

**Characterization of Potential Adverse Health Effects Associated
with Consuming Fish from**

Lake Madisonville

Madisonville, Madison County, Texas

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**Department of State Health Services
Division for Regulatory Services
Policy, Standards, and Quality Assurance Unit
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and
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INTRODUCTION

Description of Lake Madisonville

Lake Madisonville—also, known as Lake Madison—is a 64-acre community fishing lake located within the city of Madisonville in Madison County, Texas.¹ Lake Madisonville is open year-round and has sheltered picnic areas, restrooms, and a playground. For recreational fishing – an apparently common activity – the lake presents a public boat ramp and a fishing pier. It offers a variety of fish species, including sunfish, channel catfish, and largemouth bass. In 1980 and 1981, the Texas Parks and Wildlife Department (TPWD) stocked Lake Madisonville with Florida largemouth bass. The TPWD last stocked Lake Madisonville with channel catfish in 1991.²

Demographics of Madison and Walker Counties near Lake Madisonville

In 2007, the census bureau reported the population of Madison County to be 13,379 people.³ Located in central East Texas, about one hundred miles northwest of Houston,⁴ Madisonville is the seat of county government for Madison County, TX. Although small, Madisonville is the county's largest town, with an estimated population in 2007 of 4,366.^{4,5} Huntsville, TX, in Walker County (2007 population estimate 63,902 up from 61,758 in the 2000 decennial census)⁶ is approximately twenty miles south of Madisonville. Huntsville's student and permanent populations (Sam Houston State University enrollment 16,416)⁷ are approximately 51,000+ strong (35,000+ are permanent residents of Huntsville),⁸ inferring an even larger number of potential fishers in nearby areas and, thus, a larger potential “at risk” population – should people from Huntsville catch and eat fish from Lake Madisonville – than might be expected if one considers only the populations of Madisonville, TX and Madison County.

Subsistence Fishing at Lake Madisonville

The United States Environmental Protection Agency (EPA) suggests that, along with ethnic characteristics and cultural practices of an area's population, the poverty rate could contribute to any determination of the rate of subsistence fishing in an area.⁹ The EPA and the DSHS believe it important to consider subsistence fishing to occur at any water body because subsistence fishers (as well as recreational anglers and certain tribal and ethnic groups) usually consume more locally caught fish than the general population. These groups sometimes harvest fish or shellfish from the same water body over many years to supplement caloric and protein intake. If these local water bodies contain chemically contaminated fish or shellfish, people who routinely eat seafood from the water body or people who eat large quantities of fish or shellfish from the same waters, could increase their risk of adverse health effects. In the absence of definitive data on a particular water body, the EPA suggests that states assume that at least 10% of *licensed* fishers in any area are subsistence fishers. Recreational fishing at Lake Madisonville is encouraged, as shown by historical stocking practices.² Subsistence fishing, while not explicitly documented by the DSHS, likely occurs. The DSHS assumes the rate of subsistence fishing to be similar to that estimated by the EPA.⁹

History of the Tier 2 Mercury in East Texas Water Bodies Project

Three Texas agencies, the Department of State Health Services (DSHS), the Texas Commission on Environmental Quality (TCEQ), and the TPWD, have critical interests in – and responsibilities for – contaminants in the waters of Texas, their sediments, and the fish and shellfish that inhabit those waters. The Seafood and Aquatic Life Group (SALG) at DSHS determines whether chemical contaminants in fish or shellfish pose a health risk to those who would consume those fish or shellfish and – if so – is responsible for issuing health advisories or prohibiting possession of contaminated fish or shellfish from public water bodies in Texas.¹⁰ Among its other duties, the TCEQ establishes and manages water quality standards for the state and addresses pollution of Texas' public waters. The TPWD manages state fish and wildlife resources, addresses pollution that may adversely affect these resources, and enforces closures or bans issued by DSHS. These, and several other state and federal agencies, coordinate oversight of contaminant monitoring of Texas waters – and their flora and fauna – through regular meetings of the Toxic Substances Coordinating Committee (TSCC), a legislatively mandated interagency committee.¹¹

The *Tier 2 Mercury in East Texas Water Bodies Project* is a two-stage project that accesses the expertise and resources of the TCEQ, the TPWD, and the DSHS.¹² The DSHS conducts Tier 2 studies to characterize the potential human health risks associated with consumption of fish found during Tier 1 studies to contain chemical contaminants in excess of that agency's screening values. Although the DSHS may initiate Tier 1 studies, the TCEQ and/or the TPWD more likely launch the initial studies (Tier 1 studies) on a water body. The EPA financed the *Tier 2 Mercury in East Texas Water Bodies* project through fiscal year 2008 (ending December 31, 2008). The EPA funds were administered by the TCEQ. Most of the EPA grant funds for this project paid for laboratory analysis of fish tissue for chemical contaminants that, upon regular consumption of doses exceeding those unlikely to affect human health (doses represented by reference doses (RfDs) or minimal risk levels (MRLs), could adversely influence the health of individuals or populations.

Tier 1 studies were conducted by the TPWD Inland Fisheries Division^a Contaminants Assessment Team (IFDCAT) as part of a special three-year investigation of East Texas waters (see next paragraph) and by TCEQ during normal field operations. The DSHS, TPWD, and/or TCEQ selected for inclusion in the Tier 2 study those water bodies that yielded fish samples containing mercury in excess of the DSHS' mercury screening criterion (0.525 mg/kg).

In 1999, the TPWD Contaminants Assessment Team began a three-year study of sixty (60) reservoirs in fifty-seven (57) East Texas counties, the primary objectives of which were to delineate the geographical extent of mercury bioaccumulation in fish and to investigate biotic and abiotic factors associated with mercury bioaccumulation in fish.¹³ The TPWD selected East Texas as the study area because the Piney Woods and Oak Woodlands ecoregions have water, soil, and terrestrial plant communities that historically have correlated with mercury bioaccumulation in fish tissues. In addition to primary objectives, the study identified water bodies having mercury-contaminated fish in which mercury concentrations exceeded human health risk screening criteria.

^a (formerly the TPWD Resource Protection Division)

In 2000, the TPWD sampled fish from Lake Madisonville as a part of the above-outlined study.¹³ TPWD collected ten largemouth bass samples ranging in length from 13.9 to 17.0 inches. The TPWD laboratory in San Marcos, TX analyzed those samples for mercury. The DSHS and TCEQ compared the Lake Madisonville mercury concentrations to the DSHS-established human health mercury screening value (SV), which revealed that largemouth bass from Lake Madisonville contained an average mercury concentration (0.730 mg/kg) that exceeded the DSHS human health screening value (0.525 mg mercury/kg fish tissue). Based on these results, the DSHS and the TCEQ decided to include Lake Madisonville in a Tier 2 study to examine more intensively fish from the lake for chemical contaminants – in addition to mercury – that can result in adverse health effects.

Pursuant to the decision generated by data from the TPWD Tier 1 study of Lake Madisonville, the DSHS sampled this community fishing lake in January and March of 2001 to assess the potential public health risks of consuming fish from this small city lake. During the 2001 survey, the DSHS collected 22 fish consisting of 16 largemouth bass, four channel catfish, and two white crappies. Because of the existing 14-18 inch slot length limit for largemouth bass imposed by TPWD, the DSHS did not use seven of the 16 largemouth bass samples collected in 2001 to make public health-related decisions about the advisability of consuming this species from Lake Madisonville. The 2001 risk characterization revealed that, at the time, consumption of channel catfish, white crappie, and smaller largemouth bass (≤ 14 inches) from Lake Madisonville posed no apparent risk to human health. In the 2001 study, the DSHS did not examine largemouth bass ≥ 18 inches in length. Therefore, in the 2001 risk characterization, the SALG recommended that the DSHS SALG team return to Lake Madisonville to collect largemouth bass ≥ 18 inches in length. Those fish would be used to determine whether largemouth bass of this size contained mercury in excess of the health assessment comparison value (HAC_{nonca}) used by the DSHS to estimate the likelihood of systemic (noncarcinogenic) effects of consuming mercury in fish (0.700 mg/kg).

