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FDA Ban on Triclosan Leads to Major Changes in Levels of Trihalomethanes in Drinking Water Sources across the United States

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Abstract

Since its development in the mid-1960s, antimicrobial Triclosan (TCS) has been added to many everyday household products. By 2010, TCS could be found in 93% of soaps and body washes sold nationwide due to its germ-killing capabilities. TCS overuse has led to public concern for the potential emerging health risks raised in the past decades. Although TCS has antibacterial properties that prevent or deter bacterial growth, in 2016, the US Food and Drug Administration (FDA) banned the sale of consumer antiseptic wash products containing TCS as the active ingredient. The ban stated that these TCS-containing household products may not be environmentally safe and provide minimal benefits. TCS is considered an endocrine disruptor that causes immune dysfunction, microbial resistance, altered thyroid hormone activity and affects human reproductive outcomes. Previous studies have shown that TCS is toxic to aquatic organisms and invertebrates and has been linked to the etiology of breast cancer and tumor metastasis. Research shows positive associations between the occurrence of antivirals and the detection of antibiotic-resistance genes with a higher incidence of antibacterial-related allergies. Our previous research examined the overuse of TCS-containing products, increasing total trihalomethane (TTHM) levels and affecting our water supply quality. To understand the impact of the FDA ban requiring pre-market approval, we analyzed data reported between 2016 and 2020 provided by the Consumer Confidence Report (CCR) on the TTHM levels, such as chloroform, a product of free chlorine added to TCS in primary water sources across the United States, as they correlated to decreased production of products containing TCS. Our study found that limiting the production of TCS had the desired effect by lowering levels of organochlorine contaminants, leading to a decrease in TTHMs recorded by metropolitan CCR data before the requirement rollback of the FDA in response to the COVID-19 pandemic in 2020.

Keywords

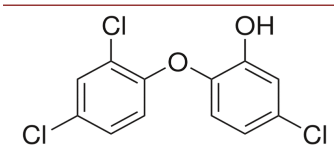
Organochlorine Contaminants, Triclosan, Trihalomethane, Chloroform, Water Quality

1. Introduction

Triclosan (TCS), a chlorinated aromatic compound containing phenol and ether functional groups, is an antimicrobial agent found in many consumer health products, notably aerosol sprays, hand sanitizers, toothpaste, and body wash. The molecular structure of TCS is displayed in **Table 1**.

TCS was first created and patented by the Swiss in 1964 to be used as surgical scrubs by hospitals and healthcare workers but entered worldwide production in 1997 as a nonionic broad-spectrum antimicrobial compound (**Figure 1**) (Ahn et al., 2008). The United States Toxic Substances Control Act monitored the production of products containing TCS, limiting manufacturing to approximately 1 million pounds per year, yet by 1998, production of TCS steadily increased from 1 million pounds to 10 million pounds, with an estimated global production of TCS in 2011 of approximately 14 million pounds (Fang et al., 2010; United States Food and Drug Administration (HHS), 2015, 2016, 2017; Perencevich et al., 2001). In 2011, United States consumers spent nearly 1 billion dollars annually on products containing TCS (Statista, 2016).

Table 1. Structure, names, and properties of Triclosan.

	5-Cloro-2-(2,4-dichlorophenoxy) phenol	$C_{12}H_7Cl_3O_2$	289.54 g/mol

(Adolfsson-Erici et al., 2002; Bhargava & Leonard, 1996; Perencevich et al., 2001; Witorsch, 2014).

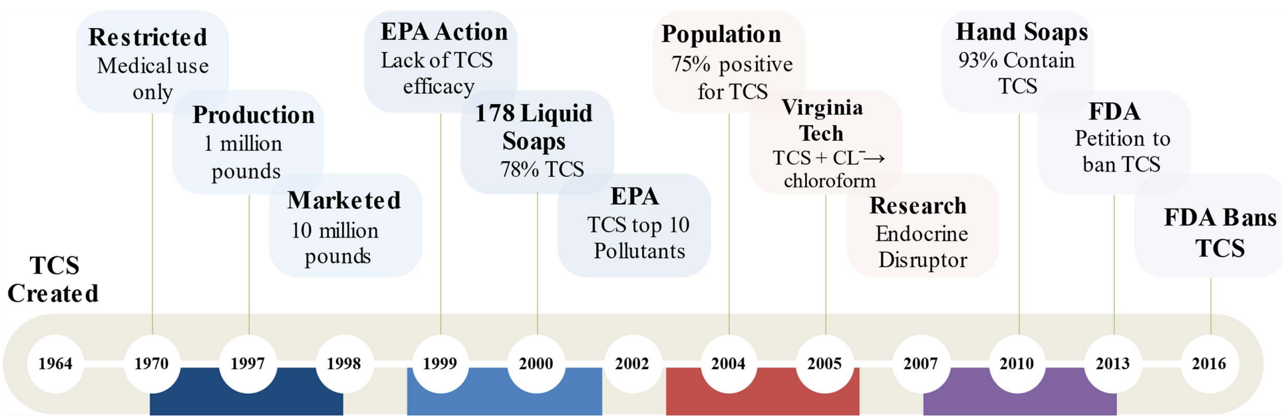


Figure 1. Historical timeline before FDA Bans Triclosan.

By 2000, TCS had been added to thousands of daily used consumer products (Weatherly & Gosse, 2017). Between September 2008 and September 2009, products containing TCS as the active antimicrobial ingredient sold at a rate of 278 million 16 oz units, totaling $886 million in total sales, resulting in annual consumption of 132 million liters (United States Food and Drug Administration (HHS), 2015; Weatherly & Gosse, 2017). By 2010, TCS was found in 93% of liquid, gel, bar, or foam soaps (United States Food and Drug Administration (HHS), 2015, 2016; Weatherly & Gosse, 2017). TCS exposure occurs primarily via consumer products that contain TCS. Measurable levels of TCS are present in the breast milk and blood of nursing mothers (Allmyr et al., 2006) and human urine (Calafat et al., 2008). TCS was detected in 75% of the US population by 2004, with urine concentrations ranging from 7.9 nM - 13.1 μM (Calafat et al., 2008). By 2009, a research study of expecting mothers in New York found TCS in 100% of the 181 samples and TCS in cord blood from the neonate in 51% (Pycke et al., 2014). The widespread use of TCS-containing products has given rise to the contamination of aquatic environments, most notably watersheds (Bhargava & Leonard, 1996; Kolpin et al., 2002; Singer et al., 2002). The EPA regulates TCS as a pesticide acceptable on solid surfaces. In contrast, the FDA regulates TCS as a drug when used in personal care items (Halden et al., 2017).

