-fold, are expected to be bioavailable.

Exposure to the contaminated groundwater may have posed a past public health hazard, particularly for persons who cannot effectively excrete metals or who are allergic to nickel. Although the extent of any past exposure is unknown, the past exposure duration was likely no more than seven years. Those persons whose wells were found to be affected should discuss the exposure with their healthcare providers.

The groundwater currently poses no public health hazard, because exposure to it has stopped.

Further monitoring is necessary to prevent future, down-gradient exposure. If the plume continues to move, proactive steps should be taken, such as abandoning shallow wells and installing deeper wells.

Purpose and Health Issues

The purpose of this health consultation is to assess public health risks and document activities conducted by the Michigan Department of Community Health (MDCH) in a community affected by chelated metals in the groundwater. The Michigan Department of Environmental Quality (MDEQ) requested assistance in determining the hazard posed by exposure to the contaminated water.

The chemicals previously detected in private residential wells above their respective drinking water screening levels were cobalt, iron, lead, manganese, and nickel. The chemicals were likely bound to the chelator EDTA, making it unclear whether they would be absorbed in the gut when the water was drunk.

MDCH conducted this health consultation for the federal Agency for Toxic Substances and Disease Registry (ATSDR) under a cooperative agreement. ATSDR conducts public health activities (assessments/consultations, advisories, education) at sites of environmental contamination and concern. ATSDR is primarily an advisory agency. Therefore, its reports usually identify what actions are appropriate to be undertaken by the regulatory agency overseeing the site, other responsible parties, or the research or education divisions of ATSDR.

Background

Abbott Laboratories (Abbott), Ross Products Division, manufactures infant formula and adult nutritional products at its facility in Sturgis, St. Joseph County, Michigan (Figure 1). The facility discharges process wastewater to a land application site under a Groundwater Discharge Permit from MDEQ. The discharge volume averages 550,000 gallons per day (GPD), with a range of 100,000 to 900,000 GPD. The land application system has been in use since its construction in 1988. Abbott directs its non-contact cooling water and storm water to a surface water discharge regulated by a National Pollution Discharge Elimination System (NPDES) permit. Sanitary sewage from the facility is routed to the city of Sturgis water treatment plant (ERM 2006).

The land application site is located about two miles from Abbott's facility (Figure 1). The site covers approximately 180 acres, about 100 of which are used for application areas. The wastewater is applied via spray irrigation systems during warm weather and infiltration basins in the winter. The resulting forage, primarily reed canary grass, is harvested several times per year and used for animal feed, bedding, or compost (ERM 2006).

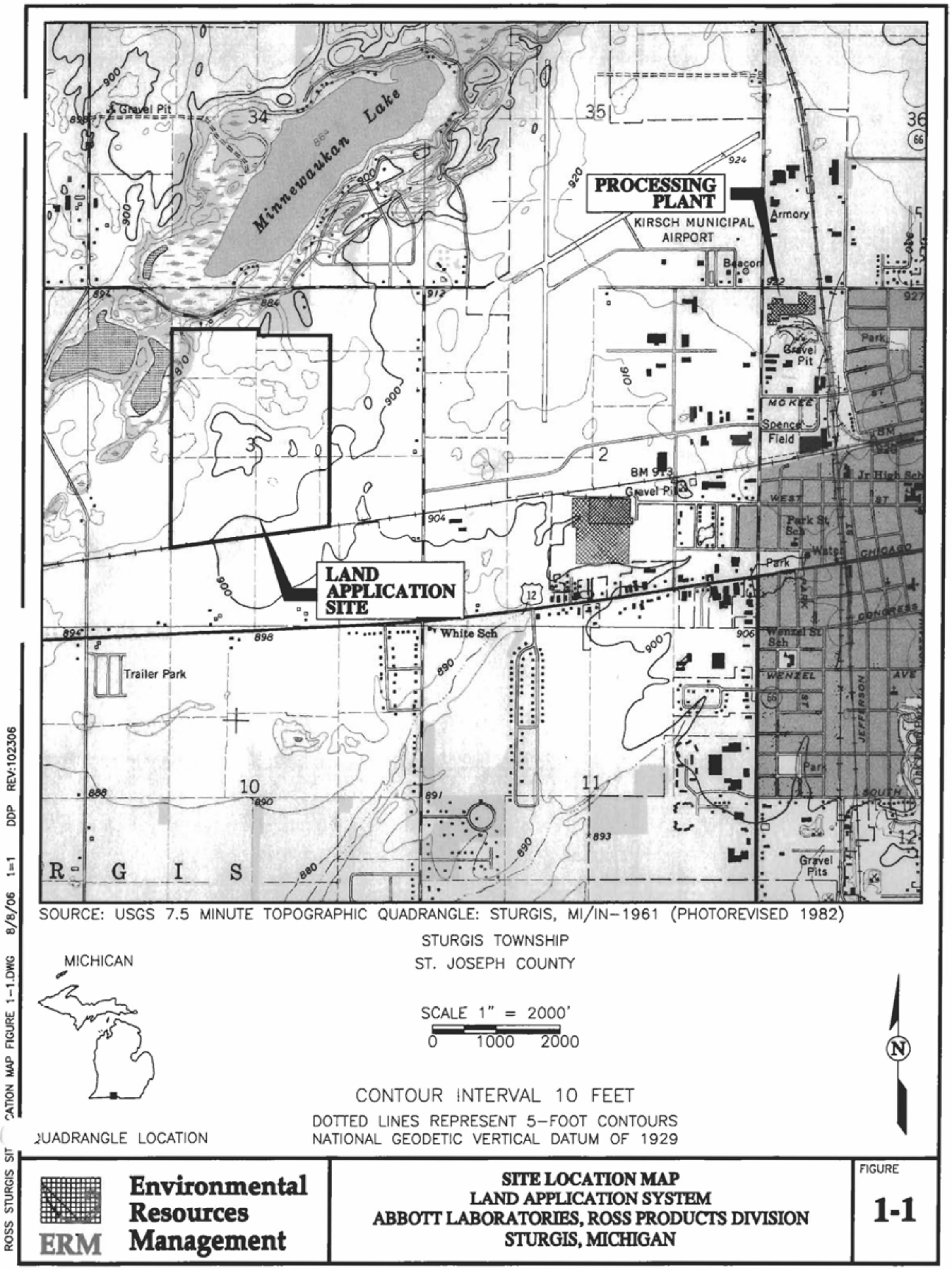
Monitoring well records obtained from MDEQ indicated that levels of some metals in groundwater from on-site wells have exceeded their respective health-based screening levels since 1999, if not earlier. Between 1999 and 2004, the concentrations of cobalt, lead, manganese, and nickel exceeded their respective standards by up to 2.5 (manganese) to 6 (cobalt) times. Note that monitoring wells are not used for drinking water purposes. However, it was not known whether the contaminated aquifer that the monitoring wells were tapped into may have been the same aquifer from which local wells drew drinking water.

