Health Consultation

Evaluation of Residential Soil Arsenic Action Level

ANACONDA CO. SMELTER NPL SITE
ANACONDA, DEER LODGE COUNTY, MONTANA

EPA FACILITY ID: MTD093291656

OCTOBER 19, 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.

HEALTH CONSULTATION

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Prepared By:

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I. Statement of Issues

The Anaconda Co. Smelter site constitutes a large area in and around Anaconda, Montana impacted by historical mining activities. The site was listed on the National Priorities List (NPL) in 1983, and characterization and cleanup of the site by the U.S. Environmental Protection Agency (EPA) and the Atlantic Richfield Company (ARCO) has continued since that time. In 2006, the Agency for Toxic Substances and Disease Registry (ATSDR) received a request from an Anaconda resident to evaluate the action level for arsenic in residential soil that had been determined in a 1998 Record of Decision (ROD) [1]. In this health consultation, ATSDR evaluates the studies and decisions made to determine the action level, responds to community questions about the decision made, and determines the public health impact of using the action level in the community.

A. Organization of Report

The "Background" section of this document will present a brief history of the Anaconda site and then detail various issues contributing to the setting of the Anaconda residential soil action level. These issues include arsenic toxicology, biomonitoring studies of residents of Anaconda and other copper smelter areas, studies on arsenic bioavailability and bioaccessibility in soil, and exposure assumptions used by EPA in risk models and to develop the screening and action levels for arsenic in soil. In the "Response to Community Requests" section of the report, ATSDR will evaluate various questions and concerns received from the community about the soil action level decision and will summarize a survey of recent arsenic soil action levels at other NPL sites. In the "Exposure Evaluation" section, ATSDR will evaluate the potential public health impacts for residential exposure to arsenic in soil at the current arsenic action level. Conclusions and recommendations for reducing or preventing any harmful exposures to residents identified will summarize the overall findings of this report.

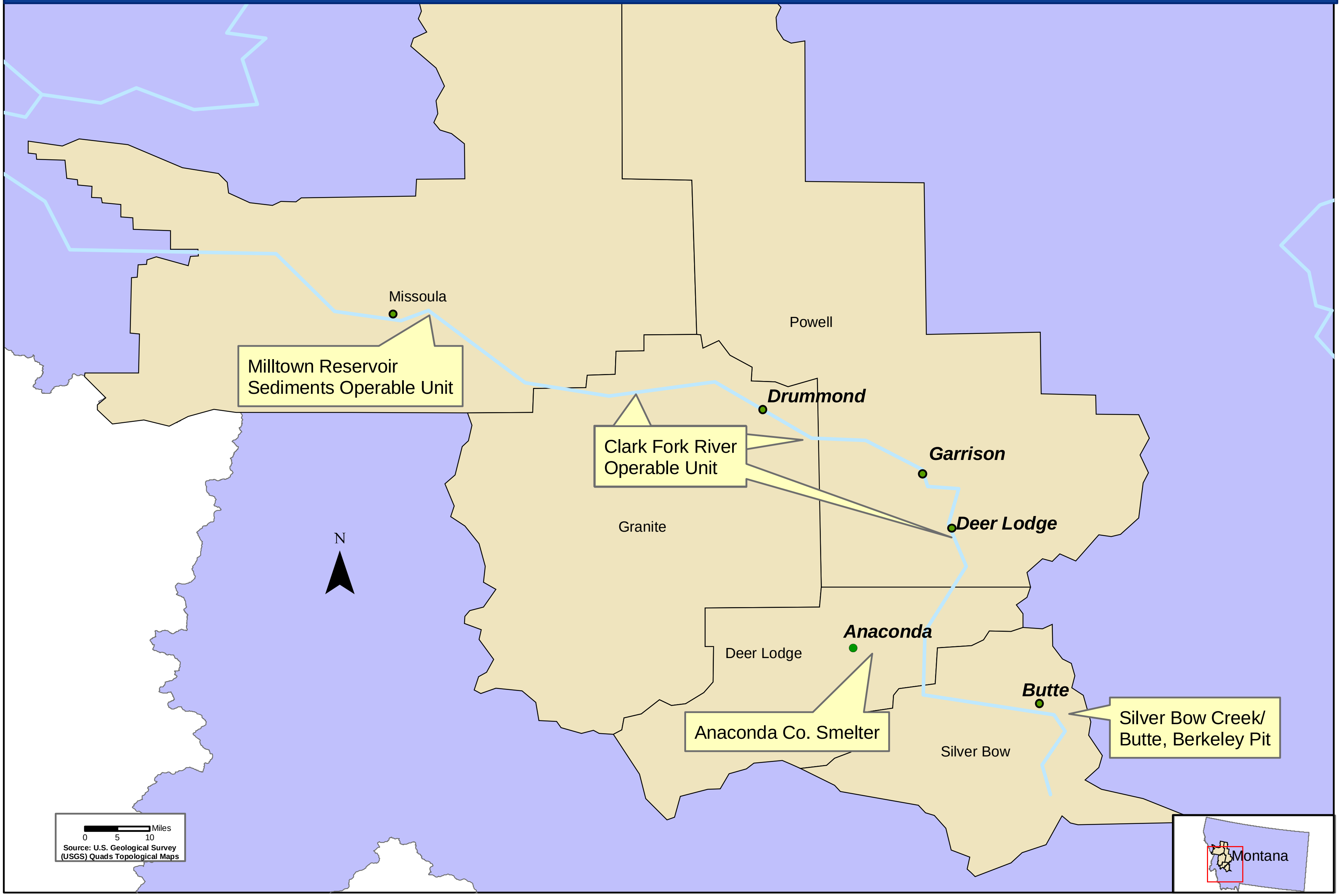
A draft of this report was released for public comment in June 2007. Public comments received and ATSDR's responses, indicating any changes made to the document, are summarized in Appendix A beginning on page 41.

II. Background

A. Site History

The following information was consolidated from various histories of the Butte-Anaconda area published online [2]. In 1881, Marcus Daly bought a small silver mine called Anaconda near Butte, Montana. Daly built a smelter at Anaconda in 1882 and connected the smelter to Butte by railroad. He continued to buy neighboring mines, and when huge amounts of copper were discovered in the area his Amalgamated Copper Mining Company, later renamed Anaconda Copper Mining Company, contributed to making Butte "the Richest Hill on Earth". Following the death of Daly and the other Butte "Copper Kings" (William A. Clark and F. Augustus Heinze), the Anaconda Copper Mining Company consolidated their holdings and continued underground copper mining until the early 1950s. At that time, the company switched to open pit mining at the Berkeley Pit. Open pit mining was far less dangerous and more economical than

Figure 1. Anaconda Co. Smelter NPL Site (Montana): Site Location Map



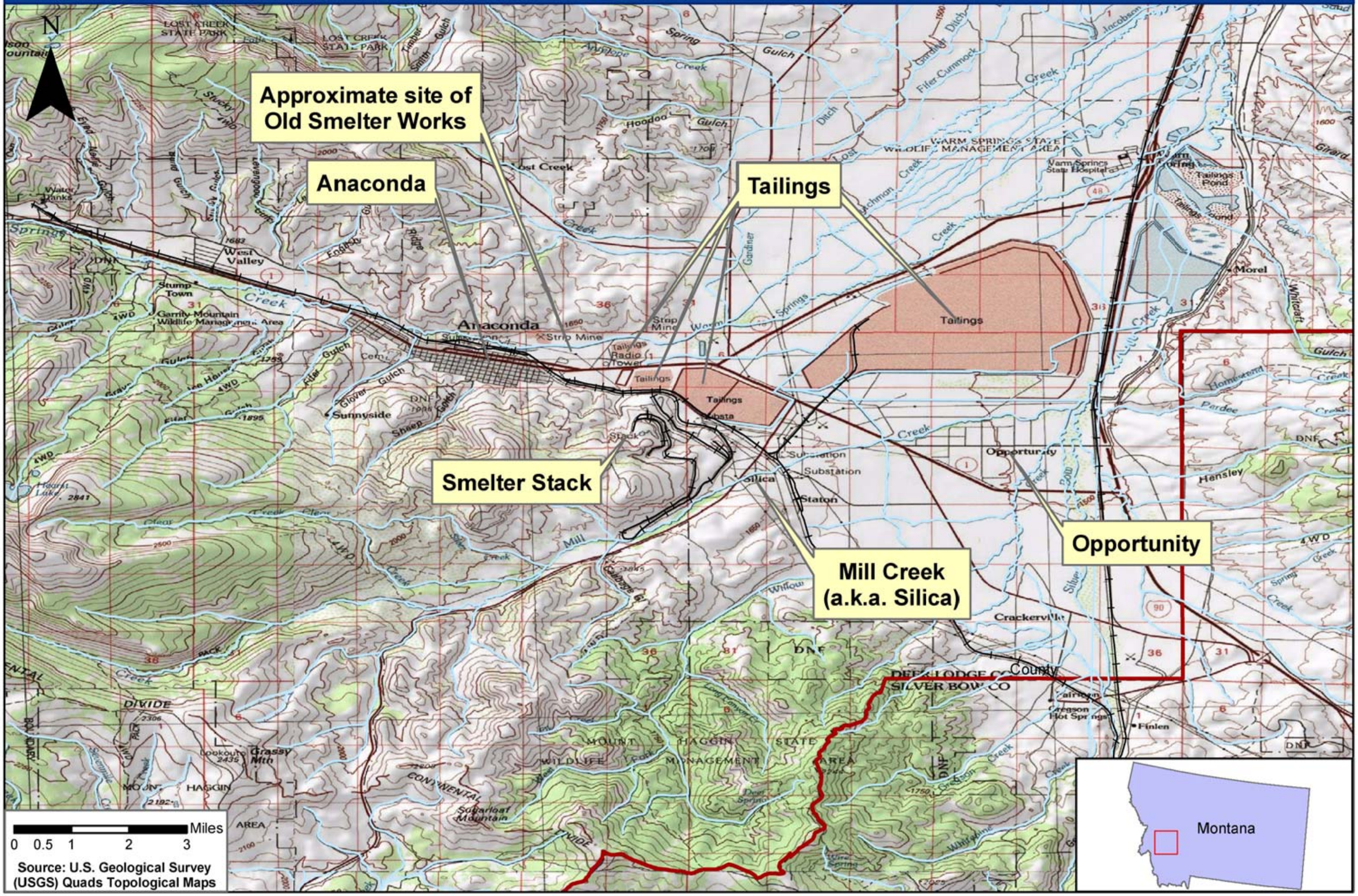
underground mining – even very low-grade ore could be recovered. Ultimately, about one billion tons of material was mined, primarily to produce copper, from the Berkeley Pit.

In 1977, ARCO bought the Anaconda Copper Mining Company, but shut down mining at Butte only a few years later because of falling metal prices. Pumps clearing water at the Berkeley Pit were shut down and the pit filled with toxic, acidic water. In Anaconda, the smelter was demolished after its closure in 1981. The smelter stack, the largest free standing brick chimney in the world, remains in place and is a well-known landmark in western Montana. Heavy metals from historical mining in the area contaminated Butte, Anaconda, and the Clark Fork River downstream to the Milltown dam in Missoula, resulting in their inclusion on the NPL for environmental cleanup in the 1980s.

The following history of site actions (focusing on residential soils) is taken from the EPA 1996 Baseline Human Health Risk Assessment for the Anaconda Co. Smelter site [3]. A schematic of the site is shown in Figure 2. Two areas of the site had past smelting activities. The Old Works, located east of Anaconda and on the north side of Warm Springs Creek, operated from around 1884 to1901. In about 1902, smelting and processing operations began at the Anaconda smelter on Smelter Hill south of Warm Springs Creek and continued until 1980. Both smelters resulted in large volumes of waste materials, disposed on the ground and in surface waters and used as fill, and aerial deposition of contaminants from stacks and waste piles near the smelters. The site was listed on the NPL in September 1983. Initial investigations indicated that the neighborhood of Mill Creek, immediately east of the Anaconda smelter, was severely impacted by contamination, and children there were found to have elevated levels of urine arsenic. Temporary relocation of the children reduced their urine arsenic levels to background, and in 1987 a Record of Decision for the Mill Creek operable unit selected permanent relocation as the remedy. By the late 1980s, a series of investigations had shown that residential soils and dust in the neighborhoods of Teresa Ann Terrace, Elkhorn Apartments, and Cedar Park Homes adjoining the Old Works smelter were also impacted. Contaminated soils from areas exceeding 250 milligrams of arsenic per kilogram soil (mg/kg) in these neighborhoods were removed and replaced with clean fill in a time-critical removal action completed in 1992.

A final Baseline Human Health Risk Assessment was produced for the site in 1996 [3]. This document addressed operable units at the site that had not been previously addressed, including community soils in Anaconda. To evaluate the residential soils pathway, the risk assessment used data on surface soils and dust collected by Bornschein in 1992 and 1994. Both lead and arsenic were evaluated in the risk assessment. Risks from lead were determined to be within EPA's acceptable range. Risks from arsenic were deemed unacceptable, and therefore arsenic was focused on as the risk driver at the site [3, personal communication, Susan Griffin, U.S. Environmental Protection Agency, March 8, 2007].

Figure 2. Anaconda Co. Smelter NPL Site (Montana): Site Features Map



B. Arsenic Background and Toxicology

The risks posed by arsenic were determined by EPA to be the main driver of risk at the site. This section presents a summary of arsenic's properties and the health effects that can result from excess arsenic exposure. Unless denoted otherwise, all information in this section comes from ATSDR's toxicological profile for arsenic, and additional information can be found there [4].

Arsenic is a naturally occurring metalloid element widely distributed in the earth's crust. In nature, arsenic is mostly found in minerals as opposed to its elemental form. Arsenic, primarily as arsenic trioxide, is a byproduct of smelting of copper, lead, cobalt, and gold ores. Major applications include the production of copper chromated arsenic (CCA, formerly used for wood preserving), pesticides and herbicides used in agriculture, and alloying agents. In recent years, the use of inorganic arsenic compounds in agriculture and wood treatment has been phased out, but many sites are contaminated with these compounds from past use. Organic arsenic compounds, which are generally less toxic, are still used commercially. The organic compound arsenobetaine is found at relatively high levels in some foods, especially seafood and shellfish, but is generally considered nontoxic.

