Health Consultation

FINAL RELEASE

Saint-Gobain Performance Plastics – McCaffrey Street: Village of Hoosick Falls Public Water System

Village of Hoosick Falls, Town of Hoosick Rensselaer County, New York

USEPA Facility ID: NYD004986741

Prepared by the New York State Department of Health Center for Environmental Health

June 20, 2024

Prepared under a Cooperative Agreement with the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Agency for Toxic Substances and Disease Registry Office of Capacity Development and Prevention Services Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

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In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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Summary

Introduction

The New York State Department of Health (NYSDOH) wants to provide the community affected by the Saint-Gobain Performance Plastics – McCaffrey Street Site (Saint-Gobain site) in the Village of Hoosick Falls, New York, with the best information available about how past drinking water exposure to site-related contaminants could affect their health.

This health consultation evaluates the public health implications of past exposure to contaminated drinking water in the Village of Hoosick Falls public water system using sampling data collected by the Village of Hoosick Falls from November 2014 to February 2015, and by the NYSDOH from June 2015 to February 2016. These data, together with information on the industrial history of the Saint-Gobain site and drinking water contaminant toxicity, inform the conclusions and recommendations made in this health consultation. The NYSDOH prepared this health consultation under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR).

The Village of Hoosick Falls is located in a rural area of northeastern New York within the Town of Hoosick, Rensselaer County. The Town of Hoosick has a total population of about 6,700 people. The Village has a population of about 3,500 people. The Saint-Gobain Performance Plastics Corporation facility is located on McCaffrey Street in the Village of Hoosick Falls.

In late 2014, a local resident sampled the Village public water system. This led to the discovery that the public drinking water supply was contaminated primarily with perfluorooctanoic acid (PFOA). In response to this discovery, the NYSDOH conducted additional testing of the public water system. The NYSDOH recommended that actions be taken to identify the sources of contamination and to reduce the levels of PFOA in the drinking water so that these exposures could be reduced, and future exposures prevented. When the contamination was discovered (late 2014), there were no federal or state public drinking water standards for PFOA or the related chemical, perfluorooctane sulfonate (PFOS). To address PFOA and PFOS contamination in New York, the NYSDOH initiated rulemaking to establish public drinking water standards (maximum contaminant levels [MCLs]) of 10 nanograms per liter (ng/L), or parts per trillion, for each chemical [NYSDOH 2019a, 2020a, 2020b, 2020c]. The standards were adopted in August of 2020.

The New York State Department of Environmental Conservation (NYSDEC) determined that local light industrial manufacturing facilities, including the Saint-Gobain facility, had used PFOA and were the sources of the contamination [NYSDEC 2016a, 2016b]. As a result of the contamination, people using the Village of Hoosick Falls water supply were exposed to PFOA through drinking water. After a granular activated carbon (GAC) filtration system was installed

in 2016, water delivered to the Village of Hoosick Falls consistently tested as non-detect (less than 2 nanograms per liter [ng/L], or parts per trillion) for PFOA.

In January 2016, the NYSDEC, in consultation with the NYSDOH, added the Saint-Gobain site (site ID 442046) to the Registry of Inactive Hazardous Waste Disposal Sites in New York State, also known as State Superfund list [NYSDEC 2016b]. The NYSDEC also referred the Saint-Gobain site to the United States Environmental Protection Agency (USEPA) for inclusion on the National Priorities List (NPL, also known as the federal Superfund list). The USEPA proposed adding the Saint-Gobain site to the NPL on September 7, 2016, and formally added the site to the List on July 31, 2017 [USEPA 2017]. In June 2016, the NYSDEC entered into a legal agreement with Saint-Gobain Performance Plastics Corporation and Honeywell International Inc. The agreement allowed NYSDEC to initiate a study to determine the nature and extent of the contamination at the Saint-Gobain site [NYSDEC 2016b].

While there may be other ways to be exposed to site contaminants, this health consultation evaluates the health risks from past exposure to PFOA in the Hoosick Falls public drinking water system. Regarding drinking water exposures, the NYSDOH reached the following two conclusions about the Saint-Gobain NPL site:

Conclusion 1

Currently, drinking, and other uses of water from the Village of Hoosick Falls public water supply are not expected to harm people's health.

Basis for Conclusion 1

Although the existing public water supply wells have site-related contaminants in the raw water, granular activated carbon (GAC) filtration has been removing contamination before the water is distributed to the public. The GAC filtration has been operating since March 2016. The public water supply is monitored on a regular basis to verify that the treatment system continues to effectively and consistently remove PFOA and other site-related contaminants to non-detect levels in the finished (treated) water before distribution.

Conclusion 2

Past exposure to PFOA in the Village of Hoosick Falls public water supply posed an increased risk for health effects, particularly noncancer health effects in infants and young children.

Basis for Conclusion 2

NYSDOH estimated past PFOA exposures from drinking water in the Village of Hoosick Falls. These past exposures exceeded the ATSDR's intermediate minimal risk level¹ for PFOA.

NYSDOH compared high end estimates of PFOA exposures from drinking public water to an estimate of PFOA exposure that could cause health effects (an estimated human effect level)². The high end PFOA exposure concentration was 983 ng/L. The comparison showed that the highest PFOA drinking water exposures were below the estimated human effect levels. However, the margin of exposure, or the measure of how many times lower the estimated environmental exposure is compared to the exposures that may cause health effects, is only 6 to 24-fold. Small margins of exposure are a health concern. The margins of exposure are smallest for infants and young children, suggesting their risks for health effects could be greater than those for older children and adults within the population. The margins of exposure are based on developmental, liver, and immune toxicity. These are among the most consistently observed and sensitive PFOA health effects in studies of laboratory animals.³

In the past, three other per- and polyfluoroalkyl substances (PFAS) were detected in drinking water: perfluorobutane sulfonate (PFBS), perfluoroheptanoic acid (PFHpA), and perfluorooctane sulfonate (PFOS). These three PFAS were detected in drinking water at much lower levels than PFOA. This means that overall, their contribution to PFAS exposures in drinking water would have been very small.

People can also be exposed to PFAS (including PFOA) through eating food that is packaged in material containing PFAS. People can also be exposed through consumer products such as stain resistant carpeting and water repellent clothing. These types of non-drinking water exposures would have contributed very little to past PFAS exposures for residents of the Village of Hoosick Falls who consumed the drinking water.

The USEPA classifies PFOA as having "suggestive evidence of carcinogenic potential" but has recently proposed to its Science Advisory Board upgrading the classification to "likely to be carcinogenic to humans [USEPA 2022a]." The International Agency for Research on Cancer (IARC) has also evaluated the carcinogenicity of PFOA and has classified PFOA as carcinogenic to humans [IARC 2023]. Elevated PFOA serum levels are associated with an increased risk for cancer in humans. Exposure to high levels of PFOA causes cancer in laboratory animals over their lifetimes. There is currently no clear agreement among health agencies on preferred methods to evaluate the risk for cancer posed to humans who are exposed to environmental

¹ The ATSDR intermediate minimal risk level for PFOA [ATSDR 2021a] is an exposure level at which health effects are unlikely and is derived for intermediate exposure (greater than 14 days to less than one year). ATSDR considers the intermediate MRL to be protective for chronic exposures. Thus, the ATSDR intermediate minimal risk level is anticipated to be protective against effects from exposures lasting up to a lifetime.

² The ATSDR estimated a human effect level (0.82 micrograms per kilogram per day [mcg/kg/day]) for PFOA as part of the derivation of its intermediate minimal risk level [ATSDR 2021a], and this value represents the human exposure that corresponds to the exposure in mice at which health effects were reported.

³ The margin of exposure calculations also includes an estimation of the human dose corresponding to the PFOA serum level in animals at which the health effects occur, which considers the significant differences between animals and humans regarding the amount of time it takes to eliminate PFOA from the body.

levels of PFOA. Therefore, the cancer risk for exposure to PFOA in the Village of Hoosick Falls water supply is considered to be indeterminant and is not assessed in this health consultation.

Next Steps

Recommendations

The NYSDOH recommends that the Village of Hoosick Falls continues to operate, monitor, and maintain the current treatment system for the public water system to ensure that PFOA and other site-related contaminants are effectively and consistently removed from the water before distribution.

The NYSDOH recommends that the NYSDEC and the USEPA, in partnership with the NYSDOH, continue to conduct a full characterization of the Saint-Gobain site and identify measures to reduce site-related contaminants in groundwater in the Village of Hoosick Falls.

The NYSDOH recommends that the NYSDEC and the USEPA, in partnership with the NYSDOH, continue to evaluate other potential exposure pathways (including exposure to site contaminants through soil, air, private drinking water wells, and soil vapor intrusion) associated with the Saint-Gobain site. Actions should be implemented to reduce the potential for exposure if other completed pathways that contribute to exposure are identified.

The NYSDOH recommends that health information related to PFOA in drinking water continues to be developed and provided to affected residents, community members, and health professionals in the area. People can further reduce their exposure by avoiding use of PFAS-containing products as identified by ATSDR [ATSDR 2020].

Regarding breastfeeding, ATSDR and the American Academy of Pediatrics generally recommend breastfeeding, despite the presence of chemicals in breast milk. Given what is currently known about PFAS exposures and risk, the benefits of breastfeeding are believed to outweigh the risks. The decision to breastfeed is an individual choice, often made after considering many different factors and in consultation with healthcare providers. Information developed by ATSDR to guide doctors [ATSDR 2024] can help with this decision-making process.

The NYSDOH recommends that the NYSDEC, in partnership with the NYSDOH, continue to participate in the Hoosick Area Community Participation Work Group (CPWG) that was established by DEC and DOH in 2018. The CPWG is designed to serve as a community liaison with government agencies. The CPWG makes recommendations and provides relevant community input regarding community concerns and perceptions as the remedial projects are being performed. The group meets on a monthly basis to review and discuss the progress of remediation activities and water supply options, and to provide the opportunity for the community's questions and concerns to be addressed before decisions are made. DOH has given presentations to the group on various topics, including the Multi-Site Study PFAS Health Study plans and status, and has facilitated presentations by the Multi-Site Study co-principal

investigator from the University at Albany School of Public Health on the PFOA and health effects literature.