FDA Ban Regulations

Humans are exposed to a variety of emerging environmental pollutants in everyday life. After some data suggested that long-term exposure to the active ingredient found in many germ-killing compounds, in 2013, the FDA proposed that TCS used in antibacterial products could pose vital health risks, such as antibiotic-resistance genes with a higher incidence of bacterial-related allergies or thyroid hormonal effects (United States Food and Drug Administration (HHS), 2016). Under the proposed rule, manufacturers must document additional data on the safety and effectiveness of certain organochlorine ingredients used in over-the-counter consumer antibacterial washes to continue marketing products containing those organochlorine ingredients. Data from clinical studies must demonstrate that these products are superior to non-antibacterial washes in preventing human illness or reducing infection (Kalelkar et al., 2022). On September 9, 2016, the United States Food and Drug Administration (FDA) started the ban on the incorporation of TCS and other antimicrobial chemicals from household soap products and, the following year, began preventing companies from using TCS in over-the-counter healthcare antiseptic products without pre-market review and approval (United States Food and Drug Administration (HHS), 2016). Since there is not enough data to assess the full impact of emerging contaminants on our ecosystems and human health, it is necessary to continue monitoring their occurrence and effects in the environment and human exposure levels. In addition to the need for more data and continuous monitoring, it would also help evaluate certain regulatory practices' effectiveness. For example, if we see that the levels of an emerging chlorination byproduct are increasing in the environment, even though there are regulations to limit its use, this could indicate that the regulations are ineffective. This information could then be used to improve the regulations or to develop new ones. Continuous monitoring of emerging TTHMs is essential to identify new sources of these byproducts, evaluate the effectiveness of regulations, and understand their impact on the environment and human health. By monitoring the levels of TTHMs over time and comparing them in different areas, we can determine whether the regulations are having the desired effect and make adjustments as needed.

2. Water Contaminants and Regulations

Drinking water quality varies depending on the treatment procedure or condition of the source water. However, it must meet US Environmental Protection Agency (EPA) standards and regulations. The underlying importance of water is understood, albeit violations do occur even with EPA standards in place. Once a violation occurs, it must be reported to the EPA. At the same time, the EPA is responsible for the Consumer Confidence Report (CCR) for informing the consumer of drinking water quality (United States Environmental Protection Agency, 2022a). The levels of contaminants found in drinking water have been studied by scientists at various agencies, such as the non-profit corporation Environmental Work Group (EWG). The EWG specializes in determining the links between tested chemical compounds found in a water source and the environmental consequences, even if the levels of the compound are within legal limits assigned by the EPA (Environmental Working Group, 2022). Previous studies from our lab showed an increase in the urgency to regulate the TTHM levels entering our interconnected watersheds that governmental agencies could use to draft guidelines to keep the population better informed of the drinking water quality in their areas (Karim et al., 2020). Other studies found a correlation between the levels of TTHM, annual household income, and poverty levels (Guha et al., 2019). Our primary exposure to environmental hazards is unsafe or exposure to underregulated drinking water.

The EPA is responsible for writing regulations to enforce water quality legislation, such as the National Primary Drinking Water Regulations, the National Primary Drinking Water Regulations Implementation, and the National Secondary Drinking Water Regulations (Baum et al., 2015). However, the EPA only requires the regulations of public drinking water systems that service at least 15 service connections or more than 25 persons (Levin et al., 2002). The Safe Drinking Water Act of 1974 requires public drinking water systems to monitor the presence of certain contaminants at specific intervals of time and at mandatory locations to ensure compliance, allowing violations to be reported to the Safe Drinking Water Information System Federal Reporting Services (SDWIS/FED), created in 1995 (Weinmeyer et al., 2017). However, a 2002 EPA audit found that only 62% of violations are ever reported, and states are only required to report a violation, not the contamination levels for water supply systems servicing 100,000 or greater. These protocol violations leave citizens with only the knowledge of a possible violation, not the specifics of the violation (United States Environmental Protection Agency, 2016).

Contaminants in Drinking Water from Triclosan Use

TCS is a common ingredient in many personal care products. It can be released into the environment when these products are washed down the drain. Even though TCS is usually present at low concentrations in wastewater, it can build up over time and cause problems for aquatic life and mammals (Mohan & Balakrishnan, 2019). TCS is also a potential human health hazard and can contribute to developing antibiotic resistance. For these reasons, TCS is currently being regulated by several government agencies. Overusing TCS-containing products in a vast array of daily necessities causes environmental migration after it is washed down the drain. However, it was observed that a considerable amount of TCS in wastewater survives treatment of wastewater treatment plants (WWTPs) and is then discharged with tap water (Lindström et al., 2002; Singer et al., 2002; Heidler & Halden, 2007; Chen et al., 2011). Although TCS is usually detected at low concentrations, chronic, low-level exposure for multiple generations causes macro ecosystem problems by interfering with many aquatic species and mammals. Thus, due to potential human toxicity and antibiotic resistance development concerns, TCS is currently the focus of several regulatory efforts (Kemsley, 2014).

According to the EPA, TCS is in the top 10 contaminants of emerging concern for watersheds in the US (Subedi et al., 2014; Vimalkumar et al., 2019; Abbott et al., 2020). Many studies have reported the occurrence of TCS and its intermediates in wastewater effluent, watersheds, and soil (Subedi et al., 2014; Karthikraj & Kannan, 2017). Once organochlorine contaminants enter WWTPs, they can be partially or entirely transformed by exposure to free chlorine during the wastewater treatment processes. These transformed contaminants can then be discharged into the environment through effluent (the treated wastewater released from the WWTP) and biosolids (the solid material removed from the wastewater during treatment and used as fertilizer) for crop application. In water disinfection processes (**Figure 2**), TCS reacts with free chlorine to produce chlorinated byproducts, including chlorinated triclosan and chlorinated phenols, resulting in the formation of enhanced chloroform (Rule et al., 2005; Fiss et al., 2007).

Our report will provide timely yet informative results for initial toxicity screening on drinking water quality and risk identification that can be incorporated into a water resource management strategy. This report will provide valuable information concerning the FDA ban regulations and the impending over-use of TCS-containing products in response to COVID-19, our third installment of the effects of TCS on TTHM levels and drinking water quality in the

US. Exposure to TTHMs can have serious adverse health effects after prolonged exposure to higher levels of contaminants. Table 2 shows common water contaminants found in the drinking water supply and their relative limits, sources, and potential health risks associated with their exposure. The limits and sources for each contaminant are listed in every CCR, and limit violations are reported by SDWIS/FED annually.

