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NATIONAL WATER-QUALITY ASSESSMENT PROGRAM

Development of Health-Based Screening Levels for Use in State- or Local-Scale Water-Quality Assessments

Water-Resources Investigations Report 03-4054

Prepared in cooperation with the Oregon Health & Science University

U.S. Department of the Interior
U.S. Geological Survey

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FOREWORD

The U.S. Geological Survey (USGS) is committed to providing the Nation with accurate and timely scientific information that helps enhance and protect the overall quality of life and that facilitates effective management of water, biological, energy, and mineral resources (http://www.usgs.gov/). Information on the quality of the Nation's water resources is critical to assuring the long-term availability of water that is safe for drinking and recreation and suitable for industry, irrigation, and habitat for fish and wildlife. Population growth and increasing demands for multiple water uses make water availability, now measured in terms of quantity and quality, even more essential to the long-term sustainability of our communities and ecosystems.

The USGS implemented the National Water-Quality Assessment (NAWQA) Program in 1991 to support national, regional, and local information needs and decisions related to water-quality management and policy (http://water.usgs.gov/nawqa). Shaped by and coordinated with ongoing efforts of other Federal, State, and local agencies, the NAWQA Program is designed to answer: What is the condition of our Nation's streams and ground water? How are the conditions changing over time? How do natural features and human activities affect the quality of streams and ground water, and where are those effects most pronounced? By combining information on water chemistry, physical characteristics, stream habitat, and aquatic life, the NAWQA Program aims to provide science-based insights for current and emerging water issues and priorities.

From 1991-2001, the NAWQA Program completed interdisciplinary assessments in 51 of the Nation's major river basins and aquifer systems, referred to as Study Units (http://water.usgs.gov/nawqa/studyu.html). Baseline conditions were established for comparison to future assessments, and long-term monitoring was initiated in many of the basins. During the next decade, 42 of the 51 Study Units will be reassessed so that 10 years of comparable monitoring data will be available to determine trends at many of the Nation's streams and aquifers. The next 10 years of study also will fill in critical gaps in characterizing water-quality conditions, enhance understanding of factors that affect water quality, and establish links between sources of contaminants, the transport of those contaminants through the hydrologic system, and the potential effects of contaminants on humans and aquatic ecosystems.

The USGS aims to disseminate credible, timely, and relevant science information to inform practical and effective water-resource management and strategies that protect and restore water quality. We hope this NAWQA publication will provide you with insights and information to meet your needs, and will foster increased citizen awareness and involvement in the protection and restoration of our Nation's waters.

The USGS recognizes that a national assessment by a single program cannot address all water-resource issues of interest. External coordination at all levels is critical for a fully integrated understanding of watersheds and for cost-effective management, regulation, and conservation of our Nation's water resources. The NAWQA Program, therefore, depends on advice and information from other agencies—Federal, State, interstate, Tribal, and local—as well as nongovernmental organizations, industry, academia, and other stakeholder groups. Your assistance and suggestions are greatly appreciated.

Robert M. Hirsch
Associate Director for Water

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ABBREVIATIONS AND ACRONYMS

µg/L ....micrograms per liter
mg/L ....milligrams per liter
L ....liter
kg body wt.........................kilograms of body weight
mg/kg/day..........................milligrams of contaminant per kilogram of body weight per day
$(mg/kg/day)^{-1}$ ....inverse of milligrams of contaminant per kilogram of body weight per day
ACT..................................Action Level
ASDWA............................Association of State Drinking Water Administrators
AWQC..............................Ambient Water Quality Criteria
DWEL ....Drinking Water Equivalent Level
DWLOC ....Drinking Water Level of Comparison
GW ....Ground Water
GWQC ....Ground-Water Quality Criteria
HBSL ....Health-Based Screening Level
HEAST.............................Health Effects Assessment Summary Tables
IRIS ....Integrated Risk Information System
Lifetime HA ....Lifetime Health Advisory
LINJ ....Long Island – New Jersey
MCL ....Maximum Contaminant Level
MCLG ....Maximum Contaminant Level Goal
MI.....................................Major Ion
MOE.................................Margin of Exposure
NA ....Not Available
NAWQA...........................U.S. Geological Survey National Water-Quality Assessment Program
NJDEP.............................New Jersey Department of Environmental Protection
NWQMC..........................National Water Quality Monitoring Council
OAR ....Office of Air and Radiation (USEPA)
OGWDW..........................Office of Ground Water and Drinking Water (USEPA)
OHSU...............................Oregon Health & Science University
OPP ....Office of Pesticide Programs (USEPA)
ORD ....Office of Research and Development (USEPA)
OSWER............................Office of Solid Waste and Emergency Response (USEPA)
OW ....Office of Water (USEPA)
PRG..................................Preliminary Remediation Goal
q_1* ....see SF
RBC..................................Risk Based Concentration
RfD...................................Reference Dose
RSC ....Relative Source Contribution
RSD..................................Risk-Specific Dose
SDWR ....Secondary Drinking Water Regulation
SF ....Slope Factor
TE.....................................Trace Element
USEPA .............................U.S. Environmental Protection Agency
USGS ................................U.S. Geological Survey
VOC ....Volatile Organic Compound

DEFINITIONS

Term	Definition
Health-Based Screening Level (HBSL)	Estimates of benchmark concentrations (for noncarcinogens) or concentration ranges (for carcinogens) in water that (1) may be of potential human-health concern; (2) can be used as threshold values against which measured concentrations of contaminants in ambient water samples can be compared; and (3) are consistent with USEPA Office of Water methodologies (U. S. Environmental Protection Agency, 1988; U. S. Environmental Protection Agency, 1993b) for setting drinking-water Lifetime Health Advisory and Risk-Specific Dose values.
Lifetime Health Advisory (Lifetime HA)	The concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects over a lifetime of exposure (70 years). The Lifetime HA is based on exposure of a 70-kg adult consuming 2 L of water per day, and assumes that only a portion (generally 20 percent) of the total exposure to a contaminant is from drinking water (U. S. Environmental Protection Agency, 1993b; U. S. Environmental Protection Agency, 2002a).
Regulated Compounds	As used in this report, compounds for which Federal and (or) State drinking-water standards have been established.
Reference Dose (RfD)	An estimate (with an uncertainty of perhaps one order of magnitude) of the daily exposure that is likely to be without appreciable risk of deleterious health effects in the human population (including sensitive subgroups) over an individual's lifetime (70 years) (U. S. Environmental Protection Agency, 1989b).
Risk-Specific Dose (RSD)	The drinking-water concentration associated with a specified cancer risk level (typically 1 in 10,000, 1 in 100,000, or 1 in 1,000,000), under certain exposure conditions: consumption of 2 L per day of drinking water by a 70-kg body weight individual over a lifetime (70 years) (U. S. Environmental Protection Agency, 1993b).
Slope Factor (SF)	The cancer potency estimate for a compound as derived from the slope of the dose-response (carcinogenicity) data extrapolated to zero using an appropriate mathematical model. If the model selected for extrapolation from dose-response data is the linearized multistage model, the SF value is also known as the q1* value (U. S. Environmental Protection Agency, 1989a; U. S. Environmental Protection Agency, 1993b).
Unregulated Compounds	As used in this report, compounds for which no Federal and (or) State drinking-water standards have been established. Note that a compound that is unregulated in drinking water (federally, under the Safe Drinking Water Act) may be regulated in other contexts and under other statutes.

Development of Health-Based Screening Levels for Use in State- or Local-Scale Water-Quality Assessments

By Patricia Toccalino[1], Lisa Nowell[2], William Wilber[3], John Zogorski[4], Joyce Donohue[5], Catherine Eiden[6], Sandra Krietzman[7], *and* Gloria Post[7]

ABSTRACT

The U.S. Geological Survey (USGS) has a need to communicate the significance of the water-quality findings of its National Water-Quality Assessment (NAWQA) Program in a human-health context. Historically, the USGS has assessed water-quality conditions by comparing water concentration data against established drinking-water standards and guidelines. However, because drinking-water standards and guidelines do not exist for many of the contaminants analyzed by the NAWQA Program and other USGS studies, this approach has proven to be insufficient for placing USGS data in a human-health context. To help meet this need, health-based screening level (HBSL) concentrations or ranges are being determined for unregulated compounds (that is, those for which Federal or State drinking-water standards have not been established), using a consensus approach that was developed collaboratively by the USGS, U.S. Environmental Protection Agency (USEPA), New Jersey Department of Environmental Protection, and Oregon Health & Science University. USEPA Office of Water methodologies for calculating Lifetime Health Advisory and Risk-Specific Dose values for drinking water are being used to develop HBSL concentrations (for unregulated noncarcinogens) and HBSL concentration ranges (for most unregulated carcinogens). This report describes the methodologies used to develop HBSL concentrations and ranges for unregulated compounds in State- and local-scale analyses, and discusses how HBSL values can be used as tools in water-quality assessments. Comparisons of measured water concentrations with Maximum Contaminant Level values and HBSL values require that water-quality data be placed in the proper context, with regard to both hydrology and human health. The use of these HBSL concentrations and ranges by USGS will increase by 27 percent the number of NAWQA contaminants for which health-based benchmarks are available for comparison with USGS water-quality data.

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USGS can use HBSL values to assist the USEPA and State and local agencies by providing them with comparisons of measured water concentrations to scientifically defensible human health-based benchmarks, and by alerting them when measured concentrations approach or exceed these benchmarks.

INTRODUCTION

The National Water-Quality Assessment (NAWQA) Program of the U.S. Geological Survey (USGS) is well known for its work in describing the status and trends in the quality of the Nation's surface- and ground-water resources, and for providing a sound, scientific understanding of the primary natural and human factors affecting the quality of these resources. NAWQA has increasingly been asked about the public-health implications of its findings. The NAWQA Program was originally designed to characterize the Nation's water resources and was not designed to answer questions about the potential safety of surface water and ground water for drinking-water use. Nonetheless, if interpreted carefully, NAWQA data can provide valuable information to State agencies, the U.S. Environmental Protection Agency (USEPA), and others interested in drinking-water quality.