The SALG team returned in 2006-2007 to reassess fish from Lake Madisonville for the presence and concentrations of mercury and other contaminants that could affect human health. The present report summarizes the results of the 2006-2007 Tier 2 evaluation of largemouth bass from Lake Madisonville. This document addresses public health implications, if any, of consuming fish from the lake – particularly largemouth bass – and suggests potential actions to protect humans from possible adverse health effects of consuming chemically contaminated fish from this small community fishing lake.

METHODS

Fish Sampling, Preparation, and Analysis

The DSHS SALG collects and analyzes edible fish from the state's public waters to evaluate potential risks to the health of people consuming contaminated fish or shellfish. Fish tissue sampling follows standard operating procedures from the DSHS *Seafood and Aquatic Life Group Survey Team Standard Operating Procedures and Quality Control/Assurance Manual*.¹⁴ The SALG bases its sampling and analysis protocols, in part, on procedures recommended by the EPA in that agency's *Guidance for Assessing Chemical Contaminant Data for Use in Fish*

*Advisories, Volume 1.*¹⁵ Advice and direction are also received from the legislatively mandated *State of Texas Toxic Substances Coordinating Committee Fish Sampling Advisory Subcommittee (FSAS)*.¹⁶ Samples usually represent species, trophic levels, and legal-sized specimens available for consumption from a water body. When practical, the DSHS collects samples from two or more sites within a water body to better characterize geographical distributions of contaminants.

Fish Sampling Methods and Description of the Lake Madisonville 2006-2007 Sample Set

In July 2006 and April 2007, SALG staff collected 30 fish samples from Lake Madisonville. Risk assessors used data from these fish to assess the potential for adverse human health outcomes from consuming fish from this lake.

Because Lake Madisonville – at 64 acres – is small, the SALG did not select discrete sample sites to provide spatial coverage of the study area. Instead, the group utilized the entire lake as a single “site” (Figure 1). Species collected represent a distinct ecological group (predators) that have some potential to bio-accumulate mercury and, perhaps, other chemical contaminants; have a wide geographic distribution; are of local recreational fishing value; or that anglers and their families commonly consume. The 30 fish collected from Lake Madisonville in July 2006 and April 2007 consisted of the one species suggested in the 2001 risk characterization as important for a complete picture of risk associated with consumption of fish from Lake Madisonville – largemouth bass (Table 1).

The SALG utilized a boat-mounted electrofisher to collect fish. SALG staff conducted electrofishing activities during daylight hours, using pulsed direct current (Smith Root 5.0 GPP electrofishing system settings: 6.0-8.0 amps, 60 pulses per second [pps], low range 50-500 volts, 80% duty cycle) to stun fish that crossed the electric field in the water in front of the boat. Staff used dip nets over the bow of the boat to retrieve stunned fish, netting only fish pre-selected as target samples. Staff immediately stored retrieved samples on wet ice in large coolers to enhance tissue preservation.

SALG staff processed fish onsite at Lake Madisonville. The SALG team weighed each sample to the nearest gram on an electronic scale and measured total length (tip of nose to tip of tail fin) to the nearest millimeter. After weighing and measuring a fish, the team used a cutting board covered with aluminum foil and a fillet knife to prepare two skin-off fillets from each fish. The foil was changed and the filleting knife cleaned with distilled water after each sample was processed. The fillet(s) were wrapped in two layers of fresh aluminum foil, placed in a clean, previously unused, pre-labeled plastic freezer bag and stored on wet ice in an insulated chest until final processing. The SALG staff transported tissue samples on wet ice to their Austin, TX, headquarters, where the samples were stored temporarily at -5° Fahrenheit (-20° Celsius) in a locked freezer. The freezer key is accessible only to authorized SALG staff members to ensure the chain of custody remains intact while samples are in the possession of agency staff. The week following each collection trip, the SALG shipped frozen fish tissue samples by commercial carrier for contaminant analysis by the Geochemical and Environmental Research Group (GERG) Laboratory at Texas A&M University, College Station, TX.

Analytical Laboratory Information

Upon the samples' arrival at the laboratory, GERG personnel notified the SALG of receipt of the 30 Lake Madisonville samples, also recording the condition of each sample and its DSHS identification number.

Using established EPA methods, the GERG laboratory analyzed fish fillets from Lake Madisonville for many inorganic and organic contaminants commonly identified in polluted environmental media. Analyses included seven metals (arsenic, cadmium, copper, lead, total mercury, selenium, and zinc), 123 semivolatile organic compounds (SVOCs), 71 volatile organic compounds (VOCs), 34 pesticides, and 209 PCB congeners. The laboratory analyzed all 30 samples for mercury. The laboratory also analyzed four of the original 30 samples for metals, pesticides, polychlorinated biphenyls (PCBs), SVOCs, and VOCs.¹⁷

Specific Details of Some Analyses with Explanatory Notes

Arsenic

The GERG laboratory analyzed each of four fish for total (inorganic arsenic + organic arsenic = total arsenic) arsenic. Although the proportions of each form of arsenic may differ among species, under different environmental and water conditions, and, perhaps, with other variables, the literature suggests that well over 90% of arsenic in fish is likely organic arsenic – a form of arsenic that is virtually non-toxic to humans.¹⁸ DSHS, taking a conservative approach, estimates 10% of the total arsenic in any fish is inorganic arsenic, deriving estimates of inorganic arsenic concentrations by multiplying reported total arsenic concentration in each fish by a factor of 0.1.¹⁸

Mercury

Nearly all mercury in upper trophic level fish three years of age or older is methylmercury.¹⁹ Thus, total mercury concentrations in upper trophic level fish of legal size for possession in Texas should serve well as surrogates for methylmercury concentration. Because methylmercury analyses are difficult to perform accurately and are more expensive than total mercury analyses, the EPA recommends that states determine total mercury concentration in a fish and that – to protect human health – the state assumes that 100% of reported mercury in fish or shellfish is methylmercury. The GERG laboratory analyzed fish tissues for total mercury. In its risk characterizations, DSHS compares mercury in tissues to a comparison value derived from the ATSDR's minimal risk level for methylmercury.²⁰ In its risk characterizations, the DSHS may interchangeably utilize the terms “mercury,” “methylmercury,” or “organic mercury” to refer to methylmercury in fish.

Polychlorinated Biphenyls (PCBs)

The EPA suggests that each state measures congeners of PCBs in fish and shellfish rather than homologs or Aroclors[®] because the federal agency considers congener analysis the most sensitive technique for detecting PCBs in environmental media.¹⁷ Although only about 130 PCB

congeners were routinely present in PCB mixtures manufactured and commonly used in the U.S., the GERG laboratory analyzes and reports the presence and concentrations of all 209 possible PCB congeners. From the congener analyses, the laboratory also computes and reports concentrations of PCB homologs and of Aroclor[®] mixtures. Despite EPA's suggestion that the states utilize PCB congeners for toxicity estimates, the toxicity literature does not reflect this state-of-the-art laboratory science. To accommodate the inconsistency, the DSHS utilizes recommendations from the National Oceanic and Atmospheric Administration (NOAA),²¹ from McFarland and Clarke,²² and from the EPA's guidance documents for assessing chemical contaminants in fish and shellfish^{15, 17} to address PCB congeners in fish and shellfish samples. The preceding references recommend using a composite of 43 specific congeners, each chosen for its likelihood of occurrence in fish, the likelihood of significant toxicity of the congener – based on structure-activity relationships – and for the relative environmental abundance of the congeners.^{21, 22} SALG risk assessors – as suggested by the EPA and others – sum the 43 congeners to derive a “total” PCB concentration in each sample. Assessors then average the summed congeners within each variable (e.g., species, site, or combination of site and species) to derive a mean PCB concentration for variables of interest.

