Chapter 2: Evaluation of Health and Occurrence Data

A chapter from:

Regulatory Determinations Support Document for Selected Contaminants from the Second Drinking Water Contaminant Candidate List (CCL 2)

EPA Report 815-R-08-012

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Abbreviations

AwwaRF	American Water Works Association Research Foundation			
BW	Body Weight			
CCL	Contaminant Candidate List			
CCL 2	Second Contaminant Candidate List			
CMR	Chemical Monitoring Reform			
CWS	Community Water System			
CWSS	Community Water System Survey			
1,3-DCP	1,3-Dichloropropene			
DCPA	Dimethyl tetrachloroterephthalate			
DDE	p,p-Dichlorodiphenyldichloroethylene or			
	1,1-Dichloro-2,2-bis(<i>p</i> -chlorophenyl)ethylene			
DWI	Drinking Water Intake			
EPCRA	Emergency Planning and Community Right-to-Know			
EPTC	s-Ethyl dipropylthiocarbamate			
FIFRA	Federal Insecticide Fungicide and Rodenticide Act			
HRL	Health Reference Level			
IOC	Inorganic Compound			
IRIS	Integrated Risk Information System			
LOAEL	Lowest-Observed-Adverse-Effect Level			
MCLG	Maximum Contaminant Level Goal			
MRL	Minimum Reporting Level			
MTBE	Methyl Tertiary Butyl Ether			
MTP	Monomethyl tetrachloroterephthalic acid			
NAWQA	National Water Quality Assessment			
NCFAP	National Center for Food and Agricultural Policy			
NCOD	National Drinking Water Contaminant Occurrence Database			
NIRS	National Inorganics and Radionuclides Survey			
NOAEL	No-Observed-Adverse-Effect Level			
NPDES	National Pollutant Discharge Elimination System			
NPS	National Pesticide Survey			
NURP	Nationwide Urban Runoff Program			
OPP	Office of Pesticide Programs			
OW	Office of Water			
PGWDB	Pesticides in Ground Water Database			
PWS	Public Water System			
RED	Reregistration Eligibility Decisions			
RfD	Reference Dose			
RL	Reporting Level			
RSC	Relative Source Contribution			
SDWA	Safe Drinking Water Act			

Synthetic Organic Compound
Semi-volatile Organic Compound
Tetrachloroterephthalic acid
Toxics Release Inventory
Unregulated Contaminant Monitoring
Unregulated Contaminant Monitoring Regulation
First Unregulated Contaminant Monitoring Regulation
Uncertainty Factor
United States Geological Survey
Volatile Organic Compound

2 Evaluation of Health and Occurrence Data

2.1 Evaluation of Adverse Health Effects

Section 1412(b)(1)(A)(i) of the Safe Drinking Water Act (SDWA) requires the Environmental Protection Agency (EPA) to determine whether each candidate contaminant may have an adverse effect on public health. This section describes the overall process the Agency used to evaluate health effects information, the approach used to estimate a contaminant health reference level or HRL (a benchmark against which to conduct the initial evaluation of the occurrence data), and the approach used to identify and evaluate information on hazard and dose-response for the contaminants under consideration. More specific information about the potential for adverse health effects for each contaminant is included in Part II of this document ("CCL 2 Contaminants Undergoing Regulatory Determination").

There are two different approaches to the derivation of an HRL. One approach is used for chemicals that cause cancer and exhibit a linear response to dose. The other applies to noncarcinogens and carcinogens evaluated using a non-linear approach.

2.1.1 Use of Carcinogenicity Data for the Derivation of a Health Reference Level

For those contaminants considered to be likely or probable human carcinogens, EPA evaluated data on the mode of action of the chemical to determine the method of low dose extrapolation. When this analysis indicates that a linear low dose extrapolation is appropriate or when data on the mode of action are lacking, EPA uses a low dose linear extrapolation to calculate risk-specific doses. The risk-specific doses are the estimated oral exposures associated with lifetime excess risk levels that range from one cancer in ten thousand (10^{-4}) to one cancer in a million (10^{-6}) . The risk-specific doses (expressed as mg/kg of body weight per day) are combined with adult body weight and drinking water consumption data to estimate drinking water concentrations corresponding to this risk range. EPA generally used the one-in-a-million (10^{-6}) cancer risk in the initial screening of the occurrence data for carcinogens evaluated using linear low dose extrapolation. Five of the eleven contaminants undergoing regulatory determination had data available to classify them as likely or probable human carcinogens. These five are also the only contaminants for which low dose linear extrapolations were performed. These five are *p*,*p*-dichlorodiphenyldichloroethylene (DDE), 1,3-dichloropropene (1,3-DCP or Telone), 2,4-dinitrotoluene, 2,6-dinitrotoluene, and 1,1,2,2-tetrachloroethane. The remaining six contaminants have not been identified as known, or likely, or probable carcinogens.

2.1.2 Use of Non-carcinogenic Health Effects Data for Derivation of an HRL

For those chemicals not considered to be carcinogenic to humans, EPA generally calculates a reference dose (RfD). A RfD is an estimate of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from either a "no-observed-adverse-effect level" (NOAEL), a "lowest-observed-adverse-effect level" (LOAEL), or a benchmark dose, with uncertainty factors applied to reflect limitations of the data used.

The Agency uses uncertainty factors (UFs) to address uncertainty resulting from incompleteness of the toxicological database. The individual UFs (usually applied as integers of one, three, or ten) are multiplied together and used to derive the RfD from experimental data. Individual UFs are intended to account for:

(1) the variation in sensitivity among the members of the human population (i.e., intraspecies variability);

(2) the uncertainty in extrapolating animal data to humans (i.e., interspecies variability);
(3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure);
(4) the uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and/or
(5) the uncertainty associated with an incomplete database.