To date, NAWQA has assessed water-quality conditions using two approaches: (1) ranking of water-quality conditions at individual surface-water sites and among networks of ground-water wells within a study unit in relation to surface-water sites and ground-water wells in other study units; and (2) comparing water-concentration data against established drinking-water standards and guidelines for the protection of human health (Gilliom and others, 1998). However, the former approach provides no information on whether the levels detected are of potential concern to human health, and the latter approach is limited by the fact that drinking-water standards and guidelines have not been established for many of the contaminants analyzed by NAWQA.

In June 1999, the USGS and Oregon Health & Science University (OHSU), in collaboration with the USEPA, began a pilot effort to develop, test, and refine concepts to more effectively communicate water-quality information in a human-health context. The USGS-NAWQA study area in Glassboro, New Jersey, was selected for a pilot effort for State-level analyses and reports. The Glassboro, New Jersey, study area overlaps with NAWQA's Long Island–New Jersey (LINJ) Coastal Drainages Study Unit, and the pilot effort focuses on ground-water data collected in the LINJ Study Unit. Representatives from the USGS LINJ Study Unit and the New Jersey Department of Environmental Protection (NJDEP), which has the responsibility for regulating drinking water in the State of New Jersey, then joined the interagency pilot effort.

After a series of workshops and written exchanges, the USGS, USEPA, NJDEP, and OHSU representatives participating in the pilot project agreed to develop health-based screening level (HBSL) concentrations and ranges for those compounds without existing drinking-water standards. HBSL values are defined as estimates of benchmark concentrations (for noncarcinogens) or concentration ranges (for carcinogens) in water that (1) may be of potential human-health concern; (2) can be used as threshold values against which measured concentrations of contaminants in ambient water samples can be compared; and (3) are consistent with USEPA Office of Water methodologies (U.S. Environmental Protection Agency, 1988, 1993b) for setting drinking-water Lifetime Health Advisory (HA) and Risk-Specific Dose (RSD) values.

This report describes the methodologies used to develop HBSL concentrations and ranges for unregulated compounds for use in State or local-scale water-quality assessments. Specifically, this report: (1) documents the history of this pilot effort and how consensus was reached on the HBSL approach; (2) defines the systematic procedures followed in the development of HBSL concentrations and ranges for contaminants analyzed by NAWQA; (3) describes the benefits of using the HBSL approach; and (4) discusses how HBSL values can be used as tools in water-quality assessments.

The scope of this pilot effort applies only to data analyzed and reported at the State or local (or study-unit) scales. Expansion of this effort to a national or regional (multi-State) scale will be more complex and is the subject of a second, national-scale pilot project. The additional complexity at the national (or multi-State) scale arises because the approach described in this report builds upon a framework of USEPA and State drinking-water standards. However, different States may not use the same drinking-water standard values, or even regulate the same contaminants in drinking water. The systematic development of HBSL concentrations and ranges will enable the USGS to present water-quality data in a human-health context for a larger suite of contaminants than have drinking-water standards and guidelines, thus providing an increased basis for interpreting the significance of the data.

ACKNOWLEDGMENTS

The authors wish to acknowledge the collaboration and cooperation provided by several USEPA offices (Office of Water (OW), Office of Pesticide Programs (OPP), Office of Solid Waste and Emergency Response (OSWER), Office of Air and Radiation (OAR), and Office of Research and Development (ORD)) and several NJDEP divisions (Division of Science, Research and Technology, Water Supply Administration, Risk Communication, and Bureau of Safe Drinking Water), without which this study could not have been completed. The authors also acknowledge and thank Bruce K. Hope of the Oregon Department of Environmental Quality, and Michael J. Focazio and Gregory C. Delzer of the USGS, for their insightful technical reviews of this report. The authors are grateful to Robyn H. Phillips and Julia E. Norman of OHSU for their careful editorial and illustration assistance. Finally, the authors also thank Ella Decker and Connie Ross who prepared this report for publication.

HISTORY OF PILOT EFFORT AND REACHING CONSENSUS

Reaching consensus on the development of HBSL concentrations and ranges was a 2.5-year process. In 1998, the USGS sought assistance and advice from the USEPA, the Centers for Disease Control, and the National Academy of Sciences on how to communicate NAWQA water-quality data in a human-health context more effectively. One suggestion by representatives of these agencies was that NAWQA should conduct a pilot study in conjunction with USEPA and other appropriate agencies.

In June 1999, the USGS met with representatives of USEPA's OW, OPP, and ORD to reach consensus on the goals of a pilot effort, and to identify one or more pilot projects of mutual interest to the USGS and USEPA. The Glassboro, New Jersey, study area, which overlaps with NAWQA's LINJ Study Unit, was selected as an appropriate pilot study for State-level analyses. At that point, representatives from the USGS LINJ Study Unit and the NJDEP were asked to collaborate in the pilot project. The scope of the initial pilot effort was limited to human-health issues involving potential exposure to individual contaminants in ground water because (1) ground water is the principal drinking-water source in the area, and (2) procedures for assessing potential risks or hazards resulting from exposure to multiple contaminants are still under development by USEPA, and they are not considered sufficiently developed for incorporation into the pilot project at this time.

OHSU personnel were asked to identify and describe currently available methods that could be used to express the Glassboro ground-water data in a human-health risk context, and to provide recommendations on which methods to use in the Glassboro pilot project (Toccalino and Binder, 2000). These methods and recommendations as well as alternative approaches were discussed at a workshop with USGS, USEPA, and NJDEP representatives in May 2000. The workshop participants agreed that the USGS should not conduct a baseline risk assessment on NAWQA data using standard deterministic approaches to place the concentration data in a risk context. Instead, the USGS should pursue a two-tiered, HBSL-based methodology for placing water-quality data in a human-health context. The participants in the May 2000 workshop did not reach consensus on exactly how the HBSL values would be developed, but there was general agreement that, for USGS analyses and reports at the State or study-unit scale, it was appropriate to use methodologies and assumptions from USEPA's OW to develop HBSL values in the absence of Maximum Contaminant Level (MCL) values.

Toccalino and others (2001) proposed a possible HBSL approach to USGS, USEPA, and NJDEP. In May 2001, USGS and OHSU personnel held a series of meetings with USEPA and NJDEP representatives to negotiate a consensus approach to developing HBSL values. Consensus was reached on an HBSL approach during these May 2001 meetings, and the approach was refined and iterated over several months (Toccalino, 2001). The consensus approach was presented to representatives of the Association of State Drinking Water Administrators (ASDWA) in May 2001, at the National ASDWA meeting in October 2001, at the National Water Quality Monitoring Council (NWQMC) meeting in May 2002, the

USEPA Office of Ground Water and Drinking Water (OGWDW) in December 2002, and the national conference on USGS health-related research in April 2003. A few technical details (such as how to resolve differences between toxicity values or cancer classifications from different USEPA sources) were resolved by March 2002. The HBSL approach described in this report is the result of the meetings and negotiations described above.

USEPA HUMAN HEALTH-BASED BENCHMARKS AND THOSE USED BY USGS

The USEPA has developed a variety of numerical water-quality standards and guidelines related to drinking water. These standards and guidelines have been used in numerous applications, including screening pollutants in environmental media, designing monitoring programs, evaluating the need for detailed water-quality assessments, conducting remedial investigations, and providing an initial cleanup goal, if applicable. Table 1 provides descriptions of 10 human-health benchmark concentrations published by the USEPA that are related to drinking water.

USGS has historically used 5 of the 10 types of USEPA human-health benchmarks presented in table 1 to evaluate NAWQA data: (1) MCL, (2) Action Level (ACT), (3) Lifetime HA, (4) RSD, and (5) Secondary Drinking Water Regulation (SDWR) (Gilliom and others, 1998). In all five cases, the benchmark levels are concentrations pertaining to long-term average exposure through drinking water. For some contaminants, more than one of these five benchmarks are available. For these contaminants, either the MCL or the ACT (for two trace elements that are regulated by treatment techniques rather than MCL values) is used, if available; otherwise, either the Lifetime HA (for noncarcinogens) or the RSD at a 10^{-5} cancer risk (for potential carcinogens) is used. For a few constituents with both a Lifetime HA and an RSD value, the lower value is used. In some analyses, the USGS also has used the SDWR for dissolved solids. In addition to these USEPA benchmarks, USGS also compares water-quality data to State standards and guidelines, where they exist, for State- and local-scale water-quality studies.

The remaining 5 of the 10 types of USEPA human-health benchmarks are not typically used to evaluate NAWQA data for a variety of reasons:

- The Drinking Water Equivalent Level (DWEL) is not used because it is an intermediate term that is calculated in the process of developing the Lifetime HA value.
- USEPA's OPP derives Drinking Water Level of Comparison (DWLOC) values only for pesticides, so these values are not available for other NAWQA analytes. The DWLOC considers multiple exposure routes to pesticides, in addition to ingestion of water, so the exposure assumptions are not comparable with those used by the OW in developing drinking-water MCL values and Lifetime HA values.
- The Maximum Contaminant Level Goal (MCLG) is identical to the MCL for most noncarcinogens. For potential carcinogens, the MCLG is set at zero, implying that there is no safe level of this chemical (under the conservative, protective model used by USEPA). A benchmark of zero has limited utility for comparison with measured contaminant concentrations. In addition, all compounds that have MCLG values also have MCL values. MCL values are enforceable standards, whereas MCLG values are unenforceable health goals.
- Both Risk Based Concentrations (RBCs) and Preliminary Remediation Goals (PRGs) are regional USEPA values. Because NAWQA is a national program, regional health-based benchmarks have less utility than national benchmarks. RBCs and PRGs for residential tap water use are calculated in a manner similar to HBSL values. However, both tap water RBCs in Region 3 and tap water PRGs in Region 9 account for inhalation of volatile organic compounds (VOCs) present in a drinking-water source (U.S. Environmental Protection Agency, 1999a, 2002f), and inhalation exposure is not considered as part of this pilot effort. Note that Region 9 tap water PRGs are presented in three ways: (1) ingestion exposure, (2) inhalation exposure, and (3) combined ingestion and inhalation exposure (U.S. Environmental Protection Agency, 2002f).