Using only a few PCB congeners to determine “total PCB concentrations” could conceivably underestimate PCB tissue levels. Nonetheless, the method complies with expert recommendations on evaluation of PCBs in fish or shellfish. Therefore, SALG risk assessors compare average concentrations of the 43 congeners with HAC values derived from information from the EPA's Integrated Risk Information System (IRIS) database on PCB mixtures.²³ As of yet, IRIS does not contain information on the systemic toxicity of individual PCB congeners. Instead, the database contains systemic toxicity information for five Aroclor[®] mixtures: Aroclors[®] 1016, 1242, 1248, 1254, and 1260. Not all information is available for all named mixtures; for instance, IRIS contains RfDs for only two Aroclor mixtures – Aroclor 1016, a commercial mixture devoid of dibenzofurans, and Aroclor 1254. Systemic toxicity estimates in the present document reflect comparisons derived from the RfD for Aroclor 1254 because Aroclor 1254 was more commonly used than was 1016, a relative late-comer to the PCB mixtures used in the United States.

For assessment of cancer risk from exposure to PCBs, the SALG uses the EPA's highest slope factor of 2.0 per (mg/kg/day) to calculate the probable lifetime excess cancer risk from PCB ingestion. The SALG based its decision to use the most restrictive slope factor available for PCBs on factors such as food chain exposure, the presence of dioxin-like, tumor-promoting, or persistent congeners, and the likelihood of early-life exposure.²³

Derivation and Application of Health-Based Assessment Comparison Values (HAC_{nonca}) for Systemic (noncarcinogenic) Effects of Consumed Chemical Contaminants

The effects of exposure to any hazardous substance depend, among other factors, on the dose, the route of exposure, the duration of exposure, the manner in which the exposure occurs, the genetic makeup, personal traits, and habits of the exposed, and the presence of other chemicals.²⁴ People who regularly consume contaminated fish or shellfish conceivably suffer repeated low-dose exposures to contaminants in fish or shellfish over extended periods (episodic exposures to low

doses). Such exposures are unlikely to result in acute toxicity but may increase risk of subtle, chronic, and/or delayed adverse health effects that include cancer, benign tumors, birth defects, infertility, blood disorders, brain damage, peripheral nerve damage, lung disease, and kidney disease, to name but a few.²⁴ If diverse species of fish or shellfish is available, the SALG presumes that people eat a variety of species from a water body. Further, SALG risk assessors at DSHS assume that most fish species are mobile. SALG risk assessors may combine data from different fish species, blue crab, and/or sampling sites within a water body to evaluate mean contaminant concentrations of toxicants in all samples as a whole. This approach intuitively reflects consumers' likely exposure over time to contaminants in fish or shellfish from any water body, but may not reflect the reality of exposure at a specific water body or a single point in time. The DSHS reserves the right to project risks associated with ingestion of individual species of fish or shellfish from separate collection sites within a water body or at higher than average concentrations (e.g. the upper 95 percent confidence limit on the mean). The SALG derives confidence intervals from Monte Carlo simulations using software developed by Richard Beauchamp, MD, a DSHS medical epidemiologist.²⁵ The group evaluates contaminants in fish or shellfish by comparing the mean or the 95% upper confidence limit on the average concentration of a contaminant to its HAC value (in mg/kg) for non-cancer or cancer endpoints.

In deriving HAC_{nonca} values for systemic effects, the SALG assumes a standard adult weighs 70 kilograms and consumes 30 grams of fish or shellfish per day (about one 8-ounce meal per week) and uses the EPA's oral RfD²⁶ or the Agency for Toxic Substances and Disease Registry's (ATSDR) chronic oral minimal risk levels (MRLs).²⁷ The EPA defines an RfD as

*An estimate of a daily oral exposure for a given duration to the human population (including susceptible subgroups) that is likely to be without an appreciable risk of adverse health effects over a lifetime.*²⁸

The EPA also states that the RfD

*... is derived from a BMDL (benchmark dose lower confidence limit), a NOAEL (no observed adverse effect level), a LOAEL (lowest observed adverse effect level), or another suitable point of departure, with uncertainty/variability factors applied to reflect limitations of the data used. [Durations include acute, short-term, subchronic, and chronic and are defined individually in this glossary] and RfDs are generally reserved for health effects thought to have a threshold or a low dose limit for producing effects.*²⁸

The ATSDR uses a similar technique to derive its MRLs.²⁷ The DSHS compares the estimated daily dose (calculated in mg/kg/day as: $\text{Dose (mg/kg/day)} = \text{concentration of toxicant in sample (mg/kg)} * \text{daily consumption (kg/day)} / \text{body weight (kg)}$ – derived from the mean of the measured concentrations of a contaminant – to the contaminant's RfD or MRL, using hazard quotient (HQ) methodology as suggested by the EPA.

A HQ, defined by the EPA, is

*...the ratio of the estimated exposure dose of a contaminant (mg/kg/day) to the contaminant's RfD or MRL (mg/kg/day).*²⁹

Note that, according to the EPA, a linear increase in the HQ for a toxicant does not imply a linear increase in the likelihood or severity of systemic adverse effects. Thus, a HQ of 4.0 does not mean the concentration in the dose will be four times as toxic as that same substance would be if the HQ were equal to 1.0. An HQ of 4.0 also does not imply that adverse events will occur four times as often as if the HQ for the substance in question were 1.0. Rather, the EPA suggests that risk assessors interpret an HQ or a HI that computes to less than 1.0 as "no cause for concern" whereas an HQ or HI greater than 1.0 "should indicate some cause for concern." Therefore, the SALG does not utilize HQs to determine the likelihood of occurrence of adverse systemic health effects. Instead, in a manner similar to the EPA's decision process, the SALG may utilize computed HQs as a point of departure for management decisions – assuming, for instance, that HQs less than 1.0 are unlikely to be an issue while HQs greater than 1.0 might suggest that a regulatory action could be taken to ensure protection of public health. Similarly, risk assessors at the DSHS may utilize an HQ to determine the need for further study of a water body's fauna. Notwithstanding the above discussion, the oral RfD derived by the EPA represents chronic consumption. Thus, regularly eating fish containing a toxic chemical, the HQ of which is less than 1 is unlikely to cause adverse systemic health effects, whereas routine consumption of fish or shellfish in which the HQ exceeds 1 represents a qualitatively unacceptable increase in the likelihood of systemic adverse health outcomes.

Although, as advised by the EPA, the DSHS preferentially utilizes the RfD calculated by federal scientists for a specifically named contaminant, should an RfD not be available for a contaminant, the EPA advises risk assessors to consider using the RfD (or an MRL) for a contaminant of similar molecular structure, or one of similar mode or mechanism of action. For instance, an RfD is not available for Aroclor[®] 1260, so the DSHS uses the RfD for Aroclor 1254 to assess the likelihood of systemic or noncarcinogenic effects of Aroclor 1260, which contains congeners overlapping those of Aroclor 1254.²⁷

In developing oral RfDs and MRLs, federal scientists review the extant literature to devise NOAELs, LOAELs, or BMDs from experimental studies. Uncertainty factors are then utilized to minimize potential systemic adverse health effects in people who are exposed through consumption of contaminated materials by accounting for certain conditions that may be undetermined by the experimental data: extrapolation from animals to humans (interspecies variability), intra-human variability, use of a subchronic study rather than a chronic study to determine the NOAEL, LOAEL, or BMD, and database insufficiencies.^{26,28} Vulnerable groups such as women who are pregnant or lactating, women who may become pregnant, infants, children, people with chronic illnesses, those with compromised immune systems, the elderly, or those who consume exceptionally large servings – all groups that risk assessors and the EPA consider sensitive groups – also receive special consideration in calculation of an RfD.^{28,30}

The primary method for assessing the toxicity of component-based mixtures of chemicals in environmental media is the HI. The EPA recommends HI methodology for groups of toxicologically similar chemicals. Although knowing the mode or mechanism of action of chemicals of interest, such information is often missing. The lack of this information often forces risk assessors to use "similarity of target organs" as the definition of "toxicological similarity." The default procedure for calculating the HI for the exposure mixture chemicals is to add the

HQs (HQ = the ratio of the external exposure dose to the RfD) for all component chemicals affecting the same target organ.

