Letter Health Consultation

Potential Health Effects of perfluorooctane sulfonate (PFOS) levels
in fish on the Conasauga River

DALTON, GEORGIA

Prepared by:
Georgia Department of Community Health

OCTOBER 7, 2010

Prepared under a Cooperative Agreement with the
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Toxic Substances and Disease Registry
Division of Health Assessment and Consultation
Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

A health consultation is a verbal or written response from ATSDR or ATSDR's Cooperative Agreement Partners 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 or ATSDR's Cooperative Agreement Partner which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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LETTER HEALTH CONSULTATION

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GEORGIA DEPARTMENT OF
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Clyde L. Reese, III, Esq., Commissioner Sonny Perdue, Governor

September 7, 2010

Dan Olone, Chief
Drinking Water Section
U.S. Environmental Protection Agency, Region IV
61 Forsyth Street SW
Atlanta, GA 30303-8960

Re: Potential Health Effects of perfluorooctane sulfonate (PFOS) levels found in fish on the Conasauga River

Dear Mr. Olone:

The Georgia Division of Public Health (GDPH) has reviewed available fish data from a section the Conasauga River located east and southeast of Dalton, Georgia. We are writing you to inform you of our findings regarding the potential for adverse health effects from exposure to perfluorooctane sulfonate (PFOS) found in fish and fresh water mussels caught in the Conasauga River near Dalton. Surface water sampling for polyfluorochemicals (PFCs) in the Conasauga River was conducted by the University of Georgia (UGA) in 2006. Results showed concentrations of perfluorooctanoic acid (PFOA) and PFOS were higher downstream than upstream of the Loopers Bend Wastewater Treatment Plant, and wastewater Land Application System (LAS) site where treated wastewater is sprayed on over 9,200 acres of wooded peninsula surrounded on three sides by the Conasauga River. These sites are located approximately 4.5 miles southeast of Dalton. The 2006 study found that PFOA concentrations ranged from 253 – 1150 nanograms per liter (ng/L); while the PFOS concentrations ranged from 192-318 ng/L. In the summer of 2009, UGA conducted a study to measure PFOS levels in fish and mussels caught in the Conasauga River near Dalton. Sampling locations included a site upstream of the Loopers Bend Wastewater Treatment Facility, at a site adjacent to the wastewater treatment site, and two sites downstream of the wastewater treatment site.

Background

PFOA and PFOS are two compounds from a broad class of manufactured chemicals known as PFCs that have been produced since the 1950s. This class of chemicals is used into make products that resist oil, stains, heat, water, and grease. These products include non-stick cookware, oil and moisture-resistant paper coatings, stain-resistant carpets and fabrics, nail polishes, and fire-fighting foam. Apart from many consumer-product uses, the aerospace, automotive, construction, chemical-processing, electrical and electronics, semiconductor, and textile industries use them as well.

Two chemicals in this class, PFOS and PFOA, have been a concern because they persist in the environment. Both PFOS and PFOA accumulate in wildlife such as bald eagles, mink, bears, sea mammals, and fish, and PFCs have been found in people. The chemical process that uses

perfluorooctanesulfonyl fluoride and results in the formation of PFOS and several other PFCs was discontinued by 2002 in the United States. However, PFOS can also form from the degradation of precursors in addition to industrial production. PFOA is currently used as a processing aid when making fluoropolymers.

In 2007, the centers for Disease Control and Prevention (CDC) published results of two studies of human exposure to 12 PFCs. In the first study, CDC measured levels of PFCs in the serum of 1,562 people 12 years old and older who took part in CDC's National Health and Nutritional Examination Survey (NHANES) during 1999 and 2000. In the second study, CDC measured levels of PFCs in the serum of 2,094 people 12 years old and older who took part in NHANES during 2003 and 2004. In both studies, PFOS and PFOA were detected in approximately 98% of the population. These findings confirm widespread PFC exposure in the U.S. population.