Arsenic is a potent toxicant that may exist in several valence states and in a number of inorganic and organic forms. Most cases of arsenic-induced toxicity in humans are due to exposure to inorganic arsenic; differences in potencies of different inorganic chemical forms are usually minor. Organic arsenic compounds (methyl and phenyl derivatives of arsenic acid are the most common) also may produce adverse health effects in humans, but it is generally considered that organic arsenicals are substantially less toxic than the inorganic forms.

Health effects depend on exposure level and can occur upon inhalation, oral, or dermal exposure to arsenic or arsenic compounds. Poisoning and foodstuff contamination cases provide the main body of knowledge about human acute and short-term exposures. Very high oral or inhalation exposures can be life-threatening or fatal. High oral exposures can cause nausea and vomiting, decreased production of red and white blood cells, abnormal heart rhythm, damage to blood vessels, and a sensation of "pins and needles" in hands and feet. High inhalation exposures can result in irritation of the lungs or throat. The main effect of dermal exposure to arsenic is local irritation and dermatitis.

In addition to acute effects, arsenic is well documented to result in adverse health effects upon chronic, lower-level exposure. Several human epidemiologic studies provide this information. Most inhalation studies focus on workers in occupational settings such as smelters and chemical plants, where the predominant form of airborne arsenic is arsenic trioxide dust. Oral studies are commonly of populations exposed to elevated levels of arsenic, presumably inorganic in form, in drinking water.

By the inhalation route, the most sensitive effect of inorganic arsenic is an increased risk of lung cancer, although respiratory irritation, nausea, and skin effects may also occur. There are only a few quantitative data on noncancer effects in humans exposed to inorganic arsenic by the inhalation route, but it appears that such effects are unlikely below a concentration of about 0.1-1.0 milligrams of arsenic per cubic meter of air (or 100-1,000 micrograms per cubic meter

($\mu g/m^3$)). Chronic inhalation exposure to much lower levels of arsenic in air increases the risk of lung cancer. EPA has set a unit inhalation risk for arsenic at 0.0043 $(\mu g/m^3)^{-1}$; this value, multiplied by the average concentration of arsenic in air a person is exposed to over a lifetime, gives the increased risk of cancer from inhalation. For screening, ATSDR uses a cancer risk evaluation guide for arsenic of 0.0002 $\mu g/m^3$. This is the estimated arsenic concentration in air that would be expected to cause no more than one additional cancer case in one million persons exposed over a lifetime. For a specific exposure scenario, information on exposure duration and frequency is used with the unit inhalation risk to obtain a more realistic estimate of risk.

At less than lethal doses, chronic oral (or inhalation) exposure to arsenic can result in such effects as a darkening of the skin and the appearance of corn- or wart-like growths on the palms, soles of the feet, or torso. In addition, serious effects on the cardiovascular system are reported. Chronic oral exposure is known to increase the risk of skin cancer and cancer in the lungs, bladder, liver, kidney and prostate.

In the case of low-level chronic exposure (usually from water), skin lesions appear to be the most sensitive indication of exposure. ATSDR considered this end point the most appropriate basis for establishing a chronic oral minimal risk level (MRL) for inorganic arsenic of 0.0003 mg/kg/day. The chronic MRL represents the dose of arsenic, in milligrams per kilogram of body weight that a person could ingest on a daily basis (for periods greater than 365 days) with no adverse health effects. The MRL is used for screening by ATSDR; doses that exceed the MRL do not necessarily result in adverse health effects but require further evaluation. The chronic MRL is based on a no effect level of 0.0008 mg/kg/day in a study of skin lesions and Blackfoot disease in a Taiwanese population exposed to high levels of arsenic in drinking water and included an uncertainty factor of 3 for human variability.

ATSDR also established a provisional acute MRL for oral exposure to arsenic of 0.005 mg/kg/day; this is the short-term dose below which no adverse effects are expected. The MRL is based on a study of poisoning cases associated with arsenic contamination of soy sauce in Japan; critical effects in the study were facial edema and gastrointestinal symptoms (nausea, vomiting, diarrhea), which were characteristic of the initial poisoning and then subsided. The MRL includes an uncertainty factor of 10 to account for use of a lower effect level rather than a no effect level.

Arsenic exposure can be measured in a person’s body in a number of ways. Urine arsenic level is considered the best method to determine exposures occurring within the past few days. “Normal” or “background” urine arsenic levels are difficult to determine because people may ingest various types and amounts of arsenic through their normal diets. Total urine arsenic concentrations in people who have not been excessively exposed to arsenic (through, for example, occupation or dietary habits) have been estimated to range from 10 to 50 micrograms of total arsenic per liter of urine (μg/L) [5]. ATSDR considers total urinary arsenic levels higher than 50 μg/L (in the absence of recent seafood consumption) to be elevated [6]. However, consumption of seafood containing the nontoxic arsenic compound arsenobetaine can greatly influence urine arsenic levels (raising them as high as thousands of μg/L). This interference can be somewhat, but not completely, circumvented by measuring “speciated” arsenic, which includes inorganic and biotransformed arsenic species and represents the total intake of inorganic arsenic. ATSDR considers speciated urinary arsenic levels elevated if they are above 10–20 μg/L. The American Council of Government and Industrial Hygienists (ACGIH) recommends a speciated arsenic urine level of 35 μg/L for a biological exposure index, based on background concentrations in subjects who were not occupationally exposed to inorganic arsenic [7]. Regardless of the measure used, no good correlation exists to predict adverse health effects from urine arsenic level.

Sometimes, urine arsenic levels are normalized in a study according to the individual's creatinine level and the result reported as micrograms of arsenic per gram (μg/g) creatinine. This procedure can be used to correct for varying dilutions of urine depending of how hydrated the person is and allows for better comparisons between individuals. However, the method is not perfect: creatinine levels can vary markedly between individuals and with time in a single individual, and no reference levels for urine arsenic on a μg/g creatinine basis are currently available. In 1991, the ACGIH proposed a value of 50 μg/g creatinine for use as a biological exposure index, and some exposure studies have used this value as a point of reference. However, the proposed index was not formally adopted [4,8, personal communication, Ketna Mistry, Senior Medical Officer, ATSDR, February 2007]. A National Exposure Report Card to be issued by the Centers for Disease Control and Prevention (CDC) in the next 2 years is expected to publish reference concentrations for speciated urine arsenic levels on both μg/L and μg/g creatinine bases [personal communication, Ken Orloff, Assistant Director of Science, ATSDR, March 2007]. The ACGIH currently still uses 35 μg/L speciated arsenic for its biological exposure index.

Arsenic also enters a person's blood, but it is rapidly eliminated, making measuring blood unreliable for measuring all but the most recent exposures [4]. Long-term storage of arsenic in other bodily compartments including the hair and nails has led to attempts to measure long-term exposure using hair and/or nail testing. The inability of analytical techniques to differentiate systemic (internal) arsenic from arsenic deposited externally on the hair or nail surface has limited the usefulness of these methods for predicting either exposure or health effects [4,9].

C. Biomonitoring to Assess Arsenic Exposures in Residents

Based on initial site characterizations, levels of arsenic in soils in and around the Anaconda Smelter were elevated to varying degrees. A number of investigations of residents were conducted to assess potential exposures. Most studies focused on younger children because their typical activities and hand-to-mouth behaviors could put them at risk for greater exposures than adults. This section will review the available studies on exposure of residents to arsenic in Anaconda. A brief description of similar studies conducted at other copper smelter sites will also be presented for comparison.

In 1975, CDC and EPA conducted a nationwide survey of children living around copper, lead, and zinc smelters [10]. Heavy metal absorption in the children was measured in hair and either blood or urine. Anaconda was one of the eleven copper smelter towns in the survey. The study did not indicate whether reported arsenic levels were for total arsenic or speciated; however, because of the date of the study total arsenic measurements are presumed (reliable speciation methods came into use later). Hair arsenic levels were much higher in Anaconda than in comparison towns without smelters. Urine arsenic levels in Anaconda children were also higher than comparison towns. Of 40 children tested, 12 had urine arsenic concentrations higher than the 95th percentile of the comparison towns, 45.5 μg/L. The geometric mean urinary arsenic concentration in Anaconda children was 30.8 μg/L, and the median was 32.9 μg/L. Maximum values were not presented in the paper, but it is likely that at least some of the total urine arsenic concentrations were higher than the level ATSDR considers elevated, 50 μg/L.

In 1978-1979, before the Anaconda smelter shut down, residents participated in a study of populations living around zinc and copper smelters [11]. In this study, published in 1983 after the smelter had been closed, metals levels were determined in air, soil, dust, tap water, and biological samples (hair, blood, urine) at Anaconda, at another copper smelter in Arizona, and at two zinc smelters in Oklahoma and Pennsylvania. (Similar to the study discussed above, reported arsenic concentrations are presumed to refer to total arsenic, not speciated arsenic.) The Anaconda results showed that dust arsenic levels correlated best with hair arsenic levels for all age groups, and that urine arsenic correlated with air, water, and dust arsenic levels for 1- to 5-year olds. Hair arsenic levels were reported, but the results cannot be used to predict health effects because of the difficulty of separating systemic arsenic from arsenic deposited externally on the hair [9]. Urine arsenic levels are thought to be a better indicator of potential health effects, but the levels measured in this study were not presented.

Another investigation focused on measuring arsenic exposure in children in Anaconda a few years after the smelter ceased operations, in 1985 [12]. Arsenic levels in soil and house dust and total urine arsenic levels in children ages 2-6 years were measured in the Mill Creek neighborhood (downwind and adjacent to the smelter stack), in Eastern Anaconda (generally upwind of the smelter stack), in Opportunity (about 4 miles downwind of the smelter stack), and in a control town not affected by the smelter. Mill Creek was found to have both higher mean arsenic soil levels (greater than 700 mg/kg vs. 100 mg/kg in Anaconda and Opportunity) and higher urinary arsenic levels in children. The mean total urine arsenic level in Mill Creek children was around 50 μg/g creatinine, as compared to around 20 μg/g in Anaconda, Opportunity, and the control town. Not corrected for creatinine (to allow comparison with reference values), the mean total urine arsenic concentrations for Mill Creek children ranged from 54-66 μg/L, higher than the level ATSDR considers elevated, 50 μg/L [6]. Although maximum values were not reported, it can be inferred that some of the Mill Creek children had highly elevated urinary arsenic levels. In comparison, the 95th percentile total urine arsenic values (again, maximums were not reported) for Anaconda, Opportunity, and the control town were 35-44 μg/L, suggesting that exposures in those locations were not as high. The results of this study were used, in part, to justify the decision by EPA to relocate the 8 residences which remained occupied in 1987 [13]. The results were also interpreted to show that child exposures to arsenic in other Anaconda locations were not significantly elevated.

Another urine arsenic investigation of children was conducted in 1992-1993 [14]. The investigators measured total and speciated urine arsenic in 414 children under 6 years old in Anaconda. The mean total urinary arsenic level was 19 μg/L and the mean speciated arsenic level was 9 μg/L. Slightly less than 8% of the children had urinary arsenic levels higher than those ATSDR considers above normal (50 μg/L for total arsenic and 20 μg/L for speciated arsenic). There was a correlation between speciated urine arsenic concentration and soil arsenic level in bare yards. The authors recommended that guardians pay close attention to children's activity, especially hand-to-mouth behavior, to prevent exposure. EPA combined the results of this study with predicted total and speciated urine arsenic concentrations from EPA's exposure assessment model for the Anaconda site and found a reasonable agreement between predicted and measured values, lending support to the exposure assumptions chosen (these will be discussed in detail later in this document) [15].

Residential exposures around other copper smelters have been published and are presented here for comparison. Children living near the Ajo, Arizona copper smelter were included in the 1975 survey described earlier and had the highest urine arsenic levels measured in the survey (geometric mean 80.8 μg/L) [10]. Children in the other copper smelter towns surveyed had lower mean urine arsenic concentrations than Ajo and Anaconda (geometric mean 30.8 μg/L), but all had elevated urine arsenic levels compared to control towns without smelters.

In 1977, another investigation of arsenic exposure of children aged 5-18 living near the Ajo smelter was conducted [16]. Tap water in the community was found to have elevated arsenic levels (averaging 90 μg/L water, higher than EPA's past maximum contaminant level of 50 μg/L water). Elevated hair and urine arsenic levels (mean of 59 μg/L urine, total arsenic presumed) were measured in Ajo children who drank tap water daily, and hair and urine arsenic was also found to have a lesser correlation with distance of residence from the smelter. The 1983 study summarized previously for Anaconda also investigated the Ajo community [11]. Environmental samples indicated that, compared to Anaconda, Ajo had lower levels of arsenic in air, dust, and soil; but higher levels of arsenic in tap water (the tap water levels in this study were about one-tenth the levels in the 1977 study, possibly due to improvements in water treatment). Results showed that dust and soil arsenic levels correlated best with hair arsenic levels across most age groups. In contrast to Anaconda, urine arsenic did not correlate with dust, but did correlate with tap water levels for some age groups in Ajo.

The community surrounding the Ruston/North Tacoma copper smelter in Washington state was investigated in 1985-1986 [17]. This plant specialized in processing copper ores rich in arsenic (10-15% by weight) for several decades before its closure just before the study. Arsenic trioxide was a commercial product of the smelting operations and the main source of contamination in the community. Urine arsenic samples were collected from residents up to 8 miles from the smelter. Although the paper cited previous studies showing average urine arsenic levels as high as 270 μg/L in residents, in this study urinary arsenic concentrations dropped off to a constant level (about 12 μg/L) within one-half mile of the smelter. Only children ages 0-6 living within one-half mile of the smelter (in the town of Ruston) had elevated levels of speciated arsenic in urine, with a mean urine arsenic of 43.6 μg/L and a 95th percentile of 120 μg/L. These levels of arsenic were determined to be the result of hand-to-mouth behavior of children increasing their exposure to soil and dust.

