EPA

United States
Environmental Protection
Agency

Review of Fluoride Occurrence for the Fourth Six-Year Review

Disclaimer

This report is in support of the revise/take no action decisions for EPA's Fourth Six-Year Review of Existing Drinking Water Standards Federal Register Notice. This report is intended to provide technical background for the fourth Six-Year Review.

This document is not a regulation itself and it does not substitute for the Safe Drinking Water Act (SDWA) or EPA's regulations. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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Abbreviations and Acronyms

CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CWS	community water system
CWSS	Community Water System Survey
DHHS	U.S. Department of Health and Human Services
EPA	U.S. Environmental Protection Agency
FR	Federal Register
GW	ground water
ICR	Information Collection Request
LOAEL	lowest-observed-adverse-effect level
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MDL	method detection limit
µg/day	micrograms per day
µg/L	micrograms per liter
mg/L	milligrams per liter
MGD	million gallons per day
MRL	minimum reporting level
NCWS	non-community water system
NPDWR	national primary drinking water regulation
NTNCWS	non-transient non-community water system
PWS	public water system
SDWA	Safe Drinking Water Act
SDWIS/Fed	Safe Drinking Water Information System Fed Data Warehouse
SMCL	Secondary Maximum Contaminant Level
SW	Surface water
SYR	Six-Year Review
SYR 1	First Six-Year Review
SYR 2	Second Six-Year Review
SYR 3	Third Six-Year Review
SYR 4	Fourth Six-Year Review
TNCWS	Transient non-community water system
WFRS	Water Fluoridation Reporting System

1 Introduction

The 1996 Safe Drinking Water Act (SDWA) Amendments require the U.S. Environmental Protection Agency (EPA or the agency) to periodically review existing National Primary Drinking Water Regulations (NPDWRs). Section 1412(b)(9) of SDWA reads:

> ...[t]he Administrator shall, not less than every 6 years, review and revise, as appropriate, each primary drinking water regulation promulgated under this title. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons.

Pursuant to the 1996 SDWA Amendments, EPA completed and published the results of its first Six-Year Review (SYR 1) July 18, 2003 (68 FR 42908 (USEPA, 2003)) after developing a systematic approach, or protocol, for the review of NPDWRs. EPA applied the same protocol with minor refinements (revised protocol) to the second Six-Year Review of NPDWRs (SYR 2), publishing the results March 29, 2010 (75 FR 15500 (USEPA, 2010)), and the third Six-Year Review of NPDWRs (SYR 3), publishing the results January 11, 2017 (82 FR 3518 (USEPA, 2017)). During SYR 3, EPA identified new information indicating potential to revise the NPDWR for fluoride based on new health risk information. EPA determined, however, that the revision was a lower priority that would divert significant resources from the higher priority candidates for revision that the Agency has identified, as well as other high priority work within the drinking water office (82 FR 3518 (USEPA, 2017)).

During the fourth Six-Year Review (SYR 4) of NPDWRs, EPA reviewed the potential to revise the fluoride NDPWR. As part of that effort, the agency estimated the occurrence and exposure to fluoride. This report describes the data, analysis, and results of that analysis.

1.1 Background

EPA published the current NPDWR for fluoride on April 2, 1986 (51 FR 11396 (USEPA, 1986)). The NPDWR established a maximum contaminant level goal (MCLG) and a maximum contaminant level (MCL) of 4.0 milligrams per liter (mg/L). The MCLG reflected the lowest effect level for crippling skeletal fluorosis of 20 mg/day with continuous exposures over a 20-year or longer period. EPA obtained the MCLG by dividing the lowest-observed-adverse-effect level (LOAEL) by an uncertainty factor of 2.5 and accounting for a drinking water intake of 2 liters/day (L/day). Drinking water was considered then to be the only source of exposure for the calculation. At the same time, EPA published a secondary maximum contaminant level (SMCL) for fluoride of 2.0 mg/L to protect against dental fluorosis, which was considered to be an adverse cosmetic effect. public water sysems (PWSs) exceeding the fluoride SMCL must provide public notification to their customers.

Because of the beneficial effects of fluoride at low level exposures, some water systems voluntarily add fluoride as a public health measure to reduce the incidence of cavities. The decision to fluoridate a water supply is made at the State or local municipality level, and is not mandated by EPA or any other Federal entity. Historically, the recommended amount of fluoride for drinking water systems that added fluoride ranged from 0.7 to 1.2 mg/L, depending on

ambient air temperatures. On January 13, 2011, the U.S. Department of Health and Human Services (DHHS) announced in the *Federal Register* (FR) a proposal to change the recommendation to 0.7 mg/L because there are more sources of fluoride available now than when water fluoridation was first introduced (DHHS, 2011). DHHS finalized the recommendation in 2015 (DHHS, 2015). The effect of this change is a reduction in fluoride concentrations at systems that add fluoride to finished drinking water.

1.2 Objective

The objective of this analysis is to estimate the occurrence of fluoride in drinking water and the size of the population exposed to concentrations greater than the following thresholds: 0.9 mg/L, 1.0 mg/L, 1.2, mg/L, 1.5 mg/L, 2.0 mg/L (the SMCL), and 4.0 mg/L (the MCL). EPA used available data to derive the estimates. EPA identified 0.9 mg/L as a potential MCLG for fluoride (USEPA, 2024b).

Because fluoridating systems add fluoride to provide public health benefits and the recommended concentration changed in 2015 from a range (0.7 mg/L to 1.2 mg/L) to 0.7 mg/L, the agency removed the fluoride concentrations believed to reflect fluoride addition. Excluding these values from the analysis avoids overstating occurrence and exposure estimates at the thresholds that overlap the old fluoridation range.

The analysis approach has three steps: (1) data collection and review; (2) merging data sets to screen out measurements that reflect fluoride addition; and (3) estimating occurrence and exposure at thresholds identified by EPA. This memorandum documents our data sources, data analysis, and resulting estimates.

1.3 Outline

This report contains the following sections. Section 2 provides descriptions of the three data sources that EPA used as inputs to the analysis: one data set with fluoride measurements and two data sets to help identify fluoridation measurements. Section 3 contains a description of the analysis method, which includes merging the source data, identifying which fluoride measurements to exclude because they represent fluoride addition, and finally estimate fluoride occurrence and exposure above the thresholds noted above. This section also addresses sources of uncertainty that affect the estimates.