PFOA and PFOS are used by some companies in the Dalton carpet industry, which produces 80 percent of the nation's carpets, to make stain-repellent floor coverings. Concerns in Dalton prompted the Georgia Environmental Protection Division (GEPD) to begin statewide sampling at drinking water intakes for PFOA in 2008. In January 2009, the United States Environmental Protection Agency (USEPA) issued Provisional Health Advisory[1] values for PFOA and PFOS. The provisional health advisory concentrations are 400 ng/L (or parts per trillion) for PFOA and 200 ng/L for PFOS in drinking water. In March 2009, USEPA, Region 4, along with GEPD, conducted a public water sampling investigation in North Georgia. Public drinking water from plants in Dalton, Calhoun, Rome and Floyd County were sampled to obtain levels of perfluorinated compounds in the drinking water. The laboratory results identified both PFOA and PFOS in samples from 2 of 15 stations. Both samples contained PFOA and PFOS at levels less than the provisional health advisory concentrations

Fish Sampling Data

In the summer of 2009, UGA collected three Spotted Bass and three Blue Catfish from each four locations on the Conasauga River east and southeast of Dalton. Background samples were obtained upstream of the Loopers Bend Wastewater Treatment Plant, approximately four miles east of Dalton, near the Hwy. 76 Bridge. Another sample location on the Conasauga River was directly south of/and adjacent to the Loopers Bend Wastewater Treatment Plant and LAS site, approximately 4.5 miles southeast of Dalton. The third sample location was approximately 6.5 southeast of Dalton near the Tilton Bridge. The fourth sample location was near the Hwy. 225 Bridge in Resaca, Georgia, approximately 11 miles southeast of Dalton (Figure 1). Three Freshwater Mussels were also caught at three of these four locations; none were found at the Tilton Bridge location. *Several additional species of fish were captured and archived from each site so that they could be analyzed at a later date.* Both the liver and fillet of the fish caught in the river were analyzed for PFOS; however, for the purpose of this health consultation, only the fillet sample results are reviewed for exposure analysis. Sample results are shown in Table 1:

[1] Provisional Health Advisory values are developed to provide information in response to an urgent or rapidly developing situation. They reflect reasonable, health-based hazard concentrations above which action should be taken to reduce exposure to unregulated contaminants in drinking water. They are updated when additional information becomes available and can be evaluated.

Table 1: Mean fish tissue sampling results in parts per billion[1]

Type of Fish	Background site PFOS Concentration	LAS site PFOS Concentration	Tilton Bridge site PFOS Concentration	Resaca site PFOS Concentration
Spotted Bass	2	140	90	180
Blue Catfish	4	18	36	45
Fresh Water Mussels	1.8	2.2	Not found	4

[1] parts per billion: ppb (micrograms per kilogram) of PFOS measured in fish fillet and mussel tissue

Exposure Evaluation

To evaluate potential PFOS exposure doses from eating fish and freshwater mussels caught in the Conasauga River southeast of Dalton, GDPH made an assumption that persons consuming these catches would be recreational freshwater anglers; not the general population. Using the mean concentrations found, and based on fish intake studies conducted by USEPA on recreational freshwater anglers, we used the 95th percentile value fish intake rate of 25,000 milligrams per day (mg/day) for the purpose of our exposure dose calculations. We also assumed that the recreational angler weighed 70 kilograms (kg). Table 2 shows the estimated exposure doses that recreational freshwater anglers may ingest from fish and freshwater mussels caught in the Conasauga River. An explanation on how estimated exposure doses were derived can be found in Appendix A of this document.

Table 2: PFOS Estimated Exposure Doses for Recreational Fresh Water Anglers on the Conasauga River near Dalton, Georgia.