Urine arsenic levels were also measured in children aged 3-11 living near a smelter producing copper, lead, and arsenic in Morales, San Luis Potosi, Mexico [18]. Total urine arsenic levels were quite varied, with maximum values ranging from 230-342 μg/g creatinine for different age groups. The geometric mean total urine arsenic level ranged from 44-80 μg/g creatinine for different age groups. For comparison, total urine arsenic measured in children from nonsmelter and nonmining areas in Mexico showed a geometric mean level of 20.4 μg/g creatinine.

ATSDR has conducted exposure investigations in which urine arsenic levels were measured in residents living in communities with elevated soil arsenic levels. These investigations typically only included a small number of participants, but those most highly exposed were targeted for participation. Although urine arsenic levels can only be used to infer recent arsenic exposures, it is of note that none of the investigations indicated levels of arsenic in urine that would be considered elevated (2-3 of the studies did not speciate arsenic, which may add uncertainty to this statement) [19–25]. In only one investigation, three participants had higher-than-normal urine arsenic levels; but these levels were determined to be due to recent seafood consumption or other exposure to organic arsenic compounds [26].

In summary, biomonitoring of children in the Anaconda area has been useful to indicate elevated past exposures while the smelter operated and, later, in the Mill Creek area of the site. More recent measurements showed average urine arsenic levels to be similar to control towns; however, some children still had elevated arsenic levels, indicating the need to continue to address arsenic exposures at the site.

During the time of these studies, a body of literature had been growing which suggested that arsenic may be less well absorbed from some soils by the gastrointestinal tract. Animal experiments on relative bioavailability (a measure of the amount of arsenic absorbed from soil compared to the amount absorbed from a reference material) were performed on soils from Anaconda, other mining sites, and other types of arsenic-contaminated sites. These studies will be discussed in the following section. In addition, laboratory methods for determining how much soil arsenic could dissolve in gastric fluids and potentially be absorbed (termed bioaccessibility) are also being developed; these will also be reviewed.

D. Studies on Bioavailability and Bioaccessibility of Arsenic in Soil

1. Relative Bioavailability of Mining-Impacted Soil – Animal Models

Prior to 1994, two site-specific studies of arsenic bioavailability in the Anaconda and Butte areas had been published. Davis *et al.* tested 2 soils, one blended from Butte soils to represent mine waste soils not impacted by smelter activities, and one collected from a roadside in Anaconda [27]. The investigators performed *in vivo* experiments with Butte soil on 24 female New Zealand white rabbits. The rabbits were sacrificed in triplicate at various time points to study the dissolution of arsenic minerals in the gastrointestinal tract; 11% of the total arsenic and 6% of the total lead were solubilized in the small intestine. (These values were determined at one time point and therefore cannot be used to estimate overall dissolution possible in the small intestine.) The investigators also performed electron microprobe analysis to characterize arsenic mineralogy of the Anaconda soil fed to one rabbit as well as mineralogy of arsenic species excreted in the feces. Readily dissolved arsenic oxides and hydrates in the Anaconda soil were not present in the feces; sulfides that predominated in the soil were present in the feces. No information was provided that would allow mass balances on excreted materials, and therefore a quantitative calculation of relative bioavailability is not possible for these experiments.

In another study reported in 1993, Freeman *et al.* dosed groups of New Zealand white rabbits (5 male and 5 female per group) with various doses of residential soil from Anaconda, MT [28].

Control groups were untreated, dosed intravenously with sodium arsenate, or dosed by gavage (*i.e.*, through a tube to the stomach) with sodium arsenate. Urinary excretion of arsenic was used to determine relative bioavailability of soil (relative to gavage sodium arsenate) to be 48%. In this study, about half the dosed arsenic was excreted in the feces of the rabbits, as opposed to very low percentages found to be excreted through feces in humans and other animal studies.

In 1994, EPA adopted a default policy for arsenic bioavailability for the Clark Fork Superfund site; this policy was adopted at adjacent sites including the Anaconda Co. Smelter site. The position paper describing this policy reviewed the literature available on absolute and relative bioavailability of arsenic in human and animal studies until that time [29]. The paper recognized that different forms of arsenic are likely to have differing bioavailabilities and that the amount of arsenic absorbed from ingested mine wastes would be most dependent on the amount that dissolves during gastrointestinal transit. However, the paper discussed significant differences between humans and the rodent and rabbit models used until then – such as feeding behavior, stomach pH, and digestive flora – which may limit the applicability of data from these species. The policy adopted included the following guidance:

- If site-specific *in vivo* data on arsenic absorption from site wastes are available, they should be relied on in proportion to the confidence placed in the data (which in turn depends on choice of animal model, concentrations of arsenic tested, exposure medium utilized, and study design).
- If site-specific *in vivo* data are lacking but mineral speciation data are available indicating 60% or more of the material is in sulfidic form in a fairly insoluble low-arsenic matrix, assume a relative bioavailability of 50%.
- If the above *in vivo* or mineralogic data are not available, assume 100% bioavailability for finely grained oxides from smelter stack emissions, pesticide/herbicide application, or wood treatment processes; or assume a default 80% relative bioavailability for other types of arsenic associated with non-food solid matrices such as soil, slag, or waste rock.

While the above policy was being developed, the Battelle group working under Dr. Freeman was studying arsenic bioavailability in another animal model, cynomolgus monkeys. Initial and final reports were reviewed by EPA [30,31]; a peer-reviewed report of the study was published in 1995 [32]. The monkey model was chosen for improved physiological and anatomical similarity to humans. The authors dosed 3 female monkeys with different amounts of soil and house dust from Anaconda. (Monkeys were cycled through different dose regimens with a “washout” period between, and were fasted for 16 hours before and 4 hours after dosing.) Absolute bioavailability referenced to intravenous sodium arsenate was calculated from urinary excretion and from blood measurements. The authors report mean absolute bioavailabilities based on urine of 19.2% for dust and 13.8% for soil [32]. However, these values were obtained by normalizing results of urinary arsenic recovery from other dose groups to compensate for a poor recovery (~70%) from the intravenous administration group. EPA determined that this normalization tended to underestimate the absorption of arsenic and recommended the use of the following unnormalized absolute bioavailabilities: 91% for gavage, 18.3% for soil, and 25.8% for dust [31]. The soil and dust absolute bioavailability values were carried over to the Anaconda Human Health Risk Assessment [3] and used interchangeably with relative bioavailability; since gavage absorption is known to be almost complete (and was complete, within experimental error, in this study) the absolute and relative bioavailabilities are essentially the same [personal communication, Susan Griffin, U.S. Environmental Protection Agency, January 8, 2007].

In the late 1990s, EPA and others began using juvenile swine for site-specific arsenic bioavailability studies [33–39]. Advantages of this animal model include its similarity to young children in body size, weight, bone-to-body weight ratio, and gastrointestinal anatomy and physiology. Swine have feeding and digestive processes similar to humans, and they also metabolize and excrete arsenic more like humans than the rabbit or rodent models used previously. In addition, later studies employed a subchronic dosing regimen thought to more closely resemble human incidental exposures over time (summarized in [39]).

Other Montana mining-impacted soil studies have shown similar bioavailability in swine testing as the Anaconda tests showed for monkeys. Butte residential soils have similar mineralogy as Anaconda soil and it was thought that bioavailability would also be similar [personal communication, Susan Griffin, U.S. Environmental Protection Agency, January 8, 2007]. Further tests of Butte soil conducted using the juvenile swine model showed relative bioavailabilities of two Butte test soils of 17% and 22%, similar to the bioavailability from the Freeman monkey studies [37].

A recent (2007) study using cynomolgus monkeys reported relative bioavailability of 13±5% for soil labeled as “Montana smelter soil” (reportedly taken from the Anaconda site but not the same soil sample tested by Freeman) [40]. Other samples tested in this study included soils from several western mining-impacted sites (mean relative bioavailabilities of 13-18%), and several pesticide or herbicide-impacted sites in various parts of the country (mean relative bioavailabilities of 5-31%). In the experiments, the authors dosed 5 male monkeys with various doses of contaminated soil from 12 sites. (Monkeys were cycled through different dose regimens with a “washout” period between and were fasted overnight before and for 4 hours after dosing.) Relative bioavailability was calculated from urinary excretion with reference to a gavage dose of aqueous sodium arsenate given to the same monkey (*i.e.*, each monkey served as its own control). The same authors had previously used a similar procedure and cebus apella monkeys to determine relative bioavailability of arsenic in five waste soils from Florida [41].

In summary, various animal models have consistently shown Anaconda Co. Smelter site soils to have a low relative arsenic bioavailability compared to aqueous sodium arsenate. Tests of soils from arsenic-contaminated sites across the country have shown relative bioavailabilities to be highly site-specific, ranging from less than 10% to near 100%. Table 1a and 1b below summarize arsenic soil bioavailability results from the available literature. The values in the third column of Table 1a (swine study results) were taken directly from the original report. Some of the results were analyzed further and refined in an EPA summary—resulting in some changes/corrections to the originally reported result. These are denoted in the second column of the table. ATSDR did not verify or reproduce the calculations leading to the results summarized in Tables 1a and 1b.

Table 1a. Soil Arsenic Relative Bioavailability Adjustments (RBAs) from Animal Studies – Swine Studies

Site/Sample Description	Recalculated RBA from EPA 2005 Summary [39]	Originally Reported RBA	Original Reference
Aberjona River Test Material 1	0.38	0.37	[36]
Aberjona River Test Material 2	0.52	0.51	[36]
Murray Smelter Slag	0.55	0.51	[34]
Murray Smelter Soil	0.33	0.34	[34]
Palmerton Location 2	0.49	0.39	[34]
Palmerton Location 4	0.61	0.52	[34]
Aspen/Smuggler Berm	-	0.62	[34]
Aspen/Smuggler/Residential	-	0.98	[34]
Bingham Creek Channel Soil (Kennecott)	0.39	0.37	[34]
Butte Soil	0.09	0.1	[34]
Butte Test Material 1	0.18	0.17	[37]
Butte Test Material 2	0.24	0.22	[37]
California Gulch AV Slag	0.13	0.07	[34]
California Gulch AV Slag T2	-	0.15	[34]
California Gulch Fe/Mn PbO	0.57	0.28	[34]
California Gulch Phase I Residential Soil	0.08	-0.08	[34]
Clark Fork Tailings	0.51	0.49	[34]
El Paso Test Material 1	-	0.44	[38]
El Paso Test Material 2	-	0.37	[38]
Midvale Slag	0.23	0.18	[34]
Ruston/North Tacoma slag	-	0.42	[33]
Ruston/North Tacoma soil	-	0.78	[33]
VBI70 Test Material 1	0.4	0.35	[35]
VBI70 Test Material 2	0.42	0.45	[35]
VBI70 Test Material 3	0.37	0.36	[35]
VBI70 Test Material 4	0.24	0.21	[35]
VBI70 Test Material 5	0.21	0.18	[35]
VBI70 Test Material 6 (not a site sample)	0.24	0.23	[35]

Table 1b. Soil Arsenic Relative Bioavailability Adjustments (RBAs) from Animal Studies – Other Animal Models

Sample Description	Animal Model	Reported RBA	Reference
Anaconda Soil	New Zealand white rabbit	0.48	[28]
Anaconda Soil	cynomolgus monkey	0.183	[30]
Anaconda Dust	cynomolgus monkey	0.258	[30]
Anaconda Soil ("Montana Smelter Soil")	cynomolgus monkey	0.13	[40]
California Mine Tailings	cynomolgus monkey	0.19	[40]
Colorado Residential Soil (VBI70)	cynomolgus monkey	0.17	[40]
Colorado Smelter Composite Soil	cynomolgus monkey	0.18	[40]
Colorado Smelter Soil	cynomolgus monkey	0.05	[40]
Florida Chemical Plant Soil	cynomolgus monkey	0.07	[40]
Florida Cattle Dip Vat Soil	cynomolgus monkey	0.31	[40]
Hawaii Herbicide Facility Soil	cynomolgus monkey	0.05	[40]
New York Orchard Soil	cynomolgus monkey	0.15	[40]
New York Pesticide Facility Soil-1	cynomolgus monkey	0.19	[40]
New York Pesticide Facility Soil-2	cynomolgus monkey	0.28	[40]
New York Pesticide Facility Soil-3	cynomolgus monkey	0.2	[40]
Washington Orchard Soil	cynomolgus monkey	0.24	[40]
Western Iron Slag Soil	cynomolgus monkey	0.13	[40]
Electrical Substation - Florida	cebus apella monkey	0.146	[41]
Cattle Dip Site - Florida	cebus apella monkey	0.247	[41]
Pesticide site #1 - Florida	cebus apella monkey	0.107	[41]
Wood treatment site - Florida	cebus apella monkey	0.163	[41]
Pesticide site #2 - Florida	cebus apella monkey	0.17	[41]

2. Bioaccessibility of Arsenic – In Vitro Models

Concurrently with recognition of site-specific bioavailability in soil, investigators have been working on *in vitro* (benchtop) models, which would allow prediction of bioavailability in a less time- and labor-intensive way than animal studies. Various methods have been developed to simulate gastric and digestive conditions and assess the amount of arsenic that would dissolve in the digestive tract—termed the bioaccessible fraction—and thus be available for absorption. Bioaccessibility is not the same as bioavailability, since time factors or active vs. passive absorption might affect both the amount dissolved and the amount actually taken through digestive membranes.

In 1994, Mullins and Norman published a study of solubility of metals in windblown dust in simulated organ fluids [42]. In samples from four sites in Butte, Montana, the authors measured arsenic, cadmium, copper, manganese, and lead levels as a function of particle size and of solubility in fluids simulating the pH of the lungs, stomach, and intestines. The authors noted that arsenic compounds had less than 3% solubility in lung or intestinal fluid; acidic stomach fluids increased the arsenic solubility to 17-42%.