Following a compliance evaluation in January 2005 and review of the groundwater water data, MDEQ directed Abbott to conduct a Remedial Investigation and Feasibility Study (RI/FS). The purpose of the RI was to assess the nature and extent of groundwater impacts at the land application site and determine if off-site migration had occurred. Abbott submitted a work plan for the RI/FS to MDEQ and began the investigation in October 2005 (ERM 2006).

In May 2006, MDEQ contacted MDCH and requested assistance in determining public health implications of oral exposure to the contaminated groundwater. MDCH staff attended several meetings with MDEQ, Abbott and its consultant Environmental Resources Management (ERM), and the local health department (Branch – Hillsdale – St. Joseph District). The agencies held a public meeting July 19, 2006, informing residents of the investigation, findings to-date, and future plans.

During the assessment of this site, MDCH sought assistance from the ATSDR Division of Toxicology and Environmental Medicine in determining whether chelated metals in drinking water would be bioavailable (absorbed from the gastrointestinal [GI] tract) in people. The Division's determination is reported in Appendix A.

Figure 1. Abbott Laboratories land application site, Sturgis (St. Joseph County), Michigan



Following the release of the public-comment document in September 2007, MDCH conducted a public information meeting in October in Sturgis Township to discuss the agency's findings.

Discussion

Environmental Contamination

Abbott's consultant, ERM, conducted additional groundwater sampling, beginning with vertical aquifer sampling (VAS), which helps determine the depths at which well screens should be placed for permanent monitoring wells. The VAS work occurred primarily off-site, with samples collected at 10-foot-depth intervals at each location. Following this initial phase of work, monitoring wells were installed. There are currently about 51 monitoring wells in place for this site (ERM 2006, 2007).

Data indicate that there are two aquifers which are separated by clay layers (except near the southern point of Minnewaukan Lake [Figure 1]). The shallow groundwater flow radiates outward in all directions from the land application site, except to the east. The deep groundwater flows primarily southwesterly. ERM estimated that the groundwater flow velocity is an average of 183 feet per year (one-half foot per day), with a maximum of 475 feet per year (ERM 2006).

The RI included residential well sampling. If a residence had a water softener, usually both pre- and post-softener samples were obtained (ERM 2006).

Groundwater concentrations of metals were compared to their respective MDEQ Part 201 Residential and Commercial I Drinking Water Criteria (DWC). The DWC is the concentration of a chemical in drinking water that is considered safe for long-term, daily residential consumption. The criteria assume a person drinks two liters of the water of interest per day, 350 days per year, for 30 years. Adverse aesthetic impacts are taken into account for some substances (such as iron and manganese) and may result in a value lower than a health-based criterion (MDEQ 2004). Exceeding a screening level or criterion does not mean that harmful effects will occur. Rather, an exceedance must be evaluated further, examining the exposure scenario and other factors, to determine level of risk.

Table 1 shows the metals in groundwater samples taken during the RI that exceeded their respective health-based DWCs. Other metals detected in the samples included cadmium, copper, and phosphorus, but the concentrations were below the DWCs for those chemicals. Only those metals that exceeded their respective DWCs are retained here for further evaluation.

To ensure that the water at the Abbott facility did not contain elevated metal concentrations that might be contributing to the contamination in the groundwater, ERM analyzed water from the manufacturing plant for a number of metals as well as arsenic, chloride, phosphorus, and sodium. (The water sampled was that used in drilling and decontamination activities and not used as product water.) Only chloride, copper, phosphorus, and sodium were detected but well below Part 201 criteria (ERM 2006).

Similarly, ERM tested the wastewater from Abbott for metals and other compounds. The only chemical detected that exceeded its health-based DWC was total iron; however, the dissolved portion was less than the aesthetic criterion (which is lower and more restrictive than the

Table 1. Metals in groundwater wells exceeding health-based criteria at the Abbott Laboratories land-application site in Sturgis, St. Joseph County, Michigan

		Up-Gradient		On-Site (Down-Gradient)		Off-Site (Down-Gradient)		Drinking Water Well	
Metal	**Health-Based Criterion**	**No. detects / No. wells**	**Max. Conc. (No. exceed's)**	**No. detects / No. wells**	**Max. Conc. (No. exceed's)**	**No. detects / No. wells**	**Max. Conc. (No. exceed's)**	**No. detects / No. wells**	**Max. Conc. (No. exceed's)**
Arsenic	10	2 / 11	8 (0)	6 / 16	104 (6)	2 / 24	31 (2)	3 / 21	3 (0)
Cobalt	40	1 / 11	106 (1)	8 / 16	75 (4)	7 / 24	1,030 (7)	4 / 37	660 (4)
Iron	2,000	4 / 11	7,090 (2)	9 / 16	33,360 (7)	15 / 24	9,910 (7)	29 / 37	15,000 (8)
Lead	4	1 / 11	5 (1)	2 / 16	14 (1)	4 / 24	24 (4)	10 / 29	77 (7)
Manganese	860	4 / 11	248 (0)	12 / 16	1,980 (1)	17 / 24	1,920 (2)	27 / 37	2,130 (1)
Nickel	100	0 / 11	ND (0)	14 / 16	168 (4)	12 / 24	352 (8)	8 / 37	330 (3)

Reference: ERM 2006

A. Reported as total metal, not dissolved metal.

B. 2006 Remedial Investigation results, no historical Monitoring Well or Vertical Aquifer Sampling data shown here (some earlier results were higher).

C. If more than one sample per well, then highest result used.

D. Drinking water well results are "pre-softener" and from pre-existing wells.

E. Upgradient cobalt exceedance well retested one month later and was non-detect.

health-based number). The findings indicated that metals in the applied wastewater were not the source of the elevated concentrations in the groundwater (ERM 2006).

To determine whether local soils contained higher than expected concentrations of metals that might be contributing to the contamination in the groundwater, ERM conducted on-site soil sampling. The consultant found no abnormally high concentrations, indicating that soils at the land application site are not different from background soils (ERM 2006).

Analysis for EDTA in the groundwater indicated that the compound was not detectable upgradient from the land application site. The maximum on-site concentration of EDTA detected during the RI was 3,200 parts per billion (ppb), whereas the maximum off-site (down-gradient) concentration was 2,100 ppb. Only one residential well showed a detectable amount of EDTA, that being 150 ppb (ERM 2006). There is no Part 201 criterion for EDTA in groundwater. The chemical is retained for further evaluation.

