STATE OF DELAWARE

DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL DIVISION OF AIR AND WASTE MANAGEMENT SITE INVESTIGATION & RESTORATION BRANCH



Arsenic Risk Management Plan Background Document

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Summary

In June 9, 2005, Governor Ruth Ann Minner directed Department of Natural Resources and Environmental Control (DNREC) Secretary John A. Hughes to "review...and propose appropriate standards and policies" for arsenic in soil, focusing on ensuring the health and safety of Delawareans. This **Arsenic Risk Management Plan** is the outcome of a process that included significant public participation and review by a wide range of scientific experts and State of Delaware agencies. The DNREC Division of Air and Waste Management staff has prepared this background document, in collaboration with the Division of Water Resources (DWR), the Division of Public Health (DPH), the Department of Agriculture (DDA) and the Department of Justice (DOJ) as part of DNREC's response to Governor Minner's directive.

A draft version of this document was released in June 2005. It was intended to support the public participation process by providing the background information and rationale for DNREC's proposal. To help facilitate this public involvement process, it was drafted for a general, not a specialized technical audience. As such it contained background information on scientific issues (e.g., chemistry, geology and toxicology of arsenic) and described the basis for setting cleanup standards and goals. After this background information, the proposal considered several policy options for alternative standards, and summarized the implications for each option. The document was intended to be used in combination with discussions between DNREC staff and interested public to allow for a constructive interaction, rather than presuming to be a stand-alone document.

Concurrently with this document, DNREC is issuing a **Response to Public Comments on the June 2005 Draft Arsenic Risk Management Plan.** The extensive comments reflect the public interest in this topic.

DNREC is also issuing **Policy Concerning the Default Background Concentration of Arsenic** which comprises the practical outcome of the Governor's initiative.

That outcome may be simply stated:

The Remediation Standards Guidance under the Delaware Hazardous Substance Cleanup Act (1999), Attachement 3: Delaware Default Background Remediation Standards Table is (1) henceforth amended so that the *default background remediation* standard for arsenic in soil is 11 milligrams per kilogram (mg/kg), and (2) updated so that the *typical Delaware soil concentration* (presented for information only) is 11 mg/kg.

The basis for DNREC's 2005 proposal (See Option C, Section 3.3) was to establish a default background concentration that would reflect actual data and protect public health and the environment (11 ppm). This proposal was effective in draft immediately upon release. For carcinogens like arsenic, Delaware law mandates that standards be set at levels associated with an incremental lifetime cancer risk increase of one in one hundred thousand (1/100,000 or 1 x 10⁻⁵) or at background. Using standard assumptions about exposure and dose, a background cleanup goal (11 ppm) could result in a slightly elevated lifetime cancer risk. DNREC staff and other participating state agencies do not believe this elevated risk is realistic because of the number of conservative assumptions on which this risk-to-dose relationship is based. These assumptions include: all individuals eat the same amount of soil during for their entire life, that all of the

arsenic to which a person is exposed is in the most toxic form, and that all the arsenic is bioavailable (See Section 1.4 and Section 1.5). Although these assumptions, adopted from U.S. EPA guidance, may appear extremely conservative, DNREC believes it is prudent to consider these assumptions to ensure protection of human health.

The background default concentration of 11 ppm should be possible to achieve during cleanups in most situations because it appears to reflect a midrange of the background concentrations of arsenic found in Delaware soils. A cleanup goal lower than 11 ppm would not be technically feasible because the background concentrations in Delaware soils are higher in many situations. The cost implication of an 11 ppm default background concentration is not yet clear. It is possible it could result in fewer cleanups being completed because of the cost to complete each cleanup to this standard. DNREC staff will continue to collect information on this issue, but will be implementing cleanups at residential sites to the goals established, regardless of the cost.

This proposal also included plans to review this standard when there is new information about the toxicity of arsenic to ensure the standard remains adequately protective and compliant with the legal requirements in Delaware. This review will include public participation.

1.0 Background Information

In 2005 concerns arose within DNREC and the general public about the arsenic standard adopted in June 2004. As a result, Governor Minner on June 9, 2005, (See Attachment A) directed DNREC Secretary John Hughes as follows:

Arsenic is among a number of toxic substances known to cause cancer and to which our citizens may be exposed to in their communities and workplaces. Whether it is derived from industrial or natural sources, we have a duty to protect our citizens from harmful exposure to toxic substances, such as arsenic.... Accordingly, I am directing you to lead an immediate and expedited review of standards and policies related to arsenic cleanup. This review should include:

- Evaluation of the best scientific information available;
- Public involvement;
- Involvement of other agencies, including the Department of Public Health and Social Services; and
- Consideration of standards and policies used by EPA and other states.

Immediately after the Governor's tasking, DNREC Division of Air and Waste Management (DAWM) Director, James D. Werner convened a meeting of technical and management staff from DNREC DAWM and the Division of Water Resources (DWR), the Division of Public Health (DPH), the Delaware Department of Agriculture (DDA) and the Department of Justice (DOJ) (see Attachment B for list of attendees) to scope out the task and develop a cooperative approach to respond. The group agreed to work together to review the existing standard and policies, per the Governor's request. The staff work group also committed to obtaining and

using the best technical and legal input in developing a proposal, and to subject that proposal to public comment.

In assessing the June 2004 Interim Standard, the Delaware state agency staff who met agreed that the DNREC was remiss in not including public involvement in the development and adoption of the current standard. From a technical perspective, the group agreed that, because the assumptions used by EPA and scientific bodies in the development of the risk assessment calculations are sufficiently conservative¹ that the interim standard did not pose an imminent risk or substantial lack of protectiveness. Nonetheless, the staff work group agreed that rigorous technical and legal analysis, with public input was appropriate to ensure developing a cleanup standard that is adequately protective of human health and has earned public confidence. Finally, the staff work group agreed that whatever standards and policies were developed, it should be reviewed on a regular basis and include public input. The June 2004 DNREC-DAWM memorandum articulating an interim policy on arsenic included among other things, a timetable for reviewing the interim policy every six months.

In addition, the staff level working group quickly reached consensus on three fundamental principles regarding the establishment of a new cleanup goal for arsenic in soil. The principles must be:

- 1. Based on adequate public comment and involvement because of the fundamental policy nature of the risk choices to be made and, accordingly, the need for public involvement in decisions that affect them;
- 2. Informed by the best available scientific information and the best available risk assessment advice from DPH and other scientific sources; and
- 3. In addition to the Governor's directive to base a new standard on the evaluation of the best scientific information available, public involvement, and consideration of standards and policies used by EPA and other States, the agency staff agreed that a new standard must also be consistent with DNREC's legal mandate for risk management.

The staff working group developed a draft outline of the topics to be covered in the proposed risk management revision and divided up task assignments. The group did not address in detail or resolve the question of what is the scope of the applicability of whatever standard is proposed and established (i.e., conversions of industrial sites to residential, agricultural site conversion, golf courses, etc.). The group agreed to seek advice from legal counsel and public input on the legal framework governing the question of scope and applicability of the standards and policies.

The general scope of the background document is focused on the issue of establishing a protective and legally mandated goal for surface soil (approximately 0-6 inches deep) concentration for arsenic in residential or unrestricted land use situations. The proposed action

¹ "Conservative" is used here to characterize erring, if anything, on the side of protectiveness. This tendency is indicated by the use of the so-called "precautionary principle." Examples of conservative assumption include the exposure assumptions that all arsenic is the most toxic inorganic form in the physical and chemical form that is most bioavailable (i.e. absorbed by the body and metabolized), and that all individuals consume through ingestion (eating) the same amount of soil contaminated with equal amounts of arsenic. Although some have argued these assumptions are overly conservative, there are other assumptions that may be used in the exposure and risk assessment that are not conservative, such as additive effective of unidentified contaminants that may be present but not found, the lack of synergistic effect (greater than the sum of effects from exposure to two or more contaminants, like tobacco smoke and asbestos), and genetic variation in sensitivity of different individuals.

level can be found in Section 3.6. Other land use situations (e.g., industrial or commercial) are addressed using risk-based corrective action guidance, which may include considerations and assumption about current and future land use. To ensure a manageable scope for this background document, it does not consider other potential exposures to arsenic in food, drinking water or occupational settings such as deep mining, metal smelting, etc. The Department sought to write the background document in plain English to maximize its accessibility to a wide and general audience and help facilitate an informed public discussion of the topic.

1.1 Arsenic

The study of toxicology is dominated by the ancient adage,

"All Substances are poisons; there is none which is not a poison. The right dose differentiates a poison and a remedy."²

Arsenic is perhaps the best example of this adage in practice. A recent *National Geographic* article referred to arsenic as "...the poison of kings and king of poisons." Arsenic is colorless, tasteless and odorless.

Only a small amount of arsenic can be harmful. Approximately 70-200 milligrams of arsenic trioxide can be fatal. Based on this assumption, an amount of arsenic weighing the same as one U.S. nickel (five grams) would contain 16 to 71 fatal doses. In the United States, the average daily dietary intake of arsenic is approximately 30 micrograms, or 0.03 milligrams – approximately 0.04 percent of a fatal dose⁴. Arsenic may enter the food chain through a variety of natural or unnatural mechanisms, such as eating shell fish, which have eaten algae in which naturally-occurring arsenic has accumulated. Hence, at least 2,000 times the average daily dietary dose in the U.S. would be required to receive a fatal dose.