In 1996, Ruby *et al.* developed a physiologically based extraction test (PBET) for predicting bioavailability [43]. This test modeled human gastrointestinal tract parameters including pH and chemistry, soil-to-solution ratio, stomach mixing, and stomach emptying rates. Two soil samples and one household dust sample from Anaconda, Montana were tested using this procedure (the same samples as tested in the Freeman rabbit and monkey studies). Relative bioaccessibility of arsenic was defined as the average soluble arsenic mass remaining at the end of the small intestinal phase of the simulation divided by the total arsenic mass added to the reaction vessel, corrected for recovery of a soluble arsenic spike in a control simulation. Soils were found to have relative bioaccessibility of 44-50% using a gastric pH of 1.3 and 31-32% using a gastric pH of 2.5. House dust was found to have a relative bioaccessibility of 35%, using a gastric pH of 2.5.

In 1999, Rodriguez *et al.* built upon the PBET to develop an *in vitro* gastrointestinal (IVG) method [44]. The authors tested the IVG method with 15 soils collected from a "typical mining/smelter site in the western U.S." and compared the results with *in vivo* results from swine dosing. In some experiments, the authors included amorphous iron hydroxide gel to simulate intestinal absorption. Soils representing calcine material (a waste product which results from smelting of arsenopyrite ore for extraction of arsenic) showed very low bioaccessibility (less than 4%), while other soils had a mean relative bioaccessibility in the range 20-25%. The authors stated that the IVG results were closer to *in vivo* results than PBET, but concluded, "It is unlikely that an *in vitro* method can be developed which will replicate *in vivo* bioavailability. The human digestive system is too complex and dynamic to simulate in the laboratory."

Soil extraction-based *in vitro* methods have been studied further and refined, but their utility in predicting human bioavailability has not been proven. Results appear to vary depending on the protocol used [45], type of soil or slag tested [46,47], aging or weathering of soil contaminants [47–49], or the presence of other materials that may increase or decrease adsorption [50,51]. In most cases, bioaccessibility results have been shown to be poor predictors of bioavailability measured in animal studies [39,46,47,52]. Novel methods, such as using bacterial sensors to assess microbial bioavailability, are being developed, but it is not known how this property may correlate with human digestive bioavailability [53]. At this time, additional research is needed to make *in vitro* methods useful for risk assessment.

E. EPA's Exposure Assessment Model Applied to Anaconda

In preparing its risk assessment for the site, EPA used a model to predict risk resulting from exposure to contaminants through various pathways. The exposure pathway applicable to this health consultation is that of exposure of residents to arsenic in soil and dust, and the calculations and assumptions made will be reviewed in this section. The first step is to determine the chronic daily intake (CDI) in milligrams of arsenic per kilogram of body weight per day (mg/kg/day) resulting from this exposure. The CDI is calculated using the following equation:

$$CDI = \frac{CS \times IR \times CF \times FI \times EF \times ED \times BAF}{BW \times AT}\text{, where}$$

CS = concentration of arsenic in soil or dust, in milligrams per kilogram (mg/kg),
IR = ingestion rate of soil and dust, in milligrams per day (mg/day),

CF = a conversion factor of 10^{-6} kilograms per milligram,
FI = fraction of ingestion from contaminant source, unitless,
EF = exposure frequency in days per year,
ED = exposure duration in years,
BAF = bioavailability factor for arsenic in soil or dust, unitless,
BW = body weight of child or adult in kilograms, and
AT = averaging time in days.

To determine the overall CDI, individual CDIs for dust and for soil, for children and adults over the time period of interest, are summed. Next, the CDI is multiplied by the oral cancer slope factor for arsenic, 1.5 $(mg/kg/day)^{-1}$ [54], to determine cancer risk. (Alternatively, to determine the noncancer hazard quotient, the CDI is divided by EPA's oral reference dose of 0.0003 mg/kg/day). Table 2 gives assumptions used by EPA in calculating risks posed by the residential soil/dust for use in the risk assessment.

Table 2. Exposure Assumptions Used by EPA to Calculate Risks from Soil/Dust Residential Exposure at the Anaconda Co. Smelter Site

Exposure Value	Assumed Reasonable Maximum Value				Source
	Children - dust	Children - soil	Adults - dust	Adults – soil	
CS	Measured values from site characterization				EPA site characterization
IR (mg/day)	200 *	200*	100*	100*	EPA Default Values
FI	0.55	0.45	0.55	0.45	Assumed
EF (days/year)	350	350	350	350	EPA Default Values
ED (years)	6	6	24	24	EPA Default Values
BAF	0.258	0.183	0.258	0.183	Site-specific monkey study [28]
BW (kg)	15	15	70	70	EPA Default Values
AT (days)	Cancer: 365*70 Noncancer: 365*ED	Cancer: 365*70 Noncancer: 365*ED	Cancer: 365*70 Noncancer: 365*ED	Cancer: 365*70 Noncancer: 365*ED	EPA Default Values
*IR, Ingestion Rate, refers to total ingestion of soil and dust. When multiplied by FI, fraction ingested, the soil or dust ingestion is obtained.					

Soil screening levels were determined by essentially reversing the above calculations, starting with risk to determine the concentration in soil and dust corresponding to that risk. In order to complete these calculations, an additional piece of information was needed, that of the contribution to dust arsenic level by soil arsenic. This information was obtained from studies by Bornschein in 1994 as reported in the risk assessment [3]. Analysis of paired soil and interior dust measurements in homes in Anaconda and in Opportunity suggest a transfer coefficient of 0.43 for movement from soil to dust. Therefore, CS_{dust} was set at $0.43 \times CS_{soil}$ in the equations, and solving for CS_{soil} for a given risk level, the corresponding soil screening level could be obtained.

Using this procedure, ATSDR reproduced the residential scenario's risk-based screening levels for arsenic reported in Table 6.6 of EPA's Baseline Human Health Risk Assessment for

Anaconda [3]. Table 3 below shows CS_{soil} values (screening levels) resulting from various risks, using an oral cancer slope factor of 1.5 $(mg/kg/day)^{-1}$ and the exposure assumptions detailed in Table 2 and in the above text.

Table 3. Anaconda Co. Smelter Site Soil Screening Level (CS_{soil}) Values Corresponding to Various Cancer Risks*

Target Cancer Risk Level	Corresponding CS_{soil} Value, mg/kg
1×10^{-4}	297
1×10^{-5}	30
1×10^{-6}	3
*Cancer risk based on 6-year child exposure plus 24-year adult exposure.	

EPA selected 250 mg/kg arsenic in soil as the action level for residential soil in Anaconda. Based on ATSDR's reproduction of the screening level calculations, given the exposure assumptions used this action level falls into the typical risk management range for EPA decisions, since the action level corresponds to an excess cancer risk of less than 1×10^{-4}.

III. Response to Community Requests

A number of requests and concerns were presented to ATSDR regarding the residential arsenic soil action level selected. In addition, a number of stakeholders and interested parties provided information for ATSDR's consideration in preparing this consultation. This information is summarized following the "References" section of this document in "Additional Information Reviewed".

The community had questions about the applicability of some of the exposure assumptions (bioavailability factor, soil ingestion rate, fraction of soil versus dust ingested, slope factor, and target risk level) used in the screening level calculations. ATSDR examined these exposure assumptions and evaluated their influence on risk calculations used to calculate screening and action levels. Another request from the community was for ATSDR to summarize arsenic residential soil action levels for other NPL sites and indicate where the Anaconda action level fit into the range. This summary will follow the exposure assumption evaluation presented below.

A. Evaluation of Exposure Assumptions Used in Determining Action Level

1. Bioavailability Factor

The community raised several issues which could affect the validity of the bioavailability factor used in the Anaconda risk assessment (25.8% for dust and 18.3% for soil). As described above, these values were determined from the Freeman monkey study using Anaconda soil [30–32]. In the following paragraphs, ATSDR presents each issue raised by the community, followed by a discussion of the issue and its potential effect on the screening level predicted from the exposure equations listed in the previous section.

Relative vs. Absolute Bioavailability

Concern: *EPA used absolute bioavailability instead of relative bioavailability, which is higher.*
Response: ATSDR found that the bioavailability factor used in the risk assessment is indeed

equivalent to the absolute bioavailability. Mathematically, the relative bioavailability is equal to the absolute bioavailability if the absolute bioavailability of the reference material (aqueous sodium arsenate in this case) is 100%. Most researchers assume that this is the case with aqueous sodium arsenate. In the Freeman monkey study, the measured absolute bioavailability of aqueous sodium arsenate based on urine was 91±4% (from data in [30,31]; the Freeman journal article [32] "normalized" the values which EPA deemed inappropriate). Blood measurements indicated the absolute bioavailability for sodium arsenate to be between 91 and 100%. EPA assumed that the aqueous sodium arsenate was actually absorbed at 100% and therefore, absolute bioavailabilities for the soil and dust materials could be used interchangeably with relative bioavailability. If 91% was used for the absolute bioavailability of aqueous sodium arsenate, the relative bioavailabilities for soil and dust would change from 18.3% to 20.1% and from 25.8% to 28.4%, respectively. This would result in a reduction in the arsenic screening level calculated for a target risk of 1×10^{-4} from 297 mg/kg to 270 mg/kg.

Number of Animals Used in Experiments

Concern: *The low number of animals used in the monkey study upon which the bioavailability factor is based make the results too uncertain.*
Response: The Freeman monkey study used 3 monkeys, which were cycled through different experimental exposures. The low number of animals is necessitated by the high cost of performing primate studies and is typical of other primate studies in the literature. Individuals may have higher or lower absorption depending on many factors; this adds uncertainty. However, the other studies performed on Anaconda and Butte soils, which obtained similar results, serve to add confidence to the Freeman monkey study result. ATSDR tested the effect of changing soil bioavailability on the screening level corresponding to a 1×10^{-4} excess cancer risk. The various studies on Anaconda and Butte soils reported bioavailabilities ranging from 13% to 22%; these soil bioavailabilities result in screening levels ranging from 366 mg/kg to 243 mg/kg. These values are higher than or very close to the 250 mg/kg arsenic soil action level selected.

Bioavailability Comparability Between Sites

Concern: *The bioavailability factor is lower at Anaconda than at other sites.*
Response: Arsenic bioavailability in soil from different sites is highly variable. As summarized in Tables 1a and 1b on pages 13 and 14, experiments conducted for other site soils have determined arsenic bioavailabilities both higher and lower than that at Anaconda (although the Anaconda soils are toward the low end for bioavailability). Risk managers at other sites may decide to use default values for bioavailability if they perceive that the cost of doing site-specific bioavailability studies is higher than the additional cleanup resulting from over-estimation of risk. The next section of this document includes a summary of soil arsenic action levels and indicates the bioavailability factor used in the decision, if available.

Rabbit Study

Concern: *Why was the Freeman rabbit study not considered to estimate bioavailability – was it dropped because the result was too high?*
Response: The 1993 Freeman study on rabbits indicated a relative bioavailability of 48% for arsenic in Anaconda soil [28]. However, the significant differences between humans and the rabbit model – including arsenic metabolism, feeding behavior, and digestive tract chemical and physical properties – make the data of little use in estimating bioavailability in humans. For example, rabbit blood cells bind arsenic more tightly than humans, and rabbits exhibit

coprophagy, where partially digested food material is excreted fecally and reconsumed to allow more nutrients to be absorbed. ATSDR considers the monkey and swine models better for representing human arsenic absorption.

Validity of Urinary Excretion to Estimate Bioavailability

Concern: *The use of urinary excretion data underestimates bioavailability.*
Response: Some researchers have questioned the utility of animal models and the procedures used to calculate relative bioavailability. In particular, they state that the calculation of bioavailability from urine excretory data alone can cause underestimation of bioavailability. Typically, dosed arsenic that is not recovered in urine and feces is neglected in urine-based relative bioavailability calculations. This could cause underestimation of relative bioavailability if the unrecovered arsenic is in fact absorbed [personal communication, Jim W. White, Washington State Department of Health, February 2, 2007]. To explore this, ATSDR examined how these concerns might impact bioavailability studies that focus on Anaconda soils.

ATSDR examined data on total arsenic recovery and fecal excretion data from the Freeman monkey study [32]. Mean total arsenic recoveries (in urine and feces) for reference, soil, and dust tests were 94.4±9.2%, 101±7%, and 95.4±5.2%. Because the arsenic is essentially all accounted for, it is unlikely that significant errors in the relative bioavailability calculated using urinary data were introduced. Standard deviations were higher for fecal data than urine data, so it is unlikely that using fecal data to calculate the relative bioavailability would give a better value. Recovery data from the recent Roberts study was also examined [40]. The arsenic recovery in the test on Anaconda soil was 95.1±11.1%, but recovery of the reference material was only 80.7±4.2%. If the unrecovered arsenic for the reference is assumed to be absorbed (i.e., added to the urinary data), it would result in a lower calculated bioavailability. As a final comparison, the swine study on Butte soil was also examined [37]. This study used a different protocol than the monkey studies. Arsenic recovery data in urine and feces was presented as 79.3% and 89.4% for the two test materials and 95.8% for the reference. This is the opposite case as previously described, since the test material had lower recovery than the reference. In this case, if the unrecovered arsenic is assumed to be absorbed (i.e., added to the urinary data), it would result in a higher calculated bioavailability.

On the basis of this evaluation, it appears that the procedures for evaluating data from animal models have the potential to introduce considerable uncertainty into calculated bioavailabilities. The experiments on which the Anaconda relative bioavailability values are based had a relatively good recovery and are thus not expected to be subject to great errors. In light of the potential uncertainty introduced, however, ATSDR will include discussion about the effect of changing soil and dust bioavailabilities on expected public health impact in the Exposure Evaluation section of this document.