Table 1. Descriptions of published USEPA human-health benchmark concentrations applicable to drinking water

[Maximum Contaminant Levels (MCLs) are enforceable standards; the remainder of the listed benchmarks are unenforceable guidelines or public-health goals. USEPA, U.S. Environmental Protection Agency; OW, Office of Water (USEPA); OPP, Office of Pesticide Programs (USEPA); ORD, Office of Research and Development (USEPA); mg/L, milligrams per liter]

Human-health benchmark	Acronym	USEPA office	Description	References
Action Level	ACT	OW	The concentration of a contaminant, which, if exceeded, triggers treatment or other requirements that a water system must follow. USEPA has action levels for lead and copper only.	(U.S. Environmental Protection Agency, 2001b, 2002a, 2002c)
Drinking Water Equivalent Level	DWEL	OW	A lifetime exposure concentration protective of adverse, noncancer health effects, that assumes all of the exposure to a contaminant is from drinking water.	(U.S. Environmental Protection Agency, 2002a)
Drinking Water Level of Comparison	DWLOC	OPP	A theoretical maximum concentration of a pesticide in drinking water that, when combined with exposures through food, residential, and other uses, would not exceed the maximum allowable dose (from toxicity studies) for that pesticide.	(U.S. Environmental Protection Agency, 2000a)
Lifetime Health Advisory	Lifetime HA	OW	The concentration of a contaminant in drinking water that is not expected to cause any adverse noncarcinogenic effects over a lifetime of exposure (70 years). The Lifetime HA assumes that only a portion (generally 20 percent) of the total exposure to a contaminant is from drinking water.	(U.S. Environmental Protection Agency, 1993b, 2002a)
Maximum Contaminant Level	MCL	OW	The highest concentration of a contaminant that is allowed in drinking water. MCLs are set as close to MCLGs as feasible using the best available treatment technology and taking cost into consideration.	(U.S. Environmental Protection Agency, 2002a, 2002b)
Maximum Contaminant Level Goal	MCLG	OW	The concentration of a contaminant in drinking water at which no known or anticipated adverse health effects occur and which allows an adequate margin of safety.	(U.S. Environmental Protection Agency, 2002a, 2002b)
Preliminary Remediation Goals (for tap water)	PRG	Region 9	Contaminant concentrations that correspond to fixed levels of risk (that is, a noncarcinogenic hazard quotient of 1, or lifetime cancer risk of 1 in 1,000,000) in soil, air, and water.	(U.S. Environmental Protection Agency, 2002f)
Risk Based Concentrations (for tap water)	RBC	Region 3	Contaminant concentrations that correspond to fixed levels of risk (that is, a noncarcinogenic hazard quotient of 1, or lifetime cancer risk of 1 in 1,000,000, whichever occurs at a lower concentration) in water, air, fish tissue, and soil.	(U.S. Environmental Protection Agency, 1999a)
Risk-Specific Dose	RSD	OW, ORD	The concentration of a contaminant in drinking water that corresponds to a specific estimated lifetime cancer risk (typically 1 in 10,000, 1 in 100,000, or 1 in 1,000,000). The RSD is always associated with a specific cancer risk level. A related benchmark is the unit drinking-water risk, which is risk per mg/L concentration.	(U.S. Environmental Protection Agency, 2001a, 2002a)
Secondary Drinking Water Regulation	SDWR	OW	Contaminant concentrations that may cause cosmetic effects (such as skin or tooth discoloration) or aesthetic effects (such as taste, odor, or color) in drinking water.	(U.S. Environmental Protection Agency, 2002a, 2002b)

HEALTH-BASED SCREENING LEVEL (HBSL) APPROACH

USGS, USEPA, NJDEP, and OHSU participants unanimously agreed to pursue the following two-tiered, screening level-based methodology for placing NAWQA water-quality data in a human-health context for State- and local-scale analyses and reports:

- Tier 1: For regulated contaminants (compounds for which Federal and (or) State drinking-water standards have been established), compare measured NAWQA concentration data with existing USEPA MCL values and applicable State standards.
- Tier 2: For contaminants that are not regulated in drinking water at either the Federal or State level, compare measured NAWQA concentration data with HBSL concentrations or ranges developed using USEPA OW methodologies (U.S. Environmental Protection Agency, 1988, 1993b).

This two-tiered approach for State- and local-scale analyses entails listing regulated compounds separately from unregulated compounds. For regulated compounds, USGS will continue to compare measured concentration data with Federal and (or) State standard values as has been done historically. Standard values are threshold values that are legally enforceable by Federal or State government agencies. HBSL concentrations or ranges will be used only for compounds for which no drinking-water standards have been established (that is, unregulated compounds).

In determining how to derive HBSL values for the Tier 2 analyses, several criteria were considered. To meet USGS needs, HBSL values must be: (1) health based, (2) systematically defined, (3) consistent for a given analyte (that is, only one HBSL value or range can exist for each analyte), (4) scientifically defensible, and (5) simple to use and interpret. The consensus approach described in this report meets all of these criteria. Note that, with respect to the last criterion, care must be taken that HBSL values are not used or interpreted inappropriately. This last caveat applies equally well, however, to comparison of measured concentrations with drinking-water standards and guidelines as it does to comparison with HBSL values, and it would apply regardless of how HBSL values were developed.

The procedures used to develop HBSL values differ for noncarcinogens and carcinogens. For unregulated compounds, the HBSL concentrations for noncarcinogens and HBSL concentration ranges for most carcinogens will be developed using (1) OW methodologies (U.S. Environmental Protection Agency, 1988, 1993b) for calculating Lifetime HA and RSD values, respectively, and (2) toxicity values from USEPA. As such, the HBSL values always will be consistent with the information about drinking water already coming from USEPA.

Toxicity values are available for many compounds analyzed by the NAWQA program that do not have USEPA standards (MCLs) or guidelines (Lifetime HA and RSD values). These toxicity values can be used to calculate HBSL values using the OW methodologies (U.S. Environmental Protection Agency, 1988, 1993b) described in this report. Drinking-water guidelines have not been established for these compounds with available toxicity values because the development of new guidelines is typically initiated when requested by States or regions for particular unregulated contaminants that frequently appear in drinking water. In recent years, requests to OW for new or updated drinking-water guidelines have been infrequent (J. Donohue, U.S. Environmental Protection Agency, written commun., 2003).

Acceptable Sources of Cancer Classifications and Toxicity Values for HBSL Development

Because the procedures used to develop HBSL values differ for noncarcinogens and carcinogens, the cancer classification of a given chemical is a critical piece of information. Also, the procedures rely on the availability of toxicity information at USEPA; that is, oral Reference Dose (RfD) or oral slope factor (SF) values for each chemical. The RfD value is an estimate (with an uncertainty of perhaps one order of magnitude) of the daily exposure that is likely to be without appreciable risk of deleterious health effects in the human population (including sensitive subgroups) over an individual's lifetime (70 years) (U.S. Environmental Protection Agency, 1989b). The oral SF value is the cancer potency estimate for a compound as derived from the slope of the dose-response (carcinogenicity) data extrapolated to zero using an appropriate mathematical model. If the model selected for extrapolation from dose-response data is the linearized multistage model, the SF value is also known as the q1* value (U.S. Environmental Protection Agency, 1989a, 1993b). The SF is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime (70 years) of exposure to a particular level of a potential carcinogen (U.S. Environmental Protection Agency, 1989b).

Exactly what constitutes an acceptable cancer classification or an acceptable toxicity value is an important technical detail in the derivation of HBSL values. The USGS, USEPA, NJDEP, and OHSU representatives involved in the pilot effort to develop HBSL values agreed that three primary sources of cancer classifications and toxicity values are acceptable to use in HBSL development. These acceptable sources of toxicity values are:

1. USEPA's Integrated Risk Information System (IRIS) database (U.S. Environmental Protection Agency, 2001a),
2. Publications from OW (U.S. Environmental Protection Agency, 2002a), and
3. Publications from OPP (U.S. Environmental Protection Agency, 1997b, 2002d, 2002e).

A fourth potential source of cancer classifications and toxicity values is the USEPA OSWER Health Effects Assessment Summary Tables (HEAST) (U.S. Environmental Protection Agency, 1997a). Neither OW nor OPP personnel use toxicity values listed in HEAST. However, the NJDEP does use toxicity information from HEAST. Consensus agreement with regard to HEAST data was that, if HEAST data have been peer reviewed as determined by consulting with ORD, then HEAST toxicity data may be used to develop HBSL values.

For some compounds, multiple USEPA cancer classifications or toxicity values for the same compound exist in different USEPA publications. The hierarchy of cancer classifications or toxicity sources to use in the development of HBSL values when toxicity values differ between various USEPA sources of information is shown in equation 1:

$$\text{IRIS} > \text{most recent of OW \& OPP} >> \text{HEAST} \quad (1)$$

HBSL values will be derived using IRIS toxicity data when these data exist, otherwise the most recent of OW and OPP toxicity data will be used. For example, if a compound has two RfD values, one published in IRIS and one published by OPP, the HBSL value will be calculated by using the RfD value published in IRIS. USGS and OHSU will consult with OW and OPP in cases when OW and OPP toxicity values differ from each other.