ERM has theorized that high concentrations of EDTA in the wastewater, in conjunction with a high biological oxygen demand (BOD) and the large volume of discharge to the land application site, have likely caused what has occurred at this site. A high BOD indicates poor water quality, as would be expected in untreated wastewater. As the wastewater seeped into the soil from the infiltration basins, air within the soil was displaced until the soil became saturated. Without oxygen, anaerobic biodegradation of the constituents in the wastewater occurred, leading to the formation of organic acids and a decrease of pH (increased acidity). As pH decreased, metals became more soluble. These conditions, along with other chemical reactions, probably freed naturally-occurring iron and manganese in the soil, which then chelated to the EDTA and entered the groundwater. As the groundwater flowed into more oxygenated zones, pH levels returned to more neutral levels. The iron and manganese then remained bound to the soil and other metals chelated to the EDTA, in this case cobalt, lead, and nickel (ERM 2006).

<u>Exposure Pathways Analysis</u>

To determine whether persons are, have been, or are likely to be exposed to contaminants, MDCH evaluates the environmental and human components that could lead to human exposure. An exposure pathway contains five elements:

- a source of contamination
- contaminant transport through an environmental medium
- a point of exposure
- a route of human exposure
- a receptor population

An exposure pathway is considered complete if there is evidence, or a high probability, that all five of these elements are, have been, or will be present at a site. It is considered either a potential or an incomplete pathway if there is no evidence that at least one of the elements above are, have been, or will be present, or that there is a lower probability of exposure. Table 2 shows the potential exposure pathways pertaining to this site.

Table 2. Potential exposure pathways for chemicals of interest at the land application site for Abbott Laboratories, Ross Products Division, Sturgis (St. Joseph County), Michigan.

Source	Environmental Transport and Media	Chemicals of Interest	Exposure Point	Exposure Route	Exposed Population	Time Frame	Exposure Status
EDTA-containing wastewater discharged to land application site	Groundwater	Cobalt, EDTA, iron, lead, manganese, nickel	Drinking water	Oral, dermal, inhalation	Residents and workers using water from contaminated aquifer	Past	Complete
						Present	Incomplete
						Future	Potential
Note: The presence of a complete exposure pathway in this table does not imply that an exposure would be substantial or that an adverse health effect would occur.							

As shown in Table 1, some drinking water wells had elevated concentrations of metals. Wells with high cobalt and nickel concentrations have been closed and new wells installed. The new wells are in the deeper aquifer, which appears to be unaffected by the contamination. Thus, current exposure has stopped. Although the amount of past exposure cannot be calculated, based on groundwater movement and the length of time persons lived at homes with affected wells, the duration of exposure was likely no more than seven years (ERM 2006). If the plume continues to move, other wells in its path will have to be tested to ensure that people are not exposed to elevated levels of metals in their drinking water.

There were no DWC exceedances of arsenic in the drinking water wells. Therefore, people are not being exposed to concentrations of arsenic above health-based standards via this route, and the chemical is not evaluated further.

High concentrations of iron occur naturally in the groundwater in the area of the land application site. Water analyses from homes with water softeners indicated that the majority of softeners removed or greatly reduced the amount of iron, lead, and manganese in the water. Softening did not affect the concentrations of cobalt and nickel.

People may be exposed to chemicals in the groundwater when they wash dishes or bathe. Their skin would be in contact with the water and they may inhale steam rising from hot water. However, metals that are dissolved in water typically do not pose a health threat via dermal or inhalation exposure routes, especially at the concentrations seen for this site. Additionally, EDTA is not likely to volatilize from solution, and only about 0.001% of dermally applied EDTA is expected to absorb through the skin (ECJRC 2004). Therefore, only the oral route of exposure will be evaluated further in this assessment.

Once a substance is swallowed, it must be absorbed by the gastrointestinal (GI) tract to have a potential effect on the body. It is believed that the metals in the groundwater at this site are 100% chelated to EDTA and not available in the bound form. However, if the metal becomes dissociated ("un-chelated") from the EDTA, then the metal is free to be absorbed and become bioavailable to the body. According to the ATSDR Division of Toxicology and Environmental Medicine, cobalt is not likely to dissociate from the EDTA. Therefore, cobalt is not expected to be absorbed, meaning no exposure to cobalt is expected (see Appendix A). However, the other metals are expected to dissociate from EDTA and be bioavailable. Therefore, iron, lead, manganese, and nickel, along with EDTA, are evaluated further under the *Toxicological Evaluation* section of this document.

Toxicological Evaluation

EDTA

EDTA is a chelator, a Greek term meaning "claw." A chelator can bind strongly to a metal atom. Calcium EDTA and other chelating drugs are used to treat heavy metal poisoning, to remove the metal from the body. EDTA also is used in the food processing and household products industries, either as a direct additive, such as to preserve color or flavor, or an indirect additive, such as used to clean pipe scale. Calcium disodium EDTA is approved for use in foods such as canned soft drinks, canned vegetables, various condiments, margarine, and canned cooked shellfish. Similarly, disodium EDTA is approved for use in a variety of foods as well as in aqueous (liquid) multivitamin preparations. Sodium iron EDTA is a component of iron-fortified cereals and other foods (Bothwell and MacPhail 2004, Heimbach et al. 2000, WHO 2003). The Food and Drug Administration (FDA) estimates that a person's total exposure to EDTA via food sources is 15 milligrams (mg) per day (Whittaker et al. 1993).

EDTA has been proven to be a reproductive and developmental toxicant in rats fed zinc-deficient diets. However, EDTA added to nutrient-sufficient diets did not cause these effects (Bothwell and MacPhail 2004, ECJRC 2004, Heimbach et al. 2000, WHO 2003).

Although neither MDEQ nor the U.S. Environmental Protection Agency (EPA) has regulatory levels for EDTA, the World Health Organization (WHO) drinking-water tolerance dose is 1.9 milligrams EDTA per kilogram body weight (mg/kg) per day. The tolerance dose takes into consideration that EDTA could chelate an essential mineral and remove it from the body, causing a deficiency (WHO 2003). The maximum concentration of EDTA found in the groundwater sampling was 21,000 ppb, or 21 mg per liter (mg/L), in an on-site monitoring well (ERM 2006). Under default risk assessment assumptions that a 70-kg adult drinks 2 liters of water a day, the maximum EDTA dose an adult would receive by drinking groundwater from this site would be 0.6 mg/kg, which is about one-third the tolerance dose. The concentration of EDTA in the only residential well with a detection (150 ppb) was far less than that detected in the monitoring well. Therefore, exposure to the concentrations of EDTA found in the groundwater near Abbott's land application site should not cause a deficiency and is not a public health concern.