For boron, the dacthal (dimethyl tetrachloroterephthalate or DCPA) mono- and di-acid degradates, s-ethyl dipropylthiocarbamate (EPTC), fonofos, and terbacil, EPA derived the HRLs using the RfD approach as follows:

HRL = [(RfD x BW)/DWI] x RSC

Where:

RfD = Reference Dose

BW = Body Weight for an adult, assumed to be 70 kilograms (kg)

DWI = Drinking Water Intake, assumed to be 2 L/day (90th percentile)

RSC = Relative Source Contribution, or the level of exposure believed to result from drinking water when compared to other sources (e.g., food, ambient air).

A 20 percent RSC is being used to estimate the HRL and screen the occurrence data because it is the lowest and most conservative RSC used in the derivation of a maximum contaminant level goal (MCLG) for drinking water. For each of the six aforementioned non-carcinogenic compounds for which the Agency has made a regulatory determination, EPA used the RfD in conjunction with a 20 percent RSC to derive a conservative HRL estimate and perform an initial screening of the drinking water occurrence data. Since the initial screening of the occurrence data at this conservative HRL value resulted in a negative determination for each of these 6 compounds, the Agency determined that it was not necessary to further evaluate the RSC in making the regulatory determination.

As discussed in Chapter 4, the HRL for the two DCPA degradates is based on the HRL value derived for the parent compound following the guidance provided by the EPA's Office of Pesticide Programs (OPP).

2.1.3 Sources of Data/Information for Health Effects

EPA used the best available peer-reviewed data and analyses in evaluating adverse health effects. Peer-reviewed health-risk assessments were available for all chemicals considered for regulatory determinations from the Agency's Integrated Risk Information System (IRIS)

Program¹ and/or the OPP Reregistration Eligibility Decisions (RED)². Exhibit 2-1 summarizes the sources of the health assessment data for each chemical under regulatory determination consideration. The Agency performed a literature search for studies published after the IRIS or OPP health-risk assessment was completed to determine if new information suggested a different outcome. The Agency collected and evaluated any peer-reviewed publications identified through the literature search for their impact on the RfD and/or cancer assessment. In cases where the recent data indicated that a change to the existing RfD or cancer assessment was needed, the updated OW assessment, as described in the health effects support document, was independently peer-reviewed. All quantitative cancer assessments conducted under the Guidelines for Carcinogen Risk Assessment (USEPA, 1986) were updated using the Guidelines for Carcinogen Risk Assessment (USEPA, 2001a).

In March 2005, EPA updated and finalized the Cancer Guidelines and a Supplementary Children's Guidance, which include new considerations for mode of action and added guidelines related to potential risks due to early childhood exposure (USEPA, 2005a; USEPA, 2005b). EPA updated the earlier assessments (based on the 1986 Guidelines) for DDE, the dinitrotoluenes (2,4 and 2,6 as a mixture), and 1,1,2,2-tetrachloroethane following the 1999 Guidelines. None of these chemicals have been determined to have a mutagenic mode of action, which would require an extra factor of safety for children's health protection. Therefore, conducting the cancer evaluation using the 2005 Cancer Guidelines would not result in any change from the assessment updated following the 1999 Guidelines.

The cancer assessment for 1,3-dichloropropene was done by OPP and IRIS (USEPA, 1998 and 2000a) under the Proposed Guidelines for Carcinogen Risk Assessment (61 FR 17960). The Administrator (USEPA, 2005c) has directed that current completed assessments can be considered to be scientifically sound based on the guidance used when the assessment was completed until a new assessment is performed by one of the responsible program offices.

¹ IRIS is an electronic EPA data base (www.epa.gov/iris/index.html) containing peer-reviewed information on human health effects that may result from exposure to various chemicals in the environment. These chemical files contain descriptive and quantitative information on hazard identification and dose response, RfDs for chronic noncarcinogenic health effects, as well as slope factors and unit risks for carcinogenic effects.

² The OPP is required under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) to review all pesticides registered prior to 1984 and determine whether to reregister them for continued use. The results of the reregistration analysis are included in the REDs. Copies of the REDs are located at the following web site: http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg.

Chemical	IRIS	Date	OPP RED	Date	
Boron	Х	2004			
Dacthal and its mono- and di-acid degradates	X	1994	Х	1998	
1,3-Dichloropropene	Х	2000	Х	1998	
DDE	Х	1988			
2,4-Dinitrotoluene	Х	1990/1992			
2,6-Dinitrotoluene	Х*	1990			
EPTC	Х	1990	Х	1999	
Fonofos	Х	1991	X**	1996	
Terbacil	Х	1989	Х	1998	
1,1,2,2-Tetrachloroethane	Х	1986			
* Applies to a mixture of 98 percent 2 4-dinitrotoluene and 2 percent 2 6-dinitrotoluene					

Exhibit 2-1: Sources and Dates of EPA Health Risk Assessments

* Applies to a mixture of 98 percent 2,4-dinitrotoluene and 2 percent 2,6-dinitrotoluene

** Health Risk Assessment; RED not completed due to pesticide cancellation.

EPA has prepared several technical health effects support documents³ for the contaminants considered for this round of regulatory determinations. These documents address the exposure from drinking water and other media, toxicokinetics, hazard identification, and dose-response assessment, and provide an overall characterization of risk from drinking water.

³ The health support documents include the following documents: *Health Effects Support Document for Boron* (EPA-822-R-06-005), *Health Effects Support Document for Dacthal Degradates: Tetrachloroterephthalic Acid* (*TPA*) and Monomethyl Tetrachloroterephthalic Acid (*MTP*) (EPA-822-R-06-006), *Health Effects Support* Document for 1,1-Dichloro-2,2-bis(p-chlorophenyl)ethylene (DDE) (EPA-822-R-06-007), *Health Effects Support* Document for S-Ethyl dipropylthiocarbamate (EPTC) (EPA-822-R-06-008), *Health Effects Support Document for* Fonofos (EPA-822-R-06-009), *Health Effects Support Document for Terbacil* (EPA-822-R-06-010), *Health Effects Support Document for* 1,3-Dichloropropene (EPA-822-R-06-011), *Health Effects Support Document for* 1,1,2,2-Tetrachloroethane (EPA-822-R-06-012), and *Health Advisory for* 2,4- and 2,6-Dinitrotoluene (EPA-822-R-06-017).