Public Health Action Plan

The NYSDOH will continue to work with the Rensselaer County Department of Health (RCDOH), NYSDEC, and the Village of Hoosick Falls to verify that the treatment system installed on the public water supply continues to effectively and consistently remove PFOA and other site-related contaminants from the water before distribution.

The NYSDOH will work with the RCDOH, NYSDEC, USEPA, and the Village of Hoosick Falls to oversee the development of an alternate drinking water source with granular activated carbon treatment and recommend modifications as appropriate.

The NYSDOH will continue to work with the NYSDEC and USEPA to evaluate the contributions of ongoing sources of contamination to the groundwater, soil. Actions will be taken to control or eliminate contributing sources that may result in exposure through ingestion, inhalation, or direct contact.

The NYSDOH will continue to work with the NYSDEC and USEPA to review investigation data, as they become available, evaluate the public health implications of the sampling results, and recommend public health actions as needed.

In September 2019, ATSDR established cooperative agreements with seven partners to conduct a national Multi-Site PFAS Health Study. Since then, the seven partners have worked with ATSDR to study the human health effects of exposures to PFAS through drinking water. The study includes two communities in New York State: Hoosick Falls and the City of Newburgh. The NYSDOH and the University at Albany School of Public Health are jointly leading the New York State portion of the PFAS study. A community advisory panel has been established to provide input and assist with carrying out a successful project. Recruitment for study participants was completed in March 2023.

Beginning in early 2024, NYSDOH offered a third round of free, voluntary PFAS blood testing to residents and individuals in the Hoosick Falls/Petersburgh area to assure residents that levels of PFAS in their blood are declining following mitigation activities. People who did not participate previously and people who did not have the opportunity to participate in the Multisite PFAS Health Study were also eligible to sign up. NYSDOH APPLETREE staff will continue to coordinate with staff from the NYSDOH biomonitoring program leading this testing effort to ensure consistency in messaging, information, any recommendations for public health actions shared with the community.

The NYSDOH will continue to work with University at Albany epidemiologists to provide more comprehensive information about breastfeeding and PFAS for this community. Information developed by ATSDR to guide doctors [ATSDR 2024] can aid in the decision-making process.

The NYSDOH will also continue to work with ATSDR to seek additional information about ongoing sources of PFAS exposures. NYSDOH will share such information with the community so people can further reduce their exposure to per- and polyfluoroalkyl substances (PFAS). For example, by avoiding using products that may contain them [ATSDR 2020].

The NYSDOH will continue to provide support to community members as needed. This will be done through public events, ongoing interactions with community groups such as the Hoosick Area Community Participation Work Group (CPWG), and one-on-one discussions about this health consultation or other health concerns that may arise.

This report will be placed in the local repository, available online at <u>https://www.health.ny.gov/environmental/investigations/saint_gobain</u>, and provided to people who request it.

Nationally, ATSDR and the Centers for Disease Control and Prevention (CDC) are working to address the concerns of community members regarding potential associations between PFAS exposure and health effects. ATSDR and CDC are also providing technical assistance to tribal, state, and territorial health departments so they can effectively evaluate and reduce PFAS exposure in contaminated communities. For more information on these efforts, please see https://www.atsdr.cdc.gov/pfas/activities/index.html.

For More Information

If you have questions about this health consultation or other health concerns about the Village of Hoosick Falls public water system or the Saint-Gobain Performance Plastics Site, please contact the NYSDOH at 518-402-7860 or email <u>BEEI@health.ny.gov</u>.

If you have questions about the environmental investigation of the Saint-Gobain Performance Plastics Site, please contact the NYSDEC, Division of Environmental Remediation at 518-402-9676.

Purpose and Introduction

The purpose of this health consultation is to evaluate human exposure pathways and the health risks from contaminants in public drinking water in the Village of Hoosick Falls, New York. The contamination stemmed from the Saint-Gobain Performance Plastics – McCaffrey Street Site (Saint-Gobain site). In late 2014, sampling of the Village public water system by a local resident showed it was contaminated primarily with perfluorooctanoic acid (PFOA). The New York State Department of Health (NYSDOH) recommended that actions be taken to identify the sources of contamination and to reduce the levels of PFOA in the drinking water such that these exposures could be reduced and future exposures prevented. Subsequently, the New York State Department of Environmental Conservation (NYSDEC) determined that PFOA from the Saint-Gobain site was a likely source of the contamination [NYSDEC 2016a,b]. In January 2016, the NYSDEC requested that the Saint-Gobain site be nominated by the United States Environmental Protection Agency (USEPA) for inclusion on the National Priorities List (NPL), also known as the federal Superfund list. The USEPA proposed that the Saint-Gobain Site be added to the NPL on September 7, 2016, and formally added the site to the list on July 31, 2017 [USEPA 2017].

Under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR), the NYSDOH used water sampling data collected from the Village public water system between November 2014 and February 2016 to determine that exposures to site-related contaminants occurred in the past, and to evaluate the public health implications of those exposures.

Background

Site Description and History

The Saint-Gobain site is located at 14 McCaffrey Street in the Village of Hoosick Falls (Appendix A). The site occupies 6.4 acres and contains an active manufacturing facility, parking areas, and lawns. An on-site 60,000 square foot building contains manufacturing operations, administrative offices, and a small research and development department. To the north, the site is bordered by wooded residential parcels on Carey Avenue. The site is bordered by wooded areas on the east, south, and west. The wooded areas extend eastward to Water Works Road and westward to the Hoosic River. The Hoosic River Greenway runs southeastward through the wooded area to the west and directly borders the site property to the southwest. The Village of Hoosick Falls public water supply wellfield, water treatment plant, and highway garage are located southeast of the site. Regional groundwater flow is generally east/northeast. However, localized influences by the Hoosic River and Village Supply wells may affect the groundwater flow in the vicinity of the site.

The original building was constructed in 1961 with additions constructed in 1967 and 1975 as operations at the facility expanded. The Saint-Gobain site has been and is currently used to manufacture polytetrafluoroethylene (PTFE) or Teflon-coated fabrics and tapes, make solid billets of PTFE for the production of thin films and other products, and to fabricate various silicone rubber products. The Saint-Gobain site has been operated by several different companies including Dodge Industries, the Oak Materials Group, Allied Signal (Honeywell), and Furon.

Operations that used PTFE also used various amounts of PFOA as a processing additive until the voluntary industry phase-out of PFOA in raw materials by 2015. PFOA is a man-made chemical within the per- and polyfluoroalkyl substances (PFAS) family of compounds. PFOA is toxic and persistent in the environment. All PTFE (with PFOA) aqueous dispersion fabric coating operations (i.e., tower oven sintering) at the Saint-Gobain site ceased in April 2003 and the related coating towers were removed. Saint-Gobain continued to extrude solid billets of PTFE using fine granular powder mixtures of PTFE with PFOA at the McCaffrey Street facility until 2015. There are no indications that the facility ever manufactured any PFAS or any PFAS-containing or PFAS-producing raw materials.

PFOA exists as a white powder or waxy white solid at room temperature and was used at the Saint-Gobain site in various forms. It is water-soluble and can easily move from soil to groundwater. PFOA does not break down in the environment and is persistent in water and soil.

Former employees of the McCaffrey Street facility describe a powder-like smoke plume that was routinely discharged to the air from the facility's smokestacks and settled on the ground and in the Hoosic River. In addition, they reported that the smokestack filters were cleaned outdoors without something to contain the runoff and materials were flushed down storm drains [USEPA 2016a].

Testing of groundwater beneath the Saint-Gobain site indicated PFOA concentrations as high as 130,000 nanograms per liter (ng/L, equivalent to parts per trillion). The Village of Hoosick Falls operates three public supply wells about one third of a mile south of the Saint-Gobain site. The wells draw water from an unconfined sand and gravel aquifer, with a radius of influence that extends out as far as two-thirds of a mile and encompasses the Saint-Gobain site [USEPA 2016a]. The Village of Hoosick Falls public water system serves over 3,500 people.

Site Visits

NYSDOH staff have conducted multiple visits to the Saint-Gobain site and have worked extensively with Village officials and water operators to ensure continued operation of the granular activated carbon filtration system. Site visits have involved on-site meetings with representatives of Saint-Gobain, the NYSDEC, and the USEPA, observation and oversight of activities associated with environmental investigations, and collection of water samples. Activities and site visits to the water treatment plant have primarily involved collection of water samples, on-site meetings with Village officials and employees, and meetings with the NYSDEC and the USEPA.

Demographics

Demographics for the Village of Hoosick Falls are presented in Table 1. This is the population served by the public drinking water wells impacted by the Saint-Gobain site. Using the 2010 Census, the NYSDOH estimated that about 3,500 people lived in the Village at that time. Based on the 2006 - 2010 American Community Survey [United States Census Bureau 2011a], the median household income within the Village was lower than in Rensselaer County or New York State, excluding New York City. NYSDOH's community demographic analysis is consistent with ATSDR's Environmental Justice Index (EJI) and ATSDR's Social Vulnerability Index (SVI) demographics concerning age, gender, race, and poverty as having nearly the same gender, age, and racial/ethnic group distributions, as well as estimates of higher than the state's average of low-income or households experiencing poverty [CDC/ATSDR 2022a, CDC/ATSDR 2022b]. Additional demographic information is shown in Table 1.