Iron

Iron is the 4^{th} most abundant element in the earth's crust and an essential nutrient. Foods with high iron content include organ meats, dried legumes, fish and shellfish, egg yolks, green vegetables, and tomatoes. Iron is necessary in the formation of heme, a component of hemoglobin, an important blood protein responsible for transporting oxygen in the body (HSDB 2005).

Excess intake of iron may cause GI upset and may interfere with some medications, such as antibiotics. Long-term exposure to too much iron can result in liver damage. Generally, the bodies of healthy individuals can adequately regulate absorption and excretion of iron.

However, persons whose livers cannot metabolize iron efficiently may be susceptible to toxic effects. Also, children taking mineral supplements without supervision may take in too much iron at once and be at risk of a fatal overdose (HSDB 2005).

The Institute of Medicine (IOM) at the National Academy of Sciences (NAS) has set the Dietary Reference Intake (DRI) value for iron at 8-11 mg/day for males, depending on age, and 8-27 mg/day for females, depending on age and reproductive status. The Tolerable Upper Intake Level (UL) is 40-45 mg/day. Assuming that a person is meeting his or her DRI through diet and supplements, the margin (difference) between the maximum DRI and the minimum UL is 29 mg/day for adult males and 13 mg/day for pregnant females (22 mg/day for non-pregnant, pre-menopausal women). The margin between the maximum DRI and the minimum UL for a child is 30 mg/day (NAS 2004). If an adult were to drink 2 L/day of groundwater at the highest concentration of iron found in a drinking water well affected by the land application site (15,000 ppb), the person would ingest 30 mg of iron per day. This excess in iron intake could negatively affect women but should not significantly affect healthy men. If a child were to drink 1 L/day of groundwater at the highest concentration of iron found in a drinking water well affected by the land application site, the child would ingest 15 mg of iron per day. This falls below the margin for children and should not result in adverse health effects. As noted in the *Exposure Pathways Analysis* section, water softeners will remove most, if not all, of the iron in the drinking water, decreasing exposure and the likelihood of adverse health effects.

Lead

Lead is a naturally occurring element. One of its former uses is as an additive to interior and exterior paint. Lead is well known for its neurotoxic effects, causing learning and behavioral difficulties in children. Nervous system effects in adults include decreased reaction times, weakness in the hands and ankles, and impaired memory. It can also damage the kidneys, the reproductive system, and cause anemia (ATSDR 1999).

The National Toxicology Program has reported that lead may be “reasonably anticipated to be a human carcinogen” (NTP 2004). This determination was based on limited evidence in human studies and sufficient evidence in animal studies. The human studies investigated occupational settings in which workers primarily were exposed by inhalation (NTP 2004). It is unknown whether exposure by ingestion has as great a cancer risk as inhalation exposure.

Rather than an external dose in milligrams of lead per kilogram of body weight per day (mg/kg/day), the level of lead in the body, usually expressed as blood lead levels (BLLs), is used to determine the potential for adverse health effects. This approach is used because exposure can occur from several different sources including air, food, water, and soil contamination. A child is considered lead-poisoned if his BLL, by venous blood sample, is 10 micrograms per deciliter (µg/dl) or higher. Models that account for multiple exposures to lead often are used to assess potential effects from exposure to lead in the environment (ATSDR 1999).

The MDEQ Direct Contact Criterion for lead in soil is based on the IEUBK (Integrated Exposure Uptake Biokinetic) model. All potential sources of lead (air, food, water, soil) must be evaluated to determine if the contribution from contaminated soil is significant (EPA 2005). Using the IEUBK model, MDCH changed the default concentrations for drinking water and soil for this site. Although the maximum concentration found in drinking water was 77 ppb (Table 1), this finding was a pre-water-softener result. The softener effectively removed the lead from the water. Therefore, MDCH chose the highest concentration found in drinking water where there was no water softener, that being 13 ppb (ERM 2006). (The default value is 4 ppb [EPA 2005].) Soil in the Sturgis area is part of the Saginaw Glacial Lobe, with the average topsoil concentration being 7.8 parts per million (ppm; MDEQ 2005), which MDCH used in the model run. With these site-specific values for water and soil concentration, and the default values for other sources (air, leaded paint dust or chips, breast milk, and diet), the IEUBK model calculated that only 0.1% of children up to 7 years of age would have a BLL greater than 10 µg/dl. Therefore, children in the land application area who are exposed to elevated levels of lead in non-softened drinking water are *not* at great risk of being diagnosed as lead-poisoned.

Manganese

Manganese is a naturally occurring metal as well as an essential trace element. Many foods contain manganese, especially nuts, legumes, grains, and tea. Insufficient dietary manganese can lead to slowed blood clotting, skin problems, changes in hair color, and alterations in metabolism (ATSDR 2000).

Humans exert an efficient homeostatic control over ingested manganese in the body. The body absorbs and uses what is nutritionally necessary and excretes the remainder. Thus, ingested manganese has rarely been associated with toxicity (EPA 1996). Individuals who cannot efficiently excrete excess metals from their bodies, such as persons with liver disorders, may be more at risk to potential toxicity. Patients receiving total parenteral nutrition (elemental liquid-form nutrition delivered intravenously because the person cannot or should not obtain his nutritional needs via the gastrointestinal tract) may receive too much manganese and experience difficulty in holding one's hand steady, performing fast hand movements, and maintaining balance when tested. However, these symptoms, known as "manganism," are more often seen in people who are exposed to manganese as an airborne dust rather than waterborne or dietary manganese (ATSDR 2000).

The DRI for manganese is 1.9-2.3 mg/day for males, depending on age, and 1.6-2.6 mg/day for females, depending on age and reproductive status. The UL for manganese is 6-11 mg/day, making the margin between the maximum DRI and the minimum UL 3.7 mg/day for males and 3.4 mg/day for females. The margin between the maximum DRI and the minimum UL for a child ranges from 0.5 to 1.8 mg/day (NAS 2004). If an adult were to drink 2 L/day of groundwater at the highest concentration of manganese found in a drinking water well affected by the land application site (2,130 ppb), the person would ingest about 4 mg of manganese per day. This is not substantially greater than the margins calculated and likely would not result in adverse effects in healthy adults. If a child were to drink 1 L/day of groundwater at the highest concentration of manganese found in a drinking water well affected by the land application site, the child would ingest 2 mg of manganese per day. While this is not substantially greater than the high end of the range for the margin for children, some individuals may be more sensitive to the effects of manganese, may not excrete it effectively, or may have additional exposures (vegetarian diets, pica behavior).   As noted in the *Exposure Pathways Analysis* section, water softeners will remove most, if not all, of the manganese in the drinking water, decreasing exposure and the likelihood of adverse health effects.