2 Data Sources

EPA collected and reviewed data from three sources: the SYR 4 Information Collection Request (ICR) fluoride compliance data; a dataset maintained by the Center for Disease Control and Prevention (CDC) that indicates which systems "adjust" fluoride (i.e., add fluoride as a public health measure); and PWS treatment information related to fluoride in EPA's Safe Drinking Water Information System Fed Data Warehouse (SDWIS/Fed). The following sections provide descriptions of each data set.

2.1 SYR 4 ICR Dataset

The SYR 4 ICR dataset contains fluoride compliance monitoring results collected from 2012 to 2019 that 59 jurisdictions (46 states, Washington D.C., three territorial or tribal governments, and nine EPA regional jurisdictions that administer tribal systems that do not have primacy) voluntarily provided to EPA. The agency reviewed the SYR 4 ICR dataset to confirm data quality and representativeness (USEPA, 2024a). Exhibit 2-1 lists key data fields in the SYR 4 ICR dataset and provides a description of field contents.

Exhibit 2-1. SYR 4 ICR Dataset Fields and Descriptions

Field Name	Description
PWSID	A unique, 9-digit identifier assigned to every PWS
SYSTEM_NAME	The formal, legal, or common name used by the PWS
SYSTEM_TYPE	Type of system based on SDWA definitions: C=community water system; NTNC=non-transient, non-community water system; TNC=transient water systems
RETAIL_POPULATION	Number of people served directly by system
ADJUSTED_POPULATION	Number of people served including retail and wholesale customers
SOURCE_WATER [a]	Code indicating type of water source: GU=ground water under the influence of surface water; GW=ground water, SW=surface water
WATER_FACILITY_ID	Unique identifier within a PWS
WATER_FACILITY_TYPE	Code identifying type of facility: CC=consecutive connection; CH=common header; CS=cistern; CW=clear well; DS=distribution system; EP=entry point; IG=infiltration gallery; IN=intake; OT=other; PC=pressure control; PF=pump facility; RS=reservoir; SP=spring; SS=sampling station; ST=storage; TM=transmission main; TP=treatment plant; WH=wellhead; WL=well.
DETECTION_LIMIT_VALUE	Numeric value of detection limit or minimum reporting value
DETECTION_LIMIT_UNIT	Measurement units, µg/L=micrograms per liter, mg/L=milligrams per liter
DETECT	Indicator for contaminant detection: 0=not detected above detection or reporting limit; 1=detected above limit
VALUE	Numeric concentration of detected sample result
UNIT	Measurement units; mg/L=milligrams per liter

a. GU systems are combined with SW systems in the occurrence analysis.

EPA excluded some types of systems from the occurrence analysis. The required estimates of fluoride are from community water systems (CWS) and non-transient, non-community water systems (NTNCWS). Therefore, EPA removed the 5,684 fluoride sample records where the SYSTEM_TYPE indicates a transient, non-community water systems (TNCWS). There were 229 records missing a SYSTEM_TYPE value. These records tended to have SYSTEM_NAME

entries that indicated the system served public parks or campgrounds, which would make them TNCWS. Therefore, EPA excluded these systems, too.

EPA reviewed the fluoride monitoring data in the DETECTION_LIMIT_VALUE, DETECTION_LIMIT_UNIT, DETECT, and VALUE fields to identify outlier values. The agency used the same approach used for SYR 3. Low outliers for fluoride detections are values less than the lowest water method detection limit (MDL). The lowest MDL for fluoride is 0.002 mg/L for Standard Method 4110B. The agency removed 194 sample records that reported detected fluoride levels less than 0.002 mg/L. There were no high outlier values among the detection records (i.e., no detected concentrations more than 40 mg/L, which is 10 times greater than the current MCL of 4 mg/L). There were a few records with non-detection results with MRL values greater than the MCL, which the agency removed.[1] Because non-detection results below 0.002 mg/L have no impact on the occurrence analysis, the agency did not remove those values.

EPA could not match WATER_FACILITY_ID values to values in a SDWIS/Fed facility flow data table to identify whether any of the fluoride sampling facilities in the SYR 4 ICR dataset were redundant. In prior review cycle datasets, some systems provided both source water samples and entry point samples. Entry point samples are a better indicator of fluoride occurrence and exposure than source water samples taken upstream of the entry point. Because no facilities could be identified as upstream of other facilities in the SYR 4 ICR dataset, the agency assumed that all monitoring locations represented water quality delivered to customers regardless of the WATER_FACILTY_TYPE value. Every facility was treated as if it represented an entry point to a distribution system. Systems often have multiple entry points such as multiple ground water (GW) wells directly connected to a distribution system or a well and a surface water (SW) treatment plant that serve different areas.

Exhibit 2-2 provides fluoride data summary statistics for the number of samples, systems, and entry points in the final SYR 4 ICR dataset. It also shows two distributions, one for source water (GW and SW) and another for system type (CWS and NTNCWS).

Exhibit 2-2: SYR 4 ICR Fluoride Data Summary Statistics by Source Water Type and System Type

Item	Total	GW Source Water	SW Source Water	CWS Type	NTNCWS Type
Samples	429,358	326,710	102,648	385,458	43,900
Systems	49,485	45,187	4,298	35,675	13,810
Entry Points	86,164	76,203	9,961	69,574	16,590

Source: Analysis of SYR 4 ICR data. Note: The values exclude systems in non-reporting jurisdictions: Georgia, Guam, Michigan, Mississippi, New Mexico, Puerto Rico, and Virgin Islands (USEPA, 2024a).

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[1] For these records, DETECT equals zero, the DETECTION_LIMIT_VALUE is greater than 4, and the DETECTION_LIMIT_UNIT is mg/L. Approved laboratories should be able to quantitate fluoride down to a concentration below the MCL. These outliers may indicate a data quality issue.

2.2 CDC Data

States voluntarily provide PWS fluoridation information to the CDC's Water Fluoridation Reporting System (WFRS). The CDC makes this information available via the My Water's Fluoride website (CDC, 2022). This information is only available at the system level. It is possible, however, for fluoridation practices and fluoride concentrations to vary throughout a system. For example, a system with mixed water sources may add fluoride to water that goes through a surface water treatment plant but not add fluoride to ground water delivered directly to customers.

EPA downloaded the data for each reporting state and created a combined dataset. Reporting formats varied across states. Exhibit 2-3 shows the fields in the combined dataset and indicates which fields may be missing from the data the participating states provided to WFRS.