Summing HQs approximates the value the mixture's "hazard quotient" likely would have taken if all chemicals in the mixture could have been simultaneously tested (as if the mixture was a single chemical). For example, the HI for liver toxicity should approximate the degree of liver toxicity likely to have been present if effects of the whole mixture were due to a single chemical. Target organs addressed by the HIs should be decided for each particular mixture assessment and a separate HI calculated for each toxic effect of concern. The mixture components to be included in the HI calculation are any chemical components showing the effect described by the HI, regardless of the critical effect from which the RfD is derived. A note of caution: because the RfD is derived for the critical effect – the "toxic effect occurring at the lowest dose of a chemical" – an HI computed from HQs derived from RfDs may be overly conservative, thereby resulting in an exaggeration of health risk from consumption of the mixture of chemicals.

The EPA states that

the HI is a quantitative decision aid that requires toxicity values as well as exposure estimates. When each organ-specific HI for a mixture is less than 1 and all relevant effects have been considered in the assessment, the exposure being assessed for potential systemic toxicity should be interpreted as unlikely to result in significant toxicity.

And

When any effect-specific HI exceeds 1, concern exists over potential toxicity. As more HI's for different effects exceed 1, the potential for human toxicity also increases.

Thus,

Concern should increase as the number of effect-specific HI's exceeding 1 increases. As a larger number of effect-specific HI's exceed 1, concern over potential toxicity should also increase. As with HQs, this potential for risk is not the same as probabilistic risk; a doubling of the HI does not necessarily indicate a doubling of toxic risk.

Derivation and Application of Health-Based Assessment Comparison Values for Application to the Carcinogenic Effects of Consumed Chemical Contaminants

The DSHS calculates HAC_{ca} values from the EPA's chemical-specific cancer potency factors (CPFs) – also known as slope factors (SFs) – derived through mathematical modeling from carcinogenicity studies. For carcinogenic outcomes, the DSHS calculates a theoretical lifetime excess risk of cancer from exposure to specific carcinogens, using the standard 70-kg body weight and the assumption that an adult consumes 30 grams of edible tissue per day. To these assumptions, SALG risk assessors utilize two additional factors to determine theoretical lifetime

excess cancer risk: (1) an acceptable lifetime risk level (ARL)²⁸ of one excess cancer case in 10,000 persons whose average daily exposure is equivalent and (2) daily exposure for 30 years. Comparison values used to assess the probability of increases in background cancer rate do not contain “uncertainty” factors as such. However, conclusions drawn from comparisons of fish tissue toxicant concentrations with HAC_{ca} values derived from probability determinations infer substantial safety margins for all people by virtue of the models utilized to derive the slope factors (cancer potency factors) used to calculate the HAC_{ca}.

Because comparison values are conservative, exceeding a HAC value does not necessarily mean adverse health effects will occur. The perceived strict demarcation between acceptable and unacceptable exposures or risks is primarily a *tool* that is used, along with other information, by risk managers to make decisions about the degree of risk incurred by those who consume contaminated fish or shellfish. Moreover, comparison values for adverse health effects do not represent sharp dividing lines (“bright-line” divisions) between safe and unsafe exposures. For example, the DSHS considers it unacceptable when consumption of four or fewer meals per month of contaminated fish or shellfish would result in exposure to contaminant(s) in excess of a HAC value or other measure of risk, but does not necessarily expect such exposures to produce negative health effects. The DSHS also uses other measures to help people minimize their exposures. For instance, the DSHS advises people who wish to minimize exposure to contaminants in fish or shellfish to eat a variety of fish and/or shellfish, to eat smaller and younger fish, and to limit consumption of those species most likely to contain toxic contaminants. The DSHS aims to protect vulnerable subpopulations with its consumption advice, assuming that advice protective of vulnerable subgroups will also protect the general population from potential adverse health effects associated with consumption of contaminated fish or shellfish.

Children’s Health Considerations

The DSHS recognizes that fetuses, infants, and children may be uniquely susceptible to the effects of toxic chemicals and suggests that exceptional susceptibilities demand special attention.^{31,32} Windows of special vulnerability; known as “critical developmental periods,” exist during development. Critical periods occur particularly during early gestation (weeks 0 through 8), but can occur at any time during pregnancy, infancy, childhood, or adolescence – indeed, at any time during development – times when toxicants can impair or alter the structure or function of susceptible systems.³³ Unique early sensitivities may exist because organs and body systems are structurally or functionally immature – even at birth – continuing to develop throughout infancy, childhood, and adolescence. Developmental variables may influence the mechanisms or rates of absorption, metabolism, storage, or excretion of toxicants, any of which factors could alter the concentration of biologically active toxicant at the target organ(s) or that could modulate target organ response to the toxicant. Children’s exposures to toxicants may be more extensive than adults’ exposures because, in proportion to their body weights, children consume more food and liquids than adults do, another factor that might alter the concentration of toxicant at the target. Infants can ingest toxicants through breast milk – an exposure pathway that often goes unrecognized (nonetheless, the advantages of breastfeeding outweigh the probability of significant exposure to infants through breast milk and women are encouraged to continue breastfeeding and to limit exposure of their infants by limiting intake of the

contaminated foodstuff). Children may experience effects at a lower exposure dose than might adults because children's organs may be more sensitive to the effects of toxicants. Stated differently, children's systems could respond more extensively or with greater severity to a given dose than would an adult organ exposed to an equivalent dose of a toxicant. Children could be more prone to developing certain cancers from chemical exposures than are adults.³⁴ In any case, if a chemical – or a class of chemicals – is observed to be – or is thought to be – more toxic to the fetus, infants, or children than to adults, the constants (e.g., RfD, MRL, or CPF) are usually further modified to assure protection of the immature system's potentially greater susceptibility.²⁶ Additionally, in accordance with the ATSDR's *Child Health Initiative*³⁵ and the EPA's *National Agenda to Protect Children's Health from Environmental Threats*,³⁶ the DSHS further seeks to protect children from the possible negative effects of toxicants in fish by suggesting that this potentially sensitive subgroup consume smaller quantities of contaminated fish or shellfish than adults consume. Thus, DSHS recommends that children weighing 35 kg or less and/or who are 11 years of age or younger limit exposure to contaminants in fish or shellfish by eating no more than four ounces per meal of the contaminated species. The DSHS also recommends that consumers spread these meals over time. For instance, if the DSHS issues consumption advice that suggests consumption of no more than two meals per month of a contaminated species, those children should eat no more than 24 meals of the contaminated fish or shellfish per year and, ideally, should not eat such fish or shellfish more than twice per month.

Data Analysis and Statistical Methods

The SALG risk assessors imported Excel[®] files into SPSS[®] statistical software, version 13.0 installed on IBM-compatible microcomputers (Dell, Inc), using SPSS[®] to generate descriptive statistics (mean, standard deviation, median, minimum and maximum concentrations, and range) on measured compounds.³⁷ In computing descriptive statistics, SALG risk assessors utilized ½ the detection limit for analytes designated as not detected (ND) or estimated (J)^b. The SALG then used those descriptive statistics to generate the present report. SALG protocols do not require hypothesis testing. Nevertheless, when data are of sufficient quantity and quality, and, should it be necessary, the SALG may determine significant differences among contaminant concentrations in species and/or at collection sites as needed. The SALG employed Microsoft Excel[®] spreadsheets to generate figures, to compute HAC_{nonca} and HAC_{ca} values for contaminants, and to calculate HQs, hazard indices (HI), cancer risk probabilities, and meal consumption limits for fish from Lake Madisonville.³⁸ When lead concentrations in fish or shellfish are high, SALG risk assessors may utilize the EPA's Interactive Environmental Uptake Bio-Kinetic (IEUBK) model to determine whether consumption of lead-contaminated fish could cause a child's blood lead (PbB) level to exceed the Centers for Disease Control and Prevention's (CDC) lead concentration of concern in children's blood (10 mcg/dL).^{39,40}

^b "J-value" is standard laboratory nomenclature for analyte concentrations that are detected and reported below the reporting limit (<RL). The reported concentration is considered an estimate, quantitation of which may be suspect and may not be reproducible. The DSHS treats J-Values as "not detected" in its statistical analyses of a sample set.