			New York State
	Village of	Rensselaer	(excluding
Census Demographics	Hoosick Falls	County	New York City)
Total Population ¹	3,501	159,429	11,202,933
Male (%)	46.7	49.4	49.0
Female (%)	53.3	50.6	51.0
Age Distribution ¹ (%)			
Less than 6 years	7.1	6.6	6.9
6 - 19 years	19.4	18.4	19.0
20 - 64 years	55.7	61.4	59.6
Greater than 64 years	17.8	13.6	14.5
Race/Ethnic Distribution ¹ (%)			
White	96.7	87.5	81.6
Black or African American	< 1	6.5	8.8
American Indian and Alaska	< 1	<i>L</i> 1	< 1
Native		< <u>1</u>	
Asian	< 1	2.2	3.4
Native Hawaiian and other	< 1	< 1	< 1
Pacific Islander			
Some other race	< 1	1.1	3.4
Two or more races	1.5	2.4	2.3
Hispanic	1.2	3.8	9.6
Minority*	4.1	14.3	23.4
Economic Description ²			
Median household income	\$44,104	\$54,152	\$59,994
Below poverty level (%)	14.1	11.7	10.5

 Table 1. Demographics of the Village of Hoosick Falls, Rensselaer County, and New York State (excluding New York City)

¹ [United States Census Bureau 2011b]

² [United States Census Bureau 2011a]

* Minorities include Hispanics, Blacks or African Americans, American Indians and Alaska Natives, Asians, Native Hawaiians, and Other Pacific Islanders individuals of some other race; and individuals of two or more races

Discussion

Environmental Contamination

In 2014, in response to community concerns, the Village of Hoosick Falls collected water samples from the Village's public water system. The samples were analyzed for PFOA and 11 other PFAS. Eurofins Scientific analyzed seven samples of finished water collected between November 4, 2014, and February 11, 2015. Finished water is water that has been treated and is ready for delivery to consumers. Five of the water samples were taken from the village water supply before distribution and two samples were taken from locations in the distribution system. PFOA was detected in each sample. The PFOA concentrations ranged from 440 nanograms per liter (ng/L, equivalent to parts per trillion) to 530 ng/L. Another related chemical, perfluoroheptanoic acid (PFHpA), was detected in six of the seven samples, each time at 10 ng/L.

The NYSDOH collected 18 samples of finished water from the Village public water system between June 4, 2015, and February 18, 2016. Three of these samples were taken from the Village's clearwell. A clearwell is a reservoir for storing water that provides chlorine contact time for disinfection. Fifteen of the samples were taken at various locations in the distribution system. The samples contained PFOA at concentrations ranging from 422 ng/L to 983 ng/L.⁴

Other related chemicals were detected in NYSDOH's sampling of finished water. The other chemicals included:

- PFHpA (detected in 13 samples ranging from 9.8 ng/L to 13 ng/L),
- perfluorobutane sulfonate (PFBS) (detected in 9 samples ranging from 1.8 ng/L to 6.2 ng/L), and
- perfluorooctane sulfonate (PFOS) (detected in 12 samples ranging from 2.6 ng/L to 4.4 ng/L).

A summary of the sampling results is presented in Table 2. The sampling data from the Hoosick Falls public water system used in this health consultation are presented in Appendix B.

⁴ PFOA was detected at 1010 ng/L in a NYSDOH sample taken from a tap in the distribution system. This tap had a point-of-use carbon filter that had not been properly maintained, which possibly resulted in the breakthrough of PFOA. Due to the uncertainties associated with this sampling result, the NYSDOH did not use the value of 1010 ng/L to estimate exposure. The choice to set the highest PFOA level at 983 ng/L rather than 1010 ng/L does not change the conclusions of the health consultation.

Description	Time Period	PFOA Range of Detection (ng/L)	PFHpA Range of Detection (ng/L)	PFBS Range of Detection (ng/L)	PFOS Range of Detection (ng/L)
Eurofins Scientific: Five treatment plant samples; two distribution system samples	November 4, 2014, to February 11, 2015	440 - 530	10ª	ND ^b	ND ^b
New York State Department of Health: Three clearwell samples; 15 distribution system samples	June 4, 2015, to February 18, 2016	422 - 983	9.8 - 13	1.8 - 6.2	2.6 - 4.4

Table 2. Summary of Sampling Results forPFOA and Related Chemicals in the Village of Hoosick Falls Public Water System

^aSix samples were reported to have the same PFHpA concentration of 10 ng/L.

^bMinimum Reporting Level < 90 ng/L and < 40 ng/L for PFBS and PFOS, respectively.

PFOA = perfluorooctanoic acid; PFHpA = perfluoroheptanoic acid; PFBS = perfluorobutane sulfonate; PFOS = perfluorooctane sulfonate; ng/L = nanograms per liter or parts per trillion; ND = not detected

At the time the contamination was discovered, the USEPA had a short-term PFOA drinking water health advisory in effect of 400 ng/L. Health advisories are non-enforceable guidelines that indicate the level of drinking water contamination below which adverse health effects are not expected to occur. The Village sampling results showed that concentrations of PFOA in the drinking water were higher than the advisory level [USEPA 2009].

In every sample from the Hoosick Falls public water system, PFOA made up more than 95% of the total concentration of PFAS⁵ tested. When other PFAS were detected, they were found in much smaller amounts than PFOA.

The USEPA and the NYSDOH have taken several public health and regulatory actions for PFOA since the contamination's discovery:

- In 2016, the USEPA issued lifetime drinking water health advisories for PFOA and PFOS. The advisory level for each chemical was 70 ng/L [USEPA 2016b,2016c]. The USEPA also established an advisory level of 70 ng/L for the combined concentration of PFOA and PFOS [USEPA 2016d].
- In 2020, the NYSDOH established enforceable PFOA and PFOS public drinking water standards of 10 ng/L for each chemical [NYSDOH 2019a, 2020a, 2020b, 2020c].
- In 2022, the USEPA issued interim lifetime drinking water health advisories of 0.004 ng/L for PFOA and 0.02 ng/L for PFOS. These advisories replace the ones issued in 2016

[USEPA 2022b]. The interim lifetime health advisories are below the minimum reporting level (the smallest concentrations that can be reliably measured by a laboratory) for PFOA and PFOS listed by the USEPA in the 5th Unregulated Contaminant Monitoring Rule [USEPA 2021a].

• In 2023, the USEPA proposed regulations to establish nationwide public drinking water standards of 4 ng/L each for PFOA and PFOS [USEPA 2023]. USEPA is currently evaluating public comments on the proposal.

In response to contamination of the water system, the NYSDOH participated in a coordinated effort to characterize and address the contamination. Village, town, county, state, and federal officials and agencies were involved in this effort. The NYSDOH provided the Village with technical guidance on sampling, treatment options, and funding for interventions to reduce exposure. The NYSDOH also provided technical assistance on evaluating a pilot study to demonstrate the effectiveness of granular activated carbon filtration in removing PFOA from the drinking water supply.

In November 2015, free bottled water was made available to Town of Hoosick residents. In December 2015, the USEPA issued a public advisory recommending that residents not use Village of Hoosick Falls public water for drinking or cooking. The NYSDOH advised people to use bottled water for drinking and food preparation or install point of use water filters. These measures helped reduce exposures to PFOA prior to initiation of long-term remedies to address the contamination. The NYSDOH also worked with NYSDEC to sample private drinking water wells and take actions to reduce exposure to PFOA in drinking water from private wells.

In early 2016, an interim granular activated carbon filtration system was installed at the Village water treatment plant. The interim filtration system was extensively tested during March 2016, and a flushing program was initiated to remove PFOA that remained in the distribution system.

On March 30, 2016, the NYSDOH announced that extensive sampling of the Village's public drinking water showed that levels of PFOA were consistently not detectable (at minimum reporting limits ranging from 1.9 to 2 ng/L) and that the water was suitable for all uses, including drinking and cooking [NYSDOH 2016].

In February 2017, the Village transitioned from the interim system to a full-capacity granular activated carbon filtration system. The full-capacity system can treat a higher volume of water. The water is regularly sampled to ensure the system is effectively and consistently removing PFOA and other site-related contaminants before distribution.

Pathways Analysis for the Public Drinking Water System

An exposure pathway refers to the way an individual can come into contact with a hazardous substance that originates from some source of contamination. There are three basic exposure pathways: inhalation, ingestion, and absorption through the skin by direct contact. A completed exposure pathway occurs when all five of the following elements exist:

- Source of contamination
- Environmental media and transport mechanisms
- Exposure point
- Exposure route
- Exposed population

The **source of contamination** is the point of contaminant release to the environment (any waste disposal area or point of discharge). If the original source is unknown, the contaminant source is comprised of the **environmental media** (soil, sediment, air, biota, or water) that are contaminated at the point of exposure. **Environmental media and transport mechanisms** carry contaminants from the source to points where people may be exposed. The **exposure point** is a location where actual or potential human contact with a contaminated medium may occur. The **exposure route** is the way a contaminant enters or contacts the body (i.e., ingestion, inhalation, or dermal absorption). The **exposed population** is the people who have or may come into contact with the contaminants.

Completed Drinking Water Exposure Pathways

Ingestion of Drinking Water

Ingestion of Hoosick Falls public drinking water was a completed exposure pathway. Based on the sampling results, people served by the system consumed water containing PFOA. The PFOA concentrations were above the ATSDR health-based comparison value of 21 ng/L and the current New York State standard of 10 ng/L. The New York State standard was established in 2020.

Inhalation and Dermal Absorption of Drinking Water

According to the ATSDR [2020], routine showering and bathing with water containing PFOA is unlikely to result in significant exposure by inhalation and dermal absorption. Therefore, these exposure pathways are considered to be insignificant compared to exposures resulting from drinking the water. These pathways are not further evaluated in this health consultation. While this health consultation focuses on the evaluation of health risks from past exposure to PFOA in the Hoosick Falls public drinking water system, it is possible there may have been other completed exposure pathways to site-contaminants (for example, exposure through inhalation of contaminants in air emissions from the facility). We have no measurements of past contaminant emissions from the facility. Therefore, we cannot evaluate this exposure pathway at this time.

A baseline human health and ecological risk assessment for the McCaffrey Street Site (Site Number 442046, USEPA ID number NYD004986741) is currently in progress. The ongoing evaluation will consider the potential of other ongoing exposure pathways, such as ingesting soil or consuming agricultural products and fish.

Additional Exposure Information from Biomonitoring for PFOA and other PFAS in Blood

In February 2016, in response to community concerns and to better understand exposures, the NYSDOH offered blood testing for PFOA to people from the Hoosick Falls area. The blood testing results provided information about exposure to PFOA through drinking water and other sources. The testing showed that people who were exposed to PFOA in their drinking water had substantially higher blood PFOA levels than the general United States population. Appendix C has the group results for the blood testing program in Hoosick Falls. The samples were taken from February to November 2016.