Exhibit 2-3. CDC Data Fields and Descriptions

Field Name	Description
PWS ID	A unique, 9-digit identifier assigned to every PWS
PWS Name	The formal, legal, or common name used by the PWS
County	Primary county served
Population Served	Number of people served by system
Fluoridated	Yes or No
Water Source [a]	Code indicating type of water source: GU=ground water under the influence of surface water; GW=ground water, SW=surface water
Fluoride Conc. [a]	Single value in mg/L
Water Source [a]	Ground or Surface
Status [a]	Adjusted=adds fluoride to its own or purchased water Consecutive=purchases adjusted or non-adjusted water from another system and does not add fluoride Defluoridated=system blends or treats to reduce high fluoride level Multi-Source=system has multiple water sources that may or may not be fluoridated Natural=a system with natural fluoride, assumed to be optimal Non-Adjusted=system with own water source that does not add fluoride or have optimal natural fluoride level Variable
Fluoride Product [a]	Natural=source water has natural fluoride that is not adjusted NaF=sodium fluoride added H_2SiF_6=hydrofluosilicic acid added Na_2SiF_6 Dry=sodium silicofluoride added

a. Field not reported by some states.

EPA used two data fields to determine which systems to classify as adding fluoride: Status and Fluoridated. As Exhibit 2-3 indicates, all participating states provided data for the Fluoridated field, which contains values of *No* or *Yes*; but Status reporting is incomplete. Exhibit 2-4 shows a cross-tabulation of the Fluoridated field values (columns showing *No* or *Yes* values) and the Status field values (indicated by row headers). The majority of records are missing a value in the Status field. For those records, the agency relied entirely on the Fluoridated field as the indicator of whether a system adds fluoride.

For systems with values in both indicator fields, EPA used both values to identify systems that distribute water with added fluoride. This group includes systems for which the Fluoridated

value of *Yes* and the Status value is *Adjusted*, *Consecutive*, *Multi-source*, or *Variable*. The agency assumed that Status values of *Natural* indicated systems with naturally occurring fluoride in the optimal range (i.e., no fluoride addition occurs). The agency also assumed that the few fluoridated systems identified as *Defluoridated* had high natural fluoride levels that were treated to remove fluoride for MCL compliance purposes.

Exhibit 2-4. CDC Fluoride Indicator Data Summary

Value of Status Field	Fluoridated Value = No	Fluoridated Value = Yes
Missing data ᵃ	18,169	**10,426**
Adjusted	0	**582**
Consecutive	577	**1,534**
Defluoridated	1	3
Multi-Source	6	**37**
Natural	0	2,452
Non-Adjusted	8,062	0
Variable	88	**14**
Total	26,903	15,048

a. Field not reported by some states. There were 77 systems with missing Status field data that reported "Mixed" for the fluoridated value. Because this response indicates fluoridation occurs in some part of the system, the Yes column includes these values.

Exhibit 2-5 provides a summary of the CDC data. It reports the total number of systems in the CDC dataset and the number that EPA classified as adding fluoride for the purpose of the occurrence analysis. The data also include source water type for almost 63% of the systems. The summary results indicate that fluoridation is more common among SW systems than GW systems.

Exhibit 2-5: CDC Data Summary Statistics by Source Water Type

Item	Total	GW Source Water	SW Source Water	Other or Missing Source Water
Total Systems	41,951	21,950	4,308	15,693
Systems Reporting Fluoride Addition	12,596	4,367	2,695	5,534
Percent of Systems Reporting Fluoride Addition	30%	20%	63%	35%

Source: CDC (2022). Note: Excludes systems in non-reporting jurisdictions: Montana, New Jersey, New York, Ohio, South Dakota, Wyoming, Washington, D.C., tribal systems, and systems in U.S. territories.

2.3 SDWIS/Fed Data

EPA extracted data from the SDWIS/Fed Facility table. EPA extracted data for a subset of systems with a facility identified as a *Treatment Plant* that included *Fluoridation* as a treatment process (Exhibit 2-6).

Exhibit 2-6. SDWIS/Fed Extract Data Fields and Descriptions

Field Name	Description
PWS ID	A unique, 9-digit identifier assigned to every PWS
PWS Name	The formal, legal, or common name used by the PWS
PWS Type	CWS or NTNCWS
Primary Source Water	GW or SW
Facility Id	A unique identifier for the facility within the PWS
Facility Type	Treatment Plant
Treatment Process	Fluoridation

Exhibit 2-7 provides a summary of the available fluoridation data, distinguishing results by water source and system type. It is possible for systems in SDWIS/Fed to have incomplete facilities information. Therefore, the number of systems with fluoridation treatment may be incomplete.

Exhibit 2-7: SDWIS/Fed Fluoridation Treatment Data Summary Statistics by Source Water Type and System Type

Item	Total	GW Source Water	SW Source Water	CWS Type	NTNCWS Type
Systems	5,618	3,403	2,215	5,585	33

Source: USEPA (2022).

3 Analysis Method and Findings

This section provides a description of the method EPA used to combine the inputs data and generate the occurrence and exposure estimates. There are two types of estimates: Stage 1, which is a comparison of maximum (peak) concentrations with the thresholds; and Stage 2, which is a comparison of mean concentrations with the thresholds.

The method has the following steps:

- Merge SYR 4 ICR fluoride measurements data with CDC and SDWIS/Fed data;
- Create system-level fluoridation variable;
- Identify and remove measurements for fluoridated entry points;
- Derive Stage 1 estimates based on maximum (peak) values; and
- Derive Stage 2 estimates based on mean values.

3.1 Data Merge

For the first step, EPA merged the SYR 4 ICR, CDC, and SDWIS/Fed data by matching system identification values (i.e., the PWSID fields common to all three datasets). The merged dataset used for the occurrence analysis contains system and entry point identifiers as well as fluoride sample records for the 49,485 systems in the SYR 4 ICR dataset. It also contains fluoridation indicator values for 27,519 systems from one or both of the supplemental datasets (i.e., 55% of the systems in the SYR 4 ICR dataset).

Most of the 27,519 systems with fluoridation indicators have information from the CDC dataset. The system overlap between the CDC and SYR 4 ICR datasets is 27,346 systems. Both datasets are incomplete and, therefore, contain systems in state or territories that are in the other dataset.