In the 5th Century B.C., Hippocrates used arsenic to treat ulcers. In the 18th Century, arsenic was an ingredient in Fowler's solution, created in 1786, for treatment of psoriasis. In the early 20th Century, Paul Ehrlich considered the father of modern chemotherapy, promoted a form of arsenic ("Salvarsan") as the first treatment for syphilis. These therapies continued in use until the 1940s when they were replaced by modern antibiotics⁵. The FDA recently approved Trisenox (arsenic trioxide) for the treatment of patients with acute promyelocytic leukemia.⁶

Traces of arsenic found in the French Emperor Napoleon's hair have led to speculation that he died of arsenic poisoning, either intentionally or accidentally. Arsenic was found in the wall paper at his Longwood estate, which was painted with Scheele's Green, which contains copper arsenide.⁷

The recent history of arsenic in Delaware is one of clear public concern and need for effective public health protection. Delawareans have expressed concerns about the incidence of cancer

² Attributed to Paracelsus, 16th Century German-Swiss physician and alchemist. See generally, Klaassen, C.D., Casarett and Doull, *Toxicology, The Basic Science of Poisons*, 5th ed., McGraw-Hill, NY, 1996.

³ Newman, Cathy, "The Poison Paradox: Too Much can Kill, A Little Can Cure," National Geographic, May 2005 page 8.

⁴ Physicians Desk Reference, see http://www.pdrhealth.com/drug_info/nmdrugprofiles/nutsupdrugs/ars_0026.shtml, Accessed on June 13, 2005.

⁵ Agency for Toxic Substances and Disease Registry, *Case Studies in Environmental Medicine: Arsenic Toxicity*, http://www.atsdr.cdc.gov/HEC/CSEM/Arsenic/exposure_pathways.html, Accessed June 13, 2005.

⁶ See http://www.fda.gov/bbs/topics/ANSWERS/ANS01040.html. Accessed June 13, 2005.

⁷ Smith, Roger, Dartmouth Medical School. See http://www.dartmouth.edu/~toxmetal/TXSHas.htm. Accessed June 13, 2005.

and the potential link to environmental causes. The potential link between arsenic and cancer has been raised in the news media and public meetings. 9

Arsenic has not been produced in the United States since 1985, although the U.S. continues to be the world's largest consumer (21,000 tons in 2003) with most arsenic being imported from China. Arsenic has been used and distributed in the environment in a variety of ways. Here are some examples of arsenic sources:

- Chromium Copper Arsenate (CCA) was used to treat wood to prevent decay and allow wood decks and fences to last longer, thereby reducing the number of trees harvested and the labor to replace the wooden structures. Arsenic was used in CCA wood treatment for nearly 50 years until a voluntary phase-out began for residential applications at the end of 2003.¹¹
- Arsenic was used in tanneries to preserve skins based on the observation that arsenic killed bacteria that cause flesh to rot.
- Arsenic was used as embalming fluid during the Civil War based on this same principle and has recently been found in Civil War cemeteries. 12
- Arsenic is used in chicken feed to prevent disease, thereby increasing productivity of growing chickens and reducing costs of food to consumers, and resulting in the land application of chicken litter to fertilize farm fields and distribution of residual arsenic on land. No widespread soil or groundwater contamination has yet been identified from this distribution, however, the University of Delaware is currently engaged in research to better understand the fate and transport of arsenic in the poultry industry.¹³
- Arsenic continues to be an ingredient in many pesticides and lawn fertilizers (see Table 1).
- Until recently, arsenic was used in "maintenance-free" auto batteries.
- Arsenic is used as an antifriction agent in ball bearings.
- Gallium arsenic and indium arsenic are used in semiconductors.

Although the selection of a standard for arsenic is ultimately a policy issue decided with public involvement (See Sections 2 and 3), there are a variety of scientific disciplines that can help form this decision, including:

• chemistry (what are the different forms of arsenic and how is it measured?);

11 See http://www.epa.gov/oppad001/reregistration/cca/ and http://www.cpsc.gov/phth/ccafact.html, June 13, 2005.

Belaware Division of Public Health/Delaware Health and Social Services, Delaware Cancer Incidence and Mortality Rates, April 2005.

Montgomery, Jeff, "State considers change in Arsenic exposure rules," *News Journal*, June 8, 2005.

¹⁰ Brooks, William E., "Arsenic", From USGS Minerals Yearbook, 2002.

¹² Konefes, J.L., and McGee, M.K., 1999, Old Cemetaries Arsenic, and Health", Cultural Resources Management Online.

¹³ Christen, Kris "Chickens, manure, and Arsenic" *Environmental Science and Technology*, March 21, 2001.

- geology (where does arsenic come from in rocks and soil?); and
- toxicology (what are the health impacts of arsenic exposures and at what dose).

Table 1: Arsenic Content of Some Commercially Available Fertilizer Products and Potting Soils¹⁴

	Arsenic Concentration
Product Name	(parts per million)
Schultz Professional Potting Soil Plus/African Violets & Blooming Plants 0.08-0.14-0.09	128
Scotts All-Purpose Plant Food 18-13-13	50.9
Schultz Professional Potting Soil Plus 0.08-0.12-0.08	34.55
Schultz Multicote Time Release Outdoor Plant Food 17-17-17	28.2
Schultz Enriched Garden Soil for Flowers & Vegetables 0.51005	25.57
Ace Premium Starter Fertilizer 18-29-6	14.6
Lesco Polyvex Professional Turf Fertilizer 18-24-12	11.68
Ortho Rosepride Flower & Rose Enhanced 12 Week Fertilizer 15-5-10	13.1
Schultz Bulb Plus Potting & Planting Mix Time Release 0.08-0.16-0.08	11.5
Ace Green Turf Starter Fertilizer 20-27-5	10.8
Bayer Advanced Lawn Season-Long Grub Control w/ Fertilizer 12-18-6	10.5
Ace Acid Loving Plant Food 30-10-30	10

1.2 Arsenic Chemistry

Arsenic, a naturally occurring element, is found throughout the environment. Arsenic is found in two forms: organic and inorganic.

Generally, arsenic combined with elements such as oxygen, chlorine and sulfur forms inorganic arsenic compounds. Examples of inorganic arsenic compounds include, but are not limited to, arsenic pentoxide and trioxide. The pentoxide form of inorganic arsenic is referred to as arsenate [As (V)] and is relatively immobile in soil. The trioxide form of inorganic arsenic is referred to as arsenite [As (III)] and is relatively mobile in soil. A United States Geological Survey (USGS) and New Jersey Department of Environmental Protection (NJDEP) study found arsenite concentrations of more than 100 ppm in soil at depths of 100 cm (approximately 3 feet). Generally, arsenic combined with carbon and hydrogen forms organic arsenic compounds. Examples of organic arsenic include, but are not limited to, arsanilic acid, arsenobetaine and dimethylarsinic acid.

Environmental arsenic testing is conducted in the field or in a fixed laboratory as a measurement of total arsenic. There are many test procedures used to calculate the concentration of total arsenic in the environment. The most common test procedures utilized to test for arsenic are: Atomic Absorption (AA), Inductive Coupled Plasma (ICP) and X-ray Fluorescence (XRF). XRF, and AA/ICP are US EPA approved methods. The results from these methods are equally accurate and precise. Only a qualified professional can interpret and compare the variations and similarities between the two methods. Arsenic risk values are based on receiving AA/ICP

Washington State's Law and Rules Governing Metals in Fertilizers, Minerals, and Lime: http://agr.wa.gov/PestFert/Fertilizers/LawsRules.htm Association of American Plant Food Control Officials (AAPFCO) Policy Regarding Metals in Fertilizers:http://www.aapfco.org/metals.htm

Source: Washington State Dept. of Agriculture: http://agr.wa.gov/PestFert/Fertilizers/ProductDatabase.htm

results. Therefore, the AA/ICP results are generally used in performing risk assessments. The cost for performing AA/ICP analysis is much higher than XRF. Therefore, XRF data is used as a screening analysis for conducting site evaluations because of cost considerations. The Standard Operating Procedure for Chemical Analytical Programs (SOPCAP) under the Hazardous Substance Cleanup Act provides detailed policy for the analysis of environmental samples and the use of XRF as a screening tool.

1.3 Geology of Arsenic

Two regional geologic provinces are present in Delaware. The northern part of the State, north of a line extending between Newark and Wilmington, is underlain by the igneous and metamorphic bedrock of the Appalachian Piedmont Province. South of the Newark-Wilmington line, the remainder of the surface deposits of the state lie within the Atlantic Coastal Plain Province. The two provinces are very different in age, in the way they formed, and in the types of rocks they contain.¹⁵

The Piedmont Province consists of very old (480 million years of age) "hard rock" or crystalline metamorphic bedrock which is generally of two distinct types; (1) the Wilmington Complex and (2) the Glenarm Series. These rocks formed from shallow coastal sediments behind a volcanic island chain that was subjected to plate deformation causing high-grade heat and pressure. ^{16,17}

The Coastal Plain Province consists of a seaward-thickening wedge of sedimentary rocks and unconsolidated sediments from 120 million years of age to recently formed marsh deposits. This wedge of gravel, sand, silt, and clay thickens from 0 feet thick to nearly 8,000 feet thick at the southern border of Delaware. These sediments came from two sources; (1) non-marine sediments eroded from the Piedmont and the Appalachian Mountains and carried by streams to the coast, and (2) marine sediments that were deposited from the ocean at times when global sea level were high. ¹⁸

There has been no comprehensive study of the relationship between the rocks of the Delaware Piedmont and the naturally-occurring arsenic in the soil. There are a number of methods used to help determine "background" (natural and other) concentrations of arsenic, which are described in Attachment D and summarized here. One method for determining natural background is to analyze arsenic concentrations in soil deep below the ground surface, which can be obtained from "borrow pits" where clean soil is excavated for use as clean fill elsewhere. The minerals that predominate in the Piedmont rocks are not generally considered arsenic bearing but the composition of in-place piedmont soils indicate that they do contain trace amounts of arsenic. The borrow pit samples were obtained from an area where there was no evidence of prior excavation or disposal. The use of deep soil for determining natural background concentrations of arsenic is a valid method if there is no mechanism for arsenic to have migrated to the deep soil. Also, the arsenic is not likely to have migrated down into deep soils because the science indicates that arsenic does not migrate through soil except for very short distances and usually at only high source soil concentrations.