2.2 Evaluation of Contaminant Occurrence and Exposure

EPA used data from several sources to evaluate occurrence and exposure for the 11 contaminants considered in these regulatory determinations. The major or primary sources of the drinking water occurrence data used to support these determinations include the following sources:

- the First Unregulated Contaminant Monitoring Regulation (UCMR 1),
- the Unregulated Contaminant Monitoring (UCM) program, and
- the National Inorganics and Radionuclides Survey (NIRS).

All three are national assessments that were administered or overseen by EPA. General background and methodological information for each of these sources is summarized in Section 2.2.1 below.

In addition to these primary sources of occurrence data, the Agency also evaluated supplemental sources of information on contaminant use and release, occurrence in ambient water, and occurrence in drinking water. These are mostly national assessments by federal agencies such as EPA and the United States Geological Survey (USGS), but they also include regional- and State-level surveys and some research performed by private institutions. Section 2.2.2 provides brief summary descriptions of some of the most important supplemental sources of occurrence information and/or data. A summary of the occurrence data and the results or findings for each of the 11 contaminants considered for regulatory determination is presented in Part II ("CCL 2 Contaminants Undergoing Regulatory Determination").

2.2.1 Primary Data Sources

As previously mentioned, the primary sources of the drinking water occurrence data used to support the regulatory determinations are the UCMR 1, the UCM program, and NIRS. Exhibit 2-2 lists the primary data sources the Agency used for each of the 11 contaminants considered for regulatory determinations.

Exhibit 2-2: Primary Sources of Drinking Water Occurrence Data Used in the Regulatory Determination Process

#		Primary Data Sources				
		UCMR 1		UCM		
	Contaminant	List 1 Assessment Monitoring	List 2 Screening Survey	Round 1 Cross Section	Round 2 Cross Section	NIRS
1	Boron					X ¹
2 3	Dacthal mono- and di-acid degradates	x				
4	DDE	Х				
5	1,3-Dichloropropene	X ²		Х	Х	
6	2,4-Dinitrotoluene	Х				
7	2,6-Dinitrotoluene	Х				
8	EPTC	Х				
9	Fonofos		Х			
10	Terbacil	Х				
11	1,1,2,2- Tetrachloroethane			х	х	

1- For boron, EPA also considered the results of a study funded by the American Water Works Association Research Foundation (AwwaRF) (Frey *et al.*, 2004).

2-1,3-Dichloropropene was sampled as a UCM Round 1 and 2 analyte but due to sample degradation concerns the contaminant was re-analyzed using the samples provided by the small systems that participated in the UCMR List 1 Assessment Monitoring.

Occurrence values from the UCMR 1, UCM, and NIRS data sets represent direct counts of the number and percent of systems, and population served by systems, with at least one analytical detection above some specified concentration threshold. EPA considered this to be the most straightforward and accurate way to present these data for the regulatory determination process.

While both UCMR 1 and UCM data could support more involved statistical modeling to characterize occurrence based on mean (rather than peak) concentrations, EPA chose not to perform this step for the regulatory determinations discussed in this document. EPA believes that presenting the actual results of the occurrence monitoring is straight-forward and the use of an analysis based on peak concentrations provides conservative estimates of occurrence and potential exposure from drinking water. Given that the regulatory determinations for the 11 contaminants discussed here are negative, it is not necessary to go beyond the conservative (peak concentration) approach used for this analysis.

The following sections provide a brief summary of the data sources and the approach used to estimate a given contaminant's occurrence. For a more detailed description of the UCM program, see USEPA (2000b) and USEPA (2008a). For a more detailed description of NIRS, please refer to Longtin (1988) and USEPA (2008a). For the UCMR program, please refer to USEPA (2001b) and USEPA (2008b).

The First Unregulated Contaminant Monitoring Regulation (UCMR 1)

In 1999, EPA developed the UCMR program in coordination with the Contaminant Candidate List (CCL) and the National Drinking Water Contaminant Occurrence Database (NCOD) to provide national occurrence information on unregulated contaminants (September 17, 1999, 64 FR 50556; March 2, 2000, 65 FR 11372; and January 11, 2001, 66 FR 2273). EPA used data from the UCMR 1 program to evaluate occurrence for nine of the eleven contaminants considered for these regulatory determinations. These nine contaminants include the dacthal mono- and di-acid degradates, DDE, 1,3-dichloropropene, 2,4-dinitrotoluene, 2,6-dinitrotoluene, EPTC, fonofos, and terbacil.

EPA designed the UCMR 1 data collection with three parts (or tiers), primarily based on the availability of analytical methods. Occurrence data for eight of the nine contaminants listed in the preceding paragraph are from the first tier of UCMR 1 (also known as UCMR 1 List 1 Assessment Monitoring). Occurrence data for fonofos are from the second tier of UCMR 1 (also known as the UCMR 1 List 2 Screening Survey). EPA has not collected data as part of the third tier due to the lack of adequate analytical methods.