Nickel

Nickel is found in all soil and is the 24th most abundant element. Pure nickel is a hard, silvery-white metal with properties that make it desirable for combining with other metals to form alloys. These alloys are then used in making coins, jewelry, heat exchangers, and stainless steel. Food is the major source of nickel, with the majority of the population eating about 170 micrograms (µg) of nickel in food every day. Foods naturally high in nickel include chocolate, soybeans, nuts, and oatmeal. The daily intake of nickel from drinking water is usually only about 2 µg (ATSDR 2005).

The most common harmful health effect of exposure to nickel is an allergic reaction. About 10 to 20% of the population is sensitive to nickel. A person can become sensitized to the metal when jewelry or other items containing nickel are in direct and prolonged contact with the skin. Once a person is sensitized, future exposure, by any route, can elicit a reaction, usually a rash. People who are not sensitive to nickel must eat very large amounts of nickel to suffer harmful health effects (ATSDR 2005). Persons living near the land application site who are sensitive to nickel may have an allergic reaction if they use water containing high concentrations of the metal.

The most serious health effects from exposure to nickel occur in the lungs, following inhalation of nickel-containing dusts (ATSDR 2005). Inhalation is not an exposure route of concern at this site, thus no harmful lung effects would be expected.

It should be noted that the ATSDR comparison value for chronic exposure to nickel in drinking water is less restrictive than the DWC. The Reference Dose Media Evaluation Guide (RMEG) for nickel is 200 ppb for children and 700 ppb for adults [ATSDR 2007]. The RMEG is similar to the DWC but is not a regulatory number. Comparing the drinking water well concentrations to the RMEG suggests that exposure to adults is not a public health concern, but exposure to children may be. There is no DRI derived for nickel, however the UL for adults is 1 mg/day and that for children aged 1 to 3 years is 0.2 mg/day (NAS 2004). Assuming that the drinking water well data in Table 1 represent the maximum historical concentration, the daily amount of nickel that an adult living near the land application site may have ingested (drinking two liters per day) would have been 660 µg (0.66 mg) and the daily amount a child may have ingested (drinking 1 liter per day) would have been 330 µg (0.33 mg). Thus, an adult would not likely experience adverse effects, but a child may, especially if he or she were sensitized to nickel.

<u>Children's Health Considerations</u>

Children may be at greater risk than adults from exposure to hazardous substances at sites of environmental contamination. Children engage in activities such as playing outdoors and hand-to-mouth behaviors that could increase their intake of hazardous substances. They are shorter than most adults, and therefore breathe dust, soil, and vapors found closer to the ground. Their lower body weight and higher intake rate results in a greater dose of hazardous substance per unit of body weight. The developing body systems of children can sustain permanent damage if toxic exposures are high enough during critical growth stages. Fetal development involves the formation of the body's organs. Injury during key periods of prenatal growth and development could lead to malformation of organs (teratogenesis), disruption of function, and premature death. Exposure of the mother could lead to exposure of the fetus, via the placenta, or affect the fetus because of injury or illness sustained by the mother (ATSDR 1998). The obvious implication for environmental health is that children can experience substantially greater exposures to toxicants in soil, water, or air than adults can.

Children drinking water affected by the land application site may be exposed to lead, along with the other metals detected. Children are more susceptible to lead's toxic effects than adults are. However, as shown in the *Toxicological Evaluation* section, children are not expected to suffer detrimental effects from exposure through the drinking water.

Children who are chronically exposed to elevated levels of manganese in the drinking water may experience manganism, especially if they cannot excrete metals effectively or if they display pica behavior. (Pica behavior is the consumption of non-food items, such as dirt or chalk. Both adults and children can display pica.) A recent case study describes a pica child showing symptoms of manganism. This child may also have a metabolic disorder (Sahni et al. 2007).

Children who have been sensitized to nickel may experience an allergic reaction (rash) if exposed to nickel in the drinking water. Otherwise-healthy children are not likely to experience adverse health effects.

Community Health Concerns

A local farmer contacted MDCH with the following concerns:

1. Does the grass grown on the land application fields take up the contaminants that are in the water, either from the infiltration basins or the spray irrigators? Where is the cut grass from these fields sent? Is it used for animal feed, potentially getting into human food (via meat or milk)?

Research has shown that EDTA is not likely to accumulate in fish, plants, or meat (ECJRC 2004).

According to the RI report, the grass, which is primarily reed canary grass, is "used for animal feed, bedding, or compost based upon an evaluation by an animal nutritionist for its suitability as animal feed" (ERM 2006). Thus, it may be used for animal feed, but since EDTA is not expected to accumulate in biota (plants and animals), it is not expected to enter the human food supply.

2. Could EDTA-containing groundwater used for irrigation leach essential nutrients from the topsoil and reduce productivity? Could the metals in the groundwater accumulate in the crops?

In order for EDTA to leach essential nutrients from the topsoil, it would have to dissociate from the metals to which it is currently chelated. For that to happen, conditions would have to be strongly acidic, with a pH approaching that of stomach acid, about 2. This level of acidity is different than that needed for plants that prefer acid soils, such as blueberries and azaleas, which is about 4.5 to 5.5 (UME 2004). Since the metals should not dissociate from the EDTA, then it is unlikely that they would accumulate in the crops.

No community health concerns were raised at the October 2007 public information meeting.

Conclusions

Because affected drinking water wells have been closed, there is no current exposure to groundwater affected by the land application site and, therefore, no current public health hazard exists. (See Appendix B for descriptions of ATSDR's public health hazard categories.) The amount of any previous exposure cannot be determined with certainty but may have constituted a public health hazard. Future exposure could occur to people who live down-gradient of the plume, if pro-active monitoring and mitigation do not take place.

Cobalt is not expected to dissociate from EDTA and become bioavailable. Therefore, there is no exposure to cobalt and there is no future public health hazard related to that metal.

Exposure to EDTA in drinking water, after the chelator dissociates from associated metals in the GI tract, is not expected to cause harm and poses no apparent public health hazard if future exposures occur.

EDTA-metal complexes in groundwater used for drinking water are not expected to cause harm to healthy men or children if future exposures occur. Pregnant women could be exposed to too much iron. Persons with metabolic deficiencies may be exposed to excess iron, which could affect the liver in the long term, or excess manganese, which could cause neurotoxic effects in the long term in these individuals. However, water softeners appear to remove much, if not all, of the iron and manganese in the water. Those homeowners without water softeners should consider installing and using them. This would also improve the aesthetic quality of the water.

While lead is expected to dissociate from EDTA and be absorbed, overall exposure to lead in this area is not expected to cause a child to be lead-poisoned. Therefore, lead in the drinking water in the land application area does not pose an apparent health hazard if future exposure occurs.