A majority of the systems in the SDWIS/Fed dataset also occur in the CDC dataset. Nevertheless, the SDWIS/Fed dataset includes a fluoridation indicator for 173 systems additional systems.

3.2 Fluoridating Entry Point Identification

Fluoridation practices during the SYR 4 ICR data period (2012 to 2019) have the potential to bias the occurrence and exposure estimates upward. The thresholds for the occurrence and exposure analysis are: 0.9 mg/L, 1.0 mg/L, 1.2, mg/L, 1.5 mg/L, 2.0 mg/L (the SMCL), and 4.0 mg/L (the MCL). These values overlap the CDC range for optimal fluoridation, which was 0.7 mg/L to 1.2 mg/L (depending on outdoor air temperature) until 2015. In 2015, the CDC revised the recommendation to 0.7 mg/L based on the increase in fluoride sources over time (80 FR 24936, May 1, 2015). If all fluoridating entry points in the ICR data maintain concentrations at 0.7 mg/L in the future, then none would exceed the thresholds. Higher fluoridation levels prior to 2015, however, could result in entry point peak concentrations or mean concentrations that exceed some thresholds. Therefore, EPA removed fluoride measurements that reflected likely fluoride addition.

To identify these measurements, EPA used the CDC and SDWIS/Fed fluoridation information in conjunction with the SYR 4 ICR data. First, the approach involved creating a single variable indicating fluoride addition at the system level. Recognizing that systems can have different fluoride addition practices across entry points, the agency combined this system-level indicator with SYR 4 ICR entry point average fluoride concentrations to identify which entry points likely add fluoride. EPA initially determined that the fluoridating entry points are those at fluoridating systems at which the average concentration is between 0.7 mg/L and 1.2 mg/L. Taking measurement accuracy into account, however, the agency reduced the lower bound to 0.63 mg/L. The acceptance limit in 40 CFR 141.23 of ± 10% for fluoride at concentrations from 1 mg/L to 10 mg/L identifies 0.63 mg/L a conservative lower bound sample measurement for water with a true concentration of 0.7 mg/L of fluoride.

Exhibit 3-1 shows the impact of excluding fluoridating entry points on the distribution of mean concentrations. Both sets of vertical bars show the number of entry points with a mean concentration in each of the discrete data ranges shown. The left-hand (blue) bars reflect all SYR 4 ICR entry points and indicate higher than expected values in the recommended fluoridation range given the approximately log-normal distribution of fluoride across entry points. The right-hand (orange) frequencies show the impact of removing the SYR 4 ICR entry points that add fluoride.

Exhibit 3-1. Distributions of Entry Point Mean Concentrations Including and Excluding Entry Points that Fluoridate
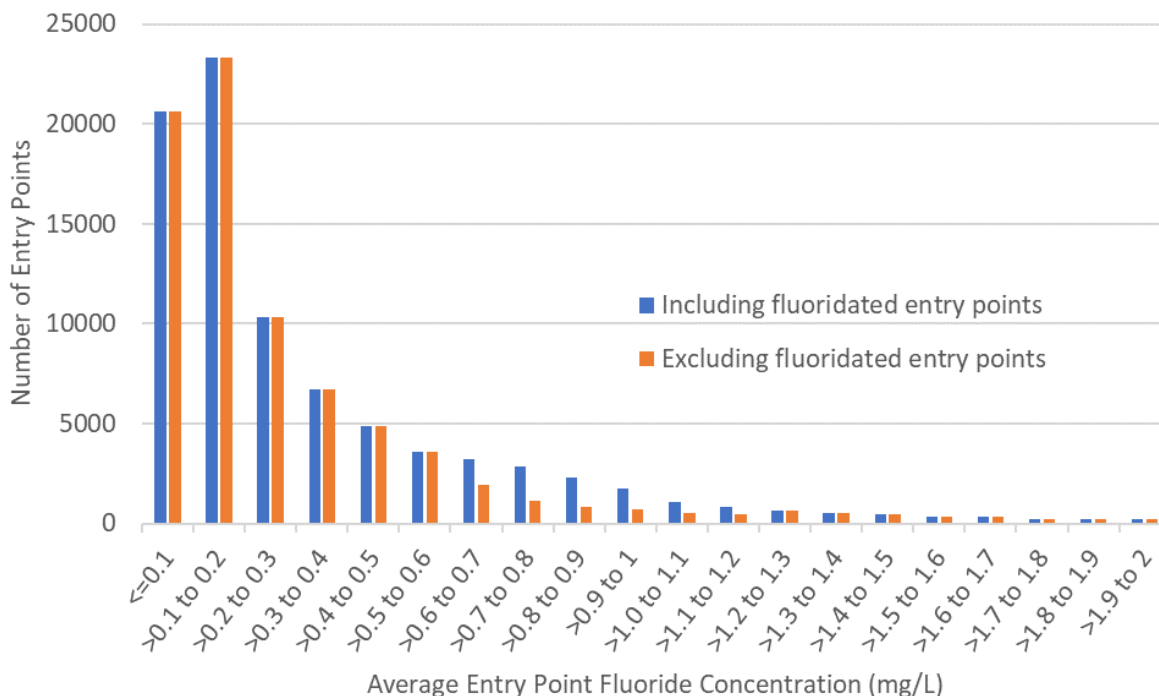
Source: Analysis of SYR 4 ICR data.

This approach results in a conservative estimate of the number of fluoridated entry points (i.e., excluding some fluoridating entry points). First, all data sources are incomplete. The fluoridating systems in the SYR 4 ICR dataset that are missing from either the CDC fluoridation dataset or

the SDWIS/Fed facility data are not identified as such. Second, it is possible that entry points that implemented fluoridation practices after 2015 might have average concentrations that are less than 0.63 mg/L. As such, they would not be identified as fluoridating. Exhibit 3-2 shows the number of entry points and associated systems identified as fluoridating.

Exhibit 3-2: SYR 4 ICR Data Summary Statistics by Source Water Type and System Type: Fluoridating Entry Points and Systems with at Least One Fluoridating Entry Point

Item	Total	GW Source Water	SW Source Water	CWS Type	NTNCWS Type
Systems	4,158	3,096	1,062	4,135	23
Entry Points	6,539	4,936	1,603	6,513	26

Source: Analysis of SYR 4 ICR data.
Note: Excludes systems in SYR 4 ICR non-reporting jurisdictions: Georgia, Guam, Michigan, Mississippi, New Mexico, Puerto Rico, and Virgin Islands.