Soil Dose

Concern: *The dose used in animal studies is unrealistic.*
Response: The Freeman monkey study used a dose of 1,500 milligrams of soil per kg body weight. Compared to a typical child's incidental ingestion of soil (200 mg/day corresponds to about 15 milligrams of soil per kg body weight), these doses are a hundred times higher than would be expected to occur normally. They are 3-4 times higher than a child who intentionally eats soil (exhibits soil pica behavior) might consume. The higher dose used in monkey

experiments could result in differences in absorption and metabolism which would add uncertainty to the result. Swine studies typically use much smaller soil doses, on the order of typical incidental soil ingestion levels, so they would be less subject to this uncertainty.

Unreliable Technique

Concern: *The lack of protocols and standard QA/QC makes bioavailability results suspect.* Response: Different researchers have used varying protocols in conducting animal experiments, and protocols and analytical techniques have been modified to improve confidence in the results. ATSDR recommends that researchers continue to look for ways to improve reliability and reproducibility of these experiments, but we also believe that results obtained to this date provide useful information and can validly be used for risk assessment for this site.

To summarize, ATSDR feels that EPA made a reasonable selection for soil and dust bioavailability factors in its exposure model for Anaconda. The results of the Freeman monkey study have been supported by additional results from swine studies on similar soils and a recent monkey study which tested Anaconda soil [37,39,40]. In addition, the bioavailability values used at Anaconda were shown to be consistent with actual exposure data from the community [15]. Finally, ATSDR looked at the effect of varying the bioavailability in exposure calculations for this site, and a reasonable degree of uncertainty in the bioavailability would not affect the screening level by a great amount.

On the other hand, ATSDR recognizes the concerns the community has pointed out about limitations of bioavailability studies in making a definitive estimate of arsenic bioavailability. Of these concerns, the one with the greatest potential for affecting estimated exposures is the possible underestimation of bioavailability resulting from incomplete arsenic recovery. Although this does not appear to be a major source of uncertainty in the Anaconda bioavailability factors, ATSDR will attempt to address the community's concerns by discussing how changing relative bioavailability for soil and dust will affect the anticipated public health effects of the exposure in the Exposure Evaluation section of this document.

2. Soil Ingestion Rate

In calculating risk and screening levels, EPA used a child reasonable maximum soil ingestion rate of 200 milligrams per day (mg/day). The community provided comments to ATSDR about this soil ingestion rate. The comments stated that EPA had revised its default values for soil ingestion and that 400 mg/day was now recommended for reasonable maximum exposure for children. This is not accurate. The Exposure Factors Handbook and Child-Specific Exposure Factors Handbook summarized findings of studies on soil ingestion [55,56]. A table in each handbook indicates 100 mg/day as the mean and 400 mg/day as the upper 95th percentile. In reference to the 400 mg/day value, the text states, "however, since the children were studied for a short period of time and usually during the summer months, these values are not estimates of usual intake." In addition, the exposure handbook recommendations are not the default values for use in risk assessment; default values are set for the Superfund program in Risk Assessment Guidance for Superfund [57,58]. In this guidance, EPA specifies the use of 200 mg/day soil ingestion for children for reasonable maximum exposure. ATSDR's Public Health Assessment Guidance Manual also recommends the use of 200 mg/day for soil exposure estimation for children [59].

Comments also cited soil ingestion studies reported by Calabrese [60]. Sixty-four randomly selected children aged 1-4 years and living in Anaconda took part in the study, which measured tracer elements in soil and dust and in children's fecal output to determine ingestion. The results showed significant variability between subjects and between tracer elements. Results using the so-called "best tracer methodology" indicated that median soil ingestion was less than 1 mg/day and the upper 95th percentile value was 160 mg/day [60]. Although not presented in the Calabrese publication, EPA's risk assessment for Anaconda reports that the study showed mean soil and dust ingestion of 83-117 mg/day and a 90th percentile of 273-277 mg/day, depending on the tracer methodology used [3]. EPA's Office of Research and Development also reviewed the study [61]. The reviewer concluded, "Balancing the available data, I do not believe that the findings of the Calabrese study in Anaconda are in conflict with the Superfund Program's usual approach that uses a value of 200 mg/day in a reasonable maximum exposure calculation" [61]. ATSDR concludes that the soil ingestion rate of 200 mg/day is appropriate.

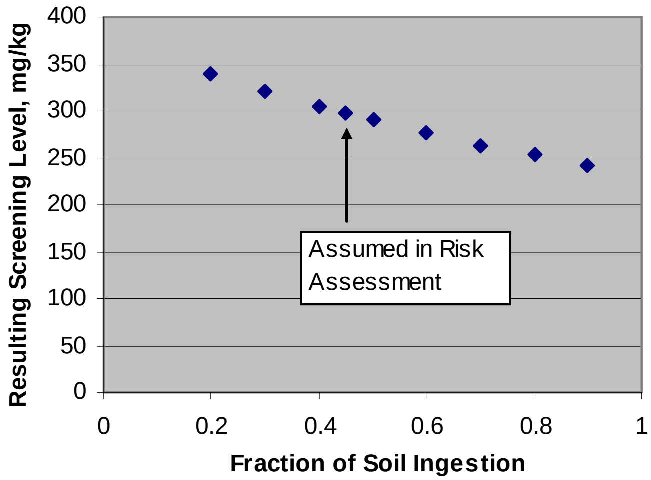
3. Fraction of Soil Versus Dust Ingested

In the risk assessment, EPA assumed that the daily soil ingestion was split into dust ingestion and soil ingestion, with 55% of the ingestion contributed by dust. Comments from the community questioned the validity of this assumption and stated that the approach was not supported by soil ingestion studies.

Superfund guidance makes the following statement about the 200 mg/day default value [emphasis added]: "The value suggested for ingestion rate (IR) for children 6 years old and younger are based primarily on fecal tracer studies and *account for ingestion of indoor dust as well as outdoor soil*…. A term can be used to account for the fraction of soil or dust contacted that is presumed to be contaminated (FI). In some cases, concentrations in indoor dust can be equal to those in outdoor soil. Conceivably, in these cases, FI could be equal to 1.0." [57] On the basis of this guidance, it is appropriate to split the daily soil ingestion rate into soil and dust fractions if the soil and dust have different bioavailabilities or different contaminant concentrations, since they contribute differently to contaminant exposure. The relative proportions used as defaults (45% outdoor soil and 55% indoor dust) are discussed in EPA's lead model (IEUBK) guidance as follows: "The ratio of soil intake to dust intake is not simply proportional to the ratio of the number of waking hours that the child spends outdoors versus indoors. Children spend only 15 to 30% of their waking hours playing outside but are more likely to be in contact with bare soil areas, in locations with large amounts of accessible loose particles, and are likely to wash their hands less often than when they are indoors. The default 45/55 ratio in the model represents our best judgment of a properly weighted ratio for this parameter." [62] ATSDR considers the rationale for choosing the default soil/dust ingestion ratio to be reasonable and equally applicable to ingestion of soil and dust containing arsenic as that containing lead.

It is possible that a greater or lesser percentage of overall incidental ingestion comes from soil. To examine the sensitivity of screening levels resulting from the assumed value of this percentage, ATSDR varied the percentage for soil ingestion from 20% to 90% (with corresponding percentages of dust ingestion percentages of 80% to 10%). As shown in Figure 3 below, the resulting screening level was relatively insensitive to the percentage chosen, and varied only from about 240 mg/kg to about 340 mg/kg over the entire range of percentages.

Figure 3. Effect of Assumed Soil Ingestion Fraction on Calculated Screening Level



4. Oral Slope Factor For Arsenic

ATSDR received questions from the community asking if proposed changes to the maximum contaminant level for arsenic in water and/or oral slope factor for inorganic arsenic ingestion would affect the protectiveness of the soil action level.

EPA has supported various reviews and updates of its risk assessment for inorganic arsenic in water [63, 64]. These draft reports have recommended changes the way the epidemiologic data forming the basis of the current oral slope factor for arsenic is analyzed. The changes would result in an increase in the oral slope factor and a correspondingly higher estimated cancer risk for a given exposure. The draft reports and recommendations are currently being reviewed by EPA's Science Advisory Board and do not represent final EPA policy or decisions. ATSDR does not know when the update will be completed. Until that time, ATSDR's policy is to continue to use the current arsenic oral slope factor of 1.5 $(mg/kg/day)^{-1}$ in its exposure calculations [personal communication, Selene Chou, Toxicological Profile Manager for Arsenic, ATSDR, March 13, 2007].

5. Target Risk Level

EPA's selected arsenic soil action level results in a calculated increased cancer risk of 8 in 100,000 (8×10^{-5}). ATSDR received comments that Montana's point of departure for cancer risk, 1 in 100,000 (1×10^{-5}), should have been used. ATSDR does not have authority to specify target risk levels for EPA risk calculations. The estimated increased risk of cancer falls within EPA's acceptable cancer risk range of 1×10^{-6} to 1×10^{-4}.

B. Survey of Residential Soil Arsenic Action Levels

A detailed compilation of arsenic soil RODs has been published in the literature, but includes only RODs through 1998 [65]. ATSDR conducted additional searches to update this information and look more closely at how the action levels were determined. Searches were conducted in EPA's Record of Decision System database to identify action levels for arsenic in residential soils [66]. The database was searched using various keywords (such as arsenic, mining, residential soil, and others) to identify potential sites, and the site RODs were then examined to determine if arsenic soil action levels were specified. Every attempt was made to identify the residential soil arsenic action levels for mining-related sites, sites that had been brought to our attention by community members, and sites representative of other industries and regions. However, the search was not exhaustive and it is probable that at least some relevant action levels were not obtained. Tables 5 and 6 summarize the findings from the database search and summarizes additional information that was obtained from other EPA sources regarding the action levels.

For mining or smelting sites (Table 5), arsenic soil action levels specified in the ROD as resulting from site-specific risk for residential soils ranged from 46 mg/kg (El Paso Residential Soils, Texas) to 340 mg/kg (California Gulch, Colorado). For information, action levels at three sites that were based on worker exposure are included in the table; the action levels based on worker risk ranged from 200 mg/kg (Silver Mountain Mine, Washington) to 1200 mg/kg (Murray Smelter, Utah). Six of the 28 mining/smelting sites had action levels denoted in the ROD as determined by screening or background levels; these ranged from 20 mg/kg (Lava Cap Mine, California) to 442 mg/kg (Fremont National Forest/White King and Lucky Lass Uranium Mines, Oregon). In many cases, information on bioavailability assumptions used in risk calculations was included in site documentation; these ranged from 18.3% (Anaconda, Montana soil) to 100% assumed due to variability in operable units (Kennecott North Zone, Utah).

Table 6 summarizes results from several non-mining, non-smelting sites. These sites were mostly pesticide/herbicide sites or wood treatment sites, which typically have high bioavailability. These sites generally have arsenic residential soil action levels of 40 mg/kg or less, although higher action levels may be set for non-residential populations or if risk management decisions justify the use of higher action levels.

Table 5. Summary of Soil Arsenic Criteria* for Selected Mining and Smelting Sites

State – Site Name	Soil Arsenic Criteria* in mg/kg (Residential Unless Indicated Otherwise)	Basis of Criteria			Notes on Relative Bioavailability Adjustment for Risk-Based Criteria	Main Info Source
		Background	Site-specific Risk	Screening or Other		
CA - Lava Cap Mine	20	X			N/A (not risk-based)	2004 Record of Decision
CO - Asarco Globe Plant	70		X		80% for soil; 30% for dust	1993 Record of Decision
CO - California Gulch	120-340		X		No information available	2003 Record of Decision
CO - Vasquez Boulevard and I-70	70		X		42% based on swine study	2003 Record of Decision
ID - Blackbird Mine	100	X			N/A (not risk-based)	2003 Record of Decision
ID - Bunker Hill Residential Soils	100		X		No information available	2002 Record of Decision
ID - Talache Mine	36 (future residential)	X			N/A (not risk-based)	EPA Fact Sheet, July 2002, "Cleanup in Depositional Area Set to Begin"
ID - Triumph Mine Tailings	300		X		16-80% based on "results of different studies and metal contaminant sources"	1998 Record of Decision
MT - Anaconda Co. Smelter	250		X		18.3% soil, 25.8% dust based on primate study	1998 Record of Decision
MT - Basin Mining Area	120		X		50% in absence of site-specific information	2001 Record of Decision
MT - Clark Fork River	150		X		50% based on swine study	2004 Record of Decision
MT - Silver Bow Creek/ Butte (Butte Priority Soils OU)	250				18.3% soil, 25.8% dust based on Anaconda Co. Smelter primate study; confirmed with swine study	2006 Record of Decision
MT - Upper Tenmile Creek Mining Area	120	X			50% in absence of site-specific information	2002 Record of Decision
NV - Anaconda Copper Co.	260 (workers)	X		X	N/A (not risk-based)	2005 Data Summary Rpt
OK - National Zinc Corp	60		X		No information available	1995 Record of Decision

* Criteria typically refer to action level for removal but may also refer to remedial goal, remedial action objective, or screening level specified in decision or site documents as criteria for determining some action on soil.

Table 5. Summary of Soil Arsenic Criteria* for Selected Mining and Smelting Sites

Site, State	Soil Arsenic Criteria* in mg/kg (Residential Unless Indicated Otherwise)	Basis of Criteria			Notes on Relative Bioavailability Adjustment for Risk-Based Criteria	Main Info Source
		Background	Site-specific Risk	Screening or Other		
OR - Fremont Natl Forest/White King and Lucky Lass Uranium Mines	442	X			N/A (not risk-based)	2001 Record of Decision
OR - Fremont Natl Forest/White King and Lucky Lass Uranium Mines (Lucky Lass Mine only)	38			X	N/A (not risk-based)	2001 Record of Decision
SD - Whitewood Creek	100		X		50% used	2001 Explanation of Significant Differences
TX - El Paso Residential Soils	46		X		37-44% based on swine study	EPA El Paso site FAQs at http://www.epa.gov/earth1r6/6sf/el_paso_faqs.htm
UT - Davenport and Flagstaff Smelters	126				51% based on animal studies from other sites	2002 Record of Decision; 2006 Explanation of Significant Differences
UT - Jacobs Smelter	100	X	X		"high" bioavailability	1999 Record of Decision
UT - Kennecott North Zone	200†				100% based on suspected variability between operating units	2002 Record of Decision
UT - Kennecott South Zone	50-100	X			39% based on swine study	2001 Record of Decision
UT - Midvale Slag	61		X		No information available	2002 Record of Decision
UT - Murray Smelter	1200 (workers)		X		26% based on swine study	1998 Record of Decision
UT - Sharon Steel Co.	70		X		80% used	1994 Record of Decision
WA - Silver Mountain Mine	200 (workers)		X		No information available	1990 Record of Decision
WA - Commencement Bay Nearshore Tidal Flats (Ruston/North Tacoma)	230‡				80% for soil and dust as a conservative assumption	1993 Record of Decision; 2000 5-Year Review

X

* Criteria typically refer to action level for removal but may also refer to remedial goal, remedial action objective, or screening level specified in decision or site documents as criteria for determining some action on soil.