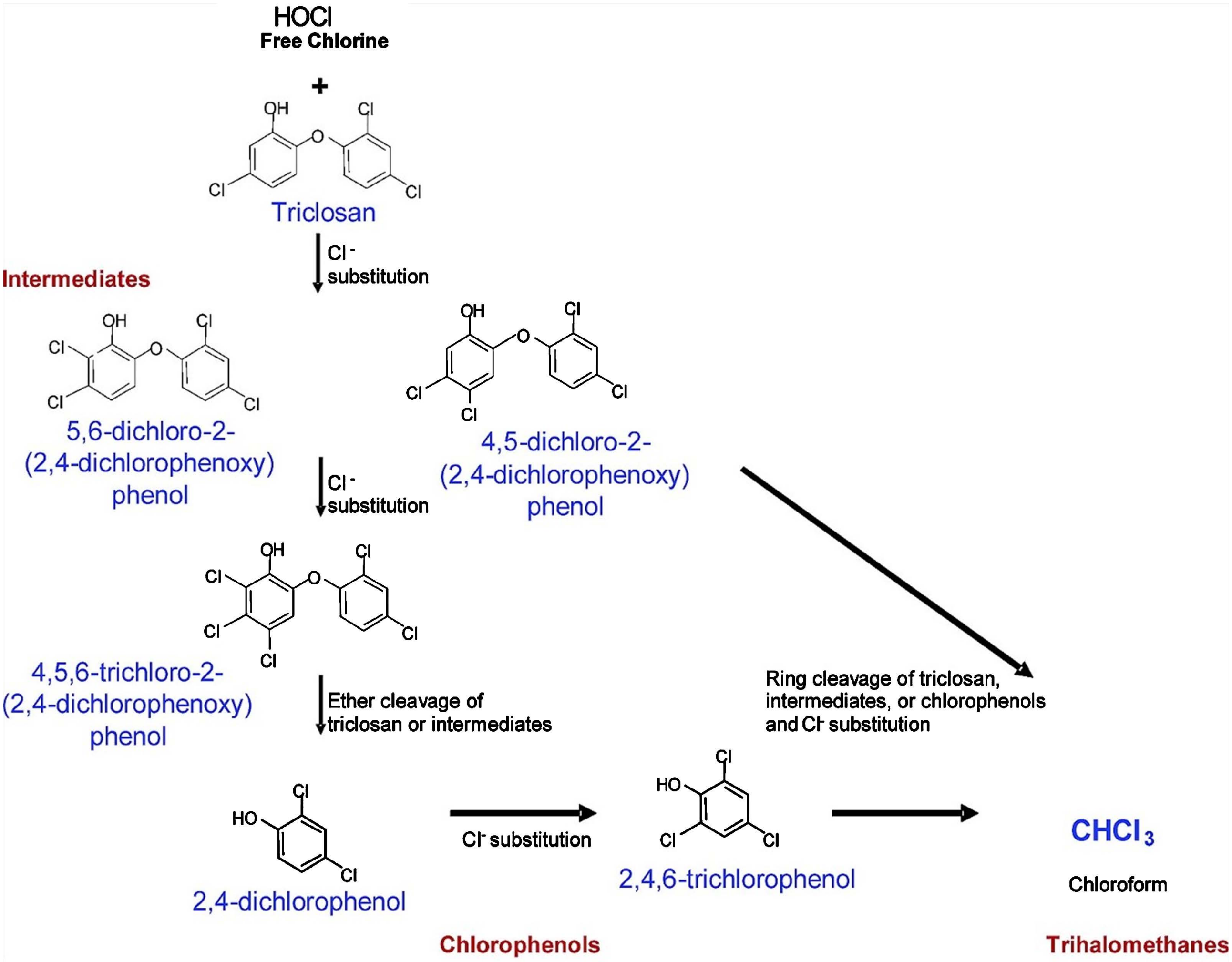


Figure 2. Mechanisms of Chlorinated TCS conversion to its intermediate products: chlorinated TCS derivatives, chloroform, and trihalomethanes (Fiss et al., 2007).

Table 2. Common drinking water contaminants with their relative limits, sources, and potential health effects.

Contaminants	Limits	Sources	Potential Health Effect
Residual Chlorine	4 mg/L	Disinfectant added to control pathogens	Nervous System Damage, Anemia, Methemoglobinemia
Trihalomethane: chloroform bromodichloromethane dibromochloromethane bromoform	80 mg/L	Byproduct of water chlorination	Cancer, Liver Disease, Kidney Failure, Nervous System Damage, Bladder Cancer, Colorectal Cancer, Adverse development, and reproductive effects during pregnancy

(United States Environmental Protection Agency, 2016; Department of Health & Human Services, 2018, 2019, 2020).

3. Materials and Methods

All secondary data related to levels of TTHM concentrations were obtained from the annual water safety reports (SDWIS/FED, MWR, and CCR) for major metropolitan water plants for each state in the US (United States Environmental Protection Agency, 2022b). The water quality data was then prepared for descriptive statistical analysis from secondary data related to drinking water quality divided into four districts or Federal Information Processing Standard (FIPS), identifying districts by regions, states, populations, and annual income in the US (United States Census Bureau, 2020, 2021, 2022; United States Environmental Protection Agency, 2022a). See Districts (**Figure 3**; **Table 3**) for each metropolitan city in the 50 states. Data, including median annual household income and population data, was obtained from the US Census Bureau (United States Census Bureau, 2020, 2021, 2022). Additional information was collected by contacting water service offices to obtain information not readily available in the annual water safety reports.

3.1. Methods

The water quality data was then prepared for descriptive statistical analysis and ANOVA from secondary data related to drinking water quality obtained from the annual water safety reports for the major cities of each state in the US divided into FIP districts (United States Census Bureau, 2020, 2021, 2022; United States Environmental Protection Agency, 2022a). Data, including median annual household income, was obtained from the US Census Bureau (United States Census Bureau, 2020, 2021, 2022).

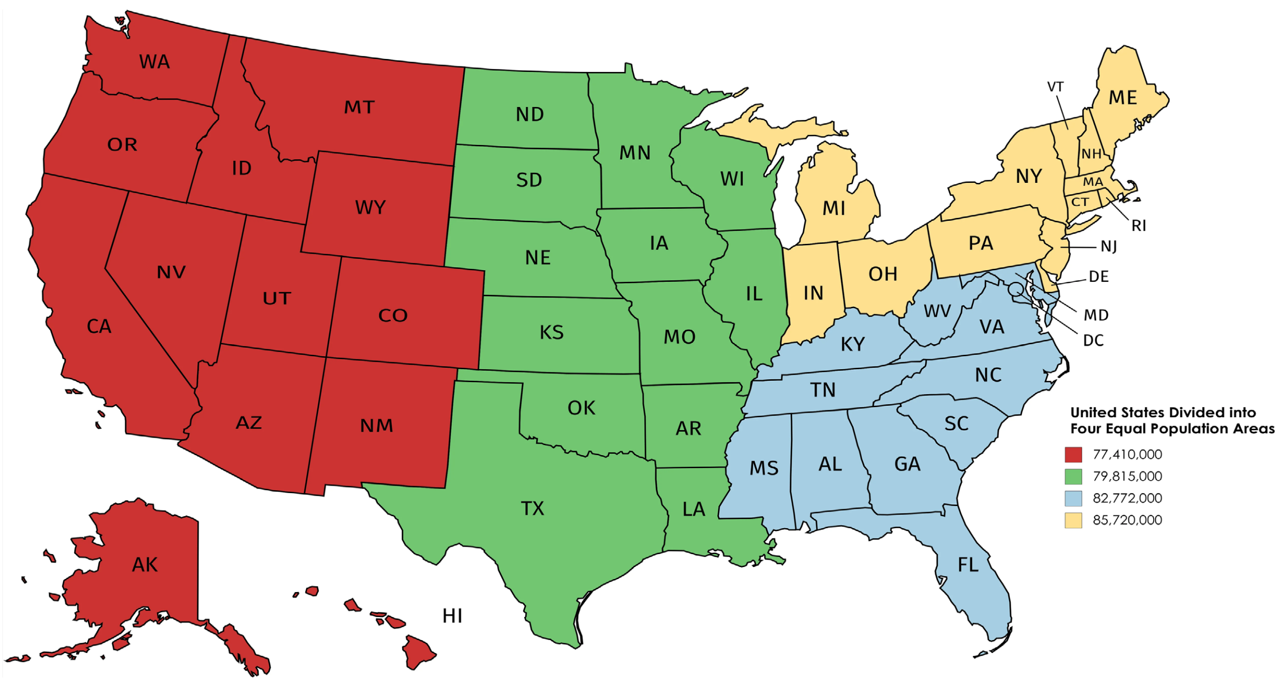


Figure 3. Map showing the census bureau regions and divisions with state FIPS codes of the United States (United States Census Bureau, 2020, 2021, 2022).