The UCMR 1 List 1 Assessment Monitoring was performed for a specified number of chemical contaminants for which analytical methods have been developed. EPA required all large⁴ public water systems (PWSs), plus a statistically representative national sample of 800 small⁵ PWSs to conduct Assessment Monitoring.⁶ Approximately one-third of the participating small systems were scheduled to monitor for these contaminants during each calendar year from 2001 through 2003. Large systems could conduct one year of monitoring anytime during the 2001-2003 UCMR 1 period. EPA specified a quarterly monitoring schedule for surface water systems and a twice-a-year, six-month interval monitoring schedule for ground water systems. The objective of the UCMR sampling approach for small systems was to collect contaminant occurrence data from a statistically selected, nationally representative sample of small systems. The small system such as ensuring the selection of at least two systems from each State. With contaminant monitoring data from all large PWSs and a statistical, nationally representative sample of small PWSs, the UCMR 1 List 1 Assessment Monitoring program provides a contaminant occurrence data set suitable for national drinking water estimates.

In total, 372,086 sample results have been collected under the UCMR 1 List 1 Assessment Monitoring program at 3,090 large systems and 797 small systems. Approximately 33,800 samples were collected for each contaminant. The UCMR 1 List 1 Monitoring program

⁴ Systems serving more than 10,000 people.

⁵ Systems serving 10,000 people or fewer.

⁶ Large and small systems that purchase 100% of their water supply were not required to participate in the UCMR 1 Assessment Monitoring or the UCMR 1 Screening Survey.

included systems from all 50 States, the District of Columbia, four U.S. Territories, and Tribal lands in five EPA Regions. An additional 3,719 samples were collected for 1,3-DCP at all small systems that conducted UCMR 1 List 1 Assessment Monitoring.

In addition to the UCMR 1 List 1 Assessment Monitoring, EPA required monitoring for selected contaminants (including fonofos) for which analytical methods were developed but not widely used. Known as the UCMR 1 List 2 Screening Survey, EPA randomly selected 300 public water systems (120 large and 180 small systems) from the pool of systems required to conduct UCMR 1 List 1 Assessment Monitoring. In total, 29,765 sample results have been collected under the UCMR 1 List 2 Screening Survey from the participating large and small systems. Approximately 2,300 samples were collected for each contaminant. The UCMR 1 List 2 Screening Survey included systems from 48 States, two U.S. Territories, and Tribal lands in one EPA Region. EPA used the occurrence data from this survey to evaluate fonofos.

EPA analyzed the UCMR 1 List 1 Assessment Monitoring and List 2 Screening Survey data to generate the following occurrence and exposure summary statistics:

- the total number of systems and the total population served by these systems,
- the number and percentage of systems with at least one observed detection that has a concentration greater than 1/2 the HRL and greater than the HRL (or in some cases greater than or equal to the minimum reporting level or MRL), and
- the number of people and percentage of the population served by systems with at least one observed detection greater than 1/2 the HRL and greater than the HRL (or in some cases greater than or equal to the MRL).⁷

The initial UCMR 1 summary occurrence statistics for dacthal mono- and di-acid degradates, DDE, 1,3-dichloropropene, 2,4-dinitrotoluene, 2,6-dinitrotoluene, EPTC, fonofos, and terbacil are presented in Part II of this document.

Note that in some cases, for example DDE, 2,4-dinitrotoluene, and 2,6-dinitrotoluene, only an MRL analysis was performed because the MRL was higher than the HRL. EPA set the MRL for UCMR contaminants based on the capability of analytical methods, not anticipated health levels. In the case of volatile organic compounds (VOCs), the MRL was determined by multiplying by 10 either the published minimum detection limit or $0.5 \mu g/L$, whichever was greater. For other contaminants, the MRL was determined by multiplying by 10 the least sensitive method's minimum detection limit, or, when available, multiplying by 5 the least sensitive method's estimated detection limit (USEPA, 2000c). MRLs were set approximately an order of magnitude higher than detection limits to ensure consistency, accuracy, and reproducibility of results.

⁷ Both Part II of this document and EPA's technical occurrence document (USEPA, 2008b) also provide summary statistics for the median and 99th percentile concentrations of all analytical detections and detailed occurrence results based on UCMR data according to source water type (surface versus ground water), system size, and State.

The Unregulated Contaminant Monitoring (UCM) Program Rounds 1 and 2

In 1987, EPA initiated the UCM program to fulfill a 1986 SDWA Amendment that required monitoring of specified unregulated contaminants to gather information on their occurrence in drinking water for future regulatory decision-making purposes. EPA used data from the UCM program to evaluate occurrence for 2 of the 11 contaminants considered for these regulatory determination. These two contaminants are 1,3-dichloropropene and 1,1,2,2-tetrachloroethane.

EPA implemented the UCM program in two phases or rounds. The first round of UCM monitoring generally extended from 1988 to 1992 and is referred to as UCM Round 1 monitoring. The second round of UCM monitoring generally extended from 1993 to 1997 and is referred to as UCM Round 2 monitoring.

UCM Round 1 monitored for 34 VOCs, including 1,3-dichloropropene and 1,1,2,2tetrachloroethane (52 FR 25720, July 8, 1987). UCM Round 2 monitored for 13 synthetic organic compounds (SOCs) and sulfate, and the same 34 VOCs from UCM Round 1 monitoring (57 FR 31776, July 17, 1992).

The UCM Round 1 database contains contaminant occurrence data from 38 States, Washington, DC, and the U.S. Virgin Islands. The UCM Round 2 database contains data from 34 States and several Tribes. Due to incomplete State data sets, national occurrence estimates based on raw (unedited) UCM Round 1 or Round 2 data could be skewed to low-occurrence or high-occurrence settings (e.g., some States only reported detections). To address potential biases in the data⁸, EPA developed national cross-sections from the UCM Round 1 and Round 2 State data using an approach similar to that used for EPA's 1999 Chemical Monitoring Reform (CMR), the first Six Year Review, and the first CCL Regulatory Determinations. This national cross-section approach was developed to support occurrence analyses and was supported by scientific peer reviewers and stakeholders. This approach identified 24 of the original 38 States from the UCM Round 1 database and 20 of the original 34 States from the UCM Round 2 data base for the national cross-section.