Type of Fish/ Catch Location	Estimated Dose (mg/kg/day)	NOAEL (mg/kg/day)
Spotted Bass		
LAS	0.00005	
Tilton Bridge	0.00003	0.03
Resaca	0.00003	
Blue Catfish		
LAS	0.000006	
Tilton Bridge	0.00001	0.03
Resaca	0.00002	
Fresh Water Mussels		
LAS	0.0000008	
Resaca	0.000001	0.03

mg/kg/day: milligrams per kilogram of body weight per day
NOAEL: No Observed Adverse Effects Level. The highest tested dose of a substance that has been reported to have no harmful (adverse) health effects on people or animals.

GDPH has no evidence that subsistence fishing occurs on the Conasauga River; however, because of the high immigrant population in the Dalton area and as a conservative measure, GDPH made this assumption to calculate potential exposure doses for subsistence anglers. Based on fish intake studies conducted by USEPA on subsistence anglers (for both marine and freshwater fish), we used the 95th percentile value fish intake rate of 170,000 milligrams per day (mg/day) for the purpose of our exposure dose calculations. Table 3 shows the estimated exposure doses that subsistence freshwater anglers may ingest from fish and freshwater mussels caught in the Conasauga River.

Table 3: PFOS Estimated Exposure Doses for Subsistence Fresh Water Anglers on the Conasauga River near Dalton, Georgia.

Type of Fish/ Catch Location	Estimated Dose (mg/kg/day)	NOAEL (mg/kg/day)
Spotted Bass		
LAS	0.0003	0.03
Tilton Bridge	0.0002	
Resaca	0.0004	
Blue Catfish		
LAS	0.00004	0.03
Tilton Bridge	0.00009	
Resaca	0.0001	
Fresh Water Mussels		
LAS	0.000005	0.03
Resaca	0.00001	

mg/kg/day: milligrams per kilogram of body weight per day
NOAEL: No Observed Adverse Effects Level. The highest tested dose of a substance that has been reported to have no harmful (adverse) health effects on people or animals.

Although epidemiological studies of exposure to PFOS and adverse health outcomes in humans are inconclusive at present, several animal toxicological studies have been conducted with PFOS. These include subchronic, developmental/reproductive, and chronic toxicity/carcinogenic studies in several animal species of both sexes. An evaluation of these studies was conducted by the European Food Safety Authority in 2008 and a No Observable Adverse Health Effects Level (NOAEL) and Lowest Observable Health Effects Level (LOAEL) and critical endpoints were identified.

Among these studies, a subchronic toxicity study in Cynomolgus monkeys (Seacat, et. al., 2002) was used by the USEPA Office of Water as the critical study for the derivation for the Provisional Health Advisory for PFOS. In the study by Seacat et. al., groups of male and female monkeys received potassium PFOS orally at doses of 0, 0.03, 0.15, and 0.75 mg/kg/day for 183 days. Compound-related mortality in 2 of 6 male monkeys, decreased body weights, increased liver weights, lowered serum total cholesterol, lowered triiodothyronine (T_3) concentration, and lowered estradiol levels were seen at the highest dose tested. At 0.15 mg/kg/day, increased levels of thyroid-stimulating hormone (TSH) in males, reduced total T_3 levels in males and

females, and reduced levels of high-density lipoproteins (HDL) in females were seen. A NOAEL of 0.03 mg/kg/day was identified in this study.

Because of the availability of limited animal studies (let alone, human studies) on the effects of PFOS, an established health guideline, such as an ATSDR minimal risk level (MRL) or an EPA reference dose (RfD), used to assess whether adverse health impacts from exposure are expected has not been established. The current practice of deriving health guidelines is to identify, usually from animal toxicology experiments, a NOAEL, which indicates that no effects are observed at a particular exposure level. The NOAEL is then modified with an uncertainty (or safety) factor, which reflects the degree of uncertainty that exists when experimental animal data are extrapolated to the human population. The magnitude of the uncertainty factor considers various factors such as sensitive subpopulations (e.g., children, pregnant women, the elderly), extrapolation from animals to humans, and the completeness of the available data. Thus, exposure doses at or below the established health guideline are not expected to cause adverse health effects because these values are much lower (and more human health protective) than doses, which do not cause adverse health effects in laboratory animal studies.