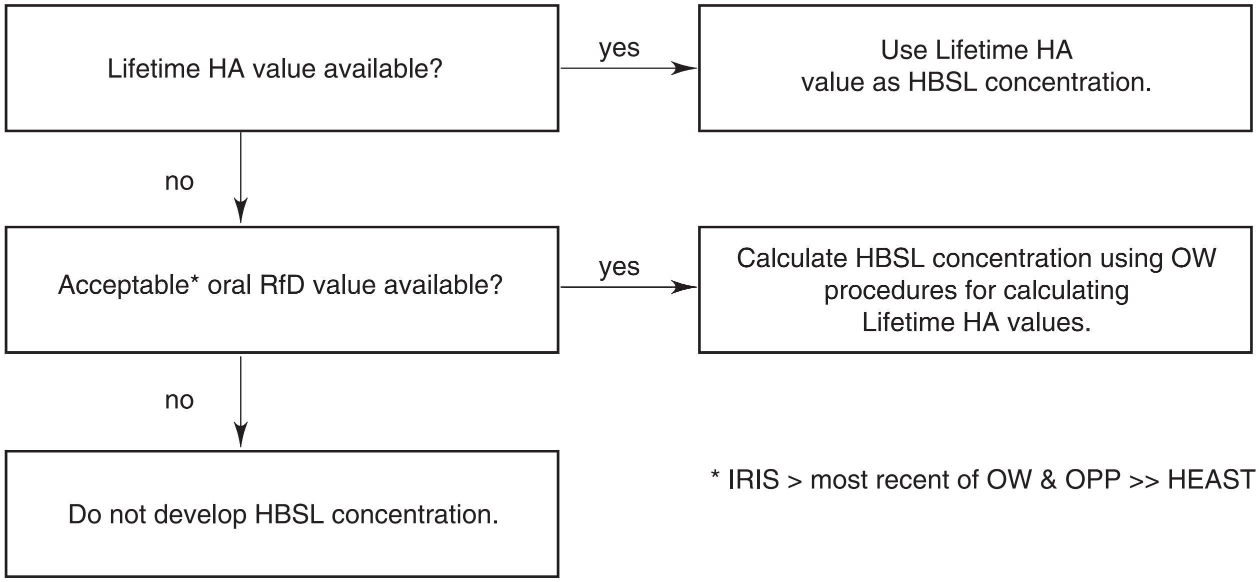
HBSL values will not be developed for compounds without acceptable toxicity values. The USGS will notify the USEPA when compounds that have no acceptable toxicity values are detected frequently in water resources.

Developing HBSL Concentrations for Unregulated Noncarcinogens

Unregulated noncarcinogens are defined here as contaminants without USEPA MCL values and (or) State standard values and having USEPA cancer classifications of Group D, Group E, "not likely to be carcinogenic to humans," "inadequate data or information," or "cannot be determined." These cancer classifications are described in USEPA's 1986 guidelines for carcinogen risk assessment (U.S. Environmental Protection Agency, 1986), USEPA's 1996 proposed guidelines for carcinogen risk assessment (U.S. Environmental Protection Agency, 1996), USEPA's 1999 draft revisions to these proposed guidelines (U.S. Environmental Protection Agency, 1999b), and USEPA's draft final guidelines for carcinogen risk assessment (U.S. Environmental Protection Agency, 2003). Note that OW considers Group C carcinogens to be noncarcinogens when developing Lifetime HA values, and introduces a risk management factor of 10 to account for potential carcinogenicity. HBSL procedures for Group C carcinogens are discussed below in the section called "Methodology for 'Suggestive Evidence' and Group C (Possible) Carcinogens."

Methodology for Unregulated Noncarcinogens

For unregulated noncarcinogens evaluated at the State or local scale, USEPA's Lifetime HA value will be used as the HBSL concentration, if available. If no Lifetime HA value is available for a noncarcinogen, but there is an acceptable RfD value, then the RfD value will be converted into a concentration using OW procedures and assumptions for calculating the Lifetime HA (U.S. Environmental Protection Agency, 1988, 1993b), and this calculated concentration will be used as the HBSL concentration. For noncarcinogens with no available Lifetime HA or RfD values, HBSL concentrations cannot be calculated (fig. 1).



[Lifetime HA, Lifetime Health Advisory; HBSL, health-based screening level; RfD, reference dose; USEPA, U.S. Environmental Protection Agency; OW, Office of Water (USEPA); IRIS, Integrated Risk Information System; OPP, Office of Pesticide Programs (USEPA); HEAST, Health Effects Assessment Summary Tables]

Figure 1. Flowchart showing development of HBSL concentrations for unregulated noncarcinogens at the State or local scale.

The OW's Lifetime HA is established for that part of an individual's lifetime exposure that is attributed to drinking water and is considered protective of noncarcinogenic adverse health effects over a lifetime of exposure (70 years). The Lifetime HA is calculated from the DWEL, which is based on the RfD value (eq. 2) (U.S. Environmental Protection Agency, 1989b).

$$\text{DWEL}\ (\mu\text{g/L}) = \frac{(\text{RfD}[\text{mg/kg/day}]) \times (70\ \text{kg body wt}) \times (1{,}000\ \mu\text{g/mg})}{(2\ \text{L water consumed/day})} \tag{2}$$

Like the DWEL, the Lifetime HA also assumes a body weight of 70 kg (kilograms) and consumption of 2 L/day (liters per day) of drinking water. OW accounts for the percentage of the total exposure typically accounted for by ingestion to drinking water using a Relative Source Contribution (RSC) factor. In the absence of actual exposure data, the RSC factor for the ingestion of drinking water is generally assumed to be 20 percent (80 percent of exposure is assumed to come from other sources) (U.S. Environmental Protection Agency, 1993b). OW now has a new RSC policy that accounts for exposures from other media (for example, nondrinking-water ingestion exposures, inhalation and (or) dermal exposures) when setting an Ambient Water Quality Criteria (AWQC) value (U.S. Environmental Protection Agency, 2000b). For the purpose of HBSL development, however, the RSC factor will remain 20 percent because only potential drinking-water exposure is considered. The Lifetime HA is calculated as shown in equation 3 (U.S. Environmental Protection Agency, 1988, 1993b). With few exceptions, OW rounds Lifetime HA values to one significant figure (U.S. Environmental Protection Agency, 2002a). HBSL values also are rounded to one significant figure.

$$\text{Lifetime HA}\ (\mu\text{g/L}) = \text{DWEL} \times \text{RSC} = \text{DWEL} \times 0.2 \tag{3}$$

Examples: Unregulated Noncarcinogens

The examples in table 2 illustrate the procedures used to develop HBSL concentrations for four unregulated noncarcinogens analyzed by NAWQA. All four of these NAWQA analytes are considered noncarcinogens because their USEPA cancer classifications are Group D (not classified—inadequate or no human or animal evidence of carcinogenicity), Group E (evidence of noncarcinogenicity), or not available. Compounds with no available cancer classifications are equivalent to Group D compounds (not classified), and the default procedure here, and for OW when developing Lifetime HA values (U.S. Environmental Protection Agency, 1988, 1993b), is to treat these compounds like noncarcinogens. For noncarcinogens, Lifetime HA values are used as the HBSL concentrations, if Lifetime HA values exist for those compounds (fig. 1).

One of the NAWQA analytes in table 2, terbacil, has a Lifetime HA value, and therefore, this Lifetime HA value is adopted as the HBSL concentration. Neither ethyl ether nor isopropyl benzene has a Lifetime HA value, but they both have RfD values, which are used as the basis for the HBSL concentration using the Lifetime HA approach (eq. 3). Fenuron, the fourth compound listed in table 2, does not have a Lifetime HA value or an RfD value, so an HBSL concentration cannot be developed for this compound.

Developing HBSL Concentrations or Concentration Ranges for Unregulated Carcinogens

Unregulated carcinogens are defined here as contaminants without USEPA MCL values or State standards and having cancer classifications of “known” (Group A), “probable” (Group B1 or B2), and “possible” (Group C) carcinogens for contaminants classified under USEPA's 1986 guidelines for carcinogen risk assessment (U.S. Environmental Protection Agency, 1986). Unregulated carcinogens also include those contaminants having cancer classifications of “known/likely,” “likely to be carcinogenic to humans,” “carcinogenic to humans,” and “suggestive evidence of carcinogenic potential” for contaminants classified under USEPA's 1996 proposed guidelines for carcinogen risk assessment (U.S. Environmental Protection Agency, 1996), USEPA's 1999 draft revisions to these proposed guidelines (U.S. Environmental Protection Agency, 1999b), and USEPA’s draft final guidelines for carcinogen risk assessment (U.S. Environmental Protection Agency, 2003). Regulated carcinogens have these same cancer classifications, but they have USEPA MCL and (or) State standard values.

Table 2. Examples of development of HBSL concentrations for unregulated noncarcinogens

[Lifetime HA, Lifetime Health Advisory; RfD, oral reference dose; HBSL, health-based screening level; USEPA, U.S. Environmental Protection Agency; OW, Office of Water (USEPA); OPP, Office of Pesticide Programs (USEPA); IRIS, Integrated Risk Information System; HEAST, Health Effects Assessment Summary Tables; µg/L, micrograms per liter; mg/kg/day, milligrams of contaminant per kilogram of body weight per day; NA, not available]

Analyte	Cancer class, source	Lifetime HA (µg/L)	RfD, source (mg/kg/day)	HBSL concentration (µg/L)	Basis for HBSL concentration
Terbacil	Group E, OW and OPP	90	0.013, IRIS and OPP; 0.01, OW	90	Lifetime HA
Ethyl ether	Not Classified	NA	0.2, IRIS and HEAST	1,000	Lifetime HA approach using IRIS RfD
Isopropyl benzene	Group D, IRIS and OW	NA	0.1, IRIS, OW, and HEAST	700	Lifetime HA approach using IRIS RfD
Fenuron	Not Classified	NA	NA	NA	Do not develop HBSL. Lack of toxicity values.

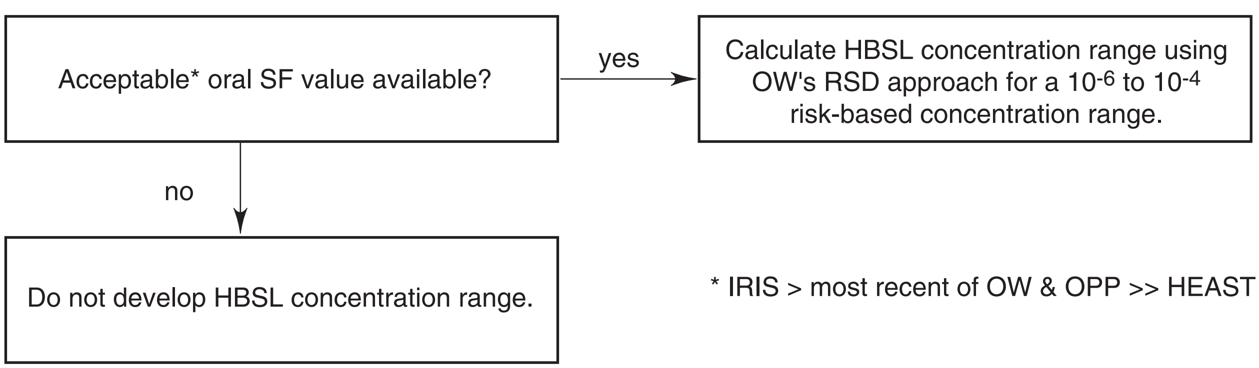
Methodology for "Known," "Likely," Group A, and Group B Carcinogens

For "known," "likely," Group A, or Group B carcinogens without USEPA MCL and (or) State standard values, an HBSL concentration range (10^{-6} to 10^{-4}) will be calculated in lieu of a single HBSL concentration for those carcinogens using an acceptable oral SF value. HBSL concentration ranges cannot be calculated for "known," "likely," Group A, or Group B carcinogens with no available SF values (fig. 2).