¹⁵ Delaware Geological Survey, 1966, Generalized Geologic Map of Delaware.

¹⁶ Delaware Geological Survey, 1966, Generalized Geologic Map of Delaware.

¹⁷ Delaware Geological Survey, 2000, <u>Bedrock Geology of the Piedmont of Delaware and Adjacent Pennsylvania</u>, Report Of Investigation No. 59 with accompanying Geologic Map No. 10.

¹⁸ Delaware Geological Survey, 1966, Generalized Geologic Map of Delaware.

Soil samples collected from borrow pits in New Castle County near Concord Pike (Rt. 202 and I-95) approximately 30-50 feet below ground surface have been found to have arsenic concentrations ranging from 3 to 18 parts per million (ppm) and a median of approximately 10 ppm (See Table 2). The source of arsenic is probably from a Glauconite green sand layer formed millions of years ago. Arsenic was part of the combination of the original elements contained on Earth when the planet was formed approximately 4.5 billion years ago. Over the billions of years, arsenic has subsequently been redistributed by a variety of normal geologic events including volcanic eruptions.

Table 2: Borrow Pit Soil New Castle County¹⁹

Sample ID	Sample Date	Arsenic Result
		mg/Kg (ppm)
G1	5/6/04	14.0
G2	5/6/04	11.0
G3	5/6/04	9.5
G4	5/6/04	6.7
G5	5/6/04	18.0
G6	5/6/04	10.0
G7	5/6/04	5.8
G8	5/6/04	7.6
G9	5/6/04	3.3
G10	5/6/04	4.9
G11	5/6/04	5.6
G12	5/6/04	13.0
G13	5/6/04	14.0
G14	5/6/04	13.0
G15	5/6/04	13.0

There is evidence for a relationship between the type of geologic unit and the arsenic soil concentration in the soil found in the Coastal Plain. The geologic creation of arsenic-bearing glauconite is the result of depositions of algae that take up, metabolize, and retain arsenic in surface waters. When the algae dies and settles to the bottom, the arsenic in the dead algae becomes part of the deposit. When this process happens over thousands of years, the arsenic will accumulate in estuaries, which are now geologically mapped as Glauconite or greensands. Glauconite is dull green iron-silicate mica mineral found in shallow marine sediments. Bands of Glauconite are found in some of the Coastal Plain of New Jersey and southern New Castle County, Delaware, and in the deeper units in southern Delaware. The soils that form over these glauconite-containing units, called "greensands", are highly productive agriculturally and have been determined to contain naturally-occurring arsenic.²⁰

A study by Dooley analyzed the composition of naturally occurring New Jersey greensands at seven sites, reporting a range of 7 to 31 mg/Kg (ppm) of arsenic. ²¹ Therefore, it has been shown that greensand soils contain arsenic as "natural background". Greensands soils have been used as

²⁰ Department of Ecology, <u>Evolution and Natural Resources</u>, Rutgers University, 2002, Greensand and Greensand Soils of New Jersey, A Review.
²¹ Dooley, J.H., 2001, Baseline Concentrations of America Parallina and Am

¹⁹ Riverfront Headquarters Site (unused borrow source), May 2004.

²¹ Dooley, J.H., 2001, <u>Baseline Concentrations of Arsenic, Beryllium, and Associated Elements in Glauconite and Glauconite Soils in the New Jersey Coastal Plain</u>, New Jersey Geological Survey, Trenton. 238 pgs.

a soil amendment to improve productivity in other less productive areas (areas not mapped as having Glauconite deposits). As a result, it is likely that arsenic containing Glauconite Greensands are now more widespread than the geologic mapping would indicate.

The USGS reported arsenic levels of 4.8 to 23 mg/Kg (ppm) in samples of stream sediments from the Lower Susquehanna River. Similar concentrations of arsenic were found in another USGS study in which the average arsenic soil concentrations were reported as 8.3 mg/Kg for New Castle County, 4.6 mg/Kg for Kent County, and 4.9 mg/Kg (ppm) for Sussex County.²²

A 1993 DNREC study found a similar distribution with average background concentrations of 10.6 mg/Kg in New Castle County, 7.8 mg/Kg in Kent County, and 8.7 mg/Kg in Sussex County. The maximum background reported was 48 mg/Kg (ppm).²³

1.4 Toxicology of Arsenic

The toxicology of arsenic mainly depends on its chemical and physical form, exposure route and dose. The most toxic form of arsenic is the inorganic form not its organic form. Among the forms of inorganic arsenic, the trioxide [As (III)] form, with a valence state (electronic charge) of 3, is more toxic than the pentaoxide form [As (V)], which has a valence state of 5. Some research has demonstrated circumstances in which the organic form of arsenic is converted to the inorganic form. The type arsenic, As (III) and/or As (V) in soil depends on the exposed environmental conditions (whether in an oxygen rich or depleted environment, the amount total organic carbon, and the ph of soil) that effect the arsenic form. Generally, the Arsenate [As (V)] is the most common oxidized form of arsenic in soil. Arsenic strongly sorbs to iron and hydroxides on soil particles. In addition, sandy particles have a lower capacity to sorb arsenic than clay and silt and therefore usually have less arsenic content.

The Food and Drug Administration established standards for the concentrations of arsenic in chickens, turkeys and swine. These animals are often fed pharmaceutical feed containing roxarsone, of 2 ppm in uncooked edible byproducts and 0.5 ppm in uncooked muscle tissue and eggs.²⁵

The International Agency for Research on Cancer (IARC) review has identified arsenic as a carcinogen with "Human Sufficient Evidence." A common toxicology reference refers to arsenic as a "Confirmed human carcinogen producing liver tumors." Arsenic in drinking water is associated with bladder cancer. 8

²⁶ http://www-cie.iarc.fr/monoeval/crthgr01.html

²⁸ 65 Fed. Reg. 24488 (April 26, 2000).

²² U.S. Geological Survey, 1984, Element Concentrations in Soils and Other Surficial Materials of the Conterminous United States, Professional Paper No. 1270.

²⁴ B. P. Jackson, P. M. Bertsch, M. L. Cabrera, J. J. Camberato, J. C. Seaman, and C. W. Wood, "Trace Element Speciation in Poultry Litter", *J. Environ. Qual.* 2003 32: 535-540.

²⁵ 21 CFR 556.60

²⁷ Lewis, Richard J. (Ed.) "Carcinogenetically Active chemicals", VanNostrand Reinhold, New York, 1991. (Arsenic, ARA750, CAS7440-38-2)

Symptoms from arsenic exposure include hyperkeratosis, blackfoot disease, myocardial ischemia, liver dysfunction, epithelioma, and several cancers. The major risk from exposure to arsenic is not from inhalation, but rather by ingestion.²⁹

1.5 Human Health Risk Assessment for Arsenic in Soil

Human Health Risk Assessment is a process to estimate the chance that a person will be harmed now or in the future if that person comes in contact with chemicals (for example arsenic) present in a property (site). This process produces numbers that show how great (or small) the risks may be. For example, a conservative risk assessment would indicate that an individual living on a residential property for 30 years with 4 ppm (mg/Kg) of arsenic in soil and ingesting (eating) 200 mg of soil as a child and 100 mg of soil as an adult each day for 350 days per year for 30 years will have an additional risk of developing cancer somewhere between zero and one in 100,000. For non-cancer health risk the acceptable standard is expressed as Hazard Index (HI) of one (1). The hazard quotient of 1 is the ratio of a representative site concentration in soil to that of a reference dose concentration determined to have non-cancer health effects. The HI of 1 for arsenic is 23 ppm, which is based on the assumption that a child age 1-6 years in a residential setting will ingest 200 mg/day of soil.

There is significant conservatism built into the risk assessment process. One of the assumptions is that 100% of the arsenic in the soil ingested by an individual will be absorbed by the human body (bioavailability). The USEPA Risk Assessment Guidance for Superfund (RAGS) Volume 1 Human Health Evaluation Manual (1989) includes a discussion of determining the relative bioavailability of a chemical in the media of interest such as soil. The bioavailability of a chemical in a soil matrix is influenced by many factors including the physical and chemical interaction with the matrix, in addition to the solubility and biological factors. For arsenic the oral toxicity factor that predicts the potential for causing cancer is based on humans ingesting arsenic in drinking water over long periods of time in Taiwan. These people experienced an increase in nonfatal skin cancers as compared to a group of people that did not ingest arsenic in drinking water. In this study, the arsenic is assumed to be 100% bioavailable for uptake into the gastrointestinal tract and the bloodstream. Arsenic in drinking water is present in a soluble form and therefore the bioavailability is high.