The USEPA used an uncertainty factor of 390 in establishing the provisional health advisory for PFOS to account for interspecies uncertainty, intraspecies uncertainty, and the toxicodynamic and toxicokinetic differences between animals and humans. Using the NOAEL and dividing it by this uncertainty factor of 390, USEPA has established a subchronic RfD of 0.00008 mg/kg/day. Let us compare this dose to the actual exposure doses from fish consumption on the Conasauga River. The exposure doses for a recreational fisherman from consuming fish analyzed in the UGA study would be approximately 2 to 100 times lower than the calculated subchronic RfD. The exposure doses for a subsistence fisherman would be approximately ± 4 to 16 times the calculated subchronic RfD.

However, when using the NOAEL established in the Seacat et. al. study, we find the estimated exposure doses that recreational freshwater anglers would receive from consuming fish caught in the Conasauga River to be approximately 300 to 600 times lower than the NOAEL. Estimated exposure doses from consuming freshwater mussels would be approximately 30,000 to 37,500 times lower than the NOAEL. The estimated exposure doses to subsistence freshwater anglers would be approximately 75 to 750 times lower than the NOAEL, while the estimated exposure doses from consuming freshwater mussels would be approximately 3,000 to 6,000 times lower than the NOAEL. Therefore, GDPH concludes that consumption of fish and freshwater mussels caught in the Conasauga River southeast of Dalton by recreational and subsistence freshwater anglers poses no risk to adverse health effects from this consumption.

Conclusions

Because of the persistent, stable nature of PFOS and PFOA, as well as their presence in the environment over the last 50 to 60 years, exposure to these chemicals is now ubiquitous. The exposure dose contribution from fish and freshwater mussels found in the Conasauga River near Dalton to recreational and subsistence freshwater anglers; however, is not expected to harm

people's health because the estimated exposure doses are many times lower than exposure doses shown to have adverse health effects in many animal studies.

Recommendations

- Recreational freshwater anglers should follow the 'Guidelines for Eating Fish from Georgia Waters' published by the Georgia Department of Natural Resources (DNR). Georgia has one of the most extensive fish monitoring programs in the southeast. Review and comparison of data collected nationally on fish tissue contamination that the U.S. Environmental Protection Agency (USEPA) has assembled shows the quality of fish in Georgia is similar to that in surrounding southeastern states. The 'Guidelines' can be found on the DNR website: http://www.dnr.org.

- The 'Guidelines' for the Conasauga River (Coosa River Basin) make a recommendation of no more than 1 meal/week for Spotted Bass and depending on the size of Blue Catfish, no more than 1 meal/week or 1 meal/month. Mercury and PCBs are the chemicals of concern measured on the Conasauga River

If you have any further question regarding this health consultation, please contact Franklin Sanchez at (404) 657-6534 or Leighann Gaines at (706) 295-6569.

Sincerely,

Leighann Gaines,
District Risk Communicator
Northwest Georgia Health District 1-1

C: Randy Manning, PhD
Environmental Toxicology Coordinator, Georgia Environmental Protection Division

Ray King
District Environmental Health Director, Northwest Georgia Health District 1-2

References

1. U. S. Environmental Protection Agency. *Sampling Investigation Trip Report of North Georgia Public Water Suppliers, Perfluorinated Compounds Study.* April 28, 2009.

2. U. S. Environmental Protection Agency. *Laboratory Report, Dalton, Georgia Water Supply Analysis.* July 2009.

3. University of Georgia. *Perfluorinated Compounds Results Summary for Freshwater Fish and Mussels Caught in the Conasauga River.* September 17, 2009.