The HBSL concentration range will correspond to an acceptable cancer risk range of 10^{-6} to 10^{-4}, and will be calculated using the OW's procedures and default assumptions for deriving RSD values. An RSD is the drinking-water concentration associated with a specified cancer risk level, under certain exposure conditions: consumption of 2 L/day of drinking water by a 70-kg body weight individual over a lifetime (70 years) (U.S. Environmental Protection Agency, 1993b). The low end of the HBSL concentration range will be equivalent to the RSD value associated with a cancer risk level of 10^{-6}, and the high end of the HBSL concentration range will be equivalent to the RSD value associated with a cancer risk level of 10^{-4}. This range is consistent with drinking-water information currently reported by USEPA. In the IRIS database, USEPA reports RSD values at risk levels of 10^{-4}, 10^{-5}, and 10^{-6} for carcinogens that have quantitative estimates of the carcinogenic risk from oral exposure (see, for example, dieldrin (U.S. Environmental Protection Agency, 1993a)). RSD values are called drinking-water concentrations at specified risk levels in the IRIS database. OW reports RSD values at a cancer risk level of 10^{-4} in its "2002 Edition of the Drinking Water Standards and Health Advisories" (U.S. Environmental Protection Agency, 2002a).

An RSD value is always associated with a specific cancer risk level, and this cancer risk level represents the upper-bound estimate of the excess cancer risk attributed to a lifetime of consumption of drinking water that contains the contaminant at the RSD concentration. RSD values are calculated from the cancer risk level and the oral SF value, also called the q_1*. The mathematical model used to derive the SF value is conservative (that is, protective), and is typically a non-threshold model, so the resulting cancer risk is an upper-limit estimate (U.S. Environmental Protection Agency, 1989a, 1993b). The RSD is calculated as shown in equation 4:

$$\mathrm{RSD}(\mu g/L) = \frac{(70\text{ kg body wt}) \times (\text{risk level})}{(2\text{ L water consumed/day}) \times (\text{SF [mg/kg/day]}^{-1}) \times (\text{mg/1,000 }\mu g)} \qquad (4)$$



[SF, slope factor; HBSL, health-based screening level; USEPA, U.S. Environmental Protection Agency; OW, Office of Water (USEPA); RSD, Risk-Specific Dose; IRIS, Integrated Risk Information System; OPP, Office of Pesticide Programs (USEPA); HEAST, Health Effects Assessment Summary Tables]

Figure 2. Flowchart showing development of HBSL ranges for unregulated "known," "likely," Group A, and Group B carcinogens at the State or local scale.

An RSD value at a 10^{-4} or 10^{-6} cancer risk level is the concentration of a potential carcinogen in drinking water that is estimated to result in an excess cancer risk of one in ten thousand, or one in one million, respectively. For carcinogens in drinking water, USEPA considers risk levels of 10^{-6} (and for some compounds, risk levels as high as 10^{-4}) to be protective of public health, provided these levels also are protective of noncancer adverse effects (U.S. Environmental Protection Agency, 1988). Selection of an acceptable risk level is a risk management decision (U.S. Environmental Protection Agency, 1995b). USEPA reviews individual State policies on cancer risk levels as part of its water-quality standards oversight function under the Clean Water Act. USEPA's policy is to accept cancer risk policies from the States in the range of 10^{-6} to 10^{-4} (U.S. Environmental Protection Agency, 1992, 1995a), although USEPA prefers risk levels of 10^{-6} and generally accepts only those State standards for the general public that are in the 10^{-5} to 10^{-6} range. The risk for highly exposed populations should not exceed 10^{-4} (U.S. Environmental Protection Agency, 2000b). Therefore, developing an HBSL concentration range for unregulated carcinogens that represents a cancer risk range of 10^{-6} to 10^{-4} is consistent with USEPA procedures and acknowledges the uncertainty of the estimate.

The importance of keeping pace with any changes in toxicity information, cancer classifications, or OW methodologies for quantifying cancer risks is acknowledged. For example, new cancer classifications (such as “likely” at high doses and “unlikely” at low doses) and methods for quantification of human risk (such as the Margin of Exposure (MOE) approach) are anticipated to be used more often by USEPA in response to revisions to USEPA’s guidelines for carcinogen risk assessment (which were proposed in 1996, revised in 1999 and 2003, but were not final as of April 2003). Currently, OPP recommends that the USGS not deviate from OW methodologies (for example, using the RSD approach), even when OPP has recommended quantification of potential human cancer risk using an approach other than a linear, nonthreshold model, such as the MOE approach. OPP has not replaced the RSD approach with the MOE approach, although it has sometimes used both approaches (C. Eiden and E. Doyle, U.S. Environmental Protection Agency, oral commun., 2001). When USEPA recommends that the MOE approach be used for carcinogens, HBSL concentration ranges for such carcinogens will be developed in consultation with USEPA.

Methodology for “Suggestive Evidence” and Group C (Possible) Carcinogens

For unregulated “suggestive evidence of carcinogenic potential” or Group C (possible) carcinogens, USEPA’s Lifetime HA value will be used as the HBSL concentration, when available (fig. 3). For those “suggestive evidence” or Group C carcinogens without a Lifetime HA and for which USEPA has recommended that an RfD approach be used for quantification of risk, the HBSL concentration will be calculated using the OW’s procedures for calculating a Lifetime HA value, using an additional uncertainty factor of 10 to account for potential carcinogenicity (eq. 5); this is OW’s standard procedure for calculating the Lifetime HA for Group C carcinogens (U.S. Environmental Protection Agency, 1993b).

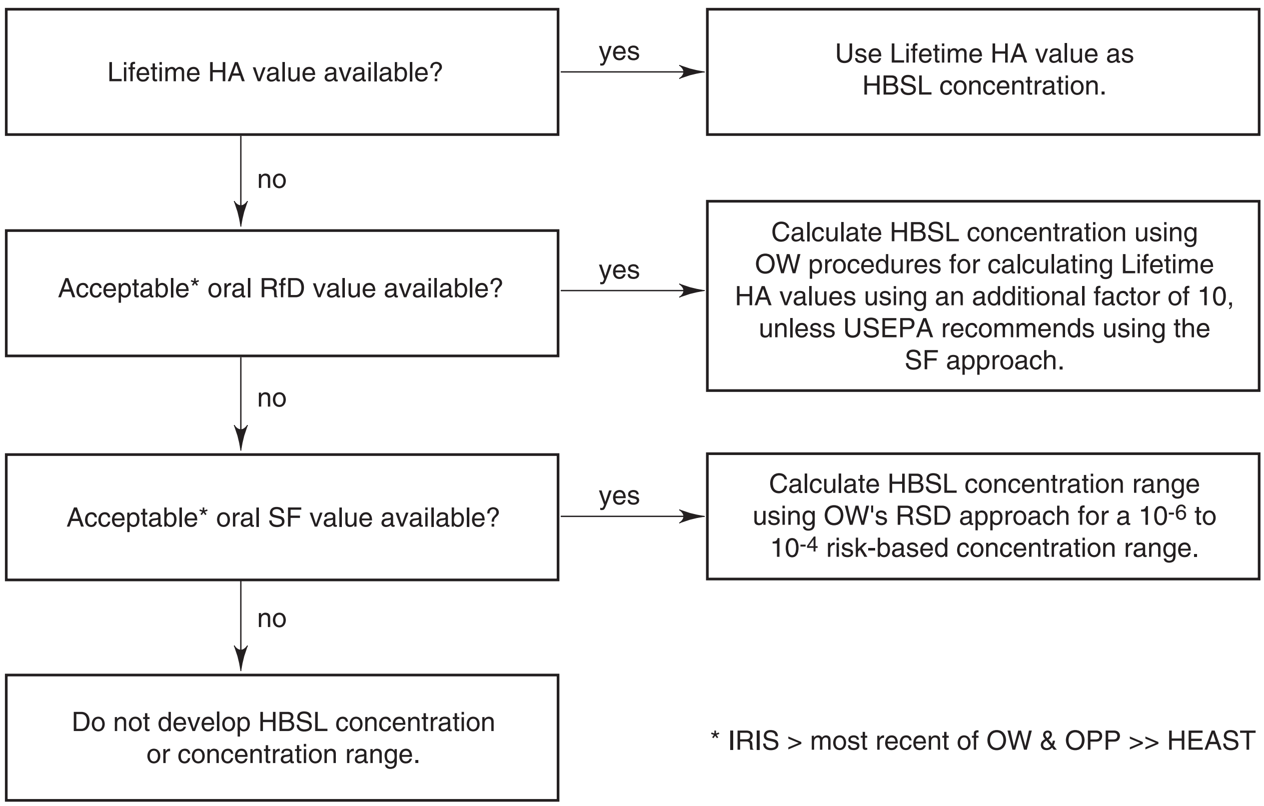
$$\text{Lifetime HA}_{\text{Group C}}\ (\mu\text{g/L}) = \frac{\text{DWEL} \times \text{RSC}}{10} = \frac{\text{DWEL} \times 0.2}{10} \qquad (5)$$

For those Group C carcinogens without a Lifetime HA and for which USEPA has recommended quantification of potential human cancer risk using a linear low-dose extrapolation model, and that do have oral SF values, an HBSL concentration range will be calculated using OW’s RSD approach (eq. 4), instead of a single HBSL concentration calculated using OW’s Lifetime HA approach. HBSL values cannot be calculated for Group C carcinogens with no available Lifetime HA, RfD, or SF values (fig. 3).