Entry point service populations are unknown. EPA used a bounding approach to estimate population exposure. The agency assumed a lower bound based on uniform population distribution across entry points within a system and an upper bound of the total system population. Exhibit 3-3 provides population estimates associated with entry points (and systems) that fluoridate. The entry point population is approximately 66% of the system population.

Exhibit 3-3: Population Served by Source Water Type and System Type: Fluoridating Entry Points and Systems with at Least One Fluoridating Entry Point

Item	Total	GW Source Water	SW Source Water	CWS Type	NTNCWS Type
System Population	128,490,690	36,316,001	92,174,689	128,303,782	186,908
Entry Point Population	85,033,173	22,965,047	62,068,127	84,846,397	186,777

Source: Analysis of SYR 4 ICR data.
Note: Excludes systems in SYR 4 ICR non-reporting jurisdictions: Georgia, Guam, Michigan, Mississippi, New Mexico, Puerto Rico, and Virgin Islands

3.3 Stage 1 Occurrence and Exposure Estimates

The Stage 1 analysis provides occurrence and exposure estimates that are based on the maximum or peak SYR 4 ICR fluoride concentrations at each entry point. EPA counted as exceedances the maximum values at each non-fluoridating entry point that exceed each threshold. Exhibit 3-4 shows that the number of exceedances increases as the threshold value decreases. Exceedances are higher among GW systems than SW systems, but do not exceed 10% of entry points, however.

Exhibit 3-4. Stage 1: Number and Percent of Entry Points with Peak Concentrations Exceeding Fluoride Thresholds

Source Water Type and Threshold	Number of Entry Points with a Peak Concentration Greater Than the Threshold	Percent of Entry Points with a Peak Concentration Greater Than the Threshold [a]
GW > MCL (4.0 mg/L)	333	0.4%
GW > SMCL (2.0 mg/L)	1,983	3%
GW > Alternate 3 (1.5 mg/L)	3,598	5%
GW > Alternate 2 (1.2 mg/L)	5,180	7%
GW > Alternate 1 (1.0 mg/L)	6,380	8%
GW > Potential MCLG (0.9 mg/L)	7,429	10%
SW > MCL (4.0 mg/L)	13	0.1%
SW > SMCL (2.0 mg/L)	92	1%
SW > Alternate 3 (1.5 mg/L)	169	2%
SW > Alternate 2 (1.2 mg/L)	254	3%
SW > Alternate 1 (1.0 mg/L)	369	4%
SW > Potential MCLG (0.9 mg/L)	534	5%
Total > MCL (4.0 mg/L)	346	0.4%
Total > SMCL (2.0 mg/L)	2,075	2%
Total > Alternate 3 (1.5 mg/L)	3,767	4%
Total > Alternate 2 (1.2 mg/L)	5,434	6%
Total > Alternate 1 (1.0 mg/L)	6,749	8%
Total > Potential MCLG (0.9 mg/L)	7,963	9%

Source: Analysis of SYR 4 ICR data. Exceedances exclude samples for entry points that likely add fluoride.
a. GW percentages are based on 76,203 GW entry points; SW percentages are based on 9,961 SW entry points; Both percentages are based on a combined total of 86,164 GW and SW entry points.

Exhibit 3-5 shows the corresponding entry point populations. The percentage exposure estimates for each threshold are smaller than the corresponding occurrence exceedance estimates. This result suggests that the exceedances tend to occur among entry points that serve smaller-than-average populations.

Exhibit 3-5. Stage 1: Sum and Percent of Population Served by Entry Points with Peak Concentrations Exceeding Fluoride Thresholds

Source Water Type and Threshold	Sum of Population Served by Entry Points with a Peak Concentration Greater Than the Threshold	Percent of Population Served by Entry Points with a Peak Concentration Greater Than the Threshold [a]
GW > MCL (4.0 mg/L)	187,964	0.2%
GW > SMCL (2.0 mg/L)	1,570,881	1%
GW > Alternate 3 (1.5 mg/L)	2,951,734	3%
GW > Alternate 2 (1.2 mg/L)	4,560,401	4%
GW > Alternate 1 (1.0 mg/L)	5,802,540	5%
GW > Potential MCLG (0.9 mg/L)	7,171,648	7%
SW > MCL (4.0 mg/L)	41,001	<0.1%
SW > SMCL (2.0 mg/L)	313,042	0.2%
SW > Alternate 3 (1.5 mg/L)	852,825	1%
SW > Alternate 2 (1.2 mg/L)	1,697,431	1%
SW > Alternate 1 (1.0 mg/L)	3,974,883	2%
SW > Potential MCLG (0.9 mg/L)	6,847,688	4%
Total > MCL (4.0 mg/L)	228,964	0.1%
Total > SMCL (2.0 mg/L)	1,883,923	1%
Total > Alternate 3 (1.5 mg/L)	3,804,560	1%
Total > Alternate 2 (1.2 mg/L)	6,257,832	2%
Total > Alternate 1 (1.0 mg/L)	9,777,423	4%
Total > Potential MCLG (0.9 mg/L)	14,019,336	5%

Source: Analysis of SYR 4 ICR data. Exceedances exclude samples for entry points that likely add fluoride. Population exposure estimated at entry point level based on uniform system population distribution across entry points.
a. GW percentages are based on a total population of 109,856,542; SW percentages are based on a total population of 160,336,716; Both percentages are based on a combined total population of 270,193,258.

EPA also developed Stage 1 system-level occurrence and exposure estimates, shown in Exhibit 3-6 and Exhibit 3-7, respectively. The occurrence exceedances are based on whether the maximum sample across all non-fluoridating entry points exceeds a threshold. The corresponding exposure estimates are total system populations. These exposure estimates overstate exposure for any systems that have fluoridating entry points as well as an exceedance at a non-fluoridating entry point.

A comparison of the entry point-level percentage estimates in Error! Reference source not found. to the system-level estimates in Exhibit 3-6 shows a reduction in occurrence frequency. For example, 9% of entry points of any water source type have peak values that exceed 0.9 mg/L, but the frequency declines to 7% for systems.

Conversely, the percent population exposure estimates based on system populations in Exhibit 3-7 are more than triple the estimates based on entry point populations in Exhibit 3-5. For example, entry points of any water source type with peak values that exceed 0.9 mg/L serve 5% of total population. The systems at which a peak concentration exceeds 0.9 mg/L serve 25% of total population. This difference between the entry point-level and system-level estimates suggests high uncertainty regarding how many people might be exposed above the thresholds.