RESULTS

The GERG laboratory completed analyses and electronically transmitted the results to the SALG at the DSHS in 2008. The laboratory reported the analytical results of mercury for all 30 largemouth bass along with the results of analysis of four of the 30 bass (LMD2, LMD4, LMD7, and LMD10) for metals, pesticides, PCBs, SVOCs, and VOCs.

For reference, Table 1 contains the total number of samples collected from Lake Madisonville in July 2006 and April 2007. Tables 2a through 2c contain summary results of metals in fish collected in July 2006 and April 2007 from Lake Madisonville. The paper does not display pesticide, PCB, SVOC and VOC data. Unless otherwise stated, table summaries present the number of samples containing a specific toxicant/number tested, the mean concentration \pm 1 standard deviation (68% of samples should fall within one standard deviation of the arithmetic mean in a sample from a normally-distributed population), and, in parentheses under the mean and standard deviation, the minimum and the maximum detected concentrations. Those who prefer to see the range may derive this statistic by subtracting the minimum concentration of a given toxicant from its maximum concentration. In the tables, results may be given as "ND" (not detected), BDL (below detection limit), or as measured concentrations. Samples with results given as BDL rely upon the laboratory's method detection limit (MDL), defined as the minimum concentration of an analyte of interest that can be measured and reported with 99% confidence that the analyte concentration is greater than zero, and the RL, defined as the concentration that can be reliably achieved within specified limits of precision and accuracy during routine sample analyses. Contaminant concentrations reported below the RL are qualified as "J" concentrations in the GERG data report.⁴¹

Inorganic Contaminants

Arsenic, Cadmium, Copper, Lead, Mercury, Selenium and Zinc

Arsenic, cadmium, lead, and selenium were not detected in the four largemouth bass from Lake Madisonville sampled for these elements (Tables 2a-2c). On the other hand, the laboratory reported all four samples to contain copper (Table 2b) and zinc (Table 2c). The mean copper concentration was 0.058 ± 0.033 mg/kg; the mean zinc concentration was 4.093 ± 1.688 mg/kg.

All 30 samples from Lake Madisonville contained mercury (Table 2b). The mean mercury concentration in largemouth bass from Lake Madisonville was 0.774 ± 0.338 mg/kg (Table 2b). The median concentration of mercury was 0.700 mg/kg. A largemouth bass weighing 0.76 pounds and measuring 13.8 inches contained 1.707 mg/kg, the maximum observed concentration of mercury in fish from this survey. The lower and upper 95% confidence limits on the mean mercury concentration were 0.648 mg/kg and 0.900 mg/kg, respectively.

The DSHS SALG examined the mercury data from Lake Madisonville largemouth bass for relationships between length and mercury concentration and between weight and mercury concentration. Statistically, the data from 2001 and 2006-2007 were from similar populations, so SALG risk assessors used data from both surveys to calculate correlation coefficients for these comparisons. Mercury was present in 46 of 46 fish collected from Lake Madisonville in 2001

and 2006-2007. Concentrations varied from 0.355 mg/kg to 1.71 mg/kg (Figures 2 and 3). Mercury concentration showed little correlation with length ($r=0.219$, $n=30$, $p=0.145$) or weight ($r=0.096$, $n=30$, $p=0.523$) of largemouth bass from Lake Madisonville (Figures 2 and 3).

Organic Contaminants

Pesticides

The GERG laboratory also analyzed the subsample of four largemouth bass samples from Lake Madisonville for 34 pesticides. One largemouth bass contained 0.003 mg/kg of 4,4'-DDE, a metabolite and/or degradation product of the insecticide 4,4'-DDT. Only trace^c quantities of 4,4'-DDE, were present in the three other largemouth bass samples analyzed. Trace quantities of chlordane and mirex were also present in these samples (data not presented). No other pesticides were reported in samples of largemouth bass collected in 2006-2007 from Lake Madisonville.

PCBs

The GERG laboratory analyzed the same four largemouth bass samples for PCBs as were examined for pesticides from Lake Madisonville. The laboratory detected trace^c quantities of PCBs representing one or more of the congeners between PCB6 and PCB209 (International Union of Pure and Applied Chemists [IUPAC] assigned numbers) in the four largemouth bass analyzed. The laboratory reported the traces of PCBs as estimated concentrations (J-values) (data not presented).

SVOCs

The GERG laboratory analyzed the same four largemouth bass samples for SVOCs as were examined for pesticides and PCBs from Lake Madisonville. The laboratory detected traces of BEHP in the four largemouth bass; in each case, the laboratory reported BEHP as an estimated concentration (J-value) (data not presented). Largemouth bass collected in 2006-2007 from Lake Madisonville contained no other detectable SVOCs.

VOCs

The GERG laboratory analyzed the same four samples for VOCs as were examined for pesticides, PCB congeners, and SVOCs from Lake Madisonville. Low but measurable concentrations of methylene chloride were present in the four largemouth bass samples analyzed. Acetone was measured in one largemouth bass sample analyzed (estimated "J" concentrations in the three other largemouth bass samples [data not presented]). Concentrations of methylene chloride and acetone were also identified in the procedural blanks, indicating the possibility that both compounds were introduced during sample preparation. Carbon disulfide was reported at a

^c Trace: an extremely small amount of a chemical compound, one present in a sample at a concentration below a standard limit. Trace quantities may be designated in the data with the "less than" (<) sign or may also be represented by the alpha character "J" – called a "J-value" defining the concentration of a substance as near zero or one that is detected at a low level but that is not guaranteed quantitatively replicable.

concentration above the reporting limit in two of four largemouth bass samples analyzed (0.057 mg/kg and 0.164 mg/kg). Trace^c quantities of chloroform, 1,2-dichloroethane, benzene, toluene, chlorobenzene, m+p-xylene, o-xylene, styrene, isopropylbenzene, 2-chlorotoluene, 4-chlorotoluene, 1,3,5-trimethylbenzene 1,4-dichlorobenzene, 4-isopropyl toluene, tert-butylbenzene, n-butylbenzene and naphthalene were also present in the four largemouth bass samples from Lake Madisonville analyzed for VOCs.

DISCUSSION

Risk Characterization

Because variability and uncertainty are inherent to quantitative assessment of risk, the calculated risks of adverse health outcomes from exposure to toxicants can be orders of magnitude above or below actual risks. Variability in calculated and in actual risk may depend upon factors such as the use of animal instead of human studies, use of sub-chronic rather than chronic studies, interspecies variability, intra-species variability, and database insufficiency. Since most factors used to calculate comparison values result from experimental studies conducted in the laboratory on nonhuman subjects, variability and uncertainty might arise from the study chosen as the "critical" one, the species/strain of animal used in the critical study, the target organ selected as the "critical organ," exposure periods, exposure route, doses, or uncontrolled variations in other conditions.²⁶ Despite such limitations, risk assessors must calculate parameters to represent potential toxicity to humans who consume contaminants in fish and other environmental media. The DSHS calculated risk parameters for systemic and cancerous endpoints in those who would consume fish from Lake Madisonville. Conclusions and recommendations predicated upon the stated goal of the DSHS to protect human health follow the discussion of the relevance of findings to risk.