Examples: Unregulated Carcinogens

The examples in table 3 illustrate the procedures used to develop HBSL concentrations and ranges for unregulated carcinogens analyzed by NAWQA. All four of the NAWQA analytes in table 3 are considered carcinogens because their cancer classifications are Group B2 (probable human carcinogen), Group C (possible human carcinogen), or “suggestive evidence.”

Each of the three Group C or “suggestive evidence” carcinogens in table 3 is treated differently. Cyanazine is a Group C carcinogen with a Lifetime HA value, so the Lifetime HA value is adopted as the HBSL concentration. Dicrotophos is a “suggestive evidence” carcinogen with no Lifetime HA value.



[Lifetime HA, Lifetime Health Advisory; HBSL, health-based screening level; RfD, reference dose; OW, Office of Water (USEPA); USEPA, U.S. Environmental Protection Agency; SF, slope factor; RSD, Risk-Specific Dose; IRIS, Integrated Risk Information System; OPP, Office of Pesticide Programs (USEPA); HEAST, Health Effects Assessment Summary Tables]

Figure 3. Flowchart showing development of HBSL concentrations or ranges for unregulated Group C and “suggestive evidence” carcinogens at the State or local scale.

However, dicrotophos does have an RfD value, which is used as the basis for the HBSL concentration using the Lifetime HA approach for Group C compounds (which includes an extra 10-fold uncertainty factor). Note that dicrotophos has two different RfD values—one published in the IRIS database, and one published by OPP. The IRIS RfD value was used to calculate the HBSL value because IRIS toxicity values take precedence in the development of HBSL values when toxicity values differ between USEPA sources of information (eq. 1). Beta-benzene hexachloride (beta-BHC) is a Group C carcinogen that does not have either a Lifetime HA value or RfD value, but does have an SF value. Therefore, the SF value is used as the basis for the HBSL concentration range using the RSD approach. The fourth compound in table 3, p,p'-DDE, is a Group B2 carcinogen with an available SF value; therefore, its SF value is used as the basis for the HBSL concentration range using the RSD approach. HBSL values are rounded to one significant figure.

Benefits of Using HBSL Benchmarks

The most useful USEPA benchmarks for comparison with contaminant concentrations in water measured by NAWQA are the MCL, Lifetime HA, and RSD values. However, these drinking-water standards and guidelines do not exist for 207 out of 329 analytes measured by the NAWQA program. Nonetheless, acceptable toxicity values are available for nearly one-half of the NAWQA analytes that do not currently (as of April 2003) have MCL, Lifetime HA, or RSD values, and these toxicity values can be used to calculate HBSL values using OW methodologies (U.S. Environmental Protection Agency, 1988, 1993b). The calculation of HBSL values will increase the percentage of NAWQA analytes that have health-based benchmarks from 37 percent to 64 percent (fig. 4). Approximately 90 new HBSL concentrations or concentration ranges can be calculated for unregulated VOCs, pesticides, pesticide degradation products, nutrients, and trace elements. Most (72) of the new HBSL values are for pesticides (fig. 4). The majority of NAWQA analytes are included in figure 4, although additional compounds are occasionally analyzed by some of the NAWQA study units. Note that because different States may not use the same drinking-water standard values, the number of compounds for which HBSL values are developed may vary from State to State. Therefore, HBSL concentrations and concentration range values are not included in this report, but will be published after the completion of the LINJ and national pilot projects referred to in the "Introduction" section.

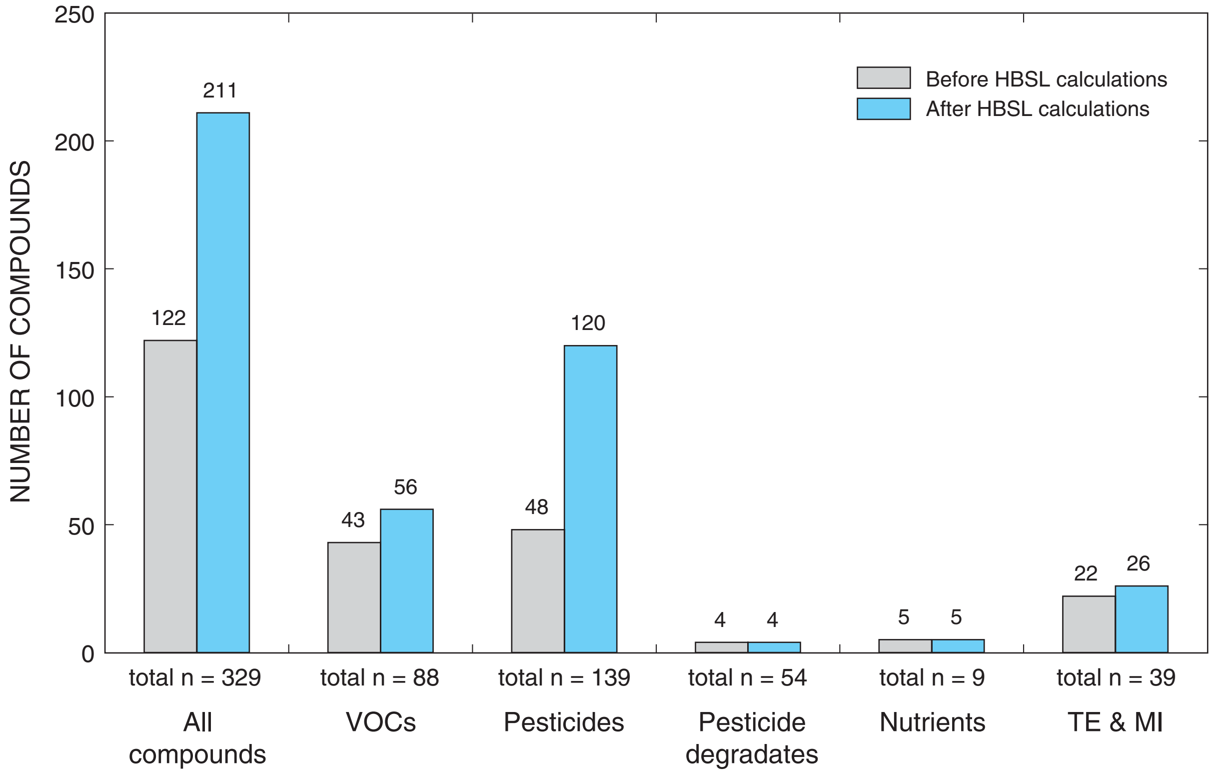
Utilizing the HBSL values also will simplify data analysis in State-level reports. The USGS will continue to compare measured concentrations of regulated compounds with Federal and State MCL values. Concentrations of unregulated compounds will be compared with HBSL values. As described above, HBSL values for noncarcinogens and Group C carcinogens will be equivalent to OW's Lifetime HA values, where Lifetime HA values exist. HBSL values for carcinogens typically are equivalent to published RSD values, unless more recent toxicity values are used to develop the HBSL concentration ranges for carcinogens than were used in RSD development. Therefore, HBSL concentrations and concentration ranges are consistent with the information about drinking water already published by the USEPA.

Finally, the HBSL values have utility beyond the USGS NAWQA program. HBSL values and the rationale used to develop these values may have potential applications to other projects and studies conducted by USGS, as well as by other agencies. Several factors must be considered, however, when applying HBSL values to studies conducted by NAWQA or by others. First, the methodologies described in this report apply only to State- and local-scale water-quality assessments. Multi-State water-quality assessments would require additional considerations, which are being investigated in a second, national-scale pilot project. Second, comparisons of raw water concentrations with HBSL values, as with any other drinking-water benchmarks such as MCL values, require careful interpretation. Lastly, HBSL values are new benchmarks that will not initially be familiar to State drinking-water agencies, water utilities, or other interested parties, so it is important that water-quality findings be communicated in consultation with the appropriate drinking-water agencies.

Table 3. Examples of development of HBSL concentrations and ranges for unregulated carcinogens

[Lifetime HA, Lifetime Health Advisory; RfD, oral reference dose; SF, oral slope factor; HBSL, health-based screening level; USEPA, U.S. Environmental Protection Agency; OPP, Office of Pesticide Programs (USEPA); HEAST, Health Effects Assessment Summary Tables; OW, Office of Water (USEPA); IRIS, Integrated Risk Information System; RSD, Risk-Specific Dose; µg/L, micrograms per liter; mg/kg/day, milligrams of contaminant per kilogram of body weight per day; NA, not available]

Analyte	Cancer class, source	Lifetime HA (µg/L)	RfD, source (mg/kg/day)	SF, source $(mg/kg/day)^{-1}$	HBSL concentration or range (µg/L)	Basis for HBSL concentration or range
Cyanazine	Group C, OPP and HEAST	1	0.002, OW, OPP, and HEAST	0.166, OPP; 0.84, HEAST	1	Lifetime HA
Dicrotophos	"Suggestive Evidence," OPP	NA	0.0001, IRIS; 0.00002, OPP	NA	0.07	Lifetime HA approach for Group C carcinogens using IRIS RfD
Beta-BHC	Group C, IRIS and HEAST	NA	NA	1.8, IRIS	0.02 to 2	RSD approach using IRIS SF
p,p'-DDE	Group B2, IRIS, OPP, and HEAST	NA	NA	0.34, IRIS and HEAST	0.1 to 10	RSD approach using IRIS SF



[NAWQA, National Water-Quality Assessment Program; VOCs, volatile organic compounds; HBSL, health-based screening level; MCL, maximum contaminant level; Lifetime HA, Lifetime Health Advisory; RSD, Risk-Specific Dose; ACT, action level; TE & MI, trace elements & major ions; n, number of compounds}

Figure 4. Number of NAWQA analytes, including VOCs, pesticides, pesticide degradation products, nutrients, and trace elements and major ions, with health-based benchmarks before and after HBSL calculations. The health-based benchmarks before HBSL calculations include MCL, Lifetime HA, RSD, and ACT values.