Because UCM Round 1 and Round 2 data represent different time periods and include occurrence data from different States, EPA developed separate national cross-sections for each data set. The UCM Round 1 national cross-section consists of data from 24 States, with approximately 3.3 million total analytical data points from approximately 22,000 unique PWSs. The UCM Round 2 national cross-section consists of data from 20 States, with approximately 3.7 million analytical data points from slightly more than 27,000 unique PWSs. The UCM Round 1 and 2 national cross-sections represent significantly large samples of national occurrence data. Within each cross-section, the actual number of systems and analytical records for each contaminant varies. The support document "The Analysis of Occurrence Data from the Unregulated Contaminant Monitoring (UCM) Program and National Inorganics and Radionuclides Survey (NIRS) in Support of Regulatory Determinations for the Second Drinking Water Contaminant Candidate List" (USEPA, 2008a) provides a description of how the national

⁸ The potential biases in the raw UCM data are due to lack of representativeness (since not all States provided UCM data) and incompleteness (since some States that provided data had incomplete data sets).

cross-sections for the Round 1 and Round 2 data sets were developed. Additional background information can be found in USEPA (2000b).

EPA constructed the national cross-sections in a way that provides a balance and range of States with varying pollution potential indicators, a wide range of the geologic and hydrologic conditions, and a very large sample of monitoring data points. While EPA recognizes that some limitations exist, the Agency believes that the national cross-sections do provide a reasonable estimate of the overall distribution and the central tendency of contaminant occurrence across the United States. See Exhibit 2-2 for a listing of States in each national cross-section.

Round 1		Round 2		
Alabama Alaska* Arizona California Florida Georgia Hawaii Illinois Indiana Iowa Kentucky* Maryland*	Minnesota* Montana New Jersey New Mexico* North Carolina* Ohio* South Dakota Tennessee Utah Washington* West Virginia Wyoming	Alaska* Arkansas Colorado Kentucky* Maine Maryland* Massachusetts Michigan Minnesota* Missouri	New Hampshire New Mexico* North Carolina* North Dakota Ohio* Oklahoma Oregon Rhode Island Texas Washington*	

Exhibit 2-3: Cross-section States for UCM Round 1 (24 States) and Round 2 (20 States)

* Cross-section States in both Round 1 and Round 2

EPA analyzed the UCM Round 1 and 2 National Cross-Section data to generate the following initial occurrence and exposure summary statistics:

- the total number of systems and the total population served by these systems,
- the number and percentage of systems with at least one observed detection that has a concentration greater than ¹/₂ the HRL and greater than the HRL (or in some cases greater than or equal to the MRL), and
- the number of people and percentage of the population served by systems with at least one observed detection that has a concentration greater than ½ the HRL and greater than the HRL (or in some cases greater than or equal to the MRL).⁹

The initial UCM summary occurrence statistics for 1,3-dichloropropene and 1,1,2,2-tetrachloroethane are presented in Part II of this document.

National Inorganics and Radionuclides Survey (NIRS)

In the mid-1980's, EPA conducted the NIRS to provide a statistically representative sample¹⁰ of the national occurrence of inorganic contaminants in community water systems (CWSs) served by ground water. EPA used data from NIRS, as well as a supplemental survey, to evaluate occurrence for boron.

The NIRS database includes 36 radionuclides and inorganic compounds (IOCs), including boron. The NIRS provides contaminant occurrence data from 989 ground water CWSs covering 49 States (all except Hawaii) and does not include surface water systems. The survey focused on ground water systems, in part because IOCs tend to occur more frequently and at higher concentrations in ground water than in surface water. Each of the 989 randomly selected CWSs was sampled once between 1984 and 1986.

EPA analyzed the NIRS data to generate the following occurrence and exposure summary statistics for boron:

- the total number of systems and the total population served by these systems,
- the number and the percentage of systems with at least one detection that has a concentration greater than ¹/₂ the HRL and greater than the HRL,
- the number of people and percentage of the population served by systems with at least one observed detection that has a concentration greater than ¹/₂ the HRL and greater than the HRL.¹¹

⁹ Part II of this document and EPA's technical occurrence document (USEPA, 2008a) also provide summary statistics for the median and 99th percentile concentrations of all analytical detections and detailed occurrence results based on the UCM Round 1 and 2 National Cross-Sections according to source water type (surface versus ground water), system size, and State.

¹⁰ NIRS was designed to provide results that are statistically representative of national occurrence at CWSs using ground water sources and is stratified based on system size (population served by the system). Most of the NIRS data are from smaller systems (92 percent from systems serving 3,300 persons or fewer).

¹¹ Part II of this document and EPA's UCM/NIRS technical occurrence document (USEPA, 2008a) also provide the number and percentage of systems with detections, the 99th percentile concentration of all samples, the 99th percentile concentration of samples with detections.

Results of the NIRS analyses of boron are reported in Part II, Chapter 3. Because the NIRS data were collected in a randomly designed sample survey, these summary statistics are representative of national occurrence in ground water CWSs.

One limitation of the NIRS is a lack of occurrence data for surface water systems. To provide perspective on the occurrence of boron in surface water systems relative to ground water systems, EPA reviewed and took into consideration a recent boron occurrence survey funded by the American Water Works Association Research Foundation (AwwaRF) (Frey *et al.*, 2004). A short description of the AwwaRF study is provided below in Section 2.2.2, and the results of the AwwaRF survey are presented in Chapter 3 (the boron chapter).

2.2.2 Supplemental Data Sources

The Agency evaluated several sources of supplemental occurrence information to augment the primary drinking water occurrence data, to evaluate the likelihood of contaminant occurrence, and/or to more fully characterize a contaminant's presence in the environment. This section provides brief descriptions of many of the supplemental information/data sources cited in Part II (and Part III) of this document.