Table 3. Census bureau regions and divisions with state FIPS codes regions division for each state in the United States.

WEST	MIDWEST	SOUTH	NORTHEAST
AK—Alaska	IL—Illinois	AL—Alabama	CT—Connecticut
AZ—Arizona	IN—Indiana	AR—Arkansas	DE—Delaware
CA—California	IA—Iowa	FL—Florida	ME—Maine
CO—Colorado	KS—Kansas	GA—Georgia	MD—Maryland
HA—Hawaii	MI—Michigan	KY—Kentucky	MA—Massachusetts
ID—Idaho	MN—Minnesota	LA—Louisiana	NH—New Hampshire
MT—Montana	MO—Missouri	MS—Mississippi	NJ—New Jersey
NV—Nevada	NE—Nebraska	NC—North Carolina	NY—New York
NM—New Mexico	ND—North Dakota	OK—Oklahoma	PA—Pennsylvania
OR—Oregon	OH—Ohio	SC—South Carolina	RI—Rhode Island
UT—Utah	SD—South Dakota	TN—Tennessee	VT—Vermont
WA—Washington	WI—Wisconsin	TX—Texas	
WY—Wyoming		VA—Virginia	
		WV—West Virginia	

Tables were generated to record income per capita for each state (provided by the Census Bureau) along with their drinking water sources (provided by the state and local water services departments) and correlated to the levels of contaminants. The disparities among the average household income in different states and their water quality are shown using multi-variable charts. Table 3 features the states divided into districts (West, Midwest, South, and Northeast) as reported by the US Census and the EPA being analyzed in this study. Additional information for each water system was obtained from the EPA website using the Safe Drinking Water Information System (SDWIS) (United States Environmental Protection Agency, 2022c). The SDWIS provided the primary water source, the number of violations, and the population served for each water system.

The median household income, population data, and % of persons in poverty were retrieved from the US Census Bureau for 2020 (United States Census Bureau, 2020, 2021, 2022) censuses. The data was obtained by accessing the Quick-Facts website for the Census Bureau. Since the release of the 2015 census, Quick-Facts have shown the information from the current censuses. The population information is reported for 2020.

3.2. Statistical Analysis

An analysis of variance, ANOVA, a statistical test that compares the means of two or more data sets, would be used for significance. The results of ANOVA shows a significant difference between the means of the data within the given experimental setup, which means that at least one of the groups had a different mean than the others. In our research, the ANOVA was used to compare the means of the data within the water quality data reported from 2016, right before the FDA ban, with the data from March 2020, after the ban but before the beginning of the COVID-19 pandemic. The Student's t-test was then used to follow up on the findings and to identify which group pairs had significantly different means (Qualtrics, 2023).

A significant ANOVA was followed by a pairwise analysis of control versus exposed data using Student's t-test; a *p*-value of less than 0.05 was considered significant. Student's t-test is a statistical test used to compare the means of two groups (water quality data reported in 2005-2015 compared to the same data reported in 2016, then finally in 2020). A *p*-value for the probability of obtaining the statistical test results if the null hypothesis is true was used. In this research, the null hypothesis is the difference between the means of the groups. A *p*-value of less than 0.05 means that the statistical test results are unlikely to have occurred by chance. Therefore, the results of the statistical analysis are considered to be significant. Applied to our results, a *p*-value of equal to or less than 0.05 means a decrease in the levels of reported TTHM could be statistically significant to the decreased production and consumer use of antibacterial products containing organochlorine contaminant TCS from 2015-2020 after the FDA ban. Our previous research showed a significant correlation between the overuse of TCS-containing products and increased TTHM in drinking water from 2005, the first required archived water quality data for TTHM levels, and 2015, after the height of production of TCS-containing products.

4. Results and Discussion

The US Census Bureau determined that the standard, full suite of 2016–2020 ACS 5-year data is unbiased for public release and statistical analysis for understanding the US population's social, environmental, and economic characteristics. The 2020 input data were integrated with the inputs processed using standard ACS methodology from 2016, 2017, 2018, and 2019 to produce the statistical analysis, according to the 2020 data from the US Census Bureau. The nation's poverty rate decreased from 15.5 percent (2016) to 12.8 percent in 2020, with a population percent increase of 11.4 percent or 37.2 million people, with a median income decrease of 2.9 percent from the 2019 median income of about $69,560. According to the 2020 US Census, the US had a population of 329.5 million, which was a 7.4% increase since the last census in 2010, and an annual income level of $67,521 before taxes, which was an annual growth rate of 3.07 percent (US Census Report), with approximately 6.91 percent under the federal poverty level (FPL) of the US (United States Census Bureau, 2020, 2021, 2022). Nevertheless, ensuring access to safe drinking water poses a considerable challenge for US water systems due to aging infrastructure, impaired source water, and strained community finances. There is a correlation between recent cases of impaired water quality that have impacted lower-income communities across the country.

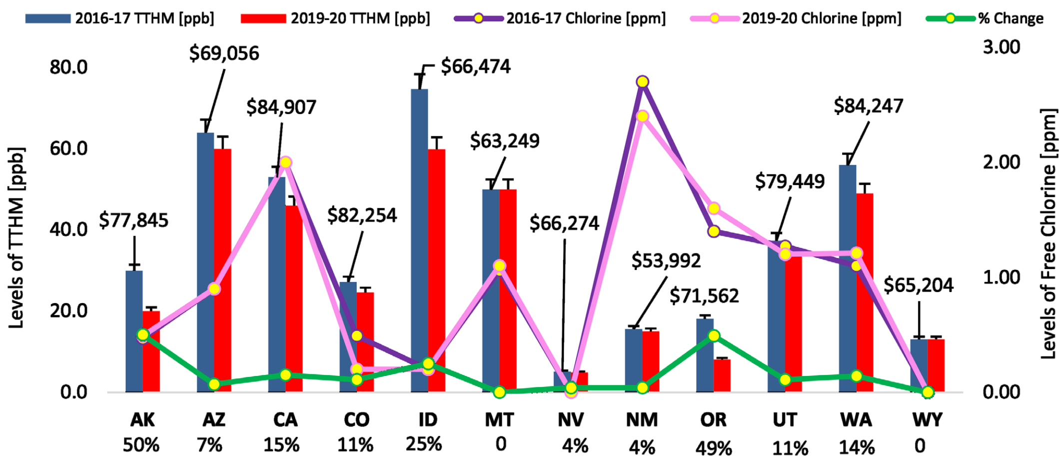
Based on Table 4 and Figure 4, the West District of the US has an average population of 8.9 million with an average annual salary of $72,043, +3.4 million people with a 3.2% average annual growth rate 2010-2020. The mean average levels of TTHM [ppb] (M) were 37.0 ± 6.4 ppb with (SD) 22.3 ppb for 2016-2017 and (M) 32.0 ± 4.7 ppb with (SD) 20.3 ppb for 2020, as shown in Table 5. A student's t test showed statistical significance in the decrease in the levels of TTHMs between 2016 and 2020 with a p value of 1.95E−12 (2-tailed) with an average decrease of 20.8% in the TTHM levels. When comparing the averages (n-91) for 2016-2020, the decrease in TTHM levels was found to be statistically significant p value of 0.004 (2-tailed ANOVA).