A second round of blood testing occurred in 2018 and 2019, approximately 2.5 years after exposures from drinking water ended. For people who participated in both blood testing rounds and who were served by Hoosick Falls public water, there was a 42% reduction in PFOA blood levels from Round 1 to Round 2 on average. The change from Round 1 to Round 2 can also be expressed as an estimated half-life for this group of participants. For these participants, the estimated half-life is 3.2 years for PFOA in blood (NYSDOH 2019b). The estimated half-life means that it takes a little over 3 years for the PFOA blood levels to be reduced by half (or 50%) after exposure to PFOA was stopped.

While Round 1 blood testing analyzed only PFOA, Round 2 analyzed five additional analytes. These included the analytes detected in the water supply, as described above, PFHpA, PFBS PFOS, as well as perfluorohexane sulfonic acid (PFHxS) and perfluorononanoic acid (PFNA). The Round 2 results showed that people served by Hoosick Falls public water had blood levels of these analytes that were very similar to the general U.S. population. For details regarding both blood testing rounds, see the NYSDOH website (NYSDOH 2017, 2019b).

Public Health Implications

Selection of Contaminants for Further Evaluation

The NYSDOH selected contaminants for further evaluation by comparing the highest contaminant levels from the Village of Hoosick Falls public water system to the available healthbased comparison values. Health-based comparison values are contaminant concentrations that are considered protective of public health. The comparison values for PFOA and related chemicals are established by the ATSDR, USEPA, and state health agencies. The NYSDOH selected individual chemicals for further evaluation if their highest detected concentrations in the drinking water were greater than their health comparison values.

PFOA, PFOS, PFHpA, and PFBS were detected in the Village of Hoosick Falls public water system. Of these, PFOA was the only contaminant having a concentration that exceeded its healthbased comparison value (Table 3). Therefore, the NYSDOH selected only PFOA for further evaluation. The highest PFOA level also exceeded the current New York State PFOA public drinking water standard of 10 ng/L [NYSDOH 2019a, 2020a, 2020b, 2020c]. Information on PFOA and its associated health effects is summarized in Appendix D.

Table 3. Highest Concentrations of PFOA and Related Chemicals Detected in the Village of Hoosick Falls Public Water System Compared to Health-Based Comparison Values

Contaminant	Highest Drinking Water Concentration (ng/L)	Health-Based Comparison Value (ng/L)	Further Evaluation
PFOA	983	21 ª	yes
PFHpA	13	21 ^b	no
PFBS	6.2	2,100 ^c	no
PFOS	4.4	14 ^a	no

^aAgency for Toxic Substances and Disease Registry intermediate environmental media evaluation guide. Public Health Assessment Site Tool Database.

^bIn the absence of a chemical-specific health-based drinking water guideline for PFHpA, the ATSDR intermediate environmental media evaluation guide for PFOA is used as a comparison value to determine if PFHpA should be further evaluated. PFHpA and PFOA are structurally similar chemicals (being 7- and 8-carbon carboxylic acids, respectively), and based on the limited available toxicity data for PFHpA, using PFOA to represent the toxicity of PFHpA is unlikely to underestimate its toxicity.

^cATSDR chronic reference dose media evaluation guide. Public Health Assessment Site Tool Database.

PFOA = perfluorooctanoic acid; PFHpA = perfluoroheptanoic acid; PFBS = perfluorobutane sulfonate; PFOS = perfluorooctane sulfonate; ng/L = nanograms per liter or parts per trillion

Risk Assessment Methods

Risk assessment is a scientific process used to describe the nature and extent of health risks from environmental exposures [USEPA 2018]. Risk assessment uses a standard approach. The assessment combines information about the frequency and extent of an environmental exposure with information about the toxicity of the chemical to draw conclusions about the risk for human health effects. Information on exposure and toxicity are usually limited, and risk assessors often make estimates and use judgment when performing risk calculations. This makes all risk estimates uncertain to some degree [USEPA 2018]. A risk assessment cannot be

used to predict if health effects will occur in the future, nor can it be used to determine if health effects have occurred in the past. A risk assessment is one of several considerations used when making risk management decisions to reduce exposures to environmental chemicals.

The NYSDOH estimated exposures to PFOA in drinking water using ATSDR's Exposure Dose Guidance for Water Ingestion [ATSDR 2023]. These methods estimate exposure for several different groups within a population based on contaminated water concentrations, estimated drinking water ingestion rates, and body weights.

Based on ATSDR's Exposure Point Concentration Guidance [ATSDR 2019a], the highest concentration of PFOA from the sampling of the public water system was used to represent exposure when evaluating noncancer toxicity.⁶ The noncancer risks for estimated PFOA exposures from drinking water were then compared to ATSDR's intermediate minimal risk level [ATSDR 2021a]. An intermediate minimal risk level is an estimate of how much PFOA you could be exposed to every day before noncancerous health effects are expected to occur. The ATSDR intermediate minimal risk level for PFOA [ATSDR 2021a] is based on exposures that occur for more than 14 days and less than one year. ATSDR considers the intermediate MRL to be protective for chronic exposure. For the remainder of this health consultation, the term "minimal risk level" refers to the ATSDR PFOA intermediate minimal risk level.

ATSDR derived its minimal risk level for PFOA based on changes in bone structure and mineral density in the offspring of mice exposed to PFOA during pregnancy [Koskela et al. 2016; ATSDR 2021a]. The lowest reported effect level is the lowest dose, or exposure level, at which health effects were observed. In this study, the lowest reported effect level was converted to an estimated human effect level. The conversion accounted for the differences in the way mice and humans absorb, distribute, and excrete PFOA. The estimated human effect level was then divided by a total uncertainty factor (UF) of 300. The uncertainty factor accounts for

- using an effect level rather than a no-effect level (UF of 10),
- the possibility that human beings are more sensitive than mice to the health effects of PFOA (UF of 3), and
- the possibility that certain members of the human population are particularly sensitive to the health effects of PFOA (UF of 10).

The result was a minimal risk level of 0.003 micrograms PFOA per kilogram body weight per day (mcg/kg/day). This level provides a margin of protection against health effects and is set at an exposure level about 300 times lower than the estimated human effect level.

⁵ ATSDR suggested calculating a 95% UCL of the mean of PFOA levels in water for a 1 to 2-month period to obtain an exposure point concentration to evaluate health risks using its PFOA minimal risk level based on developmental toxicity. None of the calculated 95% UCLs for any 1 to 2-month time period adequately fit a normal, lognormal or gamma distribution, and in such cases the Exposure Point Concentration Guidance [ATSDR 2019a] recommends the 95% UCL not be used. ATSDR subsequently recommended using the highest PFOA level for this evaluation.

ATSDR judged developmental health effects to be the strongest basis on which to derive the minimal risk level. Developmental health effects are a well-established and sensitive toxicological endpoint for PFOA [Lau et al. 2006; Onischenko et al. 2011; Sobolewski et al. 2014; Koskela et al. 2016; Goulding et al. 2017]. The relatively large total uncertainty factor (300) also provides a sufficient margin of protection against other types of health effects which may occur at relatively low levels of PFOA exposure [Perkins et al. 2004; Filgo 2015a, b; Butenhoff et al. 2002, 2004; Macon et al. 2011; DeWitt et al. 2008, 2016]. These other effects include:

- liver effects such as hepatocellular hypertrophy, inflammation, and increased weight;
- increased kidney weight; and
- a reduced immune response.

Exposure levels that are less than the minimal risk level are unlikely to pose a significant risk for noncancer health effects. If drinking water exposures exceed the PFOA minimal risk level, it does not necessarily mean that health effects will occur [ATSDR 2021b], although the margin of protection provided by the minimal risk level has been reduced. Exceedance of the minimal risk level triggers an additional evaluation. The evaluation compares the PFOA drinking water exposures to estimated PFOA exposure levels that may be associated with health effects in humans. This process evaluates the margin of exposure, or a measure of how many times lower the estimated environmental exposure is compared to the exposures that may cause health effects. The margin of exposure is calculated by dividing the estimated PFOA human effect level by the PFOA exposure in public water. Risk assessors use the margin of exposure calculation as an indicator of how much health protectiveness remains once an exposure exceeds the minimal risk level, and the preferred margin of exposure, the greater the difference between the estimated human effect level and the PFOA exposure from public water and, therefore, the lower the level of concern about the potential for health effects.

Elevated PFOA serum levels are associated with an increased risk for kidney and testicular cancer in humans [C8 Science Panel 2012; Shearer et al. 2021]. PFOA causes liver, testicular, and pancreatic cancer in laboratory animals exposed to high levels of PFOA in their lifetimes [Butenhoff et al. 2012; NTP 2020]. The USEPA classifies PFOA as having "suggestive evidence of carcinogenic potential" [USEPA 2016e]. Recently, USEPA has proposed to its Science Advisory Board upgrading the classification to "likely to be carcinogenic to humans" [USEPA 2022a]. IARC has classified PFOA as carcinogenic to humans [IARC 2023]. There is currently no clear consensus among health agencies on preferred methods to evaluate the risk for cancer posed to humans exposed to environmental levels of PFOA such as those found in drinking water. Therefore, the cancer risk for exposure to PFOA in the Village of Hoosick Falls water supply is considered indeterminant and is not assessed in this health consultation.

Detailed exposure parameters and calculations used in the evaluation of health risks for exposure to PFOA in the Village of Hoosick Falls public water system are in Appendix E. The results presented in the main text are based on ATSDR's reasonable maximum exposure assumptions. Results based on ATSDR's central tendency exposure assumptions are also in Appendix E.

Evaluation of Past PFOA Exposures in the Village of Hoosick Falls Public Water System

The NYSDOH estimated past exposure to PFOA in drinking water using the highest PFOA concentration of all samples of finished water taken by the Village of Hoosick Falls (November 2014 to February 2015) and the NYSDOH (June 2015 to February 2016). The highest concentration (983 ng/L) and similar levels were measured only in samples taken in late January 2016. The concentration was found after bottled water was provided and people were advised not to drink or cook with the water. However, it is still possible that people drank water containing the highest measured level of PFOA. Using the highest concentration is typical when evaluating developmental health effects. These health effects could result from elevated exposures over relatively short periods of exposure, such as early in pregnancy or during breastfeeding.