National Center for Food and Agricultural Policy (NCFAP) Pesticide Use Database

The National Center for Food and Agricultural Policy (NCFAP), a private non-profit institution, maintains a national Pesticide Use Database. NCFAP annual pesticide use estimates for circa 1992 and circa 1997 are based on State-level commercial agriculture usage patterns for the periods 1990-1993 and 1995-1998, and State-level crop acreage for 1992 and 1997. The database contains estimates of pounds applied and acres treated in each State for 220 active ingredients and 87 crops. The majority of the chemicals monitored are herbicides, but the database also follows significant numbers of fungicides and insecticides (NCFAP, 2000).

The NCFAP database has several limitations. First, the database only includes applications of pesticides to cropland (foliar, soil, and in furrow applications). Non-cropland applications, such as uses for homes, greenhouses, livestock, or ornamentals, are not included. The database does not include non-bearing orchards or vineyards, or governmental Areawide Eradication programs. Second, in interpreting the NCFAP database, it should be noted that records are compiled from a wide variety of sources. NCFAP states that there is no way to determine the accuracy of any of the estimates in the database, adding that some are based on surveys of farmers, while others are expert opinions from knowledgeable extension service specialists. When data for particular States and crops are unavailable, as they are in many cases, values are assigned on the basis of data from a nearby State (NCFAP, 2000).

USGS Pesticide Use Maps

The USGS has produced maps of pesticide use for 208 compounds used in U.S. crop production. The maps are based on pesticide use rates compiled by NCFAP (see NCFAP Pesticide Use Database, above). For each of the compounds, NCFAP has developed two use coefficients, the percent of acres treated for 87 specific crops and the pounds of an active ingredient applied annually to each acre of that crop. The maps combine the NCFAP State-

based pesticide use coefficients with county-level crop acreages obtained from the 1992 Census of Agriculture. This produces maps showing the distribution of average annual pesticide use. Map resolution is based at the county-level (USGS, 2004).

The maps have the same limitations in data as the NCFAP database, as described above. Additionally, the NCFAP estimates of applied pesticides are averaged at the State-level, while the maps extrapolate to the county-level by using county crop acreages from the Census of Agriculture. Consequently, the maps do not truly represent the local variability of cropping and management practices found within many States. Furthermore, the 1992 Census of Agriculture may not have represented all crop usage, nor included all types of pasture (USGS, 2004).

Toxics Release Inventory (TRI)

EPA established the Toxics Release Inventory (TRI) in 1987 in response to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA section 313 requires facilities to report to both EPA and the States annual information on toxic chemical releases from facilities that meet reporting criteria. EPCRA section 313 also requires EPA to make this information available to the public through a computer database. The database is accessible through TRI Explorer, which can be accessed at http://www.epa.gov/triexplorer. In 1990 Congress passed the Pollution Prevention Act, which required that additional data on waste management and source reduction activities be reported under TRI. The TRI database details not only the types and quantities of toxic chemicals released to the air, water, and land by facilities, but also provides information on the quantities of chemicals sent to other facilities for further management (USEPA, 2002a and 2003).

Facilities are required to report releases and other waste management activities related to TRI chemicals if they manufacture, process, or otherwise use more than established threshold quantities of these chemicals. Currently, for most chemicals the thresholds are 25,000 pounds for manufacturing and processing and 10,000 pounds for use. Both the number and type of facilities required to report has increased over time so that in 2002 over 24,000 industrial and Federal facilities submitted in excess of 93,000 reports on toxic releases. In 2000, special thresholds were added for persistent bioaccumulative toxic chemicals, for example dioxin and dioxin-like compounds (USEPA, 2002a). Today, TRI includes information on releases of nearly 670 chemicals.

Although TRI can provide a general idea of release trends, it is far from exhaustive and has significant limitations. For example, small facilities (those with fewer than 10 full-time employees and those that do not exceed manufacture and use limits) are not required to report releases. In addition, the reporting threshold for the manufacturing and processing of TRI chemicals changed between 1987 and 1989, dropping from 75,000 pounds per year in 1987 to 50,000 in 1988 to the current 25,000 in 1989; this creates the potential for misleading data trends over time (USEPA, 1996). Finally, TRI data are meant to reflect releases and should not be used to estimate general public exposure to a chemical (USEPA, 2002a).

USGS National Water Quality Assessment (NAWQA)

The USGS instituted the National Water Quality Assessment (NAWQA) program in 1991 to examine ambient water quality status and trends in the United States. The NAWQA program is designed to apply nationally consistent methods to provide a consistent basis for comparisons among study basins across the country and over time. These occurrence assessments serve to facilitate interpretation of natural and anthropogenic factors affecting national water quality. For more detailed information on the NAWQA program design and implementation, please refer to Leahy and Thompson (1994) and Hamilton *et al.* (2004).

Study Unit Monitoring

The NAWQA program conducts monitoring and water quality assessments in significant watersheds and aquifers referred to as "study units." The program's sampling approach is not "statistically" designed (i.e., it does not involve random sampling), but it provides a representative view of the nation's waters in its coverage and scope. Together, the 51 study units monitored between 1991 and 2001 include the aquifers and watersheds that supply more than 60% of the nation's drinking water and water used for agriculture and industry. The NAWQA program monitors the occurrence of chemicals such as pesticides, nutrients, VOCs, trace elements, and radionuclides, and the condition of aquatic habitats and fish, insects, and algal communities (NRC, 2002; Hamilton *et al.*, 2004). NAWQA has collected data from over 6,400 surface water and 7,000 ground water sampling points. (The NAWQA Data Warehouse can be reached via a link from the following website: http://water.usgs.gov/nawqa/data.html).