Exhibit 3-6. Stage 1: Number and Percent of Systems with Peak Concentrations Exceeding Fluoride Thresholds

Source Water Type and Threshold	Number of Entry Points with a Peak Concentration Greater Than the Threshold	Percent of Entry Points with a Peak Concentration Greater Than the Threshold [a]
GW > MCL (4.0 mg/L)	241	0.5%
GW > SMCL (2.0 mg/L)	1,469	3%
GW > Alternate 3 (1.5 mg/L)	2,632	6%
GW > Alternate 2 (1.2 mg/L)	3,739	8%
GW > Alternate 1 (1.0 mg/L)	4,636	10%
GW > Potential MCLG (0.9 mg/L)	5,380	12%
SW > MCL (4.0 mg/L)	9	0.2%
SW > SMCL (2.0 mg/L)	64	1%
SW > Alternate 3 (1.5 mg/L)	108	3%
SW > Alternate 2 (1.2 mg/L)	153	4%
SW > Alternate 1 (1.0 mg/L)	232	5%
SW > Potential MCLG (0.9 mg/L)	349	8%
Total > MCL (4.0 mg/L)	250	0.5%
Total > SMCL (2.0 mg/L)	1,533	3%
Total > Alternate 3 (1.5 mg/L)	2,740	6%
Total > Alternate 2 (1.2 mg/L)	3,892	8%
Total > Alternate 1 (1.0 mg/L)	4,868	10%
Total > Potential MCLG (0.9 mg/L)	5,729	12%

Source: Analysis of SYR 4 ICR data. Exceedances exclude samples for entry points that likely add fluoride.
a. GW percentages are based on 45,187 GW systems; SW percentages are based on 4,298 SW systems; Total percentages are based on a combined total of 49,485 GW and SW systems.

Exhibit 3-7. Stage 1: Sum and Percent of Population Served by Systems with Peak Concentrations Exceeding Fluoride Thresholds

Source Water Type and Threshold	Sum of Population Served by Entry Points with a Peak Concentration Greater Than the Threshold	Percent of Population Served by Entry Points with a Peak Concentration Greater Than the Threshold [a]
GW > MCL (4.0 mg/L)	859,731	0.8%
GW > SMCL (2.0 mg/L)	4,221,433	4%
GW > Alternate 3 (1.5 mg/L)	7,190,217	7%
GW > Alternate 2 (1.2 mg/L)	11,175,318	10%
GW > Alternate 1 (1.0 mg/L)	14,557,758	13%
GW > Potential MCLG (0.9 mg/L)	18,464,567	17%
SW > MCL (4.0 mg/L)	155,339	0.1%
SW > SMCL (2.0 mg/L)	1,762,395	1%
SW > Alternate 3 (1.5 mg/L)	4,628,972	3%
SW > Alternate 2 (1.2 mg/L)	6,435,470	4%
SW > Alternate 1 (1.0 mg/L)	15,035,550	9%
SW > Potential MCLG (0.9 mg/L)	18,464,567	12%
Total > MCL (4.0 mg/L)	1,027,619	0.4%
Total > SMCL (2.0 mg/L)	6,014,752	2%
Total > Alternate 3 (1.5 mg/L)	12,057,993	4%
Total > Alternate 2 (1.2 mg/L)	18,201,124	7%
Total > Alternate 1 (1.0 mg/L)	30,186,299	11%
Total > Potential MCLG (0.9 mg/L)	41,382,464	15%

Source: Analysis of SYR 4 ICR data. Exceedances exclude samples for entry points that likely add fluoride. Population exposure estimated at system level, however, can includeservice populations receiving fluoridated water.

a. GW percentages are based on a total GW population of 109,856,542; SW percentages are based on a total SW system population of 160,336,716; Total percentages are based on a combined total population of 270,193,258.

3.4 Stage 2 Occurrence and Exposure Estimates

EPA also developed occurrence and exposure estimates based on average entry point fluoride concentrations. There are three sets of results. They differ by the assumption made to incorporate nondetection results in the mean value formula. Nondetection results include an MRL value. The MRL is an upper bound on the actual fluoride concentration, which can range from 0 mg/L to the MRL. The agency used a substitution method to replace the MRL values. The three substitution options bound the range of uncertainty: MRL $\times$ 0, MRL $\times$ 1/2, and MRL $\times$ 1. Occurrence results based on entry point means are in Exhibit 3-8 and exposure estimates are in Exhibit 3-9.

As expected, the Stage 2 entry point occurrence estimates (Exhibit 3-8) are lower than the Stage 1 estimates (Exhibit 3-4). For example, 9% of entry points have Stage 1 (peak value; Exhibit 3-4) exceedances at 0.9 mg/L but 7% of entry points have Stage 2 (mean value; Exhibit 3-8) exceedances of the same threshold. The exposure estimates are substantially lower, however. The Stage 1 population served estimates are 5% at 0.9 mg/L (Exhibit 3-5) compared to 2% for Stage 2 (Exhibit 3-9). This result indicates that fluoride levels are higher at either smaller systems or those with multiple entry points.

Exhibit 3-8. Stage 2: Number and Percent of Entry Points with Mean Concentrations Exceeding Fluoride Thresholds