Nickel exposure in sensitized individuals may cause allergic reactions, but the metal poses no apparent public health hazard to healthy individuals if future exposure occurs.

This groundwater issue may occur at other land application sites where untreated EDTA-containing wastewater is discharged to infiltration basins.

Recommendations

1. Continue monitoring groundwater to prevent future exposures.
2. Review groundwater data from similar land application sites.
3. Persons whose wells were affected should discuss the exposure with their healthcare providers.

Public Health Action Plan

1. Abbott will continue monitoring groundwater and reporting results to MDEQ.
2. MDEQ will review groundwater monitoring data from similar sites.
3. MDCH will provide information regarding potential implications of exposure to the chelated metals in the groundwater to physicians seeking guidance for the care of their patients.

Public comments received on the earlier version of this document and MDCH's responses to them are in Appendix C.

MDCH will remain available as needed for future consultation at this site.

If any citizen has additional information or health concerns regarding this health consultation, please contact MDCH's Division of Environmental Health at 1-800-648-6942.

Preparers of Report

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Certification

This **Chelated Metals in Groundwater Health Consultation** was prepared by the Michigan Department of Community Health under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR). It is in accordance with approved methodology and procedures. Editorial review was completed by the cooperative agreement partner.

Technical Project Officer, Cooperative Agreement Program Evaluation Branch (CAPEB), Division of Health Assessment and Consultation (DHAC), ATSDR

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

Team Leader, CAPEB, DHAC, ATSDR

Appendix A. ATSDR Record of Activity report discussing bioavailability of EDTA-chelated metals in drinking water.

ATSDR Record of Activity

ROUTING:
S. Wright

ERS FILES

UID #: eol7 Date: 9/14/2006 Time: 1:15 am _ pm X

Site Name: Abbott Laboratories City: Sturgis Cnty: St. Joseph's State: MI

CERCLIS #: ________ Cost Recovery #: 5#MI Region: V

Site Status _ NPL X Non-NPL _ RCRA _ Non-Site specific _ Federal
_ Emergency Response _ Remedial _ Other:

Activities

_ Incoming Call	_ Public Meeting*	_ Health Consult*	_ Site Visit*
_ Outgoing Call	_ Other Meeting	_ Health Referral	_ Info Provided
_ Conference Call	x Data Review	x Written Response	_ Training
x Incoming Mail	_ Other :		

Requestor and Affiliation: (5) Christina Bush, Toxicologist, Michigan Dept. of Community Health
Phone: (517) 335-9717
Address: Division of Environmental and Occupational Epidemiology, Toxicology and Response Section, Capitol View Building, 4th Floor, 201 Townsend St., Lansing, MI 48913

Contacts and Affillation

1-EPA	2-USCG	3-OTHER FED	4-STATE ENV	5-STATE HLT
6-COUNTY HLTH	7-CITY HLTH	8-HOSPITAL	9-LAW ENFORCE	10-FIRE DEPT
11-POISON CTR	12-PRIV CITZ	13-OTHER	14-UNKNOWN	15-DOD
16-DOE	17-NOAA	18-OTHR STATE	19-OTHR COUNTY	20-OTHR CITY
21-INTL	22-CITZ GROUP	23-ELECT. OFF	24-PRIV. CO	25-NEWS MEDIA
26-ARMY	27-NAVY	28-AIR FORCE	29-DEF LOG AGCY	30-NRC
31-ATSDR				

Program Areas

_ Health Assessment	_ Health Studies	_ Tox Info-profile	_ Worker Hlth
_ Petition Assessment	_ Health Survellnc	_ Tox Info-Nonprofil	_ Admin
_ Emergency Response	_ Disease Regstry	x_ Subst-Spec Resch	_ Other
x Health Consultation	_ Exposr Regstry	_ Health Education	

1) Narrative Summary: Since 1988, Abbott Laboratories, a baby food processing plant in Sturgis, MI, has been using disodium EDTA as a hard water scale cleaner from its pipes and then releasing the EDTA waste water into filtration basins on the edge of the factory property. After investigation of the site, the Michigan Department of Environmental Quality (MDEQ) believes that calcium disodium EDTA that is being released with the waste water passes through the soil and drains into the aquifer. Several private wells for residences and business use this aquifer, and samples from these wells and vertical aquifer samplers (VAS) have detected high concentrations of arsenic, cadmium, cobalt, lead, iron, manganese, and nickel. None of these metals are in the factory's waste water output nor are found in significant quantity in upgradient wells; thus it is believed that the calcium disodium EDTA is chelating these metals from the local soil and that the metals detected are actually chelated to the EDTA. Cobalt, lead,

manganese, and nickel have been detected at elevated levels in monitoring wells since 1999, and, until waste management system upgrades are in place at Abbott Laboratories (anticipated to occur within about two years), EDTA will continue to be released into the soil and likely continue to chelate heavy metals present and carry them into the aquifer.

The Michigan Department of Community Health has been asked to offer health consultation and to determine whether the heavy metals present, presumed to be chelated to EDTA, pose any health risks to those currently using the involved wells. To assist to this end, the ATSDR Division of Toxicology and Environmental Medicine has been asked to address the following questions:

1) Does the EDTA-metal complex dissociate in the GI tract?
2) If dissociation occurs, is EDTA at a concentration that could chelate essential nutrients from the body?
3) If dissociation occurs, is the dissociated heavy metal absorbed by the body, and, if so, how much?
4) If EDTA gets absorbed enterally, can it cause nephrotoxicity and can there be a further nephrotoxic interaction with cadmium?
5) Can a biomarker be used to determine excessive heavy metal exposure in those who use other wells within the plume?

FINDINGS:

The following results of this analysis are based on several a priori assumptions offered by MDEQ. It is assumed, based on the fact that none of the metals are present in the plant's waste water or in upgradient wells, 100% of the metal concentrations detected in the monitoring and residential wells are chelated to EDTA. Therefore, the only route of exposure to these heavy metals would be in ingesting drinking water with EDTA-heavy metal complexes and having those complexes dissociate in the gastrointestinal tract and the free metal would be available for absorption.