Characterization of Systemic (Noncancerous) Health Effects from Consumption of Fish from Lake Madisonville

The laboratory analyzed 30 largemouth bass collected during two sampling trips to Lake Madisonville, in 2006 and 2007, for mercury. This number of samples should be adequate to determine with reasonable certainty the degree of risk associated with consumption of largemouth bass collected from Lake Madisonville during the 2006-2007 sampling period.

Inorganic Contaminants

Copper, Selenium, Zinc, Arsenic, Cadmium, Lead, and Mercury,

Four of 30 largemouth bass collected in 2006-2007 from Lake Madisonville were tested for, copper, selenium, and zinc. These trace minerals are all known to be essential to human health and to the health of other animals, but may become toxic at high concentrations – most often with acute ingestion but occasionally with long-term consumption.⁴² Copper and zinc were detected at concentrations far below the level at which toxicity overtakes the nutritional value of these substances. None of the four samples contained detectable selenium. Although limited by the small sample number, risk assessors suspect that the presence of small quantities of copper

and zinc in largemouth bass from Lake Madisonville should have no deleterious effects on the health of individuals consuming fish from this reservoir. Other species were not examined for these trace elements.

Arsenic, cadmium, and lead are all considered toxic elements; none has a known role in mammalian physiology. No arsenic, cadmium, or lead was detected in any of the four largemouth bass from Lake Madisonville tested for these metalloids. Therefore, assuming the four fish are representative of all largemouth bass from Lake Madisonville, the absence of these metalloids can only be a positive finding for human health.

Mercury was the only metallic agent for which the laboratory analyzed all 30 largemouth bass from Lake Madisonville. Mercury in fish (methylmercury) is a known fetal neurotoxicant that readily reaches the fetal brain through the maternal-fetal circulation. It is important in this context to know that most – if not all – human exposures to methylmercury derive from consumption of mercury-contaminated fish.⁴³ In Texas, the HAC_{nonca} value for methylmercury in fish – based on the neurodevelopmental effects of this toxicant – is 0.7 mg/kg, derived from the ATSDR's methylmercury-based MRL of 0.0003 mg/kg –day.⁴⁴ All 30 largemouth bass in the 2006-2007 sample from Lake Madisonville contained mercury. In these fish, the mercury concentration averaged **0.774 mg/kg** ± 0.338 mg/kg tissue (Table 2b). The upper 95% confidence limit on the mean concentration was 0.900; the lower 95% confidence limit was 0.648 mg/kg; thus, 95% of largemouth bass from Lake Madisonville are likely to contain mercury at a concentration between 0.648 and 0.900 mg/kg. In a sample from a normally distributed population, 95% of samples should fall within 2 standard deviations of the mean concentration (0.098-1.112 mg/kg). The data from the 30 fish, along with the upper limits on concentration represented by the standard deviation and/or the 95% upper confidence limit suggests a significant probability of consuming largemouth bass from Lake Madisonville that contain methylmercury at concentrations higher than the HAC_{nonca}. Should consumption occur regularly over time at concentrations in excess of 0.7 mg/kg, one must conclude that some toxicity might occur, primarily to the fetal nervous system. Other sensitive groups include pregnant women (because the maternal blood is the source of mercury that adversely affects the fetal brain) or women who might become pregnant (because methylmercury is retained for a time in the human body and, if intake exceeds excretion, will be accumulated, leading to possible fetal toxicity if a woman become pregnant), nursing infants (mercury is secreted into breast milk) and, perhaps, very small children. Although the neurotoxic effects of methylmercury appear to decrease with age (or the dose-effect curve shifts to the right), older children, adolescents, women who can no longer bear children, and adult men should know that exposure to methylmercury in infancy may increase the likelihood of hypertension and/or cardiovascular disease in later life.

Meal consumption calculations may be useful for decisions about consumption advice or regulatory actions. The SALG risk assessors used the HQ for mercury in largemouth bass to calculate the number of 8-ounce meals of largemouth bass Lake Madisonville that healthy adults could consume without significant risk of adverse systemic effects (Table 3). The SALG estimated these groups could consume 0.5 (8-ounce) meals per week of largemouth bass that may contain mercury at a concentration similar to the average concentration in samples taken in 2006 and 2007 from Lake Madisonville.

Organic Contaminants

Pesticides

Of the 34 pesticides analyzed in four of the 30 largemouth bass collected in 2006-2007 from Lake Madisonville, traces of mirex, chlordane, and 4,4'-DDE – usually a metabolite or degradation product of the insecticide 4,4'-DDT – were detected in one or more of the fish. Pesticides found at levels approaching undetectable levels likely are of no consequence to human health.

SVOCs

The four largemouth bass from Lake Madisonville scanned for SVOCs contained trace quantities of bis(2-ethylhexyl) benzene-1,2-dicarboxylate (bis(2-ethylhexyl) phthalate; di(2-ethylhexyl) phthalate; DEHP; BEHP), reported as estimated concentrations (J-values) (data not presented). Bis(2-ethylhexyl) benzene-1,2-dicarboxylate is a plasticizer that is now ubiquitous. The presence of trace concentrations of BEHP will likely neither cause nor contribute to adverse systemic health effects in humans who consume fish from Lake Madisonville.

VOCs

The GERG laboratory analyzed the subsample of four largemouth bass from Lake Madisonville for VOCs. Although VOCs were present in fish from Lake Madisonville, concentrations were, for the most part, low. Many occurred only in trace amounts (data not presented). Two VOCs, methylene chloride and acetone, were also present in the sample blanks, so were likely introduced during post-sampling handling. Although the reported VOCs could have been present in the reservoir's water, many normal cellular activities may produce trace quantities of VOCs as well. Some could also have been products of tissue necrosis or decomposition. Most importantly, all reported volatile organic compound in the samples occurred at concentrations far below HAC_{nonca} concentrations (data not presented). Thus, consumption of fish from Lake Madisonville that contain low levels of one or more of the reported VOCs is unlikely to cause adverse effects on systemic human health.

PCBs

For Lake Madisonville, the present study marks the first instance of sample analysis for PCB congeners instead of Aroclors[®]. Thus, direct comparison of PCB concentrations from this report with Aroclors[®] possibly reported in previous studies of Lake Madisonville – or the lack thereof – would be inappropriate.

The four largemouth bass from Lake Madisonville contained only trace quantities of PCBs (data not shown). All PCB concentrations were lower than the laboratory's reporting limit and, as such, none approached the HAC_{nonca} value utilized to assess the likelihood of adverse systemic effects from consumption of PCBs in fish (0.047 mg/kg). Consumption of fish from Lake Madisonville containing PCBs at concentrations similar to those in the tissue samples collected in 2006-2007 is therefore unlikely to be of significance to public health.

Characterization of Theoretical of Lifetime Excess Cancer Risk from Consumption of Fish from Lake Madisonville

Inorganic Contaminants

Cancer potency factors (slope factors) are not available for cadmium (EPA 2005 classification:⁴⁵ - LI – likely human carcinogen – cancer potential established but limited human data; Group B, 1986 classification⁴⁶), copper (IN – inadequate; data inadequate to assess; Group D 1986 classification), lead (LI; Group B), mercury (SU – suggestive evidence – human or animal data suggestive; Group C), selenium (IN; Group D), or zinc (IN; Group D).⁴² Thus, the SALG was unable to determine the probability of excess cancers from consuming fish from Lake Madisonville that contain cadmium, copper, lead, mercury, selenium, or zinc. It is important to note, however, that copper, selenium, and zinc – at appropriate intake levels – are essential trace elements, necessary for health.⁴² Selenium, in particular, has been the subject of much recent research on protection of humans from certain cancers, including prostate and colon cancers.⁴⁷

Organic Contaminants

Pesticides

The GERG laboratory reported very low concentrations of mirex, chlordane, and a metabolite of 4,4'-DDT, 4,4'-DDE in the four largemouth bass from Lake Madisonville tested for pesticides (data not presented). Mean concentrations of these three compounds did not exceed their respective HAC_{ca} values. Thus, the DSHS concludes that, accepting the limitations of the small number of samples and single species studied, consumption of fish from this reservoir that contain traces of pesticides is unlikely to contribute substantially to cancer risk in those who eat these fish.