Source Water Type and Threshold	EP# Non-detect values= Zero	EP# Non-detect values= 1/2 MRL	EP# Non-detect values= MRL	EP% [a] Non-detect values = Zero	EP% [a] Non-detect values = 1/2 MRL	EP% [a] Non-detect values = MRL
GW > MCL (4.0 mg/L)	165	165	165	0.2%	0.2%	0.2%
GW > SMCL (2.0 mg/L)	1,496	1,497	1,503	2%	2%	2%
GW > Alternate 3 (1.5 mg/L)	2,851	2,855	2,864	4%	4%	4%
GW > Alternate 2 (1.2 mg/L)	4,393	4,404	4,420	6%	6%	6%
GW > Alternate 1 (1.0 mg/L)	5,351	5,360	5,381	7%	7%	7%
GW > Potential MCLG (0.9 mg/L)	6,003	6,016	6,047	8%	8%	8%
SW > MCL (4.0 mg/L)	2	2	2	<0.1%	<0.1%	<0.1%
SW > SMCL (2.0 mg/L)	50	50	51	1%	1%	1%
SW > Alternate 3 (1.5 mg/L)	96	96	98	1%	1%	1%
SW > Alternate 2 (1.2 mg/L)	175	176	178	2%	2%	2%
SW > Alternate 1 (1.0 mg/L)	217	218	220	2%	2%	2%
SW > Potential MCLG (0.9 mg/L)	248	251	252	2%	3%	3%
Total > MCL (4.0 mg/L)	167	167	167	0.2%	0.2%	0.2%
Total > SMCL (2.0 mg/L)	1,546	1,547	1,554	2%	2%	2%
Total > Alternate 3 (1.5 mg/L)	2,947	2,951	2,962	3%	3%	3%
Total > Alternate 2 (1.2 mg/L)	4,568	4,580	4,598	5%	5%	5%
Total > Alternate 1 (1.0 mg/L)	5,568	5,578	5,601	6%	6%	7%
Total > Potential MCLG (0.9 mg/L)	6,251	6,267	6,299	7%	7%	7%

Source: Analysis of SYR 4 ICR data. Exceedances exclude samples for entry points that likely add fluoride. Columns show results for different substitutions for non-detection results made before calculating system mean concentrations: zero, ½ x MRL, or the MRL value.

a. GW percentages are based on a 76,203 GW entry points; SW percentages are based on 9,961 SW entry points; Total percentages are based on a combined total of 86,164 GW and SW entry points.

Exhibit 3-9. Stage 2: Sum and Percent of Population Served by Entry Points with Mean Concentrations Exceeding Fluoride Thresholds

Source Water Type and Threshold	EP# Non-detect values= Zero	EP# Non-detect values= 1/2 MRL	EP# Non-detect values= MRL	EP% [a] Non-detect values = Zero	EP% [a] Non-detect values = 1/2 MRL	EP% [a] Non-detect values = MRL
GW > MCL (4.0 mg/L)	57,628	57,628	57,628	0.1%	0.1%	0.1%
GW > SMCL (2.0 mg/L)	973,857	973,882	976,558	1%	1%	1%
GW > Alternate 3 (1.5 mg/L)	2,137,939	2,138,778	2,150,692	2%	2%	2%
GW > Alternate 2 (1.2 mg/L)	3,769,951	3,774,183	3,791,684	3%	3%	3%
GW > Alternate 1 (1.0 mg/L)	4,487,365	4,505,064	4,522,840	4%	4%	4%
GW > Potential MCLG (0.9 mg/L)	5,036,836	5,063,486	5,074,085	5%	5%	5%
SW > MCL (4.0 mg/L)	1,313	1,313	1,313	<0.1%	<0.1%	<0.1%
SW > SMCL (2.0 mg/L)	143,659	143,659	144,409	0.1%	0.1%	0.1%
SW > Alternate 3 (1.5 mg/L)	348,349	348,349	468,107	0.2%	0.2%	0.2%
SW > Alternate 2 (1.2 mg/L)	919,626	920,376	1,053,949	1%	1%	1%
SW > Alternate 1 (1.0 mg/L)	1,196,968	1,197,718	1,331,290	1%	1%	1%
SW > Potential MCLG (0.9 mg/L)	1,318,879	1,453,202	1,453,284	1%	1%	1%
Both > MCL (4.0 mg/L)	58,940	58,940	58,940	<0.1%	<0.1%	<0.1%
Both > SMCL (2.0 mg/L)	1,117,516	1,117,541	1,120,967	0.4%	0.4%	0.4%
Both > Alternate 3 (1.5 mg/L)	2,486,288	2,487,128	2,618,800	1%	1%	1%
Both > Alternate 2 (1.2 mg/L)	4,689,577	4,694,559	4,845,632	2%	2%	2%
Both > Alternate 1 (1.0 mg/L)	5,684,333	5,702,782	5,854,130	2%	2%	2%
Both > Potential MCLG (0.9 mg/L)	6,355,715	6,516,688	6,527,369	2%	2%	2%

Source: Analysis of SYR 4 ICR data. Exceedances exclude samples for entry points that likely add fluoride. Population exposure estimated at entry point level based on uniform system population distribution across entry points. Columns show results for different substitutions for non-detection results made before calculating system mean concentrations: zero, ½ x MRL, or the MRL value.
a. GW percentages are based on a total population of 109,856,542; SW percentages are based on total population of 160,336,716; Both percentages are based on a combined total population of 270,193,258.

EPA also developed Stage 2 system-level occurrence and exposure estimates, shown in Exhibit 3-10 and Exhibit 3-11, respectively. The occurrence exceedances are based on whether the highest entry point mean across all non-fluoridating entry points exceeds a threshold. The corresponding exposure estimates are system populations instead of entry point populations. Therefore, the exposure estimates overstate population for any systems that have fluoridating entry points in addition to an exceedance at a non-fluoridating entry point.

The Stage 2 system estimates (Exhibit 3-10) are lower than the Stage 1 system estimates (Exhibit 3-6). For example, 12% of systems regardless of water source type have peak values that exceed 0.9 mg/L compared to 9% of systems with at least one entry point mean value that exceeds 0.9 mg/L. Similarly, the Stage 2 system exposure estimates are substantially lower than the Stage 1 estimates, e.g., declining from 15% (Exhibit 3-7) to 6% (Exhibit 3-11) at the 0.9 mg/L threshold.

Exhibit 3-10. Stage 2: Number and Percent of Systems with Mean Concentrations Exceeding Fluoride Thresholds