There are two compartments in which the heavy metal-EDTA complex can dissociate in the GI tract: the low pH environment of the stomach (pH 2-3) and the neutral pH of the small intestine (pH 7-8). Heavy metal-EDTA complexes dissociated to varying degrees at varying pH ranges, and this dissociation needs to be accounted for in each pH environment. Although the amount of a particular heavy metal absorbed could be calculated using the following formula (concentration of heavy metal-EDTA complex present in drinking water x dissociation constant of heavy metal-EDTA complexes x free heavy metal bioavailability), water safety clean-up action levels have already been determined by the State of Michigan. Therefore, simply multiplying the dissociation constants by the concentration of heavy metal-EDTA complexes detected in the water can give us a corrected "free" heavy metal concentration present in the gut, and these values can be compared to the Michigan State limits. Please refer to table #1 for maximal heavy metal concentrations (presumably 100% complexed to EDTA), dissociation constants (when available) at both low pH (2-3) and at neutral pH (7-8), Michigan State action levels, free heavy metal bioavailability, and ATSDR MRLs. All assumptions are made on a worst case scenario basis. As the edge of the plume is unknown, the maximal heavy metal concentrations reported on site are being used to quantify exposure. If two different dissociation constants were found at the two different pH ranges, these were considered to be additive, although this is likely an overestimation of the amount of actual dissociation that occurs. If no dissociation constants are available, then a worst case scenario predicting 100% dissociation is assumed.

To summarize the data discovered after extensive review and in consultation with Dr. Petering, the following was determined: First, despite the a priori assumption that all arsenic present is bound to the EDTA, based on knowledge of arsenic-EDTA stability constants it is actually most probable that the arsenic is actually not bound to the EDTA and thus all arsenic levels measured represent free arsenic, not chelated arsenic. Thus it is fair to assume all arsenic detected is free for enteral absorption. Second, despite the fact that cobalt has a similar dissociation constant to other heavy metals detected, the kinetics of its dissociation cause that reaction to occur at such a slow rate that effectively no cobalt is released in the gut. If the a priori assumption is that all cobalt present is already chelated to EDTA, the failure of any significant dissociation effectively precludes any risk of enteral cobalt absorption. Third, at the low pH of the stomach, all other heavy metal-EDTA chelates almost completely dissociate and make all of the detectible heavy metal available for enteral absorption.

$CaNa_2EDTA$ has been associated with nephrotoxicity, specifically in the setting of lead and cadmium poisoning. It is believed that the nephrotoxicity in these cases is actually due to heavy metal dissociation in the renal tubules and that it is the heavy metals themselves, not the EDTA, that is causing the nephrotoxicity. Maximal EDTA concentrations detected on site were 21,000 ppb, or 21 mg/L of water. Enterally administered EDTA is poorly bioavailable, with less than 5% absorption from the gut, or, at most, 1.05 mg/L of water. Assuming a daily intake of about 2 liters of water per day, maximal EDTA absorption in a worst case scenario (consuming water with maximal EDTA concentrations, found only on-site) would be about 2.1 mg/day. WHO tolerances indicate that oral intake of 1.9 mg/kg/day, far in excess of the maximal possible amount of EDTA ingestion from drinking water at this site, would be acceptable. However, the WHO does recommend that drinking water EDTA concentrations do not exceed 600 ppb, which is well below measured EDTA concentrations found in both sampling wells and other locations downgradient from this site. The basis of this recommendation is that relatively large amounts of EDTA are present in food as preservatives, usually complexed as iron-EDTA or zinc-EDTA, and this accounts for the vast majority of daily EDTA consumption. The cutoff of 600 ppb in drinking water is aimed to keep EDTA intake via drinking water below 1% of total daily EDTA allowances, allowing a margin of safety considering EDTA intake via food. It is fair to assume that residents in this area are consuming large amounts of EDTA in their food, probably in excess of any amount found in their drinking water. No other water tolerance limits for EDTA in drinking water could be found other than those recommended by the WHO. Therefore, although the maximal amount of EDTA that could be absorbed via ingestion by a 60 kg adult drinking 2 liters of water/day would only be about 2.1 mg/day (well below the 114 mg/day allowed by WHO), the amount of EDTA ingested via food is unknown and predicted to be far greater than that ingested via drinking water. Without a true knowledge of exactly how much EDTA is being consumed daily, the potential risks associated with such consumption remain unclear. EDTA present in stoichiometric excess of heavy metals has been shown to be protective of heavy metal poisoning in animal models, specifically in regards to cadmium.

The risk of free ETDA chelating essential metals from the diet remains unclear. As stated above, the World Health Organization tolerance for EDTA is 1.9 mg/kg/day, far in excess of the 2.1 mg/day of EDTA consumed by anyone weighing more than two kilograms drinking water with the maximal concentration of EDTA detected anywhere on site. However, as stated previously, the majority of EDTA consumed daily is from food, and this EDTA is usually already complexed to either iron or zinc and causes no deficits in essential mineral absorption. The relatively small amount absorbed from the drinking water is unlikely to have any significant effect of essential mineral absorption or clearance.

The decision as to whether or not to obtain biomonitoring of the potentially affected population can only properly be made by the local health department, as ATSDR MRLs, even when surpassed, are not action levels but rather screening cutoffs to be used by health assessors. Many heavy metal levels in biologic specimens, with the exception of lead, correlate little with disease or injury and thus measuring such levels is often fraught with confusion, and the decision as to whether or not to obtain such levels must be made on an individualized and informed basis. We cannot offer any blanket recommendation regarding biomonitoring in this case.

Action Required/Recommendations/Info Provided:

Recommended actions include the use of the provided data by the local health department and other local agencies to calculate the largest possible exposure and worst case scenario to determine whether a real health risk exists. In cases where data is not available assigning the greatest possible risk, such as 100% dissociation of EDTA and heavy metals, offers the greatest margin of safety, although this strategy may not offer a realistic picture of true health risk to the population in question. Estimation of the actual health risk and determination of any action required is best done by local and state officials.

If there are any other concerns or other ways that we may be of assistance please feel free to contact us at the ATSDR Division of Toxicology and Environmental Medicine.

Signature: Damon M. Dell'Aglio, MD Date: 10/19/06

Enclosures: Yes (X) No ( ); MIS entered: Yes ( ) No ( )

cc: ATSDR Region V
MDEQ

Table 1—Concentrations of maximal heavy metal concentrations (presumably 100% complexed to EDTA), dissociation constants (when available) at both low pH (2-3) and at neutral pH (7-8), Michigan State action levels, free heavy metal bioavailability, and ATSDR MRLs.

All concentration values are in parts per billion (ppb)

Heavy Metal	Heavy Metal Concentration (ppb)	Dissociation Constant (pH =2-3)	Dissociation Constant (pH=7-8)	Michigan State Action Levels (ppb)	Bioavailability (Maximal oral)	ATSDR MRLs (mg/kg/day)
Arsenic	79	-	-	10	90%	0.0003
Cadmium	7	Almost 100%	0.06	5	20%	0.0002
Cobalt	1,000	Virtually zero	0.06	40	97%	0.01
Lead	77	Almost 100%	0.05	4	50%	-
Iron	29,200	Almost 100%	0.04	2,000	95%	-
Manganese	2,910	Almost 100%	0.07	860	7.5%	-
Nickel	385	Almost 100%	0.05	100	27%	-

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Dr. David Petering, Chemist, University of Wisconsin at Milwaukee

Kirk-Othmer Encyclopedia of Chemical Technology, 2001; John Wiley & Sons, Inc.