Based on Table 6 and Figure 5, the Midwest District of the US has an average population of 5.2 million with an average annual salary of $66,383, −410 thousand people with a 3.0% average annual growth rate 2010-2020. The mean average levels of TTHM [ppb] (M) were 26.7 ± 5.3 ppb with (SD) 18.2 ppb for 2016-2017 and (M) 22.9 ± 4.5 ppb with (SD) 15.5 ppb for 2020, as shown in Table 7. A student's t test showed statistical significance in the decrease in the levels of TTHMs between 2016 and 2020 with a p value of 7.6E−17 (2-tailed) with an average decrease of 13.7% in the TTHM levels. When comparing the averages

Table 4. West district of the United States—US Census data for the average population and annual income. The US EPA—SDWIS/FED Annual Data for the number of Total Violations, TTHM violations, and TTHM Levels reported by each state of the West District of the United States.

State		2020			2019-2020			2016-2017		
		Census Data			Violations	Chlorine	TTHM	Chlorine		TTHM
		Population	Income	Systems	Total	[ppm]	[ppb]	[ppm]	[ppb]	% Change
AK	Alaska	5,696,966	$77,845	6706	137,133	0.49	20.0	0.47	30.0	50%
AZ	Arizona	2,901,707	$69,056	15,611	143,478	0.90	60.0	0.90	64.0	7%
CA	California	20,689,846	$84,907	60,867	71,279	2.00	46.0	2.0	53.0	15%
CO	Colorado	9,665,530	$82,254	15,053	52,823	0.20	24.6	0.49	27.2	11%
HA	Hawaii	4,512,989	$84,857	1241	1325	NR	15.4	NR	NR	NR
ID	Idaho	5,075,813	$66,474	8302	46,320	0.20	59.9	0.20	74.7	25%
MT	Montana	3,141,331	$63,249	12,978	66,233	1.10	50.0	1.06	50.0	0
NV	Nevada	8,765,136	$66,274	6464	14,546	NR	4.9	NR	5.1	4%
NM	New Mexico	3,699,347	$53,992	10,145	40,312	2.40	15.0	2.70	15.6	4%
OR	Oregon	4,010,497	$71,562	14,219	119,569	1.60	8.1	1.40	18.1	123%
UT	Utah	7,188,955	$79,449	10,208	59,000	1.20	33.7	1.27	37.4	11%
WA	Washington	28,223,188	$84,247	13,598	126,893	1.21	49.0	1.10	56.0	14%
WY	Wyoming	7,497,727	$65,204	6186	15,158	NR	13.1	NR	13.1	0

Note. NR means no data recorded (United States Census Bureau, 2020, 2021, 2022; United States Environmental Protection Agency, 2022b, 2022c).



Note. % is the net change in TTHM levels from 2016 to 2020 (United States Census Bureau, 2020, 2021, 2022; United States Environmental Protection Agency, 2022b, 2022c).

Figure 4. West District of the United States—US census data for the average population and annual income. The US EPA—SDWIS/FED annual data for the number of total violations, TTHM violations, and TTHM Levels reported by each state of the west district of the United States.

Table 5. West district of the United States—Statistical descriptive data for the averages reported by the states of the west district.

Statistics	2020			2016			2020		
	Census Data			Violations	Cl^-	TTHM	Cl^-	TTHM	TTHM
	Population	Income	Systems	Total	[ppm]	[ppb]	[ppm]	[ppb]	% Change
Mean (M)	8,879,670	$72,042	15,028	74,395	1.2	37.0	1.1	32.0	20.8%
Standard Error	2.2E+6	2794	4283	13,292	0.2	6.4	0.2	4.7	10.5
Variance	6.0E+13	9.4E+7	2.1E+8	2.1E+9	0.6	22.3	0.7	20.3	12.2
Standard Deviation (SD)	7.8E+6	9679.4	14,837.9	46,048.1	0.8	22.3	0.7	20.2	34.8

Note. Underline indicates a decreased % change in TTHM levels from 2016 to 2020.

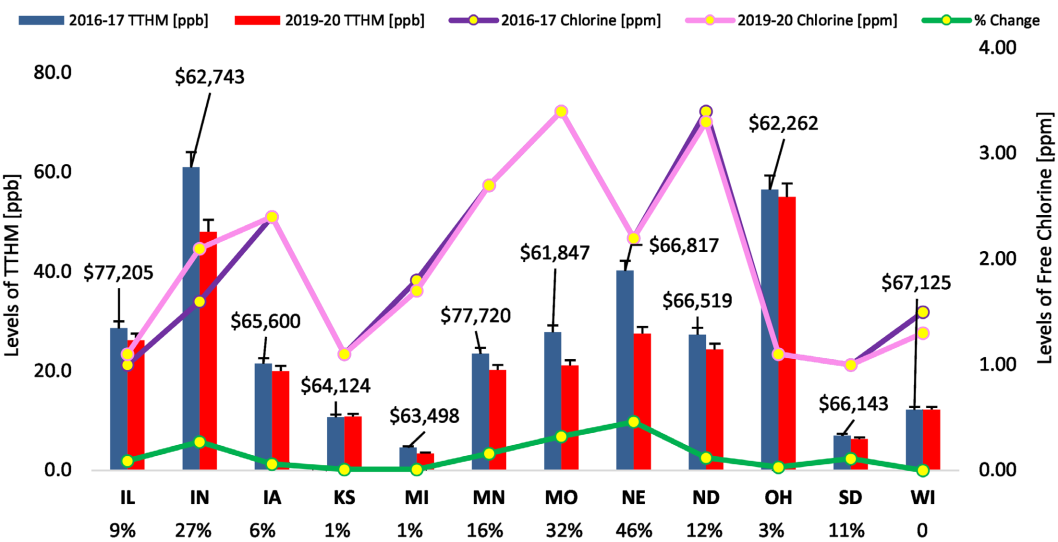
Table 6. Midwest District of the United States—US census data for the average population and annual income. The US EPA—SDWIS/FED annual data for the number of total violations, TTHM Violation, and TTHM Levels reported by each state of the Midwest district of the United States.

State		2020			2019-2020			2016-2017		
		Census Data			Violations	Chlorine	TTHM	Chlorine	TTHM	
		Population	Income	Systems	Total	[ppm]	[ppb]	[ppm]	[ppb]	% Change
IL	Indiana	12,506,244	$72,205	32,614	76,309	1.1	26.2	1.0	28.6	9%
IN	Indiana	5,461,969	$62,743	18,784	82,993	2.1	48.0	1.6	61.0	27%
IA	Iowa	2,951,224	$65,600	18,258	25,659	2.4	20.0	2.4	21.5	6%
KS	Kansas	2,828,391	$64,124	11,349	18,304	1.1	10.8	1.1	10.7	1%
MI	Michigan	8,735,388	$63,498	22,083	73,588	1.7	3.4	1.8	4.6	1%

Continued

MN	Minnesota	5,012,820	$77,720	35,547	10,301	2.7	20.2	2.7	23.5	16%
MO	Missouri	5,589,463	$61,847	21,770	44,439	3.4	21.1	3.4	27.8	32%
NE	Nebraska	1,705,357	$66,817	9677	12,373	2.2	27.5	2.2	40.2	46%
ND	N. Dakota	709,655	$66,519	2943	4,013	3.3	24.3	3.4	27.3	12%
OH	Ohio	10,914,524	$62,262	32,098	84,957	1.1	55.0	1.1	56.5	3%
SD	S. Dakota	814,159	$66,143	4310	23,270	1.0	6.3	1.0	7.0	11%
WI	Wisconsin	5,027,143	$67,125	34,404	82,289	1.3	12.2	1.5	12.2	0%

(United States Census Bureau, 2020, 2021, 2022; United States Environmental Protection Agency, 2022b, 2022c).