Monitoring of study units occurs in stages. Between 1991 and 2001, approximately onethird of the study units at a time were studied intensively for a period of three to five years, alternating with a period of less intensive research and monitoring that lasted between five and seven years. Thus, all participating study units rotated through intensive assessment in a tenyear cycle (Leahy and Thompson, 1994). The first ten-year cycle was designated Cycle 1. Summary reports are available for the 51 study units that underwent intensive monitoring in Cycle 1 (USGS, 2001). Cycle 2 monitoring is scheduled to proceed in 42 study units from 2002 to 2012 (Hamilton *et al.*, 2004).

USGS Analysis: National Synthesis Programs

Through a series of National Synthesis efforts, the USGS NAWQA program is preparing comprehensive analyses of data on topics of particular concern. These data are aggregated from the individual study units and other sources to provide a national overview.

Pesticide National Synthesis

The Pesticide National Synthesis began in 1991. Results from the most recent USGS Pesticide National Synthesis analysis, based on complete Cycle 1 (1991-2001) data from NAWQA study units, are posted on the NAWQA Pesticide National Synthesis website (Martin *et al.*, 2003; Kolpin and Martin, 2003; Nowell, 2003; Nowell and Capel, 2003). USGS considers these results to be provisional. Data for surface water, ground water, bed sediment, and biota are presented separately, and results in each category are subdivided by land use category. Land use

categories include agricultural, urban, mixed (deeper aquifers of regional extent in the case of ground water), and undeveloped. The National Synthesis analysis for pesticides is a first step toward the USGS goals of describing the occurrence of pesticides in relation to different land use and land management patterns, and developing a deeper understanding of the relationship between spatial occurrence of contaminants and their fate, transport, persistence, and mobility characteristics.

The surface water summary data presented by USGS in the Pesticide National Synthesis (Martin *et al.*, 2003) only include stream data. Sampling data from a single one-year period, generally the year with the most complete data, were used to represent each stream site. Sites with few data or significant gaps were excluded from the analysis. NAWQA stream sites were sampled repeatedly throughout the year to capture and characterize seasonal and hydrologic variability. In the National Synthesis analysis, the data were time-weighted to provide an estimate of the annual frequency of detection and occurrence at a given concentration.

The USGS Pesticide National Synthesis only analyzed ground water data from wells; data from springs and agricultural tile drains were not included. The sampling regimen used for wells was different than that for surface water. In the National Synthesis analysis (Kolpin and Martin, 2003), USGS uses a single sample to represent each well, generally the earliest sample with complete data for the full suite of analytes.

The NAWQA program monitored bed sediment and fish tissue at sites considered likely to be contaminated and at sites that represent various land uses within each study unit. Most sites were sampled once in each medium. In the case of sites sampled more than once, a single sample was chosen to represent the site in the Pesticide National Synthesis analysis (Nowell, 2003). In the case of multiple bed sediment samples, the earliest one with complete data for key analytes was used to represent the site. In the case of multiple tissue samples, the earliest sample from the first year of sampling that came from the most commonly sampled type of fish in the study unit was selected.

As part of the National Pesticide Synthesis, USGS also analyzed the occurrence of select semi-volatile organic compounds (SVOCs) in bed sediment at sites considered likely to be contaminated and sites that represent various land uses within each study unit (Nowell and Capel, 2003). Most sites were sampled only once. When multiple samples were taken, the earliest one was used to represent the site in the analysis.

Over the course of Cycle 1 (1991-2001), NAWQA analytical methods may have been improved or changed. Hence, reporting levels (RLs) varied over time for some compounds. In the summary tables, the highest RL for each analyte is presented for general perspective. In the ground water, bed sediment, and tissue data analyses, the method of calculating concentration percentiles sometimes varied according to how much of the data was censored at particular levels by the laboratory (i.e., because of the relatively large number of non-detections in these media).

VOC National Synthesis

The Volatile Organic Compound (VOC) National Synthesis began in 1994. The most comprehensive VOC National Synthesis reports to date are one random survey and one focused survey funded by the AwwaRF) and carried out by USGS in collaboration with the Metropolitan Water District of Southern California and the Oregon Health & Science University. The random survey (Grady, 2003) targeted surface and ground waters used as source water by CWSs. Samples were taken from the source waters of 954 CWSs in 1999 and 2000. The random survey (Delzer and Ivahnenko, 2003), 451 samples were taken from source waters serving 134 CWSs between 1999 and 2001. These surface and ground waters were chosen because they were suspected or known to contain methyl tertiary butyl ether (MTBE). The focused survey was designed to provide insight into temporal variability and anthropogenic factors associated with VOC occurrence. Details of the monitoring plan for these two studies, including detection limits, are provided by Ivahnenko *et al.* (2001). Separately, AwwaRF also published the results of this monitoring effort (AwwaRF, 2003).

Additional products of the VOC National Synthesis include a compilation of historical VOC monitoring data from multiple studies (Squillace *et al.*, 1999). The data, collected from 2,948 wells between 1985 and 1995 by local, state, and federal agencies, were reviewed to ensure they met data quality criteria. Most of the data were from early study unit monitoring. The samples represent both urban and rural areas, and both drinking water and non-drinking water wells. A full analysis of 10 years of study unit monitoring data has not yet been performed by the VOC National Synthesis.

Trace Elements National Synthesis

A National Synthesis effort for trace elements is underway. However, the only trace element being considered for regulatory determination at this time, boron, was not included among the analytes in Cycle 1 data collection. Boron is included among the trace element analytes in NAWQA Cycle 2.

EPA Analysis of NAWQA Study Unit Monitoring Results

Whereas the NAWQA program often uses the most representative data for a site to calculate summary statistics, EPA, with the cooperation of USGS, has performed a summary analysis of all Cycle 1 water monitoring data from all study units (1991-2001) for many of the Second Contaminant Candidate List (CCL 2) contaminants being considered for regulatory determination. EPA's analysis of the NAWQA data is analogous to the simple, straight-forward "Stage 1" analysis the Agency performed on finished drinking water data from CWS monitoring. That is, all the occurrence data for a particular contaminant were compiled and analyzed using non-parametric methods to yield simple summary statistics to characterize contaminant occurrence. The analysis was performed on Cycle 1 data for DDE, DCPA, the mono-acid degradate of DCPA, EPTC, fonofos, metolachlor, MTBE, terbacil, and 1,1,2,2-tetrachloroethane. (Data were unavailable for boron, 1,3-dichloropropene, and 2,4- and 2,6-dinitrotoluene.)