Table 4 shows comparisons of estimated exposures, for nine population groups consuming water containing 983 ng/L PFOA, to the ATSDR minimal risk level of 0.003 mcg/kg/day.

Population	Estimated PFOA Exposure from Drinking Water (mcg/kg/day)	ATSDR PFOA Minimal Risk Level (mcg/kg/day)	Result
Birth to < 1 year old	0.14	0.003	Exposure at 983 ng/L is higher than the minimal risk level.
1 Year old to < 2 years old	0.077	0.003	Exposure at 983 ng/L is higher than the minimal risk level.
2 Years old to < 6 years old	0.055	0.003	Exposure at 983 ng/L is higher than the minimal risk level.
6 Years old to < 11 years old	0.043	0.003	Exposure at 983 ng/L is higher than the minimal risk level.
11 Years old to < 16 years old	0.034	0.003	Exposure at 983 ng/L is higher than the minimal risk level.
16 Years old to < 21 years old	0.034	0.003	Exposure at 983 ng/L is higher than the minimal risk level.
Adults (≥ 21 years old)	0.038	0.003	Exposure at 983 ng/L is higher than the minimal risk level.
Pregnant women	0.034	0.003	Exposure at 983 ng/L is higher than the minimal risk level.
Breastfeeding women	0.047	0.003	Exposure at 983 ng/L is higher than the minimal risk level.

Table 4. Comparisons of Estimated PFOA Exposures at the Highest Concentration in the Hoosick Falls Public Water System (983 ng/L) to the ATSDR PFOA Minimal Risk Level

ng/L = nanograms per liter or parts per trillion; mcg/kg/day = micrograms PFOA per kilogram body weight per day; PFOA = perfluorooctanoic acid For all the age groups, and for pregnant and breastfeeding women, the estimated PFOA exposures based on the highest water concentration (983 ng/L) exceed the minimal risk level.

Since the minimal risk level was exceeded, the NYSDOH evaluated the margin of exposure. The margin of exposure is evaluated by comparing the estimated PFOA exposures from drinking public water to an estimate of the human PFOA exposure that could cause health effects. This estimate is called an estimated human effect level. ATSDR estimated a human effect level (0.82 mcg/kg/day) for PFOA as part of the derivation of its minimal risk level [ATSDR 2021a], and this value represents the human exposure that corresponds to the exposure in mice at which health effects were reported.

Table 5 compares estimated PFOA drinking water exposures, for seven age groups and for pregnant and breastfeeding women, and the estimated human effect level.

Population	Estimated PFOA Exposure from Drinking Water (mcg/kg/day)	Estimated PFOA Human Effect Level ¹ (mcg/kg/day)	Margin of Exposure ²
Birth to < 1 year old	0.14	0.82	6
1 Year old to < 2 years old	0.077	0.82	11
2 Years old to < 6 years old	0.055	0.82	15
6 Years old to < 11 years old	0.043	0.82	19
11 Years old to < 16 years old	0.034	0.82	24
16 Years old to < 21 years old	0.034	0.82	24
Adults (<u>></u> 21 Years old)	0.038	0.82	22
Pregnant women	0.034	0.82	24
Breastfeeding women	0.047	0.82	18

Table 5. Comparisons of Estimated PFOA Exposures at the Highest Concentration in the Hoosick Falls Public Water System (983 ng/L) to the Estimated Human PFOA Effect Level

¹The human effect level of 0.82 mcg/kg/day is derived by the ATSDR [2021a] and is an estimate of the human exposure that corresponds to the animal dose at which health effects were observed.

²The margin of exposure is calculated by dividing the estimated human PFOA effect level by the PFOA exposure from drinking public water. The higher the margin of exposure, the greater the difference (and margin of protection) between the PFOA exposure in drinking water and the human PFOA effect level. A margin of exposure equal to 1 means that the drinking water exposure is the same as the human PFOA effect level. A margin of exposure equal to 300 means that the drinking water exposure is the same as the ATSDR minimal risk level.

Table 5 shows that the PFOA drinking water exposures at the highest PFOA concentration of 983 ng/L are between 6 and 24 times lower than the estimated human effect level.

<u>Characterization of Risks for Past PFOA Exposures from the Village of Hoosick Falls Public Water</u> <u>System</u>

The estimated PFOA exposures (assuming the maximum PFOA water concentration), for all the age groups and for pregnant and breastfeeding women consuming Village of Hoosick Falls water, exceeded the ATSDR PFOA minimal risk level (Table 4). Based on the margin of exposure calculations (Table 5), the difference between the estimated human effect level, and exposures in the water system was between 6 and 24-fold, depending on the specific age or population group. In other words, the estimated exposures in the water system were between 6- and 24-times lower than the levels that are estimated to cause health effects in humans.

When the margin of exposure is relatively small, evaluating the risk for health effects requires a case-by-case consideration of several factors, especially those factors related to the quality and quantity of the toxicity information on the chemical. For PFOA, an important consideration is that there is incomplete information on the health effects on developing fetuses and breastfed infants. The USEPA identified fetuses and breastfed infants as the populations most sensitive to PFOA exposure [USEPA 2016d]. The possibility that those in early life stages may be more vulnerable is reflected in the fact that ATSDR based its minimal risk level on developmental effects observed in these early life stages.

Concern about early life PFOA exposure is increased by the results of several studies that evaluate PFOA serum levels in mothers and breastfed infants, either by direct measurement from blood [Fromme et al. 2010; Mondal et al 2014] or through pharmacokinetic modeling [Loccisano et al. 2013; Verner et al. 2016; Kieskamp et al. 2018]. Pharmacokinetic models mathematically estimate the absorption, distribution, metabolism, and elimination of a chemical in humans. These studies provide evidence that PFOA serum levels in breastfed children may be substantially higher than the PFOA serum levels of the mother. In addition, the Minnesota Department of Health (MNDOH) specifically considered the risk to infants when deriving its health-based water value for PFOA [MNDOH 2017]. MNDOH used pharmacokineticbased predictions of breastfed infant serum levels that were the result of exposure to PFOA in drinking water. The evaluation suggested that breastfed infants could be exposed to a greater degree of PFOA than their mothers. This resulted in the MNDOH adopting a health-based water value (35 ng/L) that was lower than the USEPA lifetime health advisory (70 ng/L) in place at the time of the analysis. In 2020, the NYSDOH established a PFOA public drinking water standard of 10 ng/L [NYSDOH 2019a, 2020a, 2020b, 2020c]. The drinking water standard incorporates a large margin of protection against health effects and considers uncertainties in the toxicological database for the chemical. In addition, several other states, including Michigan [MI EGLE 2019a], New Hampshire [NH DEP 2020] and New Jersey [NJ DEP 2020], have also adopted drinking water standards for PFOA.

The NYSDOH concludes that past exposures to PFOA in the Village of Hoosick Falls water system posed an increased the risk for health effects, particularly noncancer health effects in infants and young children. This conclusion is based on the following considerations.

- The PFOA exposures in public water exceeded ATSDR's minimal risk level for PFOA and therefore the exposures required further evaluation.
- If infants or children were exposed to the highest level measured in public water, these exposures were only 6 to 24 times lower than the ATSDR-estimated human effect level (0.82 mcg/kg/day), as indicated by the margin of exposure calculations. Therefore, the estimated exposures in infants and children are approaching harmful levels identified from animal studies.
- Evidence from published studies suggests that breastfed infants receive a greater PFOA exposure than their mothers. This possibility is not addressed in the calculation of the current PFOA minimal risk level. Consequently, exposure in breastfed infants could have resulted in a smaller margin of exposure than was indicated by the calculations (Table 5). This suggests a possible increased risk of health effects for this population.

Margins of exposure can be calculated for other important toxicological endpoints associated with PFOA exposure, such as liver and immune system toxicity. The estimated infant exposures to PFOA in public water are about 3-fold lower than the estimated human effect level that corresponds with the exposure that caused reversible increases in liver weights in offspring of dams treated during gestation [Macon et al. 2011], and about 28-fold lower than the human effect level corresponding with increased severity of liver inflammation in offspring in mice [Filgo et al. 2015a, Filgo et al. 2015b]. The doses are about 30-fold lower than the exposure that caused reduced antibody response in mice [DeWitt et al. 2016].⁶ Although there is debate

⁶ Margins of exposure (MOEs) for these endpoints were calculated as the ratio between the estimated human effect levels for liver or immune system toxicity in mice to the infant exposures in public water. The estimated human effect levels for liver and immune toxicity were calculated from measured [Macon et al., 2011] or predicted [ATSDR 2021a; Filgo et al. 2015a, 2015b; DeWitt et al. 2016] PFOA serum levels at the animal lowest observed effect level (LOEL, or the lowest dose in a study at which there was a statistically or biologically significant indication of a toxic effect) multiplied by a clearance value of 0.099 mL/kg/day, obtained from first-order one-compartment model input parameters for PFOA from ATSDR's perfluoroalkyls toxicological profile [ATSDR 2021a]. Sample MOE calculations for infant exposure to the highest PFOA concentration (983 ng/L) are shown below:

HED (reversible increases in liver weight) = LOEL serum level x PFOA clearance = 4.98 mcg/mL x 0.099 mL/kg/day = 0.49 mcg/kg/day

MOE (reversible increases in liver weight) = (0.49 mcg/kg/day)/(0.14 mcg/kg/day) = 3.5

whether the liver changes observed by Macon et al. constitute an adverse effect, the margin of exposure calculations for liver effects indicate a potentially substantial decrease in the margin of protection against liver toxicity and supports the conclusion that past PFOA exposures in public water posed an increased risk for these health effects.

In summary, based on available information on the health effects of PFOA and the margin of exposure calculations, estimated past exposures to PFOA in the Hoosick Falls public water system (assuming people were exposed to the highest detected level) posed an increased risk for PFOA-related health effects. The margins of exposure are based on developmental effects and are in a similar range for liver and immune toxicity. All three endpoints are among the most consistently observed and sensitive PFOA health effects in studies of laboratory animals.