Note. % is the net change in TTHM levels from 2016 to 2020 (United States Census Bureau, 2020, 2021, 2022; United States Environmental Protection Agency, 2022b, 2022c).

Figure 5. Midwest district of the United States—US census data for the average population and annual income. The US EPA—SDWIS/FED annual data for the number of total violations, TTHM Violation, and TTHM Levels reported by each state of the Midwest district of the United States.

Table 7. Midwest district of the United States—Statistical descriptive data for the averages reported by the states of the Midwest district.

Statistics	2020			2016-2017			2020		
	Census Data			Violations	Cl^-	TTHM	Cl^-	TTHM	TTHM
	Population	Income	Systems	Total	[ppm]	[ppb]	[ppm]	[ppb]	% Change
Mean (M)	5,188,028	$66,383	20,319	44,875	1.9	26.7	2.0	22.9	13.7%
Standard Error	1.1E+6	1314	3352	9,429	0.3	5.3	0.3	4.5	4.0
Variance	1.5E+13	2.1E+7	1.4E+6	1.1E+9	0.8	303.2	0.8	239.1	2.0
Standard Deviation (SD)	3.8E+6	4553.6	11,614.9	32,662.4	0.9	18.2	0.9	15.5	14.4

Note. Underline indicates a decreased % change in TTHM levels from 2016 to 2020.

(n-95) for 2016-2020, the decrease in TTHM levels was found to be statistically significant *p* value of 0.015 (2-tailed ANOVA).

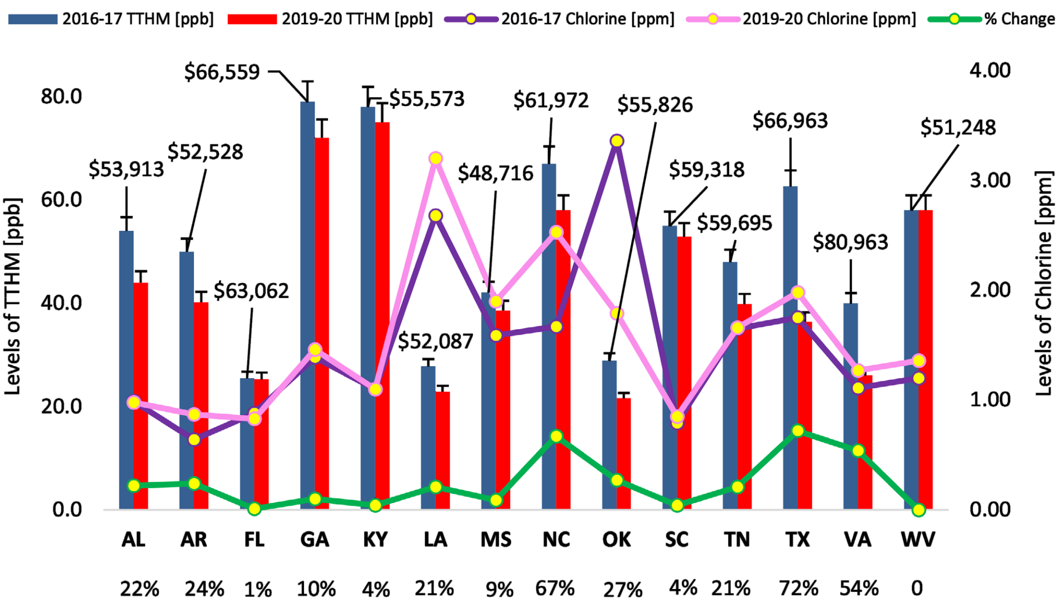
Based on Table 8 and Figure 6, the South District of the US has an average population of 8.0 million with an average annual salary of $59,173, +350 thousand people with a 2.9% average annual growth rate 2010-2020. The mean average levels of TTHM [ppb] (M) were 51.1 ± 4.6 ppb with (SD) 17.2 ppb for 2016-2017 and (M) 43.6 ± 4.7 ppb with (SD) 17.4 ppb for 2020, as shown in Table 9. A student's t test showed statistical significance in the decrease in the levels of TTHMs between 2016 and 2020 with a *p* value of 3.1E−14 (2-tailed) with an average decrease of 24.0% in the TTHM levels. When comparing the averages (n-111) for 2016-2020, the decrease in TTHM levels was found to be statistically significant *p* value of 0.001 (2-tailed ANOVA).

Based on Table 10 and Figure 6, the Northeast District of the US has an average population of 6.1 million with an average annual salary of $57,134, +500 thousand people with a 3.0% average annual growth rate 2010-2020. The mean average levels of TTHM [ppb] (M) were 47.1 ± 4.6 ppb with (SD) 15.2 ppb for 2016-2017 and (M) 43.6 ± 4.5 ppb with (SD) 15.4 ppb for 2020, as shown in Table 11. A

Table 8. South district of the United States—US census data for the average population and annual income. The US EPA—SDWIS/FED annual data for the number of total violations, TTHM Violation, and TTHM Levels reported by each state of the South District of the United States.

State		2020			2019-2020			2016-2017		
		Census Data			Violations	Chlorine	TTHM	Chlorine	TTHM	
		Population	Income	Systems	Total	[ppm]	[ppb]	[ppm]	[ppb]	% Change
AL	Alabama	5,696,966	$53,913	7557	8,757	0.98	44.0	0.99	54.0	22%
AR	Arkansas	2,901,707	$52,528	4793	14,255	0.87	40.2	0.64	50.0	24%
FL	Florida	20,689,846	$63,062	18,346	52,157	0.83	25.3	0.88	25.5	1%
GA	Georgia	9,665,530	$66,559	14,258	34,913	1.46	72.0	1.39	79.0	10%
KY	Kentucky	4,512,989	$55,573	2730	17,895	1.10	75.0	1.10	78.0	4%
LA	Louisiana	5,075,813	$52,087	12,562	19,841	3.20	22.9	2.68	27.8	21%
MS	Mississippi	3,141,331	$48,716	10,304	133,139	1.90	38.6	1.59	42.1	9%
NC	N. Carolina	8,765,136	$61,972	29,476	146,744	2.53	58.0	1.67	67.0	67%
OK	Oklahoma	3,699,347	$55,826	10,825	54,382	1.79	21.6	3.36	28.9	27%
SC	S. Carolina	4,010,497	$59,318	6067	11,299	0.85	52.9	0.79	55.0	4%
TN	Tennessee	7,188,955	$59,695	7291	11,895	1.66	39.8	1.65	48.0	21%
TX	Texas	28,223,188	$66,963	112,250	149,969	1.98	36.4	1.75	62.6	72%
VA	Virginia	7,497,727	$80,963	21,973	36,034	1.27	26.0	1.11	40.0	54%
WV	W. Virginia	1,576,588	$51,248	6366	51,205	1.36	58.0	1.20	58.0	0%

(United States Census Bureau, 2020, 2021, 2022; United States Environmental Protection Agency, 2022b, 2022c).