The arsenic present in soil is non water-soluble and binds to the soil matrix so less arsenic is available to be absorbed in human body. A recent study by Roberts et. al.³¹ showed that only about 10% to 25% of the arsenic in soil was absorbed by monkeys when they were fed arsenic contaminated soil. The State of Florida Department of Environmental Protection (FDEP) has also published a study ³² with extensive research by the University of Florida to determine the relative bioavailability for arsenic in soil as compared to the high bioavailability of arsenic in drinking water. FDEP used this information to recently make a protective science-based policy decision to adopt the default relative oral bioavailability factor of 33%, as a worst case risk assessment where

²⁹ Bhama, Rupinder K., and Max Costa, "Trace Elements, Al, As, Cd, Hg and Ni", in *Environmental Toxicants: Human Exposure and Their Health Effects*, (Morton Lippman, Ed.) VanNostrand Reinhold, New York, 1992. at page 583.

³⁰ USEPA (United States Environmental Protection Agency) (1989) Risk Assessment Guidance for Superfund. Volume 1, Human Health Evaluation Manual (Part A), Office of Emergency and Remedial Response, Washington, DC

³¹ Roberts, S.M., Weimer, W.R., Vinson, J.R.T., Munson, J.W., and Bergeron, R.J. 2002. Measurement of Arsenic Bioavailability on Soil Using a Primate Model. Tox. Sci., 67:303-310.

³² Methodology Focus Group, Contaminated Soils Forum, (2003) Arsenic Bioavailability from Florida Soils: Uncertainty Evaluation of the University of Florida/Florida Department of Environmental Protection Study, January 8, 2003.

there is potential for individuals to ingest arsenic in soil. This was implemented in February 2005 33

If DNREC were to utilize 33% as the factor to reflect the worst case bioavailability for arsenic in Delaware soil, the result would be a three-fold increase in the soil standard for arsenic to 12 ppm for 1 in 100,000 cancer risk level (1 x 10^{-5}).

Other conservative assumptions:

Exposure Assumptions used by DNREC for arsenic in soil is the worst case scenario which assumes that a child resident will ingest 200 mg of soil and an adult resident will ingest 100 mg of soil 350 days/year for a total of thirty years. This does not include a pica child.

Toxicity Assessment looks at how much of a substance causes what kind of harm to humans. Toxicity to humans is not usually measured directly by intentionally exposing people, for obvious ethical reasons. Rather it is determined indirectly, usually by extrapolation of animal studies to humans. Many conservative assumptions are made which include:

- The effects of size and biological differences between animals and humans.
- The effects of high doses fed the test animals versus the low dose humans usually encounter in their environment.

It is apparent from the discussion that uncertainties are inherent in the toxicity assumptions.

2.0 Basis for Setting Cleanup Goals and Standards

2.1 Arsenic Standard Setting Process

The process for selecting a soil concentration action level is ultimately a policy choice – a decision to be made with public involvement. The public has a fundamental right to be involved in decisions that could affect them. The decisions can and should be informed by good science and engineering, and much of this background document seeks to provide that information in a clearly accessible manner. Nonetheless, despite this sea of scientific information, however deep and carefully plumbed, the decision remains a policy choice. Hence, the process used by DNREC's Air and Waste Management Division was focused on a constructive public involvement process, using the following steps:

- 1. Development of a background document and proposed revision for internal and interagency review.
- 2. Development of a public involvement plan, ensuring adequate opportunities for meaningful input from a variety of stakeholders, including various existing and interested Department Advisory Committees and representatives of all interested parties.

³³ University of Florida, Center for Environmental and Human Toxicology, (2005) Technical Report: Development of Cleanup Target Levels (CTLs) for Chapter 62-777, F.A.C., February 2005.

- 3. Conducting public workshops to present and accept comments on the draft revision to the arsenic action level and the supporting documentation.
- 4. Based on the workshop comments and the advisory committee inputs, development of a policy for signature by the Division Director, after review by other cooperating DNREC divisions and state agencies (DHHS/DPH, DDA, DELDOT).
- 5. Implement the policy with adequate opportunities for public oversight and involvement to ensure it is being implemented fairly.
- Review and revise as necessary the policy to ensure it is keeping pace with new scientific research developments and to determine whether there are any implementation issues arising.

2.2 What Dose of Arsenic Causes Health Impacts?

The dose of arsenic ³⁴causing a health impact depends on a variety of factors, including:

- The chemical form of the arsenic (e.g., organic versus inorganic);
- The person being exposed (children are more sensitive than adults);
- The route of exposure; and
- The type of health impacts being examined.

The prudent and most conservative (i.e., most protective) basis for evaluating health impacts from exposure to toxic substances are to focus on the health impacts that occur at the lowest dose. In the case of arsenic, no lower threshold is recognized by EPA's Science Advisory Board³⁵ – i.e., some risk of cancer exists for virtually any arsenic exposure. Hence, exposure standards for carcinogens like arsenic are expressed in terms of the lifetime probability of dying of cancer, such as one chance in a million or one in ten thousand.

The underlying statute mandating the Department to protect human health and the environment regarding hazardous substances such as arsenic is the Hazardous Substance Cleanup Act (HSCA), 7 <u>Del</u>. <u>C</u>. Chapter 91 law. The HSCA regulations (Subsection 9.4(2)(b) require that the Department perform cleanup activities to achieve standards that are protective of cancer risks using a lifetime cancer risk probability of 1/100,000 or, in loose scientific notation, 1 x 10⁻⁵. In the case of arsenic, however, the background concentrations of arsenic averages approximately 11 ppm (with a range of up to 25-30 ppm), which is more than double the soil concentration (4 ppm) associated with a risk level of 10⁻⁵ for residential properties. The law and regulations directs that, in cases where the background concentration is higher than the concentrations

³⁶ 7 <u>Del</u>. <u>C</u>. Chapter 91

³⁴ The "dose" is the technical term used to described the <u>amount</u> of a substance ingested (i.e., a persons eats or drinks) or inhales, measured by weight such as milligrams, in contrast to the concentration, which is a <u>ratio</u> of weights, such as ppm). A cleanup goal or standard is typically expressed in term of a concentration, based on information about the dose known to cause a heath impact, using simple mathematical relationships and assumptions about the amount of water a persons drinks with contaminant, the amount of air a persons breathes or the amount of soil a persons eats, which are based on scientific studies about human physiology and behavior.

³⁵ This so-called "Linear No-threshold Dose-Response" assumption is sometimes criticized as too conservative and unrealistic. An alternative argument is that the conservativism in this assumption is not contradicted by any clear evidence, and that Arsenic is but one of a variety of carcinogens a person may be exposed to that may have an additive effect and consequently result in a higher probability of cancer, and in some cases these multiple exposures may have a synergistic effect where the cancer risk is higher than what would be expected by the simple additive effect of being exposed to two carcinogens simultaneously (e.g., asbestos exposure and tobacco smoke)

associated with a risk level of 10⁻⁵, then the background concentration shall be the cleanup goal for residential properties.

In addition to cancer, arsenic is known to cause a variety of non-cancer effects, including neurological dysfunction. For non-cancer health risk, the acceptable standard is expressed as Hazard Index (HI) of 1. The hazard index of 1 is the ratio of a representative site concentration in soil to that of a reference dose concentration determined to have non-cancer health effects. The HI of 1 for arsenic is 23 ppm, which is based on the assumption that a child age 1-6 years in a residential setting will ingest 200 mg/day of soil.

2.3 Legal Mandate for Protecting Public Health

DNREC's legal mandate and authority for establishing action levels for soil cleanup (including arsenic) to protect public health is based on the HSCA,³⁷ including the authority to promulgate regulations,.³⁸ (See Attachment C). The law directs DNREC to establish procedures "for identifying cleanup levels based on site specific risks."³⁹ The HSCA regulations provide a limited basis for considering cost as well as "background" concentrations, which allows for some consideration of technical practicability (i.e., can it be achieved realistically using available technology) in the law.

The Secretary of DNREC has promulgated regulations under this HSCA authority to establish procedures for determining cleanup levels for releases of hazardous substances, which includes:

All remedies performed under these regulations shall attain a degree of cleanup of hazardous substances and control of further releases of hazardous substances that ensures protection of public health, welfare, and the environment. The cleanup levels will be determined using a risk-based approach on a site specific basis. The risk-based approach may include consideration of existing and likely future uses of the facility and related natural resources. 40

Accordingly, control of future land use is essential to the protectiveness of the remedy in cases where a cleanup assumes a future land use other than "unrestricted."⁴¹

The statute governing the Department mandate to protect human health and the environment regarding hazardous substances such as arsenic is the HSCA 7 <u>Del. C.</u> Chapter 91. Section 9.4 of the HSCA regulations sets out a risk-based approach for establishing soil cleanup levels, and it identifies two types of risk to human health which must be protected: cancer risks and non cancer risks. The cancer risk level established in Subsection 9.4(2) is "10⁻⁰⁵" (also expressed as 10⁻⁵) which is defined in Subsection 2.1 to mean "the potential risk for one additional cancer death caused by exposure to a carcinogen in a human population of 100,000 in a lifetime."