† Risk management decisions justify use of criteria higher than risk-based criteria.

‡ Soils with arsenic between 20 and 230 mg/kg require community education.

Table 6. Summary of Soil Arsenic Criteria* for Selected Non-Mining Related Sites – page 1 of 1

State – Site Name	Main Source of Arsenic			Soil Arsenic Criteria[*] in mg/kg (Residential Unless Indicated Otherwise)	Basis of Criteria			Notes on Relative Bioavailability Adjustment for Risk-Based Criteria	Main Info Source
	Pesticide/Herbicide	Wood Treating	Other		Background	Site-specific Risk	Screening or Other		
CA - Koppers Inc. (Oroville Plant)		X		7.15	X			N/A (not risk-based)	1989 Record of Decision
CA - McCormick & Baxter Creosoting Plant		X		30			X	N/A (not risk-based)	1999 Record of Decision
CA - Selma Pressure Treatment Co.		X		25			X	N/A (not risk-based)	1994 Explanation of Significant Differences
CA - Valley Wood Preserving		X		25			X	N/A (not risk-based)	2003 Record of Decision Amendment
GA - Woolfolk Chemical Works	X			20		X		None	1998 Record of Decision
LA - Central Wood Preserving		X		20	X			N/A (not risk-based)	2001 Record of Decision
MN - MacGillis&Gibbs /Bell Lumber&Pole				55[†]		X		None	1994 Record of Decision
MT - Silver Bow Creek/Butte (Rocker OU)	X			380 (recreational)				None	1996 Record of Decision
NC - Barber Orchard	X			40	X	X		None	2004 Record of Decision
TX - Rockwool Industries			X	200 (workers)		X		No information available	2004 Record of Decision
UT - Hill Air Force Base			X	4.1	X			N/A (not risk-based)	1995 Record of Decision

[*] Criteria typically refer to action level for removal but may also refer to remedial goal, remedial action objective, or screening level specified in decision or site documents as criteria for determining some action on soil.
[†] Risk management decisions justify use of criteria higher than risk-based criteria.

IV. Exposure Evaluation

ATSDR evaluated representative residential exposure scenarios to assess the potential public health impact of exposure to Anaconda residential soils. The following sections describe ATSDR's evaluation of incidental and intentional ingestion of soil by children and adults. While inhalation and dermal exposures to arsenic-containing soil and dust may also occur, the risk contributed by these exposure routes is expected to be a small fraction of the risk from the ingestion route [59,67]. ATSDR notes that the residential soil action level applies to parks and school grounds within the community of Anaconda in addition to residential properties [personal communication, Charlie Coleman, September 17, 2007]. This evaluation will apply to those exposure points as well.

A. Child Chronic Incidental Ingestion of Arsenic in Soil

In this section, ATSDR will evaluate potential public health impact of residential exposure to the 250 mg/kg arsenic soil action level selected by EPA for cleanup. ATSDR assumed that a child's incidental ingestion of soil and dust was equal to ATSDR's standard conservative default of 200 mg/day. Further, ATSDR assumed that 45% of a child's daily incidental ingestion was to soil containing 250 mg/kg arsenic and that 55% was to household dust containing arsenic at 0.43 times the soil level. This is the ratio of dust arsenic concentration to soil arsenic concentration measured in the Bornschein study reported in the 1996 risk assessment for Anaconda. In addition, the calculations for incidental exposure of children assume daily contact with contaminated soil and dust and a 13.5-kg body weight (about 30 pounds, the mean weight for 2- to 3-year-old children [56]). For a starting point, bioavailability of arsenic in soil and dust was assumed to be 18.3% and 25.8%, respectively. To illustrate how assumed bioavailability affects estimated dose, the effect of raising both values to 40% was also evaluated.

Evaluating exposure to arsenic in soil at the action level of 250 mg/kg will overestimate incidental exposure. Average arsenic soil concentration in yards that were not remediated were less than 250 mg/kg, and yards that averaged more than 250 mg/kg arsenic had or will have subareas with greater than 250 mg/kg removed and replaced. The clean fill used for replacement contains less than 30 mg/kg arsenic [personal communication, Charlie Coleman, February 7, 2007]. Therefore, remediated yards will have average arsenic soil levels below the 250 mg/kg action level. For example, consider a hypothetical yard of 3 equally-sized subareas which, before cleanup, contained 400, 240, and 150 mg/kg arsenic. The pre-cleanup yard average would be $400\times(1/3) + 240\times(1/3) + 150\times(1/3) = 263$ mg/kg, thus the yard would be subject to cleanup of the subarea that was above 250 mg/kg. After cleanup, assuming the clean fill contained 30 mg/kg arsenic, the yard average arsenic soil concentration would be $30\times(1/3) + 240\times(1/3) + 150\times(1/3) = 140$ mg/kg. Of the 244 yards or lots requiring cleanup (out of 1091 yards tested), most have been cleaned up as of February 2007, with a few pending actions [68]. Therefore, the average surface soil arsenic concentration remaining in Anaconda is likely to be less than the 250 mg/kg value evaluated here.

ATSDR considers the assumptions detailed above to be conservative for assessing health risk. As described above, the average exposure concentration of arsenic is likely to be less than the 250 mg/kg value selected. In addition, the soil and dust ingestion amounts are recommended conservative values, and it is expected that most children would ingest less soil and dust. Dust arsenic concentrations would also be expected to be lowered from their current values as yards are cleaned up and as normal housekeeping activities remove dust. The calculations for incidental exposure of children assume more frequent contact with soil and a lower body weight than assumed in the risk assessment. Finally, studying a range of bioavailabilities will address potential uncertainty associated with these values.

The incidental exposure of children is then estimated as:

$$Dose = \frac{250\,\frac{mg\ As}{kg\ soil}\times 0.45\times 200\,\frac{mg\ soil}{day}\times 1\times 10^{-6}\,\frac{kg\ soil}{mg\ soil}\times 0.183}{13.5\ kg} \qquad (soil\ dose)$$

$$+ \quad \frac{0.43\times 250\,\frac{mg\ As}{kg\ soil}\times 0.55\times 200\,\frac{mg\ soil}{day}\times 1\times 10^{-6}\,\frac{kg\ soil}{mg\ soil}\times 0.258}{13.5\ kg} \qquad (dust\ dose)$$

$$= \quad 0.00053\,\frac{mg\ As}{kg\cdot day}$$

The calculated arsenic exposure dose for a child exposed to soil at the action level, 0.00053 mg/kg/day, is higher than ATSDR's minimal risk level for chronic exposure, 0.0003 mg/kg/day, so ATSDR performed further evaluation of the scenario to determine if adverse health effects would be likely [4]. ATSDR found that it is unlikely that such an exposure would result in adverse health effects in children. The estimated dose is less than the dose observed in human epidemiological studies that did not cause any health effects (the "no observed adverse effect level") [4]. Increasing the bioavailabilities of soil and dust to 0.4 (40%) to explore the potential impact of uncertainty in the bioavailability adjustments used would increase the estimated child dose to 0.001 mg/kg/day. This dose is about 25% higher than the no observed adverse effect level from human epidemiological studies. The study on which the minimal risk level is based found skin effects considered "less serious" (increased pigmentation and wart-like growths) at a level of 0.014 mg/kg/day. Because the estimated dose is an order of magnitude smaller than this effect level, and in light of the conservative assumptions discussed above (conservative assumptions for soil ingestion, exposure concentration, and duration and frequency of contact), no adverse health effects would be expected from this exposure.

B. Cancer Risk from Chronic Oral Ingestion of Soil

A calculation similar to the one above was also performed for adults. In this calculation, adults were assumed to ingest 100 mg/day of soil and dust and to weigh 70 kilograms (154 pounds). All other assumptions were similar to the ones made for children. The resulting dose for incidental exposure to soil for adults was 0.00005 mg/kg/day. To estimate cancer risk, ATSDR assumed 6 years of exposure as a child and 24 years of exposure as an adult and multiplied the resulting dose by the oral cancer slope factor, 1.5 $(mg/kg/day)^{-1}$. The resulting excess cancer risk is given as:

$$Excess\ Cancer\ Risk\ =\ \frac{(0.00053\frac{mg\ \ As}{kg\ \ day}\times 6\ yr + 0.00005\frac{mg\ \ As}{kg\ \ day}\times 24\ yr)\times 1.5\,(\frac{mg}{kg\ day})^{-1}}{70\ yr}$$

$$=\qquad 9.4\times 10^{-5}$$

To explore the potential impact of uncertainty in the bioavailability adjustments used, increasing the bioavailability of soil and dust to 40% increases the estimated adult dose to 0.0001 mg/kg/day and the resulting estimated excess cancer risk to 1.8×10^{-4}. The actual risk of cancer, however, is expected to be significantly lower than this value. Conservatively high values for soil incidental ingestion were chosen, and, as described in the chronic child ingestion scenario above, the arsenic concentration in soil a person would be exposed to over a lifetime would, on average, be far lower than 250 mg/kg because of the remediation that has taken place already. Finally, most people would spend time each day in other locations for work, school, or other daily activities, as well as travel to other places each year for vacation or other events. Children typically move to a different location after they grow up. None of these potential reductions in exposure potential were included in our calculations.

C. Child Pica Behavior

Some children exhibit what is known as “pica” behavior, or intentional consumption of soil or other non-food items (including sand, clay, paint, plaster, hair, string, cloth, glass, matches, paper, feces, and various other items) [56]. About half of children aged 1-3 years old exhibit some form of pica behavior and it is more frequent and more severe among developmentally disabled children [56]. Data on soil pica in particular are limited, but it appears to be less common than general pica. Soil pica behavior can put a child at particular risk, however, because the child can obtain a large dose of a contaminant present in soil, and because the soil would typically come from a particular location, rather than various locations which could tend to have lower average contaminant concentration. No particular concern about potential for soil pica exposures was voiced to ATSDR from the community. However, because of the potential risk to a special population, ATSDR evaluated the potential impacts of pica soil ingestion in Anaconda.

ATSDR recommends soil pica be evaluated assuming a soil ingestion of 5,000 mg/day for acute, short-term exposure [59]. Additional assumptions employed included a body weight of 12.5 kg (about 28 pounds, the mean for children aged 1-3 years old [56]) and a bioavailability of soil of 0.183. For estimating the exposure concentration of arsenic in soil, the action level of 250 mg/kg may not be a sufficiently conservative value. This is because the action level is based on yard averages; yard subareas could have higher arsenic levels as long as the yard average was less than 250 mg/kg. EPA noted that future ROD amendments are planned to specify that any single subarea in a yard whose composite surface soil average is greater than 750 mg/kg arsenic will automatically be cleaned up, regardless of the average total yard concentration [personal communication, Charlie Coleman and Susan Griffin, both of U.S. Environmental Protection Agency, November 2006 and September 2007]. Therefore, ATSDR assumed that a single exposure to soil containing arsenic as high as 750 mg/kg is still possible even with the cleanups that have reduced the average yard soil arsenic concentrations to less than 250 mg/kg.

Using these assumptions, the potential acute arsenic exposure dose upon a single pica ingestion of soil is calculated as:

$$Dose = \frac{750 \frac{mg\ As}{kg\ soil} \times 5{,}000 \frac{mg\ soil}{day} \times 1 \times 10^{-6} \frac{kg\ soil}{mg\ soil} \times 0.183}{12.5\ kg}$$

$$= \quad 0.05 \frac{mg\ As}{kg \cdot day}$$

The acute dose calculated above is ten times the provisional acute MRL of 0.005 mg/kg/day. Substituting a 40% bioavailability for soil to explore the potential impact of uncertainty in the bioavailability adjustments used increases the estimated dose to 0.12 mg/kg/day. Either of these estimated doses is of concern. The provisional acute MRL is based on a study of poisoning in which critical effects of facial edema, nausea, vomiting, and diarrhea were observed at a dose of 0.05 mg/kg/day (the effects later subsided). While it is unlikely that circumstances would converge in such a way that a susceptible child would consume the most highly contaminated soil, the calculated acute dose indicates an increased risk of such reversible health effects for any children exhibiting soil pica behavior in Anaconda. Community members, and especially parents, should be informed about soil pica behavior and how to reduce potential exposures in children.

D. Additional Potential Sources of Exposure

The above scenarios describe residential exposure to the highest arsenic concentration expected to remain in residential surface soils after remedial actions are completed. The evaluation did not include consideration of potential exposures that may occur upon excavation of subsurface soil (which could contain higher arsenic concentrations) or exposure to soil in areas that may not have been cleaned to residential levels. In most cases, if exposure is brief, adverse health effects would not be likely. However, if activities result in intense exposures or recontamination of residential surface soil with higher levels of arsenic, an increased risk to public health might be created. It is our understanding that EPA is working to characterize residual subsurface contamination at this time [personal communication, Charlie Coleman, U.S. Environmental Protection Agency, April 17, 2007]. In addition, the County, EPA, and ARCO are developing a Community Protective Measures Plan to protect the community from potential future exposures. ATSDR will provide public health input on this plan. In addition, ATSDR will, upon request, evaluate specific situations that may occur in the community in the future.