Note. % is the net change in TTHM levels from 2016 to 2020 (United States Census Bureau, 2020, 2021, 2022; United States Environmental Protection Agency, 2022b, 2022c).

Figure 6. South district of the United States—US census data for the average population and annual income. The US EPA—SDWIS/FED Annual Data for the number of Total Violations, TTHM Violations, and TTHM Levels reported by each state of the South District of the United States.

Table 9. South district of the United States—Statistical descriptive data for the averages reported by the states of the south district.

Statistics	2020			2016			2020		
	Census Data			Violations	Cl^-	TTHM	Cl^-	TTHM	TTHM
	Population	Income	Systems	Total	[ppm]	[ppb]	[ppm]	[ppb]	% Change
Mean (M)	8,046,116	$59,173	18,914	53,034	1.5	51.1	1.6	43.6	24.0%
Standard Error	2.0E+6	2260	7443	13,758	0.2	4.6	0.2	4.7	5.9
Variance	5.6E+13	7.2E+7	7.8E+8	2.7E+9	0.6	297.3	0.5	304.1	5.3
Standard Deviation (SD)	7.5E+6	8465.5	27,848.9	51,480	0.7	17.2	0.7	17.4	2.3

Note. Underline indicates a decreased % change in TTHM levels from 2016 to 2020.

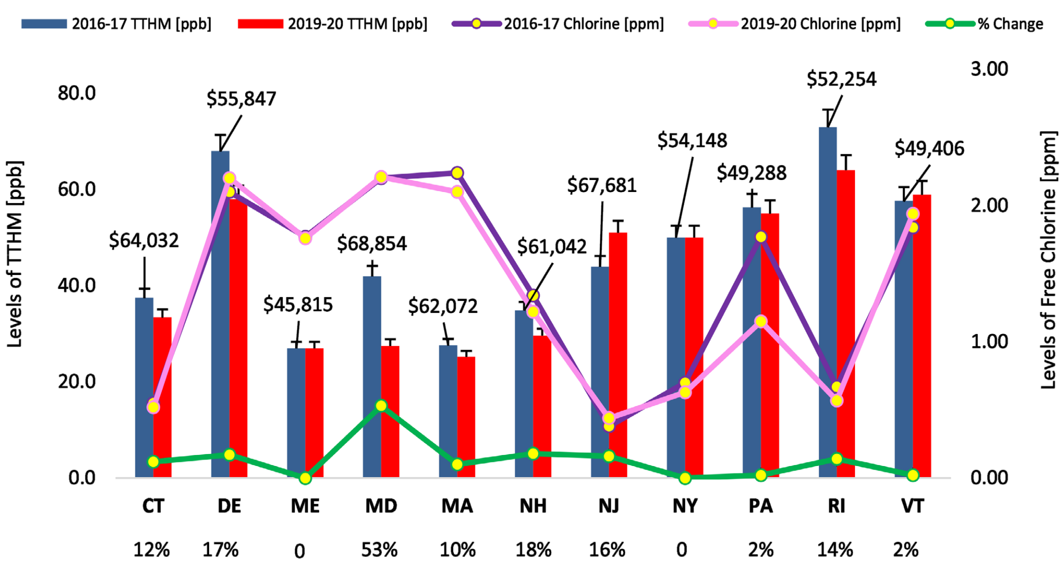
student's t test showed statistical significance in the decrease in the levels of TTHMs between 2016 and 2020 with a *p* value of 2.8E−08 (2-tailed) with an average decrease of 13.1% in the TTHM levels. When comparing the averages (n-87) for 2016-2020, the decrease in TTHM levels was found to be statistically significant *p* value of 0.042 (2-tailed ANOVA).

After compiling the secondary data, population size, annual income, and water quality for all 50 states in four districts of the US (Tables 4-11 and Figures 4-7). The average mean (M) household income was $63,673 ± 1378, standard deviation (SD) of 9647, which was a statistically significant *df* of 428, and *p* value of 83E−62 (2-tailed ANOVA). The average levels of TTHM [ppb] (M) 40.8 ± 2.9

Table 10. Northeast district of the United States—US census data for the average population and annual income. The US EPA—SDWIS/FED annual data for the number of total violations, TTHM violations, and TTHM Levels reported by each state of the northeast district of the United States.

State		2020			2019-2020			2016-2017		
		Census Data			Violations	Chlorine	TTHM	Chlorine	TTHM	
		Population	Income	Systems	Total	[ppm]	[ppb]	[ppm]	[ppb]	% Change
CT	Connecticut	2,880,001	$64,032	14,516	57,345	0.52	33.4	0.55	37.5	12%
DE	Delaware	974,687	$55,847	3471	3140	2.20	58.0	2.10	68.0	17%
ME	Maine	929,625	$45,815	11,721	33,484	1.76	27.0	1.77	27.0	0
MD	Maryland	5,915,557	$68,854	17,806	19,480	2.21	27.5	2.20	42.0	53%
MA	Massachusetts	9,802,316	$62,072	13,329	43,124	2.10	25.2	2.24	27.6	10%
NH	New Hampshire	1,201,963	$61,042	6476	39,843	1.22	29.6	1.34	34.9	18%
NJ	New Jersey	9,614,776	$67,681	17,734	81,449	0.44	51.0	0.38	44.0	16%
NY	New York	21,306,094	$54,148	53,656	145,200	0.63	50.0	0.70	50.0	0
PA	Pennsylvania	12,695,604	$49,288	38,483	337,248	1.15	55.0	1.77	56.3	2%
RI	Rhode Island	1,128,572	$52,254	3000	4248	0.57	64.0	0.67	73.0	14%
VT	Vermont	613,979	$49,406	8287	31,709	1.94	58.9	1.84	57.6	2%

(United States Census Bureau, 2020, 2021, 2022; United States Environmental Protection Agency, 2022b, 2022c).



Note. % is the net change in TTHM levels from 2016 to 2020 (United States Census Bureau, 2020, 2021, 2022; United States Environmental Protection Agency, 2022b, 2022c).

Figure 7. Northeast district of the United States—US Census Data for the average Population and Annual Income. The US EPA—SDWIS/FED annual data for the number of total violations, TTHM violations, and TTHM Levels reported by each state of the northeast district of the United States.

Table 11. Northeast district of the United States—Statistical descriptive data for the averages reported by the states of the northeast district.

Statistics	2020			2016			2020		
	Census Data			Violations	Cl^-	TTHM	Cl^-	TTHM	TTHM
	Population	Income	Systems	Total	[ppm]	[ppb]	[ppm]	[ppb]	% Change
Mean (M)	6,096,652	$57,313	17,134	72,388	1.4	47.1	1.3	43.6	13.1%
Standard Error	2.0E+6	2372	4689	29,089	0.2	4.6	0.2	4.5	4.1
Variance	4.4E+13	6.2E+7	2.4E+8	9.3E+9	0.5	237.2	0.5	225.1	2.0
Standard Deviation (SD)	6.6E+6	7869.4	15,554.4	96,479.2	0.7	15.2	0.7	15.4	1.4

Note. Underline indicates a decreased % change in TTHM levels from 2016 to 2020.