The HSCA regulations require that the Department perform remediation to achieve levels that are protective of cancer risks using a lifetime cancer risk probability of 1/100,000 or, in loose

³⁸ Section 9104(a)(2)

³⁷ 7 <u>Del</u>. <u>C</u>. Chapter 91

³⁹ Section 9104(b)(2)(g)

^{40 &}quot;Regulations Governing Hazardous Substance Cleanup" at Subsection 9.1(1).

⁴¹ Delaware legislators are now considering a bill to establish a "Uniform Environmental Covenants Act" to provide a state statutory basis for controlling future land use through enforceable restrictive covenants, which proscribe certain activity and use limitations. See S.B. 112.

scientific notation, 10^{-5} . However, when the background concentration of a hazardous substance is higher than the 10^{-5} risk level, the regulations require that the background concentrations be used as the cleanup level. In the case of arsenic, the background concentrations of arsenic average approximately 11 ppm (with a range of up to 25-30 ppm) as discussed in Section 1.3 and Attachment D. Consequently, because the observed background concentration is higher than the concentrations associated (using standard dose and exposure assumptions) with a risk level of 10^{-5} (or a 4 ppm concentration for residential properties), the law directs DNREC to use background concentrations as a cleanup goal.

The law appears clear on this issue, and this is the direction DNREC staff will follow in conducting and overseeing cleanups: remove contaminated soil until a residual concentration is achieved that is equivalent to the local natural background for the area where possible. A "default background" concentration of 11 ppm should be used in cases where the guidance or historic contamination does not allow for a meaningful determination of background that is adequately protective.

2.4 Standards used by USEPA and other states

Several methods are used to determine cleanup standards. Some states call these standards screening values, other use default/site-specific background and/or site specific risk assessments and/or some combination of the above. Table 2 illustrates the various risk management strategies (arsenic standard application) by the USEPA and states throughout the region.

Some examples of cleanup goals in certain western sites where industrial contamination has occurred (e.g., ASARCO smelter in Tacoma Washington) include residential land use cleanup of 100 ppm. In Anaconda, Montana, EPA uses residential cleanup concentrations of 250 pm arsenic.

In the District of Columbia, a panel recommends the adoption of the 20 ppm remediation level as proposed by the USEPA. The Panel believes that the 20 ppm remediation level should not pose a health hazard to the community.⁴²

Many states, however, seek to reduce arsenic concentrations to default or site specific background levels. Table 3 illustrates the default or site specific background value used by various states throughout the region. It is important to note that federal law and Delaware regulations do not require site cleanup below the background level.

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⁴² Report Of The District Of Columbia Mayor's Spring Valley Scientific Advisory Panel, June 2001.

Table 3: State Specific Default Arsenic Background Level/Range⁴³

State	Arsenic (mg/kg or ppm)
Delaware	11 average background
West Virginia	13 default background
New York	3-12 background range
Maryland	3.6-11 background range
Virginia	2.6-17 background range
Pennsylvania	Site Specific
New Jersey	20 background ⁴⁴
District of Columbia	20 background for Spring Valley project

Soil Remediation for Natural Background, Historic Fill, Barry Fraco, NJDEP, 08/12/04.
 Cleanup Standards for Contaminated Sites, NJAC 7:26D (http://www.state.nj.us/dep/srp/regs/scc/index.html)

2.5 Environmental Justice Considerations

The USEPA defines environmental justice (EJ) as the fair treatment for people of all races, cultures, and incomes, regarding the development of environmental laws, regulations and policies. DNREC has adopted this definition and policy and strives to implement cleanup strategies equitably in all communities throughout the State with explicit attention to ensuring adequate protection and public participation in situations where disadvantaged populations may bear a disproportionate amount of adverse environmental health effects from pollution. The Department ensures that facilities and environmental sites are held to the same standards throughout the State.

In determining safe cleanup standards for arsenic, EJ considerations are of paramount importance. Diverse communities are often located in older neighborhood once home to early Delaware industry, including tanneries. For this reasons, it is extremely important that the process of determining "background" concentrations do not result in a less protective cleanup goal being used, simply because of a generally higher level of arsenic not of natural origin. In other words, citizens should not be given any less protection simply because they live in old industrial neighborhood. This would not only be intolerably unjust, but would defeat the very purpose for which the environmental cleanup program is focused – to cleanup contaminated sites and make communities safe and livable.

To assure that the legacy of higher concentrations of arsenic that might occur in the soil of these communities does not result in less protective cleanup standards, DNREC staff will not use the "background" determination process prescribed in guidance for a local area unless an area can be found that is not impacted by historic contamination. If no un-impacted area can be found, a cleanup goal of 11 ppm, the average background concentration of Delaware soil, will be utilized. It is a Department priority to make EJ considerations paramount in these communities.

3.0 Policy Choices

There is no objectively "correct" soil concentration standard based solely on scientific and engineering information, although this information can certainly be useful. The selection of a soil concentrations action level and cleanup goal is ultimately a policy choice — a decision to be made with public involvement with as much public transparency as possible. The public has a fundamental right to be involved in decisions that could affect them. The decisions can and should be informed by good science and engineering, and much of this background document seeks to provide that information in a clearly accessible manner. Nonetheless, despite this sea of scientific information, however deep and carefully plumbed, the decision remains a policy choice. Hence, the **Proposed Arsenic Risk Management Plan** presented a series of possible concentrations and the implications to help inform a policy dialogue and allow for meaningful public involvement.

⁴⁵ http://www.epa.gov/compliance/environmentaljustice/index.html, June 21, 2005

3.1 Option A - 0.4 ppm

Using standard risk assessment exposure assumptions (e.g., how much soil a child or adult eats, 46) a soil concentration of 0.4 ppm would result in an incremental 47 lifetime 48 cancer risk increase of one in a million. This risk probability (1/1,000,000) is on the conservative end of the spectrum for "acceptable risks" that have been selected in the United Sates during the past 35 years of environmental policy making. Generally, environmental policy decisions in the U.S. have selected risks ranging from a high end risk of one in ten thousand (1/10,000) to one in a million (1/1,000,000). This risk-to-dose relationship (i.e., 0.4 ppm equals 1/1,000,000) also assumes that all of the arsenic to which a person is exposed is the arsenic in the most toxic form (i.e., it is inorganic arsenic not organic arsenic), and that the inorganic arsenic is all trioxide [As (III) with a valence state (electronic charge) of 3], although some arsenic exists in organic form and some inorganic arsenic has a valence state of 5 [As(V)] or pentaoxide), rather than 3 (See Section 1.2 on arsenic chemistry). It also assumes that 100% of the arsenic in soil will be absorbed by the individual. A recent study with monkeys showed that only up to 25% is absorbed (bioavailability).

Perhaps the most obvious consideration to evaluating this 0.4 ppm option is technical feasibility. This 0.4 ppm concentration standard cannot be achieved realistically in the field during cleanups because the background concentrations of arsenic found in the soil in Delaware are significantly higher than 0.4 ppm (See Table 4) Also, 0.4 ppm falsely implies a level of precision to the 1/10th of a ppm that is unattainable using typical analytical instrumentation.

3.2 Option B - 4.0 ppm

Using similar risk assessment exposure assumptions, a soil concentration of 4.0 ppm would result in an incremental lifetime cancer risk increase of one in a one hundred thousand. This risk probability (1/100,000) is in the middle of the spectrum for "acceptable risks" that have been selected in the United Sates during the past 35 years of environmental policy making.⁴⁹

This risk-to-dose relationship (i.e., 4.0 ppm equals 1/100,000) is also based on the conservative assumption that all of the arsenic to which a person is exposed is the arsenic in the most toxic form (i.e. it is inorganic arsenic not organic arsenic), and that the inorganic arsenic is all trioxide (As (III) with a valence state (electronic charge) of 3), although some arsenic exists in organic form and some inorganic arsenic has a valence state of 5 [As(V) or pentaoxide], rather than 3 (See Section 1.2 and 1.3 on the Chemistry and Geology of arsenic). It also assumes that 100% of the arsenic in soil will be absorbed by the individual. A recent study with monkeys showed that only up to 25% is absorbed (bioavailability).

⁴⁶ Referred to as "pica" behavior, EPA estimates toddlers eat 20 grams of soil per day, or a 13.3 kg toddler ingesting 5,000 mg of soil in a single event. For evaluating the risk of cancer, EPA assumed adults weighing 70 kg would be exposed to the maximum concentration of each contaminant for 350 days a year for a lifetime (70 years), and that adults are assumed to ingest 50 mg of soil a day [9]. US Environmental Protection Agency. Exposure factors handbook. Washington, DC: US Environmental Protection Agency. Office of Research and Development. EPA/600/C-99/001; February 1999.

⁴⁷ The term "incremental" here means cancer risk in addition to/above and beyond the "normal" background probability of cancer expected as a result of other factors such as other exposures, diet and genetic predisposition.

Assuming a 70-year lifetime of exposure.

Generally, environmental policy decisions in the U.S. have selected risks ranging from a high end risk of one in ten thousand (1/10,000) to one in a million (1/1,000,000).

This 4.0 ppm concentration would be difficult to achieve during cleanups in most situations because the background concentrations of arsenic found in the soil in Delaware are, on average, higher than 4.0 ppm (See Table 4).

This option could create a very significant budget shortfall to address many of the historic fill sites in the State that may not pose a risk to human health or the environment. Paradoxically, setting a more strict cleanup goal may result in less health protection because fewer sites may be cleaned up with the available funding, leaving some sites completely untouched by remediation, while other sites are cleaned up to more stringent cleanup goals.