VOCs

The GERG laboratory also analyzed the four largemouth bass from Lake Madisonville for VOCs. Only three VOCs – methylene chloride, acetone, and carbon disulfide – were identified in the samples from this small lake. Concentrations of each were low or were reported as trace quantities (data not presented). Two VOCs, methylene chloride and acetone, were also present in the sample blanks, so could have been introduced during post-sampling handling. Although the reported VOCs could also have been present in the reservoir's water, normal cells may produce traces of many VOCs. Some could also be the products of tissue necrosis or decomposition. Most importantly, the three reported volatile organic compounds in the samples occurred at concentrations far below their respective HAC_{ca} concentrations (data not presented). Cumulative cancer incidence calculations were less than 1 excess cancer per 10,000 equivalently exposed individuals, suggesting that consumption of fish from Lake containing low levels of one or more of the reported VOCs is unlikely to increase or to contribute to, an increase in the calculated theoretical excess lifetime risk of cancer.

SVOCs

The four largemouth bass from Lake Madisonville scanned for SVOCs contained trace quantities of bis(2-ethylhexyl) benzene-1,2-dicarboxylate (bis(2-ethylhexyl) phthalate; BEHP), reported as estimated concentrations (J-values) (data not presented). BEHP is a plasticizer ubiquitous in the environment. The very low levels of BEHP did not increase the calculated theoretical lifetime risk of cancer. Therefore, the DSHS concludes that consumption of largemouth bass from Lake Madisonville that contain traces of BEHP likely will neither cause nor contribute to increases in the theoretical excess lifetime cancer risk even in those who consume these fish for a 70-year lifetime.

Characterization of Calculated Cumulative Systemic Health Effects and of Cumulative Excess Lifetime Cancer Risk from Consumption of Fish from Lake Madisonville

Cumulative Systemic Effects

Cumulative systemic adverse health effects may be of concern if people are exposed simultaneously to more than one contaminant in one medium (e.g., fish) or in multiple media (multiple media are not discussed in this report because the SALG has no way of knowing the toxicants to which people may be exposed through other media). In the present risk characterization, assessors observed various metallic elements, pesticides, VOCs, and SVOCs, combinations of which could potentially increase the likelihood of damage or increase the degree of damage to organs affected by more than one of the individual components of the mixtures (for instance, the liver), the hazard indices for those combinations were far less than 1.0. Thus, consumption of largemouth bass from Lake Madisonville containing such chemical mixtures is unlikely to cause, or result in, cumulative systemic toxicity.^{48 49}

Cumulative Carcinogenicity

Consuming any single chemical in largemouth bass from Lake Madisonville did not increase the calculated theoretical excess cancer risk to a theoretical risk of more than 1 excess cancer in 10,000 equivalently exposed individuals. In most assessments of cancer risk from environmental exposures to chemical mixtures, researchers consider any increase in the number of neoplasms, whether benign or cancerous, whether in one organ or in multiple organs, to be cumulative, no matter the mode or mechanism by which the individual chemicals cause cancer. In this model, risk assessors add excess lifetime cancer risks from individual chemicals to determine cumulative excess cancer risk. In the present risk characterization, risk assessors added the calculated carcinogenic risks of individual pesticides, VOCs and SVOCs observed in largemouth bass from Lake Madisonville. Addition of the calculated theoretical lifetime risk of cancer for individual chemicals did not increase the calculated theoretical lifetime excess cancer risk for consumption of multiple carcinogens to a risk greater than one excess cancer in 10,000 equally-exposed persons – the cutoff point used by the DSHS to determine whether regulatory action or consumption advice is warranted to protect the health of populations likely to consume fish from a water body under investigation that contain carcinogenic chemicals.

CONCLUSIONS

SALG risk assessors prepare risk characterizations to determine public health hazards from consumption of fish and shellfish harvested from Texas water bodies by recreational or subsistence fishers, and – if indicated – may suggest strategies for reducing risk to the health of those who eat contaminated fish or seafood to risk managers at DSHS, including the Texas Commissioner of Health.

This study addressed the public health implications of consuming largemouth bass from Lake Madisonville. Risk assessors from the SALG conclude from the present characterization of potential adverse health effects from consuming largemouth bass from Lake Madisonville

1. That consumption of largemouth bass from Lake Madisonville containing methylmercury **poses an apparent risk to human health.**
2. That no other contaminants of concern (inorganic or organic) were found in largemouth bass from Lake Madisonville at concentrations exceeding regulatory guidelines for those toxicants (HQs for substance other than methylmercury did not exceed 1.0).
3. That hazard indices (measures of potential cumulative [additive] effects of toxicants affecting the same target organ(s)) did not exceed 1.0 and that cumulative effects from toxicants measured in largemouth bass from Lake Madisonville do not increase the likelihood of adverse systemic effects above the effects possible from exposure to methylmercury in those fish. **Cumulative effects thus pose no apparent risk to human health.**
4. That the calculated lifetime excess risk of cancer from consumption of largemouth bass taken from Lake Madisonville in 2006-2007 was not elevated for any contaminant detected (data not shown). Neither arsenic nor PCBs, both chemicals of which are considered likely carcinogens in humans, were detected in samples from Lake Madisonville. VOCs reported in these samples were measured only sporadically and at trace to low concentrations, as were SVOCs. Calculation of excess cancer risk from combinations of carcinogens observed in the largemouth bass from this reservoir showed no significant change in cancer risk. Therefore, consumption of largemouth bass from Lake Madisonville **poses no apparent increase in the lifetime excess risk of cancer.**

RECOMMENDATIONS

Risk managers at the DSHS have established criteria for issuing fish consumption advisories based on approaches suggested by the EPA.^{15, 17, 50} If a risk characterization confirms that people can eat four or fewer fish or shellfish meals per month (adults: eight ounces per meal; children: four ounces per meal) from the water body under investigation, risk managers at DSHS might recommend consumption advice for that water body. Alternatively, the department may ban possession of fish from the affected water body. Fish or shellfish possession bans are enforceable under subchapter D of the Texas Health and Safety Code, part 436.061(a).⁵¹ Declarations of prohibited harvesting areas are enforceable under the Texas Health and Safety Code, Subchapter

D, parts 436.091 and 436.101.⁵¹ DSHS consumption advice carries no penalty for noncompliance. Consumption advisories, instead, inform the public of potential health hazards associated with consuming contaminated fish or shellfish from Texas waters. With this information, members of the public can make informed decisions about whether – and how much – contaminated fish or shellfish they wish to consume. SALG risk assessors conclude from this risk characterization that consuming largemouth bass from Lake Madisonville poses **an apparent hazard to public health** because samples of this fish species contained mercury at concentrations that exceed the HAC_{nonca} for methylmercury. Therefore, the SALG recommends

1. That the DSHS advises people that largemouth bass sampled in 2006 and 2007 from Lake Madisonville contained mercury at an average concentration of 0.744 mg/kg. This concentration is slightly higher than the 0.7 mg/kg guideline concentration (HAC_{nonca} value) of methylmercury the DSHS uses to decide if consumption of fish containing mercury might cause systemic adverse health effects in sensitive groups who might consume those fish.
2. That women who are pregnant or who might become pregnant, nursing mothers, infants, and young children should not consume largemouth bass from Lake Madisonville because regular consumption of methylmercury in these fish could possibly cause subtle damage to the developing nervous system. Such damage might result in deficits in neuropsychological function.
3. That other adults and children older than 11 years of age should limit their consumption of largemouth bass from Lake Madisonville to two meals per month (8 ounces for adults; 4 ounces for children). Nervous system toxicity is not impossible if mercury consumption by these groups exceeds some higher threshold than that used to predict possible fetal damage. Mercury may have a role in the pathogenesis of hypertension in later life.^{52,53} The SALG's calculations for these groups, based on default parameters and the average mercury concentration in largemouth bass from Lake Madisonville, result in a meal size no greater than 0.83 8-oz meals per week. The SALG's recommendation of no more than two meals per month is conservative and, thus, protective of public health.