Other PFAS (PFOS, PFHpA and PFBS) were detected in the Hoosick Falls public water system during the sampling events. In every sample from the public water system, PFOA was more than 95% of the total PFAS level. When other PFAS were detected, they were found in much smaller amounts than PFOA. None of the detected levels of other PFAS exceeded any chemical-specific health comparison values or guidelines for drinking water. Thus, the other PFAS would have added minimally to the quantitative estimates of health risk provided in this health consultation, which are driven by exposure to PFOA.

People can also be exposed to PFOA through eating food packaged in material containing perand polyfluorinated substances (PFAS), and through using consumer products such as stain resistant carpeting and water repellent clothing. These types of non-drinking water exposures would be expected to have contributed relatively very little to past PFAS exposures for residents of the Village of Hoosick Falls who consumed the drinking water. Blood serum levels of PFOA and other PFAS for people who consumed the drinking water compared to levels in the general U.S. population confirm that non-drinking water exposures to PFAS would be expected to contribute only minimally to the overall exposure from drinking water [NYSDOH 2017, NYSDOH 2019b; CDC 2021].

Limitations and Uncertainties

An important limitation in this evaluation is the lack of information on the PFOA concentrations in the Hoosick Falls public water system prior to the time the contamination was discovered. Those concentrations may have been higher or lower than the levels used in this assessment. A

HED (liver inflammation in offspring) = LOEL serum level x PFOA clearance = 39.2 mcg/mL x 0.099 mL/kg/day = 3.9 mcg/kg/day

MOE (liver inflammation in offspring) = (3.9 mcg/kg/day)/(0.14 mcg/kg/day) = 28

HED (immune toxicity) = LOEL serum level x PFOA clearance = 42.5 mcg/mL x 0.099 mL/kg/day = 4.2 mcg/kg/day MOE (immune toxicity) = (4.2 mcg/kg/day)/(0.14 mcg/kg/day) = 30

further limitation, which is true for most chemicals, is the limited toxicological database for PFOA in humans, particularly with respect to children. The long-term risks for health effects in children who may be exposed to PFOA during their development is not completely understood and is a topic of active research. There is also uncertainty about how much water people actually drank. Although the NYSDOH used high-end estimates of drinking water consumption rates, some people may drink more or less water than was assumed and would have different exposure to PFOA than estimated in this analysis.

ATSDR recently initiated an extensive study on the human health effects of exposure to perand polyfluoroalkyl substances (PFAS) through drinking water at locations across the nation. The study will be conducted through cooperative agreements with several state partners, including the University at Albany and the NYS DOH, and will evaluate PFAS exposures in Hoosick Falls and Newburgh, New York [ATSDR 2019b].

Health Outcome Data Evaluation

In 2017, the NYSDOH conducted a cancer incidence investigation in the Village of Hoosick Falls to see if there were unusual elevations of cancer among people diagnosed with cancer while residing in the village. To provide residents with information about cancer rates in the Village, the NYSDOH analyzed results from New York State's Cancer Registry from January 1995 through December 2014 (the most recent year for which complete data were available). No statistically significant elevations of cancer were found for any of the cancer types associated with PFOA exposure. The only cancer found to have a statistically significant elevation was lung cancer, which has not been associated with PFOA exposure in other studies.

In three to five years, the NYSDOH will update and review the cancer data for the Village of Hoosick Falls to identify any changes in the comparative cancer profile for residents. The NYSDOH will continue to monitor cancer cases in the Village of Hoosick Falls. The NYSDOH will share new scientific findings with healthcare providers and residents as new information becomes available.

A copy of the *Cancer Incidence Investigation 1995-2014, Village of Hoosick Falls, Rensselaer County, New York* report can be accessed on the NYSDOH website [NYSDOH 2017].

Community Health Concerns

Community health concerns have been expressed to state, county, and federal staff and elected officials at numerous public meetings and availability sessions, and through one-on-one contact. Primary community concerns include health risks associated with drinking contaminated water and the need for an alternative water supply. Additional community health concerns have been expressed regarding direct contact with contaminants in soils, swimming

pools, and various other media (e.g., gardening). NYSDOH staff met numerous times with town officials to provide expertise on options for an alternative water supply. They also addressed the other concerns on an individual or small group basis via phone calls, emails, public availability sessions, and several larger public meetings (see Public Health Action Plan for additional information on the NYSDOH response to community concerns). NYSDOH will continue to provide support to community members through public meeting forums and one-one discussions to encourage dialogue on any public health concerns that may arise.

Conclusions

The NYSDOH reached the following two conclusions about the Saint-Gobain NPL site.

- Currently, drinking or using water from the Village of Hoosick Falls public water supply is not expected to harm people's health. Although some of the public supply wells still have Saint-Gobain site-related contaminants in the raw water, a granular activated carbon (GAC) filtration system has been put in place to remove the contamination before the water is distributed to the public. The public water supply is monitored on a regular basis to verify that the treatment system continues to effectively and consistently remove PFOA and other site-related contamination to non-detect levels in the treated water.
- 2. Past exposure to PFOA in the Village of Hoosick Falls public water supply posed an increased the risk for health effects, particularly noncancer health effects in infants and young children. The estimated past PFOA exposures from drinking water for residents of the Village of Hoosick Falls exceeded the ATSDR's intermediate minimal risk level¹. NYSDOH compared high end estimates of the PFOA exposures from drinking public water to an estimate of the human PFOA exposure that could cause health effects (an estimated human effect level)². The comparison shows that the PFOA drinking water exposures at the highest PFOA concentration of 983 ng/L are still below the estimated human effect level. However, this margin of exposure is only 6 to 24-fold. Small margins of exposure are a health concern and are smallest for infants and young children. Small margins of exposure suggest that the risks for health effects could be greater than those of older children, teenagers, and adults within the population. The margins of exposure are based on developmental, liver, and immune toxicity. These are among the most consistently observed and sensitive PFOA health effects in studies of laboratory animals.³

The contribution of other PFAS chemicals detected at relatively much lower levels than PFOA in the water system (i.e., PFOS, PFHpA and PFBS) to the overall risk is relatively very small. The other PFAS would have added minimally to the quantitative estimates of health risk provided in this health consultation, which are driven by exposure to PFOA. People can also be exposed to PFAS such as PFOA through eating food packaged in material containing PFAS, and through using consumer products such as stain resistant carpeting and water repellent clothing. These non-drinking water exposures are expected to have contributed relatively very little to past PFAS exposures for residents of the Village of Hoosick Falls who consumed the drinking water.

The USEPA classifies PFOA as having "suggestive evidence of carcinogenic potential" but has recently proposed to its Science Advisory Board upgrading the classification to "likely to be carcinogenic to humans" [USEPA 2022a]. The International Agency for Research on Cancer (IARC) has also evaluated the carcinogenicity of PFOA and has classified PFOA as carcinogenic to humans [IARC 2023]. Elevated PFOA serum levels are associated with an increased risk for cancer in humans. PFOA causes cancer in laboratory animals exposed to high levels for their lifetimes. There is currently no clear consensus among health agencies on preferred methods to evaluate the risk for cancer posed to humans who are exposed to environmental levels of PFOA such as those found in drinking water. Therefore, the cancer risk for exposure to PFOA in the Village of Hoosick Falls water supply is considered indeterminant and was not assessed in this health consultation.

Recommendations

- The NYSDOH recommends that the Village of Hoosick Falls continue to operate, monitor, and maintain the current treatment system for the public water system to ensure that PFOA and other site-related contaminants are effectively and consistently removed from the water before distribution.
- 2. The NYSDOH recommends that the NYSDEC and the USEPA, in partnership with the NYSDOH, continue to conduct a full characterization of the Saint-Gobain site and investigate measures to reduce site-related contaminants in groundwater in the Village of Hoosick Falls, including per- and polyfluoroalkyl substances, and thereby reduce the need to treat the groundwater prior to distribution in the public water system.
- 3. The NYSDOH recommends that the NYSDEC and the USEPA, in partnership with the NYSDOH, continue to evaluate other potential exposure pathways (including exposure to site contaminants through soil, air, private drinking water wells, and soil vapor intrusion) associated with the Saint-Gobain site. Actions should be implemented to reduce the potential for exposure if other completed pathways that contribute to exposure are identified.
- 4. The NYSDOH recommends that the NYSDEC, in partnership with the NYSDOH, continue to participate in the Hoosick Area Community Participation Work Group (CPWG) that was established by DEC and DOH in 2018. The CPWG is designed to serve as a community liaison with government agencies. The CPWG makes recommendations and provides relevant community input regarding community concerns and perceptions as the remedial projects are being performed. The group meets on a monthly basis to review and discuss the progress of remediation activities and water supply options, and to provide the opportunity for the community's questions and concerns to be addressed before decisions are made. DOH has given presentations to the group on various topics, including the Multi-Site Study PFAS Health Study plans and status, and has facilitated presentations by the Multi-Site Study co-principal investigator from the University at Albany School of Public Health on the PFOA and health effects literature.

- 5. The NYSDOH recommends that health education information related to PFOA in drinking water continue to be developed and provided to affected residents, community members, and health professionals in the area. People can further reduce their exposure by avoiding use of PFAS-containing products as identified by ATSDR [ATSDR 2020].
- 6. Regarding breastfeeding, ATSDR and the American Academy of Pediatrics generally recommend breastfeeding, despite the presence of chemicals in breast milk. Given what is currently known about PFAS exposure, the benefits of breastfeeding are believed to outweigh any risks. A woman's decision to breastfeed is an individual choice, made after consideration of many different factors (many unrelated to PFAS exposure) and in consultation with her healthcare providers.

Public Health Action Plan

The public health action plan for the Saint-Gobain site contains a description of actions taken or planned to be taken by the NYSDOH, RCDOH, NYSDEC, or USEPA. The public health actions for the Village of Hoosick public water system are below.