Appendix B. ATSDR Public Health Hazard Categories

Depending on the specific properties of the contaminant(s), the exposure situations, and the health status of individuals, a public health hazard may occur. Sites are classified using one of the following public health hazard categories:

Urgent Public Health Hazard

This category applies to sites that have certain physical hazards or evidence of short-term (less than 1 year), site-related exposure to hazardous substances that could result in adverse health effects. These sites require quick intervention to stop people from being exposed. ATSDR will expedite the release of a health advisory that includes strong recommendations to immediately stop or reduce exposure to correct or lessen the health risks posed by the site.

Public Health Hazard

This category applies to sites that have certain physical hazards or evidence of chronic (long-term, more than 1 year), site-related exposure to hazardous substances that could result in adverse health effects. ATSDR will make recommendations to stop or reduce exposure in a timely manner to correct or lessen the health risks posed by the site.

Indeterminate Public Health Hazard

This category applies to sites where critical information is lacking (missing or has not yet been gathered) to support a judgment regarding the level of public health hazard. ATSDR will make recommendations to identify the data or information needed to adequately assess the public health risks posed by this site.

No Apparent Public Health Hazard

This category applies to sites where exposure to site-related chemicals might have occurred in the past or is still occurring, but the exposures are not at levels likely to cause adverse health effects. ATSDR may recommend any of the following public health actions for sites in this category:

- cease or further reduce exposure (as a preventive measure)
- community health/stress education
- health professional education
- community health investigation.

No Public Health Hazard

This category applies to sites where no exposure to site-related hazardous substances exists. ATSDR may recommend community health education for sites in this category.

For more information, consult Chapter 9 and Appendix H in the 2005 ATSDR Public Health Assessment Guidance Manual (http://www.atsdr.cdc.gov/HAC/PHAManual/index.html).

Appendix C. Public comments received on the September 10, 2007 release of the draft health consultation, and MDCH's responses.

Page and paragraph numbering refers to the draft version of this document. Comments are in bold print, responses in regular print.

<u>Page 4, Para. 1</u>

Abbott Nutrition, Sturgis Plant does not use EDTA to "remove hard-water scale from pipes." EDTA is an ingredient in two of our cleaning products that are used to remove residual product from processing tanks and associated equipment.

MDCH has changed the language to reflect this information.

<u>Page 4, Para.3</u>

The sentence that reads "However, the duration and extent of any past exposure are unknown" is not correct. We know that the land application system went into operation in 1988. It is also reasonable to assume that private drinking water supplies were not impacted immediately. Based upon the hydraulic conductivity testing conducted by ERM, it would probably have taken over two years for the groundwater to have migrated from the land application site to the nearest private water supply well. Thus, until the time that the impacts were discovered and the private water supplies were improved in 2006, the maximum time of impact was likely no more than 16 years. Furthermore, and even more important, we know that none of the residents using the impacted private wells resided in these homes for the full 16 years. In fact, based on discussions with the current residents, the most time that any individual would have used an impacted groundwater supply is no more than seven years. Thus, we do know the approximate duration and extent of past exposure. Therefore, we suggest replacing the sentence in question with the following: "Based upon the length of operation of the land application system and the amount of time that any individual lived in the impacted areas, it is unlikely that any individual was exposed to drinking water that did not meet drinking water criteria for more than seven years."

While maximum duration of exposure may be estimated, the amount to which people may have been exposed is still unclear and cannot be calculated. MDCH has changed the language here, in the paragraph following Table 2, and in the Conclusions to reflect this information.

<u>Page 4, Para. 7</u>

Cobalt, iron, lead, manganese and nickel are no longer present in any private residential wells. Suggested language for the first sentence is, "The chemicals previously detected in private residential wells…."

MDCH has changed the language to reflect this information.

<u>Page 7, Para. 2</u>

The shallow groundwater does not radiate outward from the land application site to the east. Numerous monitoring data indicates that the groundwater does not flow to the east at all.

MDCH has changed the language to reflect this information.

<u>Page 7, Para. 6</u>
Abbott Nutrition requests that line 4 be changed to the following, "The water sampled was that used in drilling and decontamination activities and is not used as product water."

MDCH has changed the language to reflect this information.

<u>Page 10, Table</u>
We feel the second row in last column of the table should state "Complete" vs. the current "Incomplete." We feel the RI portion of the investigation is complete and there are currently no workers or residents exposed to EDTA containing wastewater.

The intent of the last column in Table 2 is to determine whether the exposure pathway is complete, not whether the investigation is complete. MDCH has added the word "Exposure" to the heading in the last column to help clarify the language.

<u>Page 10, Para. 1</u>
Abbott Nutrition requests that the sentence that begins in line 4 be changed from "As the plume continues to move…." To "If the plume continues to move…." Abbott has taken a number of steps to stop or reduce the leaching of metals at the site. We do not know if the plume will continue to move.

MDCH has changed the language to reflect this information.

<u>Page 16, Para. 1</u>
See previous comments on Page 4, Paragraph 3, regarding the duration and extent of past exposure.

See earlier response given to this matter.

<u>Page A2, last Para.</u>
Abbott has operated the land application site since 1988 but has not used EDTA containing cleaners since 1988. Also, as stated previously, Abbott Nutrition, Sturgis Plant does not use EDTA to "remove hard-water scales from pipes." EDTA is an ingredient in two of our leaning products that are used to remove residual product from processing tanks and associated equipment.

Appendix A was prepared by the ATSDR Division of Toxicology and Environmental Medicine and is a stand-along document. It cannot be corrected by anyone other than the original author. Additionally, the document in Appendix A was written before the Remedial Investigation occurred and was not as up-to-date as the current database for the site. Your comment here will stand as a surrogate to correcting the record.

Page A3, Para. 1

The report states "EDTA will continue to be released into the soil and likely continue to chelate heavy metals present and carry them into the aquifer." Abbott has taken steps to significantly reduce the concentration of EDTA in its wastewater effluent being discharged to the land application site. Abbott has also discontinued the use of the infiltration basins during the winter months as well as taken other steps that should reduce the amount of metals leaching occurring at the land application site. We do not know that "EDTA will continue to be released into the soil and likely continue to chelate heavy metals present and carry them into the aquifer."

Please see response to previous comment.

Page A3, Para. 4

The report states that "As the edge of the plume is unknown…." Abbott has installed over 50 monitoring wells in and around the land application site. The sampling conducted to date has defined the edge of the plume. Abbott will continue to monitor these wells to assure that no downgradient receptor is affected.

Please see response to previous comment.