USE OF HBSL VALUES AS TOOLS IN WATER-QUALITY ASSESSMENTS

This section provides step-by-step procedures, followed by a general hypothetical ground-water example, for the application of HBSL concentrations and ranges in water-quality assessments. A real, more detailed example of how HBSL values can be used to analyze water-quality data in State- or local-scale reports in a human-health context, is being prepared using data from the Glassboro-LINJ State-level pilot project. The USGS, USEPA, NJDEP, and OHSU agreed that, in State and local-scale reports and analyses, water-quality concentration data will be presented in two tables. The first table will list USEPA MCL values and (or) State drinking-water standards for compounds that are regulated at the Federal and (or) State level. The second table will list HBSL concentrations (for noncarcinogens) and HBSL concentration ranges (for most carcinogens) for compounds that are not regulated.

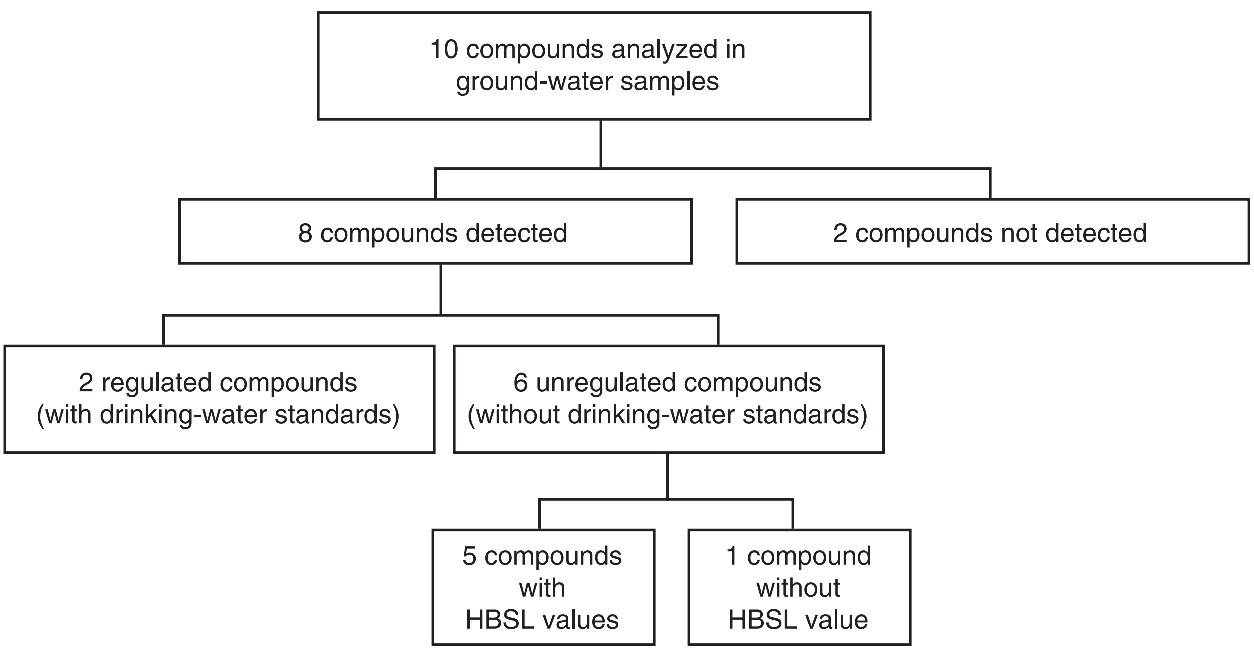
In order to present water-quality concentration data in two tables, one each for regulated and unregulated compounds, follow four general steps:

1. Determine which of the detected compounds are regulated and which are unregulated by locating the USEPA MCL and State drinking-water standard values for each detected compound. Current (as of April 2003) USEPA MCL values are published in the USEPA drinking-water standards and health

advisories document (U.S. Environmental Protection Agency, 2002a). State MCL values are typically published on State drinking-water program Internet sites (for example see, Association of State Drinking Water Administrators, 2002). Regulated compounds have established Federal and (or) State drinking-water standards, and unregulated compounds do not. Standards are threshold values that are legally enforceable by agencies of the Federal or State governments.

2. List regulated compounds in a table along with the applicable Federal and State drinking-water standard values. For these regulated compounds, compare measured concentrations for the regulated compounds with all applicable standards.
3. List compounds that are unregulated at both the Federal and State levels in a second table along with HBSL values and any applicable State guideline values. Guidelines are threshold values that were issued in an advisory capacity and are not legally enforceable. Then, compare measured concentrations for the unregulated compounds with State drinking-water guidelines values (if available) and with HBSL concentrations or concentration ranges.
4. Interpret the results, bearing in mind the limitations of comparing measured concentrations in untreated water resources with drinking-water standards and HBSL values. Data should be interpreted and published in collaboration or consultation with the appropriate State and (or) local drinking-water agencies.

An example demonstrating these four steps follows. In the following hypothetical example, assume that 10 compounds were analyzed in 10 ground-water samples collected from 10 different wells, and that 8 of these 10 compounds (arbitrarily named AAA through HHH) were detected at various frequencies in the samples. Two of the eight detected compounds are regulated, and six are unregulated. Five of the six unregulated compounds have available toxicity data, and therefore HBSL values, and one of the unregulated compounds does not have an HBSL value (fig. 5). Further assume that State standards and guidelines apply to this example.



[HBSL, health-based screening level]

Figure 5. Flowchart for hypothetical ground-water example showing the number of detected compounds that are regulated and unregulated, and the availability of HBSL values for unregulated compounds.

In the first step, list the eight compounds detected in ground-water samples, along with all available USEPA MCL and State standard values (table 4). Compounds GGG and HHH are considered regulated compounds because they have USEPA MCL values and (or) State MCL values.

In the second step, compare measured ground-water concentrations for the regulated compounds with USEPA MCL values and State MCL values (table 5). The measured concentrations may be presented in a variety of ways, depending on the objectives of the analyses. Table 5 presents median concentrations and maximum concentrations along with the frequency of detection of each regulated compound. In this hypothetical example, the maximum concentration of compound HHH exceeds both the USEPA and State MCL values. However, the median concentration of compound HHH does not exceed either the USEPA or State MCL values. Neither the maximum concentration nor median concentration of compound GGG exceeds USEPA or State MCL values. Because compound GGG was detected infrequently (1 out of 10 samples), the median concentration for compound GGG is presented as less than the method detection limit (in this case, 0.002 µg/L (micrograms per liter)). Tables like table 5 may include additional information (such as the number of samples that exceed each standard), if desired. Note that table 5 follows a format similar to that currently used by the USGS in reporting its water-quality data.

In the third step, compare measured ground-water concentrations (for example, median concentrations, maximum concentrations, etc.) for the unregulated compounds with HBSL concentrations and concentration ranges, and with any applicable State guideline values (table 6). Not all States have drinking-water guidelines, but some State guideline values are called ground-water quality criteria (GWQC) that specify the concentrations of constituents in the untreated ground-water resource, concentrations above which the ground-water would pose an unacceptable risk for drinking water. In this ground-water example, the median concentration and maximum concentration for compound BBB exceeds both the State GWQC and the low end of the HBSL concentration range. All of the remaining unregulated compounds were detected at concentrations below HBSL values. Table 6 also indicates the frequency of detection of each unregulated compound, as well as the basis for the HBSL (the approach and the source and type of toxicity data used to calculate the HBSL concentrations and ranges). For compounds that were detected infrequently (compounds AAA, DDD, and FFF), the median concentration is presented as less than the method detection limit (in these cases, 0.002 µg/L). Again, additional information (such as the number of samples that exceed the HBSL or State GWQC guideline values) could be included in the table, if desired.

Table 4. Regulated versus unregulated compounds in hypothetical ground-water example

[USEPA, U.S. Environmental Protection Agency; OW, Office of Water (USEPA); MCL, Maximum Contaminant Level; µg/L, micrograms per liter; NA, not available]

Contaminant name	USEPA OW MCL (µg/L)	State MCL (µg/L)	Regulated/ unregulated
AAA	NA	NA	Unregulated
BBB	NA	NA	Unregulated
CCC	NA	NA	Unregulated
DDD	NA	NA	Unregulated
EEE	NA	NA	Unregulated
FFF	NA	NA	Unregulated
GGG	2	2	Regulated
HHH	5	1	Regulated

Table 5. Comparison of measured concentrations with USEPA and State drinking-water standards for regulated compounds in hypothetical ground-water example

[Bold type indicates measured concentration exceeds standard. GW, ground water; USEPA, U.S. Environmental Protection Agency; OW, Office of Water (USEPA); MCL, Maximum Contaminant Level; µg/L, micrograms per liter; <, less than]

Contaminant name	Number of samples with detections (out of 10)	Median GW concentration (µg/L)	Maximum GW concentration (µg/L)	USEPA OW MCL (µg/L)	State MCL (µg/L)
GGG	1	<0.002	0.07	2	2
HHH	7	0.06	**7**	5	1

Table 6. Comparison of measured concentrations with State guideline values and HBSL concentrations and ranges for unregulated compounds in hypothetical ground-water example

[Bold type indicates measured concentration exceeds State guideline value and the low end of the HBSL range. GW, ground water; GWQC, Ground-Water Quality Criteria; HBSL, health-based screening level; RSD, Risk-Specific Dose; USEPA, U.S. Environmental Protection Agency; OPP, Office of Pesticide Programs (USEPA); q1*, cancer potency factor; IRIS, Integrated Risk Information System; SF, oral slope factor; Lifetime HA, Lifetime Health Advisory; RfD, oral reference dose; µg/L, micrograms per liter; NA, not available; <, less than]

Contaminant name	Number of samples with detections (out of 10)	Median GW concentration (µg/L)	Maximum GW concentration (mg/L)	State guideline value (GWQC) (µg/L)	HBSL concentration or range (µg/L)	Basis for HBSL
AAA	1	<0.002	0.06	NA	2 to 200	RSD approach using OPP q1*
BBB	8	**0.03**	**0.05**	0.002	0.002 to 0.2	RSD approach, using IRIS SF
CCC	10	0.008	0.02	NA	NA	No HBSL because there are no toxicity data
DDD	1	<0.002	0.01	NA	1	Lifetime HA approach for Group C carcinogens using IRIS RfD
EEE	9	0.009	0.7	NA	100	Lifetime HA value
FFF	2	<0.002	0.03	NA	700	Lifetime HA approach using IRIS RfD

In the fourth step, interpreting the water-quality results, any exceedances (or lack of exceedances) of MCL values and HBSL values should be put in the proper context, with regard to both hydrology and to human health. Detection frequency, contaminant sources, the physical-chemical properties of the contaminants, and potential exposure considerations (table 7) should all be taken into account when interpreting the results. When a sampled water resource is currently used as a source of drinking water, it is particularly important to consider whether the water will be treated prior to consumption, and to acknowledge the effects that treatment processes are likely to have on contaminant concentrations. It is also important to consider how changes within the distribution system may affect contaminant concentrations. Note that although the hypothetical example discussed in this section is for a ground-water resource, most of the factors identified in table 7 to consider when interpreting water-quality data also apply to surface-water resources. A detailed example that provides guidance on how to consider the factors listed in table 7 (detection frequency, etc.) will be presented in a planned report for the Glassboro-LINJ pilot project.