Public Health Actions Taken

In November 2015, free bottled water was made available to those families who relied on the Village of Hoosick Falls public water system for their drinking water. The USEPA issued a public advisory in December 2015 that recommended residents not use Village of Hoosick Falls public water for drinking or cooking. The NYSDOH advised that people use bottled water for drinking and food preparation or install point of use water filters. The NYSDOH worked with NYSDEC to sample private drinking water wells and take actions to reduce exposure to PFOA in drinking water prior to initiation of long-term remedies to address the contamination.

The NYSDOH offered blood testing for PFOA to people from the Hoosick Falls area from February through November 2016, and for PFOA and five other PFAS in 2018-2019. The 2016 blood testing results provided information about elevated levels of exposure to PFOA. The Round 2 results from 2018-2019 showed that levels in blood are declining. Group results for the blood testing program in Hoosick Falls are found in Appendix C and on the DOH website (NYSDOH 2017, NYSDOH 2019b). NYSDOH APPLETREE staff coordinated with staff from the NYSDOH biomonitoring program who led this testing effort to ensure consistency in messaging, information, and recommendations for public health actions that were shared with the community.

In early 2016, an interim granular activated carbon filtration system was installed at the Village water treatment plant. In February 2017, the Village transitioned from the interim system to a new full capacity granular activated carbon filtration system, which allowed for treatment of a

higher volume of water. The water is sampled routinely for PFOA and related chemicals to ensure the system is effectively and consistently removing PFOA and other site-related contaminants to non-detectable levels in the finished drinking water before distribution.

The NYSDOH coordinated with NYSDEC and USEPA to provide health education to Village residents affected by the PFOA contamination. Activities included public meetings, public availability sessions, creation of a Hoosick Falls information page on the NYSDOH website, fact sheets, and in-person information sessions with local residents.

For local health care providers, NYSDOH toxicology and epidemiology experts traveled to Hoosick Falls NY, Cambridge NY, and Bennington Vermont for in-person presentations and discussions with local providers. The ATSDR document, "Overview of Perfluoroalkyl and Polyfluoroalkyl Substances and Guidance for Clinicians Responding to Patient Exposure Concerns," was mailed to approximately 300 health care providers whose names were provided by PFOA blood testing participants. More information about the efforts to address community health concerns can be accessed from the NYSDOH website [NYSDOH 2018].

The NYSDOH has worked with the RCDOH, NYSDEC, and USEPA to evaluate potential alternate drinking water sources for the Village of Hoosick Falls. Five options were evaluated:

- 1) Developing a new groundwater source (with and without granular activated carbon treatment)
- 2) Developing a new surface water source
- 3) Interconnecting with an existing municipal system
- 4) Continuing use of the existing Village well field with appropriate treatment
- 5) Continuing use of the existing Village well field with appropriate treatment and operation of the interim remedial measure at the McCaffrey Street site

The NYSDOH concurred with the NYSDEC's recommendation to develop a new groundwater source with granular activated carbon treatment.

The NYSDOH conducted a cancer incidence investigation in the Village of Hoosick Falls. No statistically significant elevations of cancer were found for any of the cancer types associated with PFOA exposure. The NYSDOH will update and review the cancer data for the Village of Hoosick Falls in three to five years.

PFOA and PFOS Drinking Water Standards

In response to concerns about PFAS contamination in drinking water, in December 2018, the New York State Drinking Water Quality Council recommended that the NYSDOH adopt maximum contaminant levels (MCLs) of 10 ng/L for both PFOA and PFOS [NYSDOH 2020a]. The NYSDOH accepted this recommendation, and in July 2019 began the formal rulemaking process

to establish the recommended MCLs as standards for public water systems in New York State [NYSDOH 2019a, 2020b]. The NYSDOH responded to numerous public comments on the proposed MCLs and published the Notice of Adoption for the PFOA and PFOS standards in the New York State Register on August 26, 2020 [NYSDOH 2020c]. The NYSDOH will continue to work with NYSDEC and county health agencies, as well as with the New York State Drinking Water Quality Council to evaluate PFOA and PFOS data collected by public water supply systems to address and reduce drinking water exposures to PFOA and PFOS.

Public Health Actions Planned

The NYSDOH will work with the RCDOH, NYSDEC and the Village of Hoosick Falls to verify that the treatment system installed on the public water supply continues to effectively and consistently remove PFOA and other site-related contamination from the water before distribution.

The NYSDOH will work with the RCDOH, NYSDEC, USEPA, and the Village of Hoosick Falls to oversee the development of an alternate drinking water source with granular activated carbon treatment and recommend modifications as appropriate.

The NYSDOH will work with the NYSDEC and USEPA to evaluate the contributions of on-going sources of contamination to the groundwater, soil, and air. Actions will be taken to control or eliminate contributing sources that may result in exposure through ingestion, inhalation, or direct contact.

The NYSDOH will work with the NYSDEC and USEPA to review investigation data as they become available, evaluate the public health implications of any sampling results, and recommend public health actions as needed.

A national Multi-Site Health Study was initiated in September 2019. Seven entities nationwide are receiving funding for PFAS health study projects. Since then, the seven partners have worked with ATSDR to study the human health effects of exposures to PFAS through drinking water. The study includes two communities in NYS, Hoosick Falls and the City of Newburgh. The NYSDOH and the University at Albany School of Public Health are jointly leading the NYS project for Hoosick Falls and Newburgh. A community advisory panel has been established to provide input and assistance with carrying out a successful project. Recruitment for study participants was completed in March 2023.

Beginning in early 2024, NYSDOH offered a third round of free, voluntary PFAS blood testing to residents and individuals in the Hoosick Falls/Petersburgh area to assure residents that levels of PFAS in their blood are declining following mitigation activities. People who did not participate previously and people who did not have the opportunity to participate in the Multisite PFAS

Health Study were also eligible to sign up. NYSDOH APPLETREE staff will continue to coordinate with staff from the NYSDOH biomonitoring program leading this testing effort to ensure consistency in messaging, information, any recommendations for public health actions shared with the community.

The NYSDOH will continue to work with University at Albany epidemiologists to provide more comprehensive information about breastfeeding and PFAS for this community. Information developed by ATSDR to guide doctors [ATSDR 2024] can aid in the decision-making process.

The NYSDOH will also continue to work with ATSDR to seek additional information about ongoing sources of PFAS exposures. NYSDOH will share such information with the community so people can further reduce their exposure to per- and polyfluoroalkyl substances (PFAS). For example, by avoiding using products that may contain them [ATSDR 2020].

The NYSDOH will continue to provide support to community members through public meeting forums and one-on-one discussions to encourage dialogue on this health consultation or other health concerns that may arise. This report will be placed in the local repository and provided to people who request it.

Report Preparation

The New York State Department of Health prepared this health consultation for the Saint-Gobain Performance Plastics Site, McCaffrey Street/Village of Hoosick Falls Public Water System, located in the Village of Hoosick Falls, Town of Hoosick, Rensselaer County, New York under a cooperative agreement (CDC-RFA-TS-23-0001) with the federal Agency for Toxic Substances and Disease Registry (ATSDR). It is in accordance with the approved agency methods, policies, and procedures existing at the date of publication. The New York State Department of Health evaluated and summarized the data used in this health consultation. ATSDR reviewed this document and concurs with its findings based on the information presented by the New York State Department of Health.

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Appendix A: Saint-Gobain Site Location



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Appendix B: Sampling Data for the Hoosick Falls Public Water System

	(/ 60p.66 66)				
Sampling Location	Sample Date	PFOA	PFHpA	PFBS	PFOS
Treatment Plant	11/4/2014	440	10	ND	ND
Treatment Plant	12/1/2014	440	NA	NA	NA
Treatment Plant	1/29/2015	530	10	ND	ND
Highway Garage	1/29/2015	520	10	ND	ND
Rt. 22 True Value	1/29/2015	510	10	ND	ND
Treatment Plant	2/11/2015	500	10	ND	ND
Treatment Plant	2/11/2015	480	10	ND	ND
Village Clearwell	6/4/2015	662	NA	NA	NA
Distribution system ^A	6/4/2015	618	NA	NA	NA
Distribution system ^A	6/4/2015	612	NA	NA	NA
Village Clearwell	1/28/2016	983	NA	NA	NA
Distribution system ^A	2/2/2016	954	NA	NA	NA
Village Clearwell	2/16/2016	422	9.8	6.2	ND
Department of Public Works /Village Garage (11 Water Works Road)	2/18/2016	460	11	ND	4.1
Distribution system ^A	2/18/2016	490	11	1.9	4.4
Distribution system ^A	2/18/2016	460	10	ND	3.6
Hoosick Falls Municipal Building (24 Main Street)	2/18/2016	470	10	1.9	2.6
Distribution system ^A	2/18/2016	480	10	1.9	2.7
Distribution system ^A	2/18/2016	490	13	ND	3.2
Distribution system ^A	2/18/2016	470	10	2.1	3.6
Distribution system ^A	2/18/2016	460	10	2.4	3.6
Distribution system ^A	2/18/2016	470	11	2.1	3.2
Distribution system ^A	2/18/2016	490	10	ND	3.9
Distribution system ^A	2/18/2016	490	11	1.8	3.3
Distribution system ^A	2/18/2016	440	11	2.2	3.5

Sampling Data for the Hoosick Falls Public Water System from November 4, 2015, through December 18, 2016 (All samples are in ng/L)

^AThe locations of the distribution systems are not specified to maintain privacy.