3.3 *Option C- 11 ppm*

Using similar risk assessment exposure assumptions, a soil concentration of 11 ppm would result in an incremental lifetime cancer risk increase of approximately three in a one hundred thousand. This risk probability (3/100,000) is roughly in the middle of the spectrum for "acceptable risks" that have been selected in the United Sates during the past 35 years of environmental policy making. It is important to note that risk probabilities are generally not intended to be interpreted as anything more precise that order of magnitude (i.e., $1/10^{th}$ or $1/100^{th}$ NOT 2/100 or 3/100) estimates, so a risk extrapolation of 3/100,000 may imply greater precisions than is technically possible.

This risk-to-dose relationship (i.e., 11 ppm equals 3/100,000) is also based on the conservative assumption that all of the arsenic to which a person is exposed is the arsenic in the most toxic form (i.e., it is inorganic arsenic not organic arsenic), and that the inorganic arsenic is all trioxide (As (III) with a valence state (electronic charge) of 3), although some arsenic exists in organic form and some inorganic arsenic has a valence state of 5 [As(V) or pentaoxide], rather than 3 (See Section 1.2 on the arsenic chemistry). It also assumes that 100% of the arsenic in soil will be absorbed by the individual. A recent study with monkeys showed that only up to 25% is absorbed (bioavailability).

This 11 ppm concentration would be possible to achieve during cleanups in most situations because the background concentrations of arsenic found in the soil in Delaware are, on average, higher than 4.0 ppm (See Table 4). In some cases, the wide area background concentrations of arsenic are higher than 11 ppm, and significant resources could be used in seeking to attain a cleanup goal of 11 ppm, which would be a relatively small decrease in the arsenic concentration and accordingly a small incremental decrease in risk.

This option could create a significant budget shortfall to address many of the historic fill sites in the State that may not pose a risk to human health or the environment. Paradoxically, setting a more strict cleanup goal may result in less health protection because fewer sites may be cleaned up with the available funding, leaving some sites completely untouched by remediation, while other sites are cleaned up to more stringent cleanup goals.

3.4 Option D-23 ppm

Using similar risk assessment exposure assumptions, a soil concentration of 23 ppm would result in an incremental lifetime cancer risk increase of one in twenty thousand. This risk probability

(approximately 1/20,000) is toward the high end of the spectrum for "acceptable risks" that have been selected in the United Sates during the past 35 years of environmental policy making.⁵⁰

This risk-to-dose relationship (i.e., 23 ppm equals 1/20,000) is also based on the conservative assumption that all of the arsenic to which a person is exposed is the arsenic in the most toxic form (i.e., it is inorganic arsenic not organic arsenic), and that the inorganic arsenic is all trioxide [As (III)] with a valence state (electronic charge of 3), although some arsenic exists in organic form and some inorganic arsenic has a valence state of 5 [As(V) or pentaoxide] rather than 3 (See Section 1.2 on the arsenic chemistry).

The then DNREC-DAWM Director signed a memorandum in June 2004 designating 23 ppm as the interim action level and later referred to it as a standard. The basis for this number appears to be the use of a hazard index of 1.0. Because the carcinogen risk is lower (i.e., 4 ppm associated with a risk of 1/100,000) then the hazard index number is not controlling. Moreover, because the background level is lower than this hazard index number, then it does not appear to have a role in carrying out DNREC's mandate to protect human health and the environment to the extent feasible in HSCA.

3.5 Option E-40 ppm

Using similar risk assessment exposure assumptions, a soil concentration of 40 ppm would result in an incremental⁵¹ lifetime⁵² cancer risk increase of one in a ten thousand. This risk probability (1/10,000) is on the high end of the spectrum for "acceptable risks" that have been selected in the United Sates during the past 35 years of environmental policy making.⁵³

This risk-to-dose relationship (i.e., 40 ppm equals 1/10,000) is also based on the conservative assumption that all of the arsenic to which a person is exposed is the arsenic in the most toxic form (i.e., it is inorganic arsenic not organic arsenic), and that the inorganic arsenic is all trioxide [As (III) with a valence state (electronic charge) of 3], although some arsenic exists in organic form and some inorganic arsenic has a valence state of 5 [As(V) or pentaoxide], rather than 3 (See Section 1.2 on the Chemistry of arsenic).

This arsenic concentration limit has historically been used for industrial sites as an action level and cleanup goal. This limit should not therefore be considered adequately protective of individuals in residential settings, using common exposure and dose assumptions.

3.6 DNREC Option Analysis

Based on the above options, and the information currently available, the Department will continue a risk-based approach to cleanup in accordance with 7 <u>Del.C</u>. Chapter 91 and the HSCA regulations. The HSCA and regulations allow for the use of background levels. In cases where a

⁵⁰ Generally, environmental policy decisions in the U.S. have selected risks ranging from a high end risk of one in ten thousand (1/10,000) to one in a million (1/1,000,000).

⁵¹ The term "incremental" here means cancer risk in addition to/above and beyond the "normal" background probability of cancer expected as a result of other factors such as other exposures, diet and genetic predisposition.
⁵² Assuming a 70-year lifetime xxx of exposure.

⁵³ Generally, environmental policy decisions in the U.S. have selected risks ranging from a high end risk of one in ten thousand (1/10,000) to one in a million (1/1,000,000).

local background level cannot be developed, the Department will utilize the default background level of 11 ppm.

4.0 Implementation

The revised arsenic action level will be for all cleanup sites for which future land use is reasonably anticipated to be residential or unrestricted and under the regulatory authorities of the DAWM. The sites include old industrial properties being redeveloped, active facilities conducting a cleanup and old industrial site undergoing a cleanup. The revised action level is effective in draft immediately upon release and as a final action level upon adoption by the Secretary of the Department.

4.1 Process for Determining Background Concentrations

The "background concentration" approach relies on empirical correlation between bulk soil concentrations and presumed least impacted, NOT "natural", locations in the State. Establishing a natural (i.e., uncontaminated by any anthropogenic, or human produced or moved, arsenic) soil location and concentrations is very difficult. Ultimately, it is impossible to prove a negative – in the case, "Prove that this site has never been contaminated by human beings." It is important to recognize that background standards merely provide some context for risk-based standards. As a technical analysis, background standards cannot be considered a substitute for consideration of fate, transport, exposure and risk, but a full site-specific risk assessment is not always feasible, and cleaning up to background is as much as is technically feasible in most cases. The procedure for determining site specific background levels is found in the Delaware Hazardous Substance Cleanup Act Remediation Standards Guidance,

http://www.dnrec.state.de.us/dnrec2000/Divisions/AWM/sirb/DOCS/PDFS/Misc/RemStnd.pdf. This document will be used by DNREC staff to establish site specific background levels.

4.2 Review Process

The Department will track all relevant arsenic data obtained at sites regulated by the Department after the effective date of the new policy. The data will be reviewed by the Department in consultation with staff from DDA and DHHS/DPH. The Department will report on the results of its review and invite public comment, providing public workshops and following the public participation plan process to review and revise the policy within five years. The public review process will involve interested Department advisory committees and the following questions: What should the arsenic action level be? Should it apply to golf courses, orchards or other sites with properly applied pesticides and fertilizers? Is the public involvement plan adequate? If not, how should it be changed?

5.0 Public Participation Plan

In order to ensure the public has ample opportunity to participate in the continued development and adoption of arsenic action level(s) for the State, DNREC developed a public participation plan (see Table 4) for future use. With this plan, DNREC will encourage comments from the general public and all interested parties. As part of its review process, DNREC will involve all advisory committees, host a minimum of one public workshop in each county, offer to attend any civic or other organization meeting, notice the proposed policy in the Delaware Register of

Regulations and make press announcements on the draft policy proposal. DNREC will staff all meetings to take notes on the issues and concerns raised.

The final policy will be noticed in the Delaware Register of Regulations, the News Journal and press releases will be sent out. In addition, DNREC is prepared to provide a presentation to any organization or governmental entity that requests such.

The DNREC will continue to provide staff support to existing advisory committees for both the administrative and technical needs. The DNREC will coordinate with other State and Federal agencies and when necessary, seek outside contractual support for technical issues. This will require significant staff resources from both the Site Investigation and Restoration Branch and the Public Affairs Office. Future revisions to the policy will undergo a 6 month review process.

Table 4: Future Implementation Schedule

Activity	Timeframe
Involve Existing Advisory Committees	2 weeks
Attend Advisory Committee Meetings	1 month
Revise Draft Proposal	1 week
Notice Public Workshops in Register	20 days
Press Release on Draft Proposal	1 week
Hold Public Workshops	2 weeks
Attend Civic Organization Meetings	2 weeks
Draft Response to Issues	2 weeks
Attend Advisory Committee Meetings	1 month
Notice Final Policy	20 days
Implement Final Policy	6 months from start

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ATTACHMENT A: Governor's Directive



State of Delaware Office of the Governor

Ruth Ann Minner Governor

To: Secretary John Hughes

From: Governor Ruth Ann Minner

Date: June 9, 2005

Cc: David Small

James Werner

Re: Protecting Delaware Citizens from Arsenic

Arsenic is among a number of toxic substances known to cause cancer and to which our citizens may be exposed in their communities and workplaces. Whether it is derived from industrial or natural sources, we have a duty to protect our citizens from harmful exposure to toxic substances, such as arsenic.