V. Conclusions and Recommendations

On the basis of the available literature and evaluation, ATSDR makes the following conclusions:

- ATSDR considers the exposure and bioavailability assumptions made in EPA's 1996 Baseline Human Health Risk Assessment for Anaconda to be reasonable in estimating risk. However, ATSDR recognizes the potential for uncertainty in the bioavailability factors chosen for soil and dust in Anaconda.
- Chronic exposure to soil at the residential action level of 250 milligrams of arsenic per kilogram of soil would not be expected to result in adverse health effects for resident children or adults. This conclusion would not change within anticipated uncertainties of bioavailability or other exposure assumptions from EPA's 1996 Baseline Human Health Risk Assessment.
- Children who exhibit soil pica behavior could experience adverse health effects if they ingested gram quantities of soil containing arsenic. This conclusion would not change within anticipated uncertainties of bioavailability or other exposure assumptions from EPA's 1996 Baseline Human Health Risk Assessment. Areas containing soil with arsenic at levels high enough to cause adverse health effects upon soil pica behavior could remain, even after cleanup.
- Changing conditions at the soil surface due to activities such as excavation could increase the risk and may require further evaluation.

ATSDR makes the following recommendations to prevent potentially harmful exposures:

- EPA and ARCO should continue cleanup of residential properties.
- The Community Protective Measures Plan should include education of parents about risks associated with soil pica behavior in children.
- The Community Protective Measures Plan should include measures to protect against potential recontamination of residential surface soils with arsenic-contaminated subsurface soils.

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68. Neuman D. Memo to G. Emilsson of CDM, RE: Data gap analysis of Community Soils OU Residential RA database. Bozeman: Reclamation Research Group, LLC. March 30, 2007.

VIII. Additional Information Reviewed

Information provided by private citizens:

- Private Citizen. Letter to L. Campbell of the Agency for Toxic Substances and Disease Registry requesting evaluation of arsenic levels in the Anaconda, Montana area. June 6, 2006.
- Washington State Department of Ecology. Questions and answers, Tacoma Smelter plume, year end 2001. Publication 01-09-087, January 2002.
- Washington State Department of Ecology. Dirt alert, arsenic and lead in soils. Publication 03-09-036. Not dated.
- Printed web material from Washington State Department of Ecology site regarding Moses Lake City Maintenance Facility, what is area-wide soil contamination, dated 5/30/2006.
- Source unknown, [Montana] County [cancer] incidence rates by site with 95% confidence intervals. Not dated.
- Excerpt from conference proceedings regarding smelter arsenic production and historical disease rates in Butte and the county where the smelter was located. Dated 1990.
- Association for the Environmental Health of Soils. Study of state soil arsenic regulations. Amherst (MA): Association for the Environmental Health of Soils. Not dated.
- Montana Department of Environmental Quality Remediation Division. Action level for arsenic in soil. Dated April 2005.
- Source unclear. Table E-1. Example of round 1 sampling of residential yards and alleys. Not dated.
- State of Montana Department of Public Health and Human Services. Results of chemical analysis for arsenic and cadmium on soil sample. Dated March 3, 2006.
- Snohomish Health District, Guidelines for reducing potential exposure, Everett Smelter Site. Not dated.
- Private Citizen. Letter to R. Bertram of U.S. Environmental Protection Agency commenting on Superfund program cleanup proposal for the Butte Priority Soils Operable Unit of the Silver Bow Creek/Butte Area Superfund site. January 25, 2005.
- Anaconda site map and photos. Not dated.

Information provided by Anaconda-Deer Lodge County [all received by ATSDR in Atlanta electronically on February 27, 2007]:

- Michaud B. Memo to J. Kuipers of Kuipers and Associates, RE: Preliminary findings, residential arsenic soil action level, Anaconda Smelter Superfund site. Fairfax (VA): SRA International, Inc. February 25, 2007.
- Microsoft Word summary entitled “Mining Sites with Soil Arsenic and Lead Action/Cleanup Levels”
- Microsoft Word summary entitled “Sites with Soil Arsenic and Lead Action/Cleanup Levels”

Information provided by ARCO:

- Schoof R, Nelson D. Memo to L. Birkenbuel of Atlantic Richfield Co., RE: Basis for and

protectiveness of arsenic soil cleanup level for Anaconda Community Soils OU. Mercer Island (WA): Integral Consulting Inc. February 26, 2007.

Information provided by EPA:

- Griffin S. Memo to C. Coleman of U.S. Environmental Protection Agency, RE: comments on memorandum from SRA International entitled “preliminary findings, residential arsenic soil action level Anaconda Smelter Superfund site.” Denver: U.S. Environmental Protection Agency, Region 8. March 6, 2007.
- Verbal information regarding site history, decisions, procedures – Charles Coleman, Remedial Project Manager and Susan Griffin, Senior Toxicologist.
- Site documents not available on Internet.

Other information conveyed (includes information obtained from multiple sources):

- Telephone discussion on February 2, 2007 and draft unpublished report, Jim W. White, Toxicologist, Washington State Department of Health.
- Tracy J. Report calls into question arsenic cleanup: consultant suggests different standards used in other mining-impacted towns. Anaconda Leader, Wednesday, February 28, 2007.
- Tracy J. ARCo report supports higher arsenic levels: EPA agrees with assessment of health risks, urges county to ‘get on board.’ Anaconda Leader, March 2, 2007.

IX. Appendix A. Public Comments and Responses

This health consultation was available for public review and comment at the Hearst Free Library in Anaconda, Montana. The document was also available for viewing or downloading from the ATSDR web site. The official public comment period was open from June 1, 2007 through July 13, 2007, and requests from the public to submit comments into August 2007 were accepted.

The public comment period was announced to local media outlets. ATSDR presented and discussed the findings of the health consultation with community members at a public meeting and availability sessions held on June 13 and 14, 2007, at the Hearst Free Library in Anaconda, Montana. The health consultation was sent to federal, state, and local officials as well as certain private citizens who had expressed interest in results of the consultation. Comments were received from EPA, a local community group, Anaconda-Deer Lodge County, contractors working on behalf of the county, and a private citizen. Comments are paraphrased for brevity and organization below, along with ATSDR responses. Some of the comments received were not directly related to ATSDR's work at the site and are not reproduced herein; these comments were forwarded to appropriate local or federal officials for consideration.

Comment from an EPA official:

Comment A1: It is important to communicate to the public how infrequently soil pica behavior actually occurs, both from a population perspective and from a repeated activity perspective. At ATSDR's expert workshop on soil pica behavior in June 2000, the experts noted that the soil pica ingestion rate of 5000 mg/day is supported by only a few subjects in soil ingestion studies. In a review of a number of key soil ingestion tracer studies (Binder et al, 1986; Clausing et al, 1987; Calabrese et al, 1989; Davis et al, 1990; Van Wijnen et al 1990, Stanek and Calabrese, 1995; Thompson and Burmaster 1991; and Sedman and Mahmood, 1994) only one child out of over 600 children involved in all the studies showed pica behavior. The child in question exhibited daily soil ingestion rates which ranged from 74 to 13,000 mg/day during the two week study. Although soil pica behavior does occur in a small percentage of the population, it does not occur on a repeated basis over an extended period of time. The use of the acute MRL to compare with a pica intake is appropriate because it represents an infrequent or one-time event. My concern is that the general population may think a child engaging in pica behavior will do this every day over several years.

A1 Response: Thank you for providing this information. We agree that current studies suggest that soil pica does not appear to be very common or persist for lengthy periods in children. However, because the phenomenon has not been particularly well characterized or studied and could result in harmful exposures, we believe it is appropriate to inform parents of this potential risk.

Comments from a citizens' group:

Comment A2: They based all their statistical information on someone else's data… none of it recent and no samples from actual yards in either Anaconda or Opportunity.… The study was done using a hypothetical model, meaning no actual testing of soil from our homes was used.

The study did not include any recreational property such as playgrounds, parks or anywhere else that our kids and pets play, just a “typical” home with no access to any dirt below 2 inches.

A2 Response: ATSDR was asked to evaluate whether the arsenic residential action level was protective, so we focused our evaluation on residential properties and assumed residential exposure to soil at the action level. This would be a “worst-case” scenario for residential exposure, since many yards contained arsenic at average levels lower than the action level, and those with higher average levels are or will be cleaned up to the action level. Although ATSDR had access to data on residential soil arsenic levels, it was not necessary to use them in the evaluation. Regarding playgrounds and parks, the Record of Decision for Anaconda states that playgrounds and parks within Anaconda are to be subject to the residential arsenic action level, so this evaluation is applicable to those areas as well (see comment A7 below for specifics).

Comment A3: The evaluation does not pertain to people who live on larger plots of land or if children play outdoors more than 20 days a year. The evaluation does not include demographic variables for this area.

A3 Response: The evaluation assumed children were exposed to residential soils on a daily basis, so it is applicable to children who play outdoors every day. (To be conservative, we did not reduce the outdoor usage assumption even though it is unlikely children are exposed to soil as much in the winter due to cold or snow cover.) The evaluation is valid for all residential plots subject to the residential soil arsenic action level, regardless of the acreage.

Comment A4: If you took all the appropriate precautions THEN the 250 mg/kg action level was safe. Why should we have to take all these precautions to feel safe in our own yards?

A4 Response: The commenter’s statement is inaccurate. The evaluation performed assumed normal activities with no special precautionary measures. The action level was found to be protective for chronic exposures in this case. If residents are still concerned about arsenic exposure despite this finding, precautionary measures can be taken to give an additional degree of safety. Additional actions might be warranted to prevent acute exposures if a child exhibits soil pica behavior (eating teaspoon quantities of dirt), and we recommend educating parents about ways to minimize the likelihood of such exposures.

Comment A5: Why isn’t the EPA telling ARCO that resident’s of ADLC and surrounding areas deserve to live and breathe in a safe environment instead of hiring another government agency to perform such an irrelevant study and then present such a study to the community telling them they are safe?

A5 Response: EPA did not hire ATSDR to do this evaluation. A private resident of Anaconda requested ATSDR to perform this evaluation. While EPA cooperated with ATSDR in providing data and background information, ATSDR performed the evaluation independently and considered information from local citizens, officials, and others not associated with EPA or ARCO.

Comment A6: OCPA members asked questions relating the cancer and respiratory illness seen so profoundly in our neighborhoods and were directed to the Health and Human Services "Tumor Registry" to access that information.

A6 Response: Yes, that's correct. Questions about cancers and reportable diseases in the community should be directed to Dr. Carol Ballew with the Montana Department of Public Health and Human Services (DPHHS). Dr. Ballew (406-444-6988) is an Epidemiologist assigned to the Montana Tumor Registry which routinely responds to inquiries. ATSDR does not conduct routine surveillance of state tumor or reportable disease registries. However, ATSDR will assist state, federal and local public health agencies to investigate cancer/disease clusters associated with unplanned chemical releases into the environment.

Comment A7: When we realized that this study was not reflective of our real situation we asked if they could do another study using data from actual testing done from the area, not obtained by ARCO, and to consider the following demographics of this area: 1. Include playgrounds, parks and school yards and other recreational areas; 2. Factor in the large number of days we are exposed; 3. Consider that we disturb the soil more than 2 inches on a regular basis; 4. That it is not reasonable to expect that this population routinely practices the safety measures that this study recommends.

A7 Response: As described above, the current health consultation did account for points 2 and 4 in the comment; daily exposure to residential soil with no added precautionary measures was assumed. In addition, point 3 was considered and ATSDR concluded that disturbance of subsurface soils could change our conclusions and would require further evaluation. ATSDR recommended that the Community Protective Measures Plan address the possibility of recontamination of surface soil with arsenic-containing subsurface soils. Finally, the purpose of the consultation was to answer the question of whether the residential action level for arsenic was protective; however, according to EPA's Record of Decision for the Community Soils Operable Unit,

> Residential soils include yards, parks, school grounds, or other play areas. Also included are barren driveways, alleys, or other common areas adjacent to yards which may contribute to the contamination of yards and which may be frequented by children [1].

Therefore, the areas within town such as school grounds and parks would be subject to the same residential soil action level and cleanup criteria as residential properties. The conclusions ATSDR reached for the protectiveness of the residential action level would also apply to these areas. Recreational areas not in town would be subject to the action level of the adjoining property, so for example walking trails near the Old Works golf course would be subject to the recreational action level. ATSDR finds this policy to be protective of the use of these areas.

Comment A8: It appears that this hypothetical study did two things. It got Arco off the hook and provided job security for folks working for another Government agency that is self serving.

A8 Response: ATSDR attempted to perform an unbiased evaluation of the initial question posed to us by the Anaconda resident, considering all the scientific evidence available. We recognize some community members' feeling that they are bearing an unfair burden due to past mining practices in their town. We hope that the findings of this evaluation will reassure residents that it is possible to live a normal life in the area without adverse health impact.

Comments from Anaconda-Deer Lodge County:

Comment A9: The assumptions and studies used to derive the residential arsenic soil action level for the AR/BP site are significantly less conservative than those used to derive similar levels at other mining and smelter sites and results in significant uncertainties regarding the protectiveness of this action level which are not adequately identified and addressed in the ATSDR report.

A9 Response: ATSDR does not agree with this comment. At the request of the community, ATSDR included in Table 5 a summary of arsenic soil action levels from other sites. The soil and dust bioavailabilities for the Anaconda site soil were lower than bioavailabilities used at other sites. However, ATSDR's review of bioavailability studies for various sites indicated that assumptions used and interpretation of study results to obtain a site-specific bioavailability were similar for Anaconda and the other mining sites. In addition, as documented in the report, other assumptions used in developing the action level for the Anaconda site were found to be appropriate. These were addressed on a point-by point basis in the section of the report entitled "III. Response to Community Requests."

Comment A10: If the 250 part per million residential action level is to be used for the AR/BP Site remedy a comprehensive and conservative Community Protection Measures Program (CPMP) must be developed and implemented, with adequate funding for ADLC involvement, to ensure that the remedy is protective of human health and the environment.