Table 12. United States—Statistical descriptive data for the averages reported for the West, Midwest, South, and Northeast districts.

Statistics	2020			2016			2020		
	Census Data			Violations	Cl^-	TTHM	Cl^-	TTHM	TTHM
	Population	Income	Systems	Total	[ppm]	[ppb]	[ppm]	[ppb]	% Change
Mean (M)	7,112,677	$63,673	17,907	60,612	1.5	40.8	1.5	35.7	18.5%
Standard Error	9.4E+6	1378	2656	8056	0.1	2.9	0.1	2.7	3.3
Variance	4.4E+13	9.3E+7	3.5E+8	3.6E+9	0.6	413.2	0.6	355.2	5.5
Standard Deviation (SD)	6.6E+6	9646.8	18,595.1	59,542.8	3.8	20.2	0.8	3.8	23.4

Note. Underline indicates a decreased % change in TTHM levels from 2016 to 2020.

Table 13. United States—Statistical descriptive data for the averages reported for the West, Midwest, South, and Northeast districts in 2005 to 2015 from archived date, 2017 the FDA Ban, and 2020 pre-COVID-19.

District	2004-2005	2014-2015	2016-2017	2019-2020
West	25.31	62.53	37.02	32.03
Midwest	30.51	58.93	26.74	22.92
South	36.14	67.67	51.14	43.62
Northeast	30.63	67.64	47.08	43.60
df	47	47	55	43
F critical	2.82	2.82	2.78	2.84
p value	1.10E−05	9.15E−05	2.77E−06	2.28E−05

with (SD) 20.2 for 2016 and (M) 35.7 ± 2.7 ppb (SD) 3.8 ppb for 2020, as shown in Table 12. A student's t test showed statistical significance in the increase in the levels of TTHMs between 2016 and 2020 with a p value of 1.1E−07 (2-tailed). When comparing the averages (n-436) for 2016-2020, the increase in TTHM levels was found to be statistically significant *p* value 8.3E−62, with an overall average % decrease in the levels of TTHM was 18.5 percent from 2016-2020 (2-tailed ANOVA).

The EPA first archived data records were collected in 2005; the average levels of TTHM [ppb] (M) 30.9 ± 1.9 with (SD) 12.9, for height of TCS-product manufacturing in 2015 (M) 64.3 ± 2.3 ppb (SD) 16.2 ppb a 108.1% increase that is statistically significant with a *p* value of 3.0E-19 in TTHMs; for 2016 the start of the FDA ban (M) 40.8 ± 2.9 ppb (SD) 20.3 ppb a 57.6% decrease with a *p* value of 0.005; and lastly for 2020 pre-COVID-19 (M) 35.7 ± 2.7 ppb (SD) 18.8 ppb a 14.2% decrease with a *p* value of 2.3E−12, as shown in **Table 13**. When comparing the averages (n-94) for 2016-2020, the increase in TTHM levels was found to be statistically significant with a *p* value of 2.0E−18, with an overall average % increase in the levels of TTHM of 15.5% from the first required EPA archived data of 2005 (2-tailed ANOVA).

5. Conclusion

Recently, the FDA banned TCS, but only from specific soap and hand sanitizing products; we want to look at the level of TTHM in drinking water after the ban went into effect in 2016. Antimicrobial TCS remains in many consumer products, including popular toothpaste and mouth rinses. Consumers are exposed to these organochlorine-containing products, as evidenced by numerous studies showing detectable levels of TCS in skin, urine, and blood plasma ranging from 5.0 to 0.05 µM concentrations (Wilburn et al., 2021). There remains controversy regarding whether TCS concentrations absorbed into the human body might induce adverse effects noted in lab studies. Considering these significant findings, incorporating this antimicrobial containment into readily available consumer products, not just in soap, needs to be re-evaluated, and the biological effects of its breakdown products and metabolites need to be investigated, especially in aquatic environments.

Scientific evidence has demonstrated various adverse health impacts of TCS exposure, exacerbation of allergic response, endocrine disruption, and amplifying the activities of natural hormones, which can cause adverse reproductive and developmental effects and allergies (Sinicropi et al., 2022). In addition, there is substantial evidence that the broad use of these compounds promotes the emergence of bacteria resistant to antibiotic medications and antimicrobial cleansers necessary in health care, thus contributing to the severe issue of antibiotic resistance in strain-resistant bacteria (Carey & McNamara, 2015). Since 95% of the TCS from consumer products goes down residential drains and into the soil, groundwater, and waterways, there is great concern about the environmental effects (Amigun Taiwo et al., 2022). Recent environmental studies show that TCS is one of the most frequently detected compounds at the highest concentrations in waterways. The risks associated with using TCS include but are not limited to water contamination, fragile aquatic ecosystems, algae toxicity, bioaccumulation in the fatty tissues of fish, and potential interference with thyroid hormone production and other endocrine functions (Dann & Hontela, 2011). Water treatment plants do not entirely remove TCS from treated water; thus, it becomes an unregulated contaminant of treatment plants (Mohan & Balakrishnan, 2019).

Our research showed that all states had little to no increase in the levels of TTHM after the FDA ban took effect and that most states had slight decreases in major metropolitan water plants and water sources. Most states had statistically significant variability for averages of slight decreases in TTHM levels from 2016-2020. All the states showed a statistically significant decrease overall after the ban compared to the increases seen in data we compiled for 2005-2015 before the FDA issued the ban. The most significant increase in TTHM levels seen before the ban in the West District was in Idaho (2015), 75.0 ppb +239.0% compared to (2020) 59.9 ppb 25.2% decrease, and the lowest increase was in Montana (2015), 71.0 ppb +78.0% compared to (2020) 50.0 ppb 56.0% decrease. The Midwest state with the most significant increase in TTHM was Kansas (2015), 36.0 ppb +87.0% compared to 10.8 ppb 233.0% decrease, with all other states having the lowest overall increases or staying the same. The South District's most significant increase was seen in Florida (2015), 71.0 ppb +294.0% compared to the decrease to 25.3 ppb in 2020. Lastly, the Northeast District had the most substantial increases in 2015, with the most significant increase in the seventh smallest state, Massachusetts, 77.0 ppb +450.0%, decreased to 25.2 ppb, a 205.6% decrease. Our review assesses the positive impact on water quality caused by the 2016-2017 FDA partial ban on products containing the active antiviral, antifungal, antibacterial, or antimicrobial ingredient organochlorine, TCS. Our results showed an overall average decrease of 18.5% in TTHM levels in drinking water supplies.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Abbreviations and Acronyms

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
SDWIS/FED	Safe Drinking Water Information System/Federal Reporting Services
CCR	Consumer Compliance Report
CDC	Centers for Disease Control and Prevention
MWR	Major Water Report
EWG	Environmental Work Group
WWTP	Wastewater Treatment Plant
DBP	Disinfectant Byproduct
TCS	Triclosan
TTHM	Total Trihalomethanes