4. Agency for Toxic Substances and Disease Registry. *ToxTAQ's: Perfluoroalkyls.* May 2009.

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6. U. S. Environmental Protection Agency. *Provisional Health Advisories for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS).* January 9, 2009.

7. U. S. Environmental Protection Agency. *Exposure Factors Handbook.* Volumes 1,2, and 3. 1997. Available at: http://www.epa.gov/ncea/pdfs/efh/front.pdf.

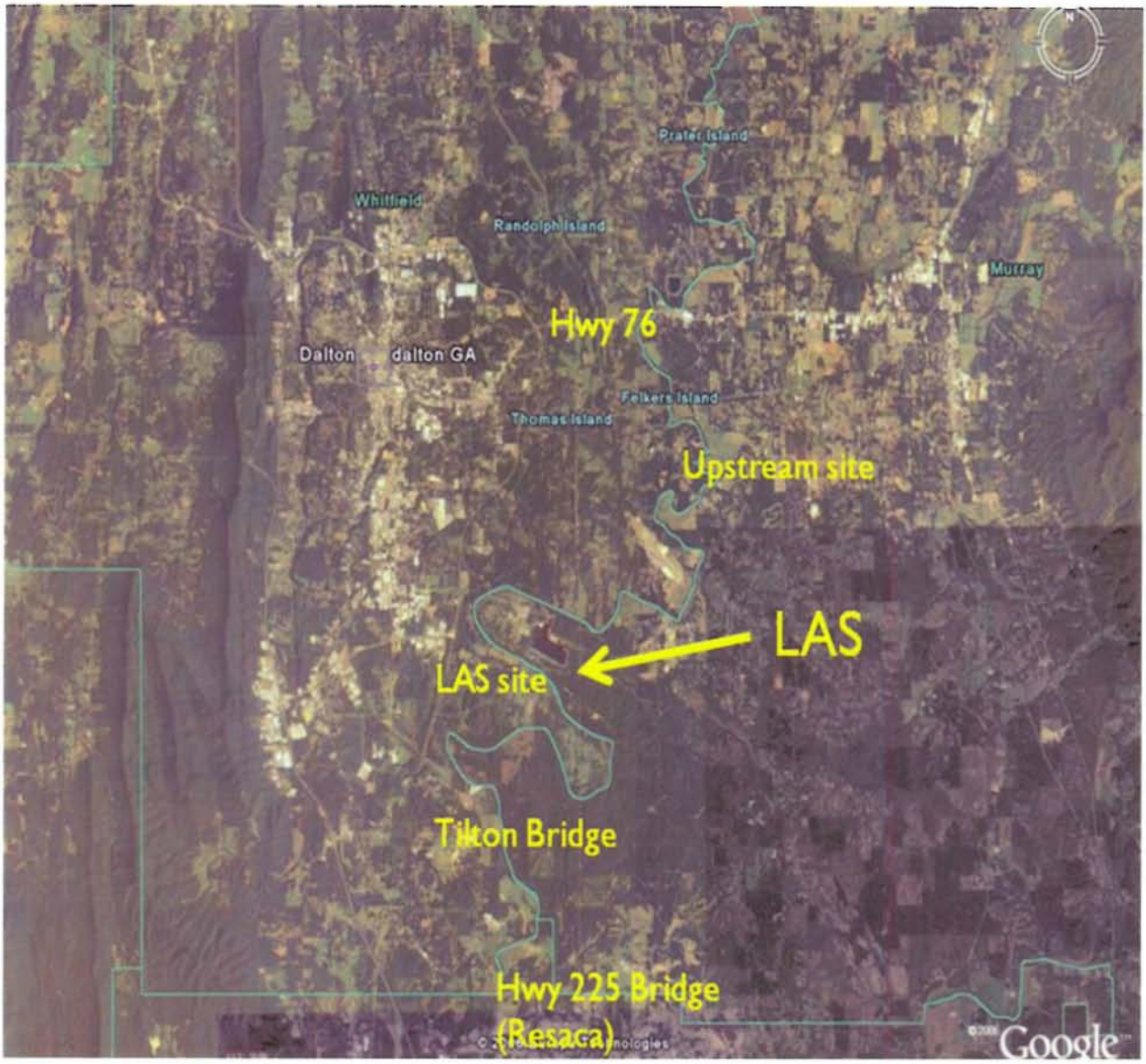
8. Agency for Toxic Substances and Disease Registry, *Public Health Assessment Guidance Manual (update).* January 2005.