A10 Response: ATSDR supports development of an appropriate CPMP and made recommendations in the consultation to address issues we identified in which adverse health effects could be possible given the current action level and cleanup plans. ATSDR does not control funding issues; however, ATSDR is willing to work with the local community, upon request, to give further public health input on the CPMP as it is developed.

Comment A11: Review of this action level should be required as a significant part of the five-year remedy review process to ensure that current science is applied that might change these and other previous findings and to address the significant uncertainties in EPA's determination of the arsenic action level.

A11 Response: ATSDR agrees that this would be a prudent public health action. However, EPA determines the scope of its five-year reviews. We note, also, that the conclusions we reached in this consultation are based on the information currently available. Our conclusions could change on the basis of new site- or substance-related information.

Comments from contractors working on behalf of Anaconda-Deer Lodge County:

Comment A12: Our analysis suggests that the protectiveness of the Anaconda Smelter remedy is very sensitive to arsenic bioavailability assumptions, and the remedy relies on interpretations of the bioavailability data that are not supported by the science and are inconsistent with the state of past and present risk assessment and management practice. Very modest increases in bioavailability factor (BAF) values for soil and dust (<1%) suggest that the cancer risk associated with a residential arsenic soil action level of 250 mg/kg exceeds EPA's risk range. More conservative interpretations of the Anaconda Smelter bioavailability study, consistent with risk management decisions at other Superfund sites, would suggest a much lower action level.

A12 Response: ATSDR's evaluation showed that the bioavailability factors assumed for the Anaconda site are valid. As detailed in the section on bioavailability factors starting on page 17, ATSDR found that reasonable uncertainty in the assumed bioavailability factors for soil and dust would not likely impact the calculated screening level to a significant degree. ATSDR's exposure evaluation considered uncertainty in assumed bioavailability factors; ATSDR's conclusions were unchanged for bioavailability factors up to 40%.

Comment A13: The Community Protective Measures Plan (CPMP) should consider the relatively high degree of uncertainty associated with the residential soil arsenic action level and should focus on a broader range of issues, including more generally focused education and community awareness programs, cleanup of house dust and control of non-soil sources of arsenic, and attention to the effectiveness of surface soil reclamation in both residential and surrounding areas.

A13 Response: The arsenic action level is an EPA-determined value. The health consultation showed that its implementation would be protective of public health. If the community desires to address perceived uncertainty in risk associated with that value by increasing community awareness and undertaking additional contaminant reduction programs, those measures would add to protection of public health.

Comment A14: The ATSDR report states, "…with the exception of Mill Creek children who have long since been relocated, biomonitoring has not detected elevated levels of arsenic in Anaconda or Opportunity children or adults, at least since the smelter ceased operations." According to the Anaconda Smelter Baseline Human Health Risk Assessment (HHRA), Appendix D, the Bornschein study found that 27 out of 364 children for which data were available (7.4%) had total arsenic levels in urine at or above 50 ug/L, and 28 out of 366 children for which data were available (7.7%) had speciated arsenic levels in urine at or above 20 ug/L, levels at which ATSDR considers arsenic exposure "elevated" (CDM 1996).

A14 Response: Thank you for pointing out this error. In reviewing the Hwang study [14], ATSDR misinterpreted column headings on one of the tables. Appendix D of the HHRA includes the complete data set for the samples collected in the Hwang study, and the values cited by the commenter are accurate. ATSDR has revised discussion of this study on pages 8 and 10 of the document in response to the comment.

Comment A15: The ATSDR report does not consider the uncertainty inherent in the bioavailability studies and whether the interpretation of the Anaconda study was appropriate given the state of the science, risk assessment practice, and risk management decisions at the time and since. The state of the science and practice, then and now, suggest that the interpretation of the Anaconda study was not conservative. Risk assessors since the Anaconda study have consistently employed more conservative interpretations for site-specific risk assessment. See the May 4, 2007 memorandum, page 5, *Interpretation of Site-Specific Bioavailability Study* for a more detailed discussion of this issue.

A15 Response: ATSDR does not agree with the statements in this comment. ATSDR considered and found that the selection of bioavailability factor for the Anaconda site was appropriate and within normal risk assessment practice. Bioavailability factors are determined similarly, through urinary excretion factors, in all the studies cited in the health consultation; ATSDR was not able to discern any change in how the determination was made between studies in previous years or since. The commenter states elsewhere that upper confidence limit values for RBA should be used in preference to mean RBAs; however, in all studies reviewed by ATSDR, the mean RBA was used. (In one case for the VBI-70 site, multiple RBAs were determined for various regions of the site and the upper confidence limit value of those <u>mean</u> RBAs was used for site-wide calculations.) As detailed in the health consultation, a number of other bioavailability studies have consistently shown the Anaconda bioavailability to be similar to or lower than the selected value; therefore, there is no justification for using a more conservative value than would have been selected using normal risk assessment practice.

Comment A16: See the May 4, 2007 memorandum, page 5, *Interpretation of Anaconda Urine Study* for comments on the limitations of the approach used to evaluate exposure assessment model and findings regarding the model's ability to predict yard-specific exposure.

A16 Response: ATSDR agrees that it is virtually impossible to predict individual or yard-specific exposures. We support the use of exposure assessment models to make site decisions, affecting the community in general, in a reasonable manner. As detailed in the health consultation, ATSDR concluded that the assumptions made by EPA in developing the exposure assessment model for Anaconda were appropriate.

Comment A17: EPA guidance states that urinary excretion fractions (UEFs) do not account for all absorbed arsenic, including arsenic administered as aqueous sodium arsenate. EPA notes that relative bioavailability (RBA) calculated as a ratio of UEFs should be used for BAF values to account for this phenomenon.

A17 Response: As detailed beginning on page 17 of the document, we confirmed your point that, technically, relative bioavailability should be used rather than absolute bioavailability. However, as discussed, interchanging the two does not make a significant difference in the screening level obtained.

Comment A18: The report states "the bioavailability values used at Anaconda were shown to be consistent with actual exposure data from the community." This conclusion depends on the degree to which the urinary arsenic data are representative of actual exposures of the average individual and, thus, provide a sound basis for evaluating the CTE assumptions.

A18 Response: The statement from the report is true. It is also true that actual exposure data from the community may not entirely describe every individual's arsenic level at every time. However, the use of such community information is typically and appropriately used to make inferences about exposure and site-wide exposure assumptions.

Comment A19: Our review indicates that the majority of Superfund arsenic exposure assessments use 95% upper confidence limits (UCLs) of experimentally-determined arsenic RBAs. Use of the 95% UCL arsenic bioavailability estimate based on the Anaconda study would depress the residential soil arsenic action level to 162 mg/kg, a 35% reduction. This is in direct contrast to the ATSDR finding.

A19 Response: All studies reviewed by ATSDR (and documented in the health consultation) used means (averages) of experimental data, not upper confidence limits, for determining relative bioavailability. ATSDR found one case where the upper confidence limit of several mean RBAs for a particular site was used to determine a site-wide RBA. ATSDR concluded that the procedure used by EPA to determine the bioavailability for the Anaconda site was appropriate.

Comment A20: The report states, "… the one [concern] with the greatest potential for affecting estimated exposures is the possible underestimation of bioavailability resulting from incomplete arsenic recovery." Our analysis suggests that that the use of relative versus absolute bioavailability would have little effect on estimating exposures. The non-conservative interpretation of the Anaconda bioavailability study has had the greatest effect on the estimation of arsenic exposures. Table 2 of the May 4, 2007 memorandum compares the effect of different exposure assumptions on the residential soil arsenic action level.

A20 Response: ATSDR concluded that the original interpretation of the Anaconda bioavailability study was appropriate and valid.

Comment A21: Concern with 1) appropriate soil ingestion rate to be used as the basis for apportioning ingestion - Default combined soil and dust ingestion rates are based on tracer concentrations in soil only and they underestimate combined soil and dust ingestion rates. 2) the impact of isolating separate media in the derivation of risk-based action/cleanup levels - because action levels are calculated for one medium at a time, the apportionment of exposure to more than one solid medium will unequivocally result in less conservative action levels.

A21 Response: As stated in the health consultation, Superfund Risk Assessment Guidance states that the 200 mg/day ingestion rate accounts for both soil and dust exposure. In addition, EPA guidance recommends the method of apportioning soil and dust using the apportionment method. As described in the health consultation, Anaconda-specific data on soil ingestion do not justify deviating from normal guidance procedures. Therefore, the method used in the health consultation and EPA's exposure assessment calculations is appropriate.

Comment A22: Bioavailability assumptions used to derive the action level for the Anaconda Smelter site are significantly less conservative than those used to derive arsenic action levels at similar mining and smelter sites. The ATSDR report provides inadequate information for a comparison of critical factors driving differences in action/cleanup levels.

A22 Response: ATSDR included the 7 sites reviewed by this commenter in our table, along with other sites, to give a more complete picture of the range of action levels at arsenic sites. ATSDR included this information at the request of the community. The soil and dust bioavailabilities for the Anaconda site soil were lower than bioavailabilities used at other sites. However, ATSDR's review of bioavailability studies for various sites indicated that assumptions used and interpretation of study results to obtain a site-specific bioavailability were similar for Anaconda and the other mining sites. ATSDR would have liked to provide more information on how bioavailability and other risk management factors influenced action level determination, but in most cases, available documentation for the listed sites did not include these details.

Comment A23: It is unclear why the NOAEL is a more appropriate point of reference than the MRL for evaluating potential health effects from arsenic exposure in Anaconda.

A23 Response: ATSDR's minimal risk levels are levels below which health effects are not expected and are therefore used as an initial screen. Exceedances of these screening levels do NOT indicate that health effects are likely; they merely indicate a need for further evaluation. This further evaluation can include modifying exposure assumptions to more closely reflect actual exposures. ATSDR then compares these more realistic exposure estimates with known toxicological and epidemiological no-effect or lower-effect levels (NOAELs or LOAELs) to make a final determination of whether a given exposure is likely to result in adverse health effects. Please refer to ATSDR's Public Health Assessment Guidance Manual, which can be found on the Internet at http://www.atsdr.cdc.gov/HAC/PHAManual/, for further information about how ATSDR evaluations are performed.

Comment A24: Bioavailability estimates used in the Anaconda exposure assessment are not conservative and do not account for significant uncertainty regarding the factors affecting arsenic bioavailability in humans, potential variability within the human population, sources of experimental error in bioavailability studies, and the ability of existing animal models to predict bioavailability in humans…. The assumption that the default soil ingestion rate can be apportioned between soil and dust ingestion introduces another source of non-conservatism to the exposure model. These non-conservative assumptions should be weighed when making judgments regarding the potential for adverse health effects from arsenic exposure in Anaconda.

A24 Response: ATSDR did address potential uncertainty in the bioavailability factors as well as the other issues raised in this comment. We found that, even with uncertainty, ATSDR's conclusions remain the same.

Comment A25: After accounting for computational issues, an increase in the soil and dust BAFs of less than 1% would correspond to a an excess lifetime cancer risk in excess of $1x10^{-4}$ at a residential arsenic soil action level of 250 mg/kg…it would be reasonable to conclude that the actual risk of cancer could be greater than $1x10^{-4}$ at the 250 mg/kg action level. This finding should be weighed in the ATSDR report when making judgments regarding the likelihood of cancer effects from arsenic exposure in Anaconda.

A25 Response: ATSDR's cancer risk evaluation included consideration of potential uncertainty in bioavailability assumptions and found that an increased risk of cancer was unlikely. ATSDR continues to conclude that chronic exposure to the residential soil action level would be unlikely to increase the risk of cancer.

Comment A26: The ATSDR report concludes, “Chronic exposure to soil at the residential cleanup level of 250 milligrams of arsenic per kilogram of soil would not be expected to result in adverse health effects for resident children or adults.” In contrast, our findings conclude that significant uncertainty remains regarding the protectiveness of the residential soil arsenic action level, as outlined above and in our May 4, 2007 memorandum.

A26 Response: We recognize that some in the community feel that the action level is inconsistent with other sites. However, ATSDR continues to conclude that chronic exposure to soil at the residential action level of 250 milligrams of arsenic per kilogram of soil would not be expected to result in adverse health effects for resident children or adults.

Comment A27: If the non-conservative assumptions regarding bioavailability under-predict actual exposure, the action level of 250 mg/kg may not be protective of human health. If this is the case, areas could exist within the community that comply with the 250 mg/kg action level but, nonetheless, present unacceptable risk.

A27 Response: ATSDR continues to conclude that chronic exposure to the action level would not result in health effects. ATSDR continues to conclude that soil pica behavior could result in health effects if a child ingested teaspoon amounts of arsenic-contaminated soil. This risk for acute (short term) effects could exist even within properties whose average soil level is below the action level.

Comment A28: Given the relatively high degree of uncertainty associated with the 250 mg/kg residential soil arsenic action level, we believe that in addition to addressing the issues outlined by ATSDR, the CPMP should focus on a broader range of issues, including: (1) more generally focused education and community awareness programs that: encourage parents to minimize activities that involve incidental soil ingestion, regardless of whether their children exhibit pica behavior; encourage residents to follow housekeeping practices that minimize the accumulation of dust in living spaces; and encourage residents to maintain vegetative cover on soil on their properties; and (2) adequate, sustainable funding and staffing for local programs to: carry out the community education and awareness programs; support the investigation and mitigation of sources of arsenic contamination unrelated to outside soil, including attic dust and worker clothing; support residents’ efforts to maintain vegetative cover on soil on their properties; and ensure the continued effectiveness of surface soil reclamation activities in other residential and surrounding areas.

A28 Response: ATSDR’s recommendations for the CPMP were meant to address issues we identified in which adverse health effects could be possible given the current action level and cleanup plans, not to limit the CPMP. If the community or individuals want an added sense of security, additional precautionary measures could serve to further minimize risk. ATSDR is willing to work with the local community, upon request, to give further public health input on the Community Protective Measures Plan as it is developed.