The surface water data consist of stream samples; all surface water data were included in the EPA summary analysis. For ground water, all well data were used; as with the USGS National Pesticide Synthesis, data from springs and drains were excluded. For each contaminant, EPA calculated detection frequencies simply as the percentage of samples and the percentage of sites with at least one detection. (A detection is an analytical result equal to or greater than the reporting limit.) EPA used USGS data without any censoring or weighting. From samples with detects a number of descriptive statistics were also calculated, including the minimum, median, 95th percentile, 99th percentile, and maximum concentrations. Reporting limits varied over time during the NAWQA program. The highest reporting limit used for each contaminant is presented with the results of the analysis. Note that because reporting limits varied, the minimum concentration reported as a detection is often lower than the highest reporting limit. All statistics were calculated in SAS[®].

USGS National Highway Runoff Data and Methodology Synthesis (USGS Stormwater Studies)

In addition to the NAWQA project, USGS has prepared additional surveys of national contaminant occurrence. For the National Highway Runoff Data and Methodology Synthesis, USGS conducted a review of 44 studies of SVOCs and VOCs in runoff conducted since 1970 (Lopes and Dionne, 1998). Most of the studies focused on SVOCs in urban stormwater and sediments. USGS evaluated the reviewed studies for data quality, including documentation of sampling protocols and methods, limits of reporting and detection, and protocols of quality-control and quality-assurance.

The Synthesis reports on a number of deficiencies in available data on highway and stormwater runoff which prevent full comparisons between studies. The greatest problem reported was that only 10 percent of the studies accurately described where in the stream cross-section study samples were taken. As SVOCs concentrate in suspended solids and suspended solids are seldom uniformly distributed in the stream profile, the absence of such data limits the reliability of findings. Another problem reported was that only 30 percent or fewer of the studies documented detection limits or quality control procedures. This limits the extent to which the findings of different studies can be compared. Finally, the report noted that many of the loading factors and regression equations used in the reviewed sources (particularly those from the 1970s) were out-of-date and needed to be readjusted if their results are to be adapted to the present day.

Of the 44 publications that the Synthesis reviews, two types of studies (encompassing several publications) deserve mention due to their wide geographic distribution. The first is the priority pollutant monitoring project of the Nationwide Urban Runoff Program (NURP). This program reported monitoring of EPA priority pollutants in 15 cities in 14 States from 1979 to 1982. The second is a set of USGS urban stormwater studies conducted in cities with a population of 100,000 or more that were required by EPA to obtain National Pollutant Discharge Elimination System (NPDES) permits. These studies involved monitoring in 16 cities in 11 States since 1991.

Pesticides in Ground Water Database (PGWDB)

The Pesticides in Ground Water Database (PGWDB) is a compilation of data from ground water studies conducted by federal, State, and local governments, the pesticide industry, and other institutions between 1971 and 1991 (USEPA, 1992). Data from 68,824 wells in 45 States are included. The vast majority of the wells (65,865) were drinking water wells. Monitoring was conducted for 258 pesticides and 45 degradates. Not all studies tested for every compound.

Because PGWDB data come from multiple sources, they should be interpreted with caution. Different studies were conducted for different reasons, and used different sampling techniques and analytical methods. Detection limits were not uniform. The data are not geographically representative: results might be biased high because areas with suspected contamination are likely to have been sampled more frequently than pristine areas.

National Pesticide Survey (NPS)

In 1990, EPA completed a national survey of pesticides in drinking water wells. The purpose of the National Pesticide Survey (NPS) was to determine the national occurrence frequencies and concentrations of select pesticides in the nation's drinking water wells, and to improve EPA's understanding of how pesticide occurrence in ground water correlates with patterns of pesticide usage and ground water vulnerability. The survey included approximately 1,300 CWS wells and rural domestic wells. Sampling was conducted between 1988 and 1990. The survey targeted areas representing a variety of pesticide usage levels and ground water vulnerability. The survey was designed to provide a statistically reliable estimate of pesticide occurrence in the nation's drinking water wells. It was not designed to provide statistically valid results at the State- or local-level. Wells were sampled for 101 pesticides, 25 pesticide degradates, and nitrate (USEPA, 1990).

Community Water System Survey (CWSS)

The 2000 Community Water System Survey (CWSS) (USEPA, 2002b; 2002c) gathered data on the financial and operating characteristics of a random sample of CWSs nationwide. In addition, the Survey asked all "very large" CWSs, those that serve more than 500,000 people (a total of 83 systems), to provide monitoring results for five regulated compounds (arsenic, atrazine, 2,4-D, simazine, and glyphosate) and four unregulated compounds (radon, MTBE, metolachlor, and boron), including results from raw water at each intake and from finished water at treatment plant. EPA received completed questionnaires from 58 systems. However, not all systems answered every question. Note that because reported results are incomplete, they are more illustrative than statistically representative.

AwwaRF Boron Study

The American Water Works Association Research Foundation funded a survey to evaluate the occurrence of boron (as well as hexavalent chromium) in drinking water sources (Frey *et al.*, 2004). The AwwaRF study recruited 189 PWSs representing 407 source waters in 41 States. Of the 407 source water sample kits distributed in 2003, approximately 342 were returned. Of these 342 samples, 341 were analyzed for boron. Approximately 67 percent (or 228) represented ground water sources and 33 percent (or 113) represented surface water sources.

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