9. Seacat AM, Thomford PJ, Hansen KJ, et. al. (2020). *Subchronic toxicity studies on perfluorooctanesulfonate potassium salt in Cynomolgus monkeys.* Toxicol. Sci. 68, 249-264.

Division of Public Health

M. Rony Francois, MD, MSPH, PhD, Director of Public Health and State Health Officer ♦ Phone: 404-657-2700 ♦ Fax: 404-657-2715

Figure 1: Fish sampling sites



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APPENDIX A: Explanation of Toxicological Evaluation

Step 1--The Screening Process

In order to evaluate the available data, GDPH used comparison values (CVs) to determine which chemicals to examine more closely. CVs are contaminant concentrations found in a specific environmental media (for example: air, soil, or water) and are used to select contaminants for further evaluation. CVs incorporate assumptions of daily exposure to the chemical and a standard amount of air, soil, or water that someone may inhale or ingest each day. CVs are generated to be conservative and non-site specific. The CV is used as a screening level during the health consultation process where substances found in amounts greater than their CVs might be selected for further evaluation. CVs are not intended to be environmental clean-up levels or to indicate that health effects occur at concentrations that exceed these values.

CVs can be based on either carcinogenic (cancer-causing) or non-carcinogenic effects. Cancer-based CVs are calculated from the U.S. Environmental Protection Agency's (EPA) oral cancer slope factors for ingestion exposure, or inhalation risk units for inhalation exposure. Non-cancer CVs are calculated from ATSDR's minimal risk levels, EPA's reference doses, or EPA's reference concentrations for ingestion and inhalation exposure. When a cancer and non-cancer CV exist for the same chemical, the lower of these values is used as a conservative measure. The chemical and media-specific CVs used in the preparation of this health consultation are listed below:

Step 2--Evaluation of Public Health Implications

The next step in the evaluation process is to take those contaminants that are above their respective CVs and further identify which chemicals and exposure situations are likely to be a health hazard. Separate child and adult exposure doses (or the amount of a contaminant that gets into a person's body) are calculated for site-specific scenarios, using assumptions regarding an individual's likelihood of accessing the site and contacting contamination. A brief explanation of the calculation of estimated exposure doses used in this health consultation are presented below. Calculated doses are reported in units of milligrams per kilogram per day (mg/kg/day).

Consumption of contaminants present some types of fish on the Conasauga River

Exposure doses for the consumption of contaminants present in fish were calculated using the average detected concentrations of contaminants in micrograms per (ug/kg [same as ppb]). The following equation is used to estimate the exposure doses resulting from ingestion of contaminated fish:

$$ED_F = \frac{C \times IR \times EF \times CF}{BW}$$

where;

ED_F = exposure dose from eating fish (mg/kg/day)
C = contaminant concentration (mg/kg)
IR = intake rate of contaminated medium (based on the 95th percentile nationwide for recreational freshwater anglers).
EF = exposure factor (based on frequency of exposure, exposure duration, and time of exposure). The exposure factor used for the purpose of this analysis was one. This is the most conservative exposure factor assuming exposure is occurring 24 hours per day, 7 days per week.
CF = conversion factor (10^{-6} kg/mg)
BW = body weight (based on average rates for adults: 70 kg