It has become clear that there is a lack of understanding regarding the Department's rationale and method for setting an acceptable limit for arsenic in soil **and** whether the current level is protective of public health. This situation has been caused in part by numerous changes to the limit over the years **and** in part by a lack of public input in the recent change in the limit.

Accordingly, I am directing you to lead an immediate and expedited review of standards and policies related to arsenic cleanup. This review should include:

- Evaluation of the best scientific information available;
- Public involvement:
- Involvement of other agencies, including the Department of Health and Social Services; and
- Consideration of standards and policies used by EPA and other states.

My request is that you begin this review immediately and take action to propose appropriate standards and policies within two weeks.

Tatnall Building, Dover, Delaware 19901 (302) 744-4101 (302) 739-2775 fax Carvel State Office Building, Wilmington, Delaware 19801 (302) 577-3210 (302) 577-3118 fax

ATTACHMENT B: Staff Work Group Meeting

Attendance at June 7, 2005 Staff Work Group Meeting To Discuss Changes in DNREC Risk Management for Arsenic (Lukens Drive Building, New Castle, DE)

DNREC/DAWM:

- Kathy Stiller Banning
- Betsy Rogers
- Bob Schulte
- Jim Werner

DNREC/DWR:

• Rick Greene

Division of Public Health:

- George Yocher
- Thomas May
- Gerald Llewellyn (on phone),

Department of Agriculture:

• Grier Stayton

<u>AG:</u>

• Bob Kuehl

ATTACHMENT C: Legal Basis For Arsenic Risk Management Standards

The Hazardous Substance Cleanup Act, 7 <u>Del. C.</u> Chapter 91 ("HSCA"), gives the Secretary of the Department of Natural Resources and Environmental Control ("DNREC") certain powers and authorities to investigate and remediate releases of hazardous substances. See, generally, 7 <u>Del. C.</u> Section 9104. Section 9104(a)(2) grants the Secretary the authority to draft regulations:

"The Secretary shall, after notice and public hearing, promulgate and revise such regulations as deemed necessary for the implementation, administration and enforcement of this Chapter."

In drafting regulations, Section 9104(b)(2)(g) directs the Secretary to establish procedures "for identifying cleanup levels based on site specific risks."

The Secretary has used this authority granted by HSCA to promulgate the Regulations Governing Hazardous Substance Cleanup ("Regulations"). Section 9 of the Regulations establishes procedures for determining cleanup levels for releases of hazardous substances. Subsection 9.1(1), which establishes a risk based approach to cleanup levels, states:

All remedies performed under these regulations shall attain a degree of cleanup of hazardous substances and control of further releases of hazardous substances that ensures protection of public health, welfare, and the environment. The cleanup levels will be determined using a risk-based approach on a site specific basis. The risk-based approach may include consideration of existing and likely future uses of the facility and related natural resources.

Section 9.4 sets out a risk-based approach for establishing soil cleanup levels, and it identifies two types of risk to human health which must be protected: cancer risks and non cancer risks. The cancer risk level established in Subsection 9.4(2) is "10E⁻⁰⁵" which is defined in Subsection 2.1 to mean "the potential risk for one additional cancer death caused by exposure to a carcinogen in a human population of 100,000 in a lifetime." The non-cancer risk level established in Subsection 9.4(2) is a "hazard index value of one." A "hazard index" is defined in Subsection 2.1 to mean "the numerical value obtained by dividing a person's expected daily intake of a non-carcinogen by a level which is not expected to produce toxic effects." By establishing a "hazard index of one" (expressed as "HI-1") the Regulations require a soil cleanup level where the daily intake of a hazardous substance is not expected to produce toxic (i.e. non-cancer) effects.

The Regulations also provide that the risk-based cleanup level for a hazardous substance will vary depending on the type of use (such as residential, commercial or industrial) which will occur on the site or property. Subsection 9.1(5) sets out two types of cleanup levels where the risks from hazardous substances are quantifiable: compliance cleanup levels (also referred to as "unrestricted" or "residential" cleanup levels), and conditional cleanup levels (also referred to as "restricted" or commercial or industrial" cleanup levels). These are defined in Subsection 9.1(5) as follows:

- (a) <u>Compliance cleanup levels</u>: These will be established at concentrations which are protective of public health, welfare, and the environment and, which require no restrictions on the use of the facility. Compliance cleanup levels shall be established in accordance with Subsections 9.2 9.4 and as directed by the Department.
- (b) <u>Conditional cleanup levels</u>: These represent concentrations which are protective of public health, welfare, and the environment under restricted facility use conditions. Conditional cleanup levels may be established where the person undertaking the remedy can demonstrate that such levels are consistent with state and federal laws, that all practicable methods of treatment are utilized, and that institutional controls are implemented in accordance with conditions as determined to be appropriate by the Department.

Generally, compliance (i.e. unrestricted/residential) cleanup levels are lower than conditional (i.e. restricted/commercial or industrial) cleanup levels for a given hazardous substance because a residential setting will result in more prolonged exposure to the hazardous substance (in terms of hours of exposure over a lifetime) than will a commercial or industrial setting. Therefore, it will represent a higher risk, and the risk-based cleanup level will be lower in a residential setting than in a commercial or industrial one.

When the risks from a hazardous substance are not quantifiable, Subsection 9.1(5)(c) states:

When there are multiple contaminants at a facility, the cleanup level of each contaminant shall be such that sum of the risks posed by the contaminants shall not exceed $10E^{-05}$ cancer risk or a hazard index value of one.

Many hazardous substances, like arsenic, are naturally occurring. Once a risk-based cleanup level is established for a hazardous substance, it must be compared to the natural background level for that hazardous substance. Section 2.1 of the Regulations defines "Background" or "Natural Background" as "the level of contamination present in an area from naturally occurring substances, excluding contaminants and other contributions resulting from human activity." Essentially, this represents the level of a naturally occurring hazardous substance that would have existed in the environment before human activity.

The Regulations do not permit cleanup levels to be set below the natural background level of a hazardous substance. Subsection 9.4(2)(a) states:

When the natural background level exceeds the $10E^{-05}$ cancer risk level or a hazard index value of one level, for direct exposure or inadvertent ingestion, then the background level will be the cleanup level.

Thus, where the natural background level is higher than the risk-based cleanup level for a hazardous substance, the background level becomes the cleanup level.

Alternatively, when the natural background level is below the risk-based cleanup level for a hazardous substance, then the risk-based cleanup level is the cleanup level. Subsection 9.4(2)(b) states:

When the natural background level is less than the $10E^{-05}$ cancer risk level or a level corresponding to a hazard index value of one, for direct exposure or inadvertent ingestion, then the $10E^{-05}$ cancer risk level or a level corresponding to a hazard index value equal to one becomes the cleanup level.

The Regulations require that the cleanup levels established in Section 9 be used in determining an appropriate remedial alternative (i.e. type of cleanup or "remedial action") for a particular site.

The procedure for developing remedial alternatives is described in Subsection 8.5(4)(a), which states:

An initial screening of alternatives to narrow the list of potential remedies for further detailed evaluation. The initial screening shall be conducted to eliminate from the evaluation those alternatives which need no further consideration in the context of the following broad criteria:

- (i) The effectiveness in meeting the cleanup level in Section 9 of these regulations to protect public health, welfare, and the environment.
- (ii) Acceptable engineering practices based on the following criteria:
 - (A) applicability to the problem;
 - (B) feasibility for the locations and conditions of release; and
 - (C) reliability; and
- (iii) Relative cost of the remedial action.

After a number of remedial alternatives are developed, they are evaluated using a number of factors. Subsection 8.5(4)(b) states:

After the initial screening is performed, an evaluation shall be conducted of the remaining alternatives considering the following factors:

- (i) The protection of public health, welfare, and the environment. The remedial action that attains compliance cleanup levels, in accordance with Section 9, shall be presumed to demonstrate compliance with this paragraph unless the person undertaking the remedy can demonstrate that conditional cleanup levels, as set forth in section 9.1, are fully protective in accordance with Section 9. When the compliance cleanup levels or conditional cleanup levels cannot be established, a remedial action which complies with Section 9.1(5)(c) shall be presumed to demonstrate compliance with this paragraph.
- (ii) Compliance with all applicable local, state and federal laws and regulations;

- (iii) Community acceptance of the alternatives;
- (iv) Monitoring the success of the remedial action. In considering this factor the Department will evaluate whether the alternative will provide for monitoring in accordance with Subsection 8.8 of these regulations;
- (v) Technical practicability of the alternative at the facility. In considering this factor, the Department will evaluate whether the alternative will meet the following factors:
 - (A) (I) Technical feasibility;
 - (II) Ability to be implemented.
 - (B) A remedial action may not be considered technically practicable if the incremental cost of the cleanup action is substantial and disproportionate to the incremental degree of protection it would achieve.
- (vi) A reasonable restoration time frame as determined by the Department;
- (vii) Reduction of toxicity, mobility, and volume through treatment or containment of the hazardous substances, either on-site or at an approved off-site facility;
- (viii) Long-term effectiveness; and
- (ix) Short-term effectiveness.

Subsection 8.4(4)(c) describes how the remedial alternatives are ranked in order of preference:

For remedial action alternatives which comply with Subsection 8.5(4)(b)(i) and (ii), and satisfy the remaining evaluation criteria of subsection 8.5 (4)(b), preference shall be given to the remedial action which is most cost effective, and cost shall include present and future direct and indirect capital costs, operation and maintenance costs, compliance monitoring costs, and other foreseeable costs.