In interpreting the water-quality results, care must be taken that the HBSL values are not used or interpreted inappropriately. Table 8 summarizes what HBSL values are and what they are not, and what it means if measured concentrations exceed HBSL values. Health-based benchmarks (including MCL and HBSL values) are based on a lifetime (70 years) of exposure (table 8). Therefore, it is important to determine which measured concentration (for example, median concentration, maximum concentration, etc.) to compare with these benchmarks in a given hydrologic system. In surface-water bodies, contaminant concentrations can change significantly as a function of time, and comparing time-weighted average concentrations with health-based benchmarks may be most appropriate. In ground water, contaminant concentrations change more slowly as a function of time, and, depending on the objectives of the analysis, it may be appropriate to compare a variety of concentrations with health-based benchmarks (examples include median and maximum concentrations, a median-detected concentration (which excludes nondetected concentrations), and (or) a range of percentiles such as the 25th, 50th, and 75th percentiles). Note that the median-detected concentration may be biased towards the high end of the concentration distribution, particularly when there are a significant number of samples with nondetected concentrations. It is also important to recognize that comparisons between maximum concentrations and health-based benchmarks are highly conservative and may overestimate the hazard or risk associated with potential exposure to the water resource. Exposure over the long-term, as measured by average or median concentrations (as opposed to 1-day maximum-detected concentrations), is more relevant to benchmarks based on a lifetime of exposure, particularly for surface-water bodies.

It is important to consult with the appropriate State or local drinking-water agencies before presenting or publishing interpretive statements about drinking-water quality or exposure. These agencies have regulatory responsibilities in the area of drinking water, they will be stakeholders in the results, and they have significant technical expertise in risk assessment and risk communication that can be brought to bear in assessing the results. In some cases, it may be appropriate for the USGS to issue a joint press release with appropriate State or local agencies.

Table 7. Examples of factors to consider when interpreting results of water-quality analyses

[MCL, Maximum Contaminant Level; HBSL, health-based screening level]

Detection frequency and contaminant source considerations	Physical-chemical property considerations	Potential exposure considerations
• How frequently is the contaminant detected in an area? • How often were MCL or HBSL values exceeded and not exceeded? • How far above or below the MCL or HBSL values are the measured concentrations? • Are there possible natural and anthropogenic sources of the contaminant in the vicinity of the sampled sites? • What is the land use in the vicinity of the sampled sites (for example, agricultural, residential, etc.)?	• What do the physical and chemical properties of the contaminant indicate about its fate and transport? • How biodegradable is the contaminant? • How long is the contaminant likely to persist in surface water or ground water? • Is the contaminant likely to migrate to other water resources? • What were the hydrologic conditions at the time of sample collection? • If ground water is sampled, what were the important geochemical conditions in the aquifer at the time of sample collection? • Were filtered or whole water samples analyzed?	• Is the sampled surface water or ground water a current drinking-water source, or a potential future drinking-water source? • Is the surface water or ground water treated before it is consumed? If so, what is the potential for common treatment practices to reduce or remove the contaminant? • Are contaminant concentrations expected to change in distribution systems? • If ground water is sampled, what types of wells were sampled (for example, monitoring wells versus domestic wells and public-supply wells)? • If ground water is sampled, is it shallow ground water that is not directly consumed but that may be both a contributor to, and a predictor of, contaminant concentrations in deeper aquifers at some later period of time? • If surface water is sampled, what type of surface water was sampled (for example, agricultural drainage ditch, creek, stream, river, reservoir, etc.) and what is the distance (if known or can be estimated) to a drinking-water intake (if any)?

Table 8. What are HBSL values, and what does it mean if HBSL values are exceeded?

[HBSL, health-based screening level; USEPA, U.S. Environmental Protection Agency; OW, Office of Water (USEPA); Lifetime HA, Lifetime Health Advisory; RSD, Risk-Specific Dose; RSC, Relative Source Contribution; MCL, Maximum Contaminant Level]

What HBSL values are, and what it means if an HBSL is exceeded	What HBSL values are not, and what HBSL exceedances do not mean
• HBSL values provide human health-based benchmarks, against which measured contaminant concentrations can be compared, that are consistent with OW methodologies for setting drinking-water Lifetime HA and RSD values. • The use of HBSL values expands the number of contaminants for which human health-based benchmarks (such as drinking-water standards or guidelines) are available for comparison with water-quality data. • HBSL values are a useful trigger or threshold for notifying the appropriate State drinking-water agencies and the USEPA when measured concentrations meet or exceed the HBSL concentrations or ranges. • HBSL values are defined systematically. HBSL values for noncarcinogens are consistent with Lifetime HA values and HBSL ranges for carcinogens are consistent with RSD values at risk levels of 10^{-6} to 10^{-4}. • HBSL values entail the same assumptions as USEPA Lifetime HA and RSD values for humans: consumption of 2 liters of water per day over a 70-year lifetime by the general adult population (70-kilogram body weight). For noncarcinogens, HBSL concentrations and (in the absence of data to support a different RSC) Lifetime HA values also assume that a default 20 percent of exposure comes from drinking water. • For potential carcinogens, the HBSL range merely indicates concentrations that are associated with worst-case estimates of cancer risk between 10^{-6} and 10^{-4}. For carcinogens in drinking water, USEPA considers risk levels of 10^{-6} (and for some compounds, risk levels as high as 10^{-4}) to be protective of public health, provided these levels also are protective of noncancer adverse effects (U.S. Environmental Protection Agency, 1988). Exceedance of the lower end of the HBSL range indicates that the worst-case cancer risk associated with a lifetime consumption of drinking water at that concentration would exceed one in a million. • HBSL values can be used as a planning tool to identify water resources with contaminant concentrations of potential concern, to support science-based decisions to manage these water resources, to identify locations for future water-supply development, and to help direct future scientific research.	• Exceedance of HBSL values does not indicate any violation of drinking-water standards, State or Federal. • HBSL concentrations do not necessarily indicate safe drinking-water concentrations. • Exceedance of HBSL values does not necessarily mean that people who potentially ingest the water are adversely affected because (1) the models used by OW are intentionally conservative (protective) and include safety factors; (2) the models assume lifetime exposure to these concentrations, whereas the concentrations of contaminants may change seasonally or over time; (3) raw water is often treated prior to consumption and contaminant concentrations may be substantially reduced by treatment methods, particularly in surface water. • HBSL values, like USEPA drinking-water standards, Lifetime HA values, and RSD values, do not take into account the effects of mixtures of contaminants. • HBSL values are not the same as State or USEPA MCL values. MCL values sometimes consider factors such as treatment feasibility and analytical detection limits, as well as health effects. • HBSL values, as developed in this report, are appropriate to use at the State and local scales, but not in national and multi-State studies, which are more complex because multiple States are affected.

SUMMARY

Drinking-water standards and guidelines do not exist for many of the contaminants analyzed by the U.S. Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Program and in other USGS water-quality studies. Therefore, an interagency pilot effort was begun in June 1999 in New Jersey to develop, test, and refine concepts to improve the communication of USGS water-quality findings in State- and local-scale reports. After a series of workshops and written exchanges over 2.5 years, the USGS, U.S. Environmental Protection Agency (USEPA), New Jersey Department of Environmental Protection, and Oregon Health & Science University representatives participating in the New Jersey pilot project agreed to develop health-based screening level (HBSL) concentrations and ranges for compounds without existing drinking-water standards. HBSL values are defined as estimates of benchmark concentrations (for noncarcinogens) or concentration ranges (for carcinogens) in water that (1) may be of potential human-health concern; (2) can be used as threshold values against which measured concentrations of contaminants in ambient water samples can be compared; and (3) are consistent with USEPA Office of Water (OW) methodologies for setting drinking-water Lifetime Health Advisory (HA) and Risk-Specific Dose (RSD) values.

The pilot project representatives agreed to pursue a two-tiered, screening level-based methodology for placing NAWQA water-quality data in a human-health context for State- and local-scale analyses and reports. In Tier 1 analysis, ground-water concentration data for regulated compounds will continue to be compared with USEPA and (or) State standard values, as has been done historically. In Tier 2 analysis, ground-water concentration data for unregulated compounds will be compared with newly established HBSL concentrations or ranges. HBSL concentrations (for unregulated noncarcinogens) and HBSL concentration ranges (for most unregulated carcinogens) are being developed using USEPA OW methodologies for calculating Lifetime HA and RSD values for drinking water. Therefore, HBSL concentrations and concentration ranges are consistent with the information about drinking water already coming from USEPA.

HBSL values can be used as tools in water-quality assessment and their use will expand the number of NAWQA contaminants for which health-based benchmarks are available for comparison with USGS water-quality data from 122 to 211 out of 329 compounds, a 27 percent increase. Because the systematic development of HBSL concentrations and ranges will enable the USGS to present its water-quality data in a human-health context for a larger suite of contaminants than have existing drinking-water standards and guidelines, the use of HBSL values will increase the basis for interpreting the significance of water-quality data. When interpreting water-quality results, comparison of measured water concentrations with Maximum Contaminant Level values and HBSL values needs to be placed in the proper context, both hydrologically and with regard to human health. USGS can use HBSL values to assist the USEPA and State and local agencies by providing them with comparisons of measured water concentrations to scientifically defensible human health-based benchmarks, and by alerting them when measured concentrations approach or exceed these benchmarks.

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