Non-cancer Health Risks

The doses calculated for exposure to individual chemicals are then compared to an established health guideline, such as an ATSDR minimal risk level (MRL) or an EPA reference dose (RfD), in order to

assess whether adverse health impacts from exposure are expected. Health guidelines are chemical-specific values that are based on available scientific literature and are considered protective of human health. Non-carcinogenic effects, unlike carcinogenic effects, are believed to have a threshold, that is, a dose below which adverse health effects will not occur. As a result, the current practice to derive health guidelines is to identify, usually from animal toxicology experiments, a no observed adverse effect level (NOAEL), which indicates that no effects are observed at a particular exposure level. This is the experimental exposure level in animals (and sometimes humans) at which no adverse toxic effect is observed. The known toxicological values are doses derived from human and animal studies that are summarized in ATSDR's *Toxicological Profiles (www.atsdr.cdc.gov/toxpro2.html)*. The NOAEL is modified with an uncertainty (or safety) factor, which reflects the degree of uncertainty that exists when experimental animal data are extrapolated to the human population. The magnitude of the uncertainty factor considers various factors such as sensitive subpopulations (e.g., children, pregnant women, the elderly), extrapolation from animals to humans, and the completeness of the available data. Thus, exposure doses at or below the established health guideline are not expected to cause adverse health effects because these values are much lower (and more human health protective) than doses, which do not cause adverse health effects in laboratory animal studies.

For non-cancer health effects, the following health guidelines were used in this health consultation:

Minimal Risk Levels (MRLs) are developed by ATSDR for contaminants commonly found at hazardous waste sites. The MRL is developed for ingestion and inhalation exposure, and for lengths of exposures: acute (less than 14 days); intermediate (between 15-364 days), and chronic (365 days or greater). ATSDR has not developed MRLs for dermal exposure (absorption through skin).

If the estimated exposure dose to an individual is less than the health guideline value, the exposure is unlikely to result in non-cancer health effects. If the calculated exposure dose is greater than the health guideline, the exposure dose is compared to known toxicological values for the particular chemical and is discussed in more detail in the text of the health consultation. A direct comparison of site-specific exposures and doses to study-derived exposures and doses found to cause adverse health effects is the basis for deciding whether health effects are likely to occur.

It is important to consider that the methodology used to develop health guidelines does not provide any information on the presence, absence, or level of cancer risk. Therefore, a separate cancer risk evaluation is necessary for potentially cancer-causing contaminants detected at this site.

Cancer Risks

Exposure to a cancer-causing chemical, even at low concentrations, is assumed to be associated with some increased risk for evaluation purposes. The estimated risk for developing cancer from exposure to contaminants associated with the site was calculated by multiplying the site-specific doses by EPA's chemical-specific cancer slope factors (CSFs) available at *www.epa.gov/iris*. This calculation estimates a theoretical excess cancer risk expressed as a proportion of the population that may be affected by a carcinogen during a lifetime of exposure. For example, an estimated risk of 1×10^{-6} predicts the probability of one additional cancer over background in a population of 1 million. An increased lifetime cancer risk is not a specified estimate of expected cancers. Rather, it is an estimate of the increase in the probability that a person may develop cancer sometime in his or her lifetime following exposure to a particular contaminant under specific exposure scenarios. For children, the theoretical excess cancer risk is not calculated for a lifetime of exposure, but from a fraction of lifetime; based on known or suspected length of exposure, or years of childhood.

CERTIFICATION

This letter health consultation was prepared by the Georgia Division of Public Health under a cooperative agreement with the federal Agency for Toxic Substances and Disease Registry (ATSDR). It was completed in accordance with approved methodologies and procedures existing at the time the health consultation was initiated. Editorial Review was completed by the Georgia Division of Public Health.

Technical Project Officer, CAT, CAPEB, DHAC

The Division of Health Assessment and Consultation (DHAC), ATSDR, has reviewed this health consultation and concurs with its findings.

Team Lead, CAT, CAPEB, DHAC, ATSDR