The method of selection of a remedial action from the remedial alternatives is set out in Subsection 8.6 which states:

The Department shall select a remedial action from the alternatives developed for the facility based on the determination of which remedial action complies with Subsection 8.5(4)(b)(i) and (ii) and best complies with the remaining criteria in Subsection 8.5(4)(b), and complies with Subsection 8.5(4)(c).

Therefore, the selected remedial action must be one that:

- 1) complies with the cleanup levels established in Section 9 Subsection 8.5(4)(b)(i);
- 2) complies with all applicable local, state and federal laws and regulations (Subsection 8.5(4)(b(ii);
- 3) best complies with the remaining criteria in Subsection 8.5(4)(b)(iii)-(ix); and
- 4) is the most cost effective (Subsection 8.5(4)(c)).

ATTACHMENT D: Natural Background Concentrations of Arsenic in Delaware Soils

Determining background concentrations of arsenic is important to risk management and standard setting because the background information typically provides a lower boundary below which cleanup concentrations cannot normally be achieved. Accordingly, it is equally important that DNREC exercise great care in it evaluation of background concentrations to seek to distinguish between natural background concentrations and background concentrations of arsenic that may result from widespread distribution as a result of human activity (i.e., "anthropogenic" arsenic). For this reason, DNREC staff analyzed multiple sources of data on arsenic concentrations to better understand background concentrations and seek to determine what a reasonable "natural" concentration of arsenic would be.

There are a number of methods used to help determine "background" (natural and other) concentrations of arsenic: average, the 95% upper confidence level to name a few. The following is a brief summary in determining background: One method for determining natural background is to analyze arsenic soil concentrations below the ground surface, which can be obtained from "borrow pits" where clean soil is excavated for use as clean soil elsewhere such at new construction sites. Soil samples collected from borrow pits in New Castle County near Concord Pike (Rt. 202 and I-95) approximately 30-50 ft below ground surface have been found to have arsenic concentrations ranging from 3 to 18 ppm and a median of approximately 10 ppm (See Table 3). The source of arsenic is probably from the formation of Glauconite over many years. The minerals that predominate in the Piedmont rocks are not generally considered arsenic bearing but they do contain trace amounts of arsenic. The borrow pit samples were obtained from an area where there was no evidence of prior excavation or disposal. The use of deep soil for determining natural background concentrations of arsenic is a valid method if there is no mechanism for arsenic to have migrated to the deep soil. Also, the arsenic is not likely to have migrated down into deep soils because the science indicates that arsenic does not migrate through soil except for very short distances and at high source soil concentrations. Although analysis of deep borrow pit data may not be representative of surface soils to which the public may be exposed (i.e. surface soils may have more organic matter), it is useful as a basis for comparison. For example, if deep borrow pit soils have comparable levels of arsenic to surface soils in undisturbed areas, it suggests that arsenic from air sources is an insignificant source of contamination. In addition, scientific data suggests that arsenic is not very mobile except in extremely high concentrations also supports this hypothesis.

A second method for determining background concentrations of arsenic is direct analysis of Delaware surface soil from location not believed to have been contaminated from industrial sources. DNREC staff analyzed soil samples from various locations throughout the state (See Figure 1) to better understand soil concentrations of arsenic and to contribute, along with other sources of information, to a determination of background concentrations, natural and otherwise in Delaware. This analysis is described in more detail in a technical background memorandum from Rick Greene, DNREC/DWR to James D. Werner, Director, DNREC/DAWM http://www.dnrec.state.de.us/dnrec2000/Divisions/AWM/sirb/clnupnum.asp.

The DNREC soil assessment considered two primary datasets with a total of 55 samples analyzed: 20 soil samples collected from various parks in the Wilmington area at locations unaffected by any known direct industrial input; and 35 soil samples collected through Delaware

at background locations as part of analysis to determine area background concentrations during waste site assessments. The samples from this second data set were collected at locations similar in soil and other geological characteristics, but where there was no evidence of being affected by the waste disposal or contamination at the subject waste site.

The results of this analysis provide useful insight into understanding background concentrations of arsenic in Delaware soils. First, the background concentration of arsenic in Delaware soils is not a single, constant value. Rather 'background' is a range of values, which can be described as data distributions. Based on the available data, the range of background arsenic concentrations in Delaware soils falls between 0.58 and 31 ug/g dw (micrograms arsenic per gram of soil on a dry weight basis, which is approximately the same as milligrams per kilograms or parts per million or ppm).

A second observation regarding this soil concentration data is that the soil concentrations are not distributed with a central tendency of average concentration (i.e. clumped in the middle of the range like a bell-shaped curve of the largest number of sample concentrations in the middle and fewer data points at the low and high extremes, often referred to as a "normal" distribution). Instead, the data appears to be distributed in a "logarithmic" pattern. The implication of this data distribution is that selecting an average concentration to reflect the observed background concentrations would be relatively arbitrary and would not reflect the actual concentrations of arsenic concentrations found in soil in Delaware. Moreover, characterizing an average concentration as reflecting "background" would result in half of observed soil concentrations therefore being "above background" when in fact they are actually legitimately within the range of observed background concentrations, and simply above average.

A third observation from the soil arsenic concentration assessment was the analysis of the upper end of the observed soil concentrations. Using all available background arsenic data statewide, the 95th percentile concentration (the concentration below which 95 percent of all soil samples are expected to be found) is 29.1 ppm. The 95th percentile for all New Castle County (including Wilmington data) is 21.6 ppm. The 95th percentile concentrations for Kent and Sussex Counties are 24.8 and 14.9 ppm, respectively. This latter observation indicates that, despite the widespread application of chicken litter containing arsenic residues, no widespread elevated concentrations of arsenic in Sussex County were observed in this data analysis.

Finally, a third method of evaluating background soil arsenic concentrations is to compare Delaware data to national data. The U.S. Geological Survey in 1984 published a comprehensive analysis of thousands of soil sample form around the country, including analysis of arsenic. The results of the analyses show that the range of arsenic concentrations is up to nearly 100 ppm, with an average concentration of approximately 10 ppm. The higher concentrations tend to be present in western alkaline soils. Although this range does not necessarily reflect the pattern DNREC believe to be present in Delaware, it indicates that the other data sources are in the same order of magnitude range of observed concentrations.

Shacklette, Hansford T. and Boerngen, J.G., "Elemental Concentrations I Soils and other Surficial Materials of the Coterminous United States", U.S. Geological Survey Professional Paper 1270, GPO, 1984.

Because of the similarity of the findings for multiple studies, using independent data sets and independent analyses, the results appear to be reproducible. In scientific studies, when an analyst observes such reproducibility of results, it tends to provide additional support for the robustness (i.e., reliability and confidence) of the results.

ATTACHMENT E: University of Delaware Study: Scope, Summary and Schedule

http://www.dnrec.state.de.us/dnrec2000/Divisions/AWM/sirb/clnupnum.asp

ARSENIC STUDY BY UNIVERSITY OF DELAWARE

The University of Delaware (Dr. D.L. Sparks and Dr. J. Thomas Sims) conducted a study of arsenic (As) in Delaware soils in conjunction with the Department of Natural Resources and Environmental Control under a Collaborative Agreement. A draft of the study was completed in November 2006. The study report will be completed in 2007.

Background: Arsenic commonly occurs in soil and water due to natural geological processes and due to human activities. Agricultural sources of arsenic to Delaware soils include Poultry Litter (PL), historic use of pesticides, and municipal sewage sludge's used as soil amendments. Industrial sources of arsenic include wastes from tanneries, wood treating facilities and coal combustion for electric power. Long-term inputs from human activities (e.g., inorganic and organic arsenical pesticides, defoliants, wood preservatives, manures, and biosolids) to agricultural fields have increased total arsenic levels up to as high as 165 ppm (mg/Kg) in soil. The Delmarva Peninsula is one of the most concentrated poultry production areas in the US. Poultry litter is generally applied on agricultural lands. Total arsenic concentrations in PL vary. Limited data have shown ground water from agricultural fields of the Pocomoke River Basin in Maryland and Delaware having total dissolved arsenic concentrations as high as 23 ppb (μ g/L). A majority of the Delaware soils are highly susceptible to arsenic leaching to ground waters due to their sandy texture, low organic matter, clay, and metal oxide contents.

Purpose: The purpose of the study is to characterize the amount, chemical forms, speciation, and solubility of arsenic in agricultural, industrial soils and forested soils in Delaware.

Objectives: The collaborative effort has the following objectives:

- 1. To characterize the speciation and distribution of As in major Delaware soils, as impacted by long-term applications of all potential As sources, such as poultry litter (PL), biosolids, and other organic by-products or industrial wastes.
- 2. To determine factors controlling the retention, release, and potential mobility to ground waters of As in Delaware soils, as affected by soil properties and competing anions.
- 3. To quantify the potential for As leaching in Delaware soils, the As species in leaching waters, and the potential for best management practices to mitigate As leaching.
- 4. To speciate As in soils and determine the associations and distributions of As and other cocontaminating metals in tannery contaminated soils using a combination of chemical extraction, desorption, and molecular scale x-ray absorption and fluorescence spectroscopic approaches.
- 5. To lead, in cooperation with the University of Delaware *Institute of Soil and Environmental Quality* (ISEQ), a multi-party discussion of the implications of the findings of this research to

the quality of Delaware's environment.

Timeline: The study report is scheduled for completion in early 2007.

Figure 1: ARSENIC CONCENTRATION MAP 1