PUBLIC HEALTH ACTION PLAN

Communication to the public of new and continuing possession bans or consumption advisories, or the removal of either, is essential to effective management of risk from consuming contaminated fish. In fulfillment of the responsibility for communication, the DSHS takes several steps. The agency publishes fish consumption advisories and bans in a booklet available to the public through the SALG. To receive the booklet and/or the data, please contact the SALG at 1-512-834-6757.⁵⁴ The SALG also posts the most current information about advisories, bans, and the removal of either on the internet at <http://www.dshs.state.tx.us/seafood>. The SALG regularly updates this Web site. The DSHS also provides the EPA (<http://epa.gov/waterscience/fish/advisories/>), the TCEQ (<http://www.tceq.state.tx.us>), and the TPWD (<http://www.tpwd.state.tx.us>) with information on all consumption advisories and possession bans. Each year, the TPWD informs the fishing and hunting public of consumption

advisories and fishing bans on its Web site and in an official hunting and fishing regulations booklet available at many state parks and at all establishments selling Texas fishing licenses.⁵⁵ Readers may direct questions about the scientific information or recommendations in this risk characterization to the SALG at 512-834-6757 or may find the information at the SALG's Web site. Secondly, one may address inquiries to the Environmental and Injury Epidemiology and Toxicology Branch (EIETB) of the DSHS (512-458-7269). The EPA's IRIS Web site (<http://www.epa.gov/iris/>) contains information on environmental contaminants found in food and environmental media. The Agency for Toxic Substances and Disease Registry (ATSDR), Division of Toxicology (888-42-ATSDR or 888-422-8737 or the ATSDR's Web site (<http://www.atsdr.cde.gov>) supplies brief information via *ToxFAQs*.TM *ToxFAQs*TM are available on the ATSDR Web site in either English (<http://www.atsdr.cdc.gov/toxfaq.html>) or Spanish (http://www.atsdr.cdc.gov/es/toxfaqs/es_toxfaqs.html). The ATSDR also publishes more in-depth reviews of many toxic substances in its *Toxicological Profiles*TM. To request a copy of the *ToxProfiles*TM CD-ROM, PHS, or *ToxFAQs*TM call 1-800-CDC-INFO (800-232-4636) or email a request to cdcinfo@cdc.gov.

Figure 1. Lake Madisonville Sample Sites



TABLES

Table 1. Fish samples collected from Lake Madisonville on July 18, 2006 and on April 16, 2007. Sample number, species, length, and weight were recorded for each sample collected.			
Sample Number	Species	Length (mm)	Weight (g)
LMD1	Largemouth bass	387	668
LMD2	Largemouth bass	420	991
LMD3	Largemouth bass	421	1030
LMD4	Largemouth bass	450	1242
LMD5	Largemouth bass	392	783
LMD6	Largemouth bass	420	940
LMD7	Largemouth bass	409	880
LMD8	Largemouth bass	367	671
LMD9	Largemouth bass	395	730
LMD10	Largemouth bass	430	1073
LMD11	Largemouth bass	296	290
LMD12	Largemouth bass	363	611
LMD13	Largemouth bass	350	346
LMD14	Largemouth bass	368	583
LMD15	Largemouth bass	420	958
LMD16	Largemouth bass	350	610
LMD17	Largemouth bass	426	1206
LMD18	Largemouth bass	400	752
LMD19	Largemouth bass	295	272
LMD20	Largemouth bass	317	359
LMD21	Largemouth bass	274	263
LMD22	Largemouth bass	300	346
LMD23	Largemouth bass	308	346
LMD24	Largemouth bass	285	266
LMD25	Largemouth bass	285	254
LMD30	Largemouth bass	521	2031
LMD31	Largemouth bass	475	1483
LMD32	Largemouth bass	525	2284
LMD33	Largemouth bass	513	1986
LMD34	Largemouth bass	461	1232

Table 2a. Arsenic (mg/kg) in largemouth bass from Lake Madisonville, 2006-2007.					
Species	# Detected/ # Sampled	Total Arsenic Mean Concentration ± S.D. (Min-Max)	Inorganic Arsenic Mean Concentration ^d	Health Assessment Comparison Value (mg/kg) ^e	Basis for Comparison Value
Largemouth bass	0/4	ND ^f	ND	0.7 0.362	EPA chronic oral RfD for Inorganic arsenic: 0.0003 mg/kg-day EPA oral slope factor for inorganic arsenic: 1.5 per mg/kg-day

Table 2b. Inorganic contaminants (mg/kg) in largemouth bass (LMB) from Lake Madisonville, 2006-2007.				
Species	# Detected/ # Sampled	Mean Concentration ± S.D. (Min-Max)	Health Assessment Comparison Value (mg/kg)	Basis for Comparison Value
Cadmium				
Largemouth bass	0/4	ND	0.47	ATSDR chronic oral MRL: 0.0002 mg/kg-day
Copper				
Largemouth bass	4/4	0.058±0.033 (BDL ^g -0.108)	333	National Academy of Science Upper Limit: 0.143 mg/kg-day
Lead				
Largemouth bass	0/4	ND	0.6	EPA IEUBKwin
Mercury				
Largemouth bass	30/30	0.774±0.338 (0.355- 1.707)	0.7	ATSDR chronic oral MRL: 0.0003 mg/kg-day
LMB ≤14"	10/10	0.689±0.395 (0.355- 1.707)		
LMB 14-18"	15/15	0.855±0.345 (0.431- 1.700)		
LMB ≥18"	5/5	0.698±0.102 (0.597- 0.842)		
LMB (harvestable size)	15	0.692±0.321 (0.355- 1.707)		

^d Most arsenic in fish and shellfish occurs as organic arsenic, considered virtually nontoxic. For risk assessment calculations, DSHS assumes that total arsenic is composed of 10% inorganic arsenic in fish and shellfish tissues.

^e Derived from the MRL or RfD for noncarcinogens or the EPA slope factor for carcinogens; assumes a body weight of 70 kg, and a consumption rate of 30 grams per day, and assumes a 30-year exposure period for carcinogens and an excess lifetime cancer risk of 1×10^{-4} .

^f ND: "Not Detected" was used to indicate that a compound was not present in a sample at a level greater than the MDL.

^g BDL: "Below Detection Limit" – Concentrations were reported as less than the laboratory's method detection limit ("J" values). In some instances, a "J" value was used to denote the discernable presence in a sample of a contaminant at concentrations estimated as different from the sample blank

Table 2c. Inorganic contaminants (mg/kg) in largemouth bass from Lake Madisonville, 2006-2007.				
Species	# Detected/ # Sampled	Mean Concentration ± S.D. (Min-Max)	Health Assessment Comparison Value (mg/kg)	Basis for Comparison Value
Selenium				
Largemouth bass	0/4	ND	6	EPA chronic oral RfD: 0.005 mg/kg-day ATSDR chronic oral MRL: 0.005 mg/kg-day NAS UL: 0.400 mg/day (0.005 mg/kg-day) RfD or MRL/2: (0.005 mg/kg-day)/2= 0.0025 mg/kg-day) to account for other sources of selenium in the diet
Zinc				
Largemouth bass	4/4	4,093±1,688 (2,810-6,550)	700	EPA chronic oral RfD: 0.3 mg/kg-day

Table 3. Hazard quotients for mercury in largemouth bass collected from Lake Madisonville in 2006-2007. Table 3 also provides suggested weekly eight-ounce meal consumption rates for 70-kg adults.^h		
Species	Hazard Quotient	Meals per Week
Largemouth bass	1.1	0.8
Largemouth bass (harvestable size)	1.0	0.9

^h DSHS assumes that children under the age of 12 years and/or those who weigh less than 35 kg eat 4-ounce meals.

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