Source Water Type and Threshold	EP# Non-detect values= Zero	EP# Non-detect values= 1/2 MRL	EP# Non-detect values= MRL	EP% [a] Non-detect values = Zero	EP% [a] Non-detect values = 1/2 MRL	EP% [a] Non-detect values = MRL
GW > MCL (4.0 mg/L)	113	113	113	0.3%	0.3%	0.3%
GW > SMCL (2.0 mg/L)	1,116	1,117	1,123	2%	2%	2%
GW > Alternate 3 (1.5 mg/L)	2,077	2,081	2,090	5%	5%	5%
GW > Alternate 2 (1.2 mg/L)	3,165	3,173	3,187	7%	7%	7%
GW > Alternate 1 (1.0 mg/L)	3,865	3,870	3,888	9%	9%	9%
GW > Potential MCLG (0.9 mg/L)	4,337	4,348	4,374	10%	10%	10%
SW > MCL (4.0 mg/L)	1	1	1	<0.1%	<0.1%	<0.1%
SW > SMCL (2.0 mg/L)	32	32	33	0.7%	0.7%	0.8%
SW > Alternate 3 (1.5 mg/L)	60	60	62	1%	1%	1%
SW > Alternate 2 (1.2 mg/L)	99	100	102	2%	2%	2%
SW > Alternate 1 (1.0 mg/L)	117	118	120	3%	3%	3%
SW > Potential MCLG (0.9 mg/L)	128	131	132	3%	3%	3%
Total > MCL (4.0 mg/L)	114	114	114	0.2%	0.2%	0.2%
Total > SMCL (2.0 mg/L)	1,148	1,149	1,156	2%	2%	2%
Total > Alternate 3 (1.5 mg/L)	2,137	2,141	2,152	4%	4%	4%
Total > Alternate 2 (1.2 mg/L)	3,264	3,273	3,289	7%	7%	7%
Total > Alternate 1 (1.0 mg/L)	3,982	3,988	4,008	8%	8%	8%
Total > Potential MCLG (0.9 mg/L)	4,465	4,479	4,506	9%	9%	9%

Source: Analysis of SYR 4 ICR data. Exceedances exclude samples for entry points that likely add fluoride. Columns show results for different substitutions for non-detection results made before calculating system mean concentrations: zero, ½ x MRL, or the MRL value.

a. GW percentages are based on 45,187 GW systems; SW percentages are based on 4,298 SW systems; Total percentages are based on a combined total of 49,485 GW and SW systems

Exhibit 3-11. Stage 2: Sum and Percent of Populaiton Served by Systems with Mean Concentrations Exceeding Fluoride Thresholds

Source Water Type and Threshold	EP# Non-detect values= Zero	EP# Non-detect values= 1/2 MRL	EP# Non-detect values= MRL	EP% [a] Non-detect values = Zero	EP% [a] Non-detect values = 1/2 MRL	EP% [a] Non-detect values = MRL
GW > MCL (4.0 mg/L)	148,868	148,868	148,868	0.1%	0.1%	0.1%
GW > SMCL (2.0 mg/L)	2,595,045	2,595,070	2,616,602	2%	2%	2%
GW > Alternate 3 (1.5 mg/L)	4,716,872	4,718,021	4,746,231	4%	4%	4%
GW > Alternate 2 (1.2 mg/L)	8,165,486	8,170,270	8,198,785	7%	7%	7%
GW > Alternate 1 (1.0 mg/L)	10,021,420	10,105,582	10,134,525	9%	9%	9%
GW > Potential MCLG (0.9 mg/L)	11,033,767	11,128,757	11,152,387	10%	10%	10%
SW > MCL (4.0 mg/L)	12,472	12,472	12,472	<0.1%	<0.1%	<0.1%
SW > SMCL (2.0 mg/L)	463,990	463,990	464,740	0.3%	0.3%	0.3%
SW > Alternate 3 (1.5 mg/L)	2,083,436	2,083,436	2,203,194	1%	1%	1%
SW > Alternate 2 (1.2 mg/L)	4,634,456	4,635,206	5,001,814	3%	3%	3%
SW > Alternate 1 (1.0 mg/L)	5,310,030	5,310,780	5,677,388	3%	3%	4%
SW > Potential MCLG (0.9 mg/L)	5,539,003	5,906,361	5,906,443	3%	4%	4%
Both > MCL (4.0 mg/L)	161,340	161,340	161,340	0.1%	0.1%	0.1%
Both > SMCL (2.0 mg/L)	3,059,035	3,059,060	3,081,342	1%	1%	1%
Both > Alternate 3 (1.5 mg/L)	6,800,308	6,801,457	6,949,425	3%	3%	3%
Both > Alternate 2 (1.2 mg/L)	12,799,942	12,805,476	13,200,599	5%	5%	5%
Both > Alternate 1 (1.0 mg/L)	15,331,450	15,416,362	15,811,913	6%	6%	6%
Both > Potential MCLG (0.9 mg/L)	16,572,770	17,035,118	17,058,830	6%	6%	6%

Source: Analysis of SYR 4 ICR data. Exceedances exclude samples for entry points that likely add fluoride. Columns show results for different substitutions for non-detection results made before calculating system mean concentrations: zero, ½ x MRL, or the MRL value.

a. GW percentages are based on a total GW system population of 109,856,542; SW percentages are based on a total SW system population of 160,336,716; Total percentages are based on a combined total population of 270,193,258.

4   Uncertainty and Limitations

Data limitations introduce four sources of uncertainty that affect the occurrence and exposure estimates. This section provides a discussion of each data limitation and their potential effect on the estimates.

First, there are systems missing from the SYR 4 ICR dataset (e.g., from states and territories that did not voluntarily provide data). If there are systems in these jurisdictions with natural fluoride concentrations greater than one or more of the thresholds, then the estimates provided have a downward bias.

Second, the fluoridation information is incomplete. There are systems in the SYR 4 ICR dataset that do not appear in either the CDC or SDWIS/Fed datasets. Approximately 13% (10,843) of the entry points in the SYR 4 ICR fluoride data are in states or territories excluded from the CDC dataset. Only 446 of these entry points are at systems present in the SDWIS/Fed dataset. The fluoridation status is unknown for the remaining 10,397 entry points. If any systems do add fluoride at those entry points, they cannot be identified as such. If their mean concentrations exceed thresholds such as 0.9 mg/L, then the occurrence and exposure estimates include these fluoridating entry points and are upwardly biased.

Third, the fluoride monitoring results in the SYR 4 ICR dataset introduce some uncertainty. The non-detection results complicate efforts to estimate entry point mean concentrations. EPA bounded this source of uncertainty by calculating entry points means that included non-detection results that range from zero to MRL values. The Stage 2 results indicate that this source of uncertainty is relatively small.

Fourth, the population exposed at the entry point level is uncertain. EPA also bound these estimates with the entry point population estimates based on a uniform population distribution across entry points to system-level population estimates. As the Stage 1 and Stage 2 exposure estimates show, the source of uncertainty generates large differences.

The overall direction of bias is unknown. The first and second sources have some potential to offset one another, but the net impact is unknown. The third source of uncertainty can be bounded with fairly narrow ranges. The bounding ranges for the fourth source of uncertainty are large, however.

5   References

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