PFOA = perfluorooctanoic acid; PFOS = perfluorooctane sulfonate; PFHpA = perfluoroheptanoic acid; PFBS = perfluorobutane sulfonate; NA =not analyzed; ND = not detected; ng/l = nanograms per liter

Appendix C: Blood Testing Results

Table 1

PFOA Blood Test Results¹ for Adults and Children Served by

Village of Hoosick Falls Public Water Compared with Results for General U.S. Population²

	Village of	Village of Hoosick Falls	General U.S.	General U.S.
	HOUSICK Fails	HOUSICK Fails	Population	Population
Population	Number of	Geometric Mean ³	Number of	Geometric
	Participants	PFOA Serum	Participants	Mean ³ PFOA
		Level (mcg/L)		Serum Level
				(mcg/L)
People Aged 12 Years and Over				
All Participants	1442	46.1	2165	1.94
People Aged 12 Years and Over by Gender				
Females	792	42.7	1134	1.66
Males	650	50.6	1031	2.29
People Aged 12 Years and Over by Age Group				
Age 12 to 19 Years	165	25.5	401	1.66
Age 20 Years and Over	1277	49.8	1764	1.98
People Aged 12 Years and Over by Gender and Age Group				
Females				
Age 12 to 19 Years	91	23.8	NA	NA
Age 20 Years and Over	701	46.1	NA	NA
Males				
Age 12 to 19 Years	74	27.7	NA	NA
Age 20 Years and Over	576	54.7	NA	NA
Children Aged 3 to 11 Years				
All Participants	172	26.6	639	1.92
Children Aged 3 to 11 Years by Gender				
Females	84	26.9	296	1.90
Males	88	26.3	343	1.95
Children Aged 3 to 11 Years by Age Group				
Age 3 to 5 Years	52	27.2	181	2.00
Age 6 to 11 Years	120	26.4	458	1.89
Children Aged 3 to 11 Years by Gender and Age Group				
Females				
Age 3 to 5 Years	19	22.9	NA	NA
Age 6 to 11 Years	65	28.2	NA	NA
Males				
Age 3 to 5 Years	33	30.0	NA	NA
Age 6 to 11 Years	55	24.3	NA	NA
	•			

¹Samples taken from February to November 2016.

²Center for Disease Control and Prevention. 2018. National Report on Human Exposure to Environmental Chemicals (Updated Tables, March 2018) [accessed 2018 April 5] Available at <u>https://www.cdc.gov/exposurereport/index.html</u>. Survey Years 2013-2014.

³Geometric means are a way of calculating the middle level. They are used in science to prevent the highest and lowest values from distorting the average when the rest of the data are close together.

PFOA = perfluorooctanoic acid; mcg/L = micrograms per liter; NA = not available

Appendix D: Health Effects of Chemicals Selected for Further Evaluation

All chemicals can cause health effects. The risk for adverse health effects from any chemical depends on

- the chemical's toxicity,
- the amount of the chemical to which a person is exposed, and
- how long and how often the exposure occurs.

The risks also depend on the characteristics of the exposed person, such as age, sex, diet, family traits, lifestyle, genetic background, the presence of other chemicals in their body (e.g., alcohol, prescription drugs), and general state of health.

Below is some general information about the kinds of health effects that are associated with exposure to perfluorooctanoic acid (PFOA). PFOA was selected for further evaluation in this health consultation. Many of the health effects described below occur at exposure levels much higher than those resulting from the contamination of the public water system.

Perfluorooctanoic Acid (PFOA)

PFOA belongs to a group of manufactured chemicals called per- and polyfluoroalkyl substances (PFAS). PFOA was once widely used to make nonstick cookware. It had many other uses, including being used in surface coatings for stain-resistant carpets and fabric and in paper and cardboard food packaging such as microwave popcorn bags and fast-food containers. PFOA has also been used in fire-fighting foam and in many other products for the aerospace, automotive, building/construction, and electronics industries.

Animal Studies

The primary noncancer effects observed in laboratory animals exposed to high levels of PFOA include organ effects (increased liver weight and cell damage, increased kidney weight), developmental effects (reduced body weight of offspring, delayed bone development, accelerated puberty), and immune system effects (reduced immune response when exposed to infectious agents) [DeWitt et al. 2008; Lam et al. 2014; Lau et al. 2006; Koustas et al. 2014; Perkins et al. 2004; White et al. 2009; Wolf et al. 2007].

Male rats who were fed large amounts of PFOA in their food over their lifetimes developed cancers of the liver, pancreas, and testis [Butenhoff et al. 2012; USEPA, 2016e; NTP 2020]. Another lifetime study where male and female rats were exposed to PFOA at lower doses did not find evidence of PFOA causing cancer [Biegel et al. 2001; USEPA, 2016e]. PFOA has not been tested for its cancer-causing potential in mice or any other animal species.

Human Studies

Currently, human studies on the health effects of PFOA show associations between increased exposures to PFOA, as measured by levels in blood, and an increased risk for several health effects [ATSDR 2021a; USEPA 2016e].

Some of the effects associated with PFOA exposure were identified through a study of Ohio and West Virginia residents. The residents lived near or worked in a PFOA manufacturing plant in the Ohio River Valley [Frisbee et al. 2009] and consumed water contaminated with PFOA. The study enrolled 69,030 people. PFOA serum data and clinical laboratory data were collected for over 65,000 of them. Numerous studies on various health effects have been conducted for this population. These studies, often called the C8 studies, were reviewed by three epidemiologists, known as the C8 Science Panel, which was created as part of a legal settlement process. The panel was asked to make determinations about the existence of "probable links" between PFOA exposures and specific health effects in the Mid-Ohio Valley population. The term "probable link⁸" was required by the legal process and is not a scientific or medical term usually used by epidemiologists. Stating that a probable link exists does not mean they identified a cause-and-effect relationship between PFOA and the health outcome, but rather that associations between PFOA and health effects were shown.

Based on the C8 studies [Barry et al. 2013; Darrow et al. 2013; Fitz-Simon et al. 2013; Frisbee et al. 2009, 2010; Lopez-Espinosa et al. 2012; Savitz et al. 2012a, 2012b; Steenland et al. 2009, 2013; Steenland, Woskie 2012; Stein et al. 2009; Vieira et al. 2013; Winquist, Steenland 2014a, 2014b] and other information, the C8 Panel concluded that there was a "probable link" between PFOA exposures and the following health effects

- high cholesterol levels,
- thyroid disease,
- ulcerative colitis (autoimmune disease),
- pre-eclampsia (a complication of pregnancy that includes high blood pressure), and
- kidney and testicular cancer [C8 Science Panel 2012].

More recently, the ATSDR identified health effects in adults that are consistently associated with PFOA exposures [ATSDR 2021a]. These were

 increased serum uric acid levels, which may be associated with an increased risk of high blood pressure,

⁸ A "probable link" was defined as part of a legal settlement process as meaning that, given the available scientific evidence, it is more likely than not that a connection exists between PFOA exposure and a particular human disease for people living in the exposed West Virginia and Ohio communities, the population involved in the class action lawsuit (see http://www.c8sciencepanel.org/prob_link.html). Three epidemiologists comprised the panel that made these determinations. Criteria used to evaluate the evidence for a probable link included the strength and consistency of reported associations, evidence of a dose-response relationship, the potential for associations to occur as a result of chance or bias, and plausibility based on experiments in laboratory animals.

- increased serum cholesterol levels, and
- alterations in biomarkers of liver damage (that is, increased serum liver enzyme levels).

The C8 studies concluded there were **not** "probable links" between PFOA exposure and the following conditions

- liver disease,
- diabetes,
- chronic kidney disease,
- high blood pressure, and
- coronary artery disease [C8 Science Panel 2012].

The C8 studies also concluded there were **not** "probable links" with the following autoimmune diseases

- rheumatoid arthritis,
- lupus,
- type 1 diabetes,
- Crohn's disease, and
- multiple sclerosis.

In assessing the negative findings, it should be noted that the power of the C8 studies to provide evidence that would support a positive finding (that is, a "probable link") was limited by several factors. For a particular health endpoint, these could include small numbers of cases, low ranges of exposure levels, exposure misclassification, lack of validation of self-reported data, limited toxicological data in animal or humans, short durations of exposure, and short durations of observation. The C8 studies that were used to determine the "probable link" were completed in 2012.

Studies published after 2012, by researchers in the United States and other countries, have contributed information on the potential health effects of PFOA. Based on information from subsequent studies, liver effects are considered to be consistently associated with PFOA exposure [ATSDR 2021a]. A report by the National Toxicology Program [NTP 2016] concluded that "there is moderate confidence that exposure to PFOA is associated with suppression of the antibody response in humans based on the available studies." It is expected that the body of evidence about PFOA and human health effects will continue to grow and evolve over time.

Data on the effects of PFOA in children are mixed. Some studies show no association between increased blood PFOA levels and increased risk of stillbirths, premature birth, or birth defects [Nolan et al. 2009, 2010; Stein et al. 2009]. Other studies show an association between increased PFOA blood levels and increased risks for several health effects in children including effects on birth weight, immune function, and cholesterol levels [Fei et al. 2007, 2008; Frisbee et al. 2010; Grandjean et al. 2012; Johnson et al. 2014; Lopez-Espinosa et al. 2011].

The C8 studies concluded that there were <u>not</u> "probable links" between PFOA exposures and any of the following outcomes

- miscarriage and stillbirths,
- preterm birth and low birthweight,
- birth defects, and
- neurodevelopmental disorders in children, including attention deficit disorders and learning disabilities [C8 Science Panel 2012].

These negative findings for the effects of early life exposures share the same limitations as the negative findings for adults. The currently available data on the relationship between early life PFOA exposures and adult effects later in life are relatively limited [Halldorsson et al. 2012; Kristensen et al. 2013; Vested et al. 2013; Strom et al. 2014].

There are currently hundreds of studies on PFOA and humans, and diverse health effects have been studied. To date, overall study findings are difficult to interpret because results for some health outcomes are not consistent among studies [ATSDR 2021a]. For one group of effects, several studies provide evidence of an association between PFOA exposure and a health endpoint (for example, effects on the liver). For another group of effects, some studies found associations between increased PFOA exposure and health effects, while other studies did not (for example, certain types of cancer). Overall, the results of currently available human studies provide varying levels of support for the effects of PFOA exposure shown in animal studies.

Appendix E: Hazard Quotient and Margin of Exposure Example Calculations for PFOA in the Village of Hoosick Falls Public Water System

- 1. Calculation of Chronic Noncancer Ingestion Exposures: Exposure dose, hazard quotient, and margin of exposure
- A. Noncancer Ingestion Exposure Dose:

 $\mathsf{D} = \mathsf{C} x \mathsf{IR} x \mathsf{CV}$

D = exposure dose (mcg/kg/day)
C = contaminant concentration in drinking water (ng/L)
IR = age-specific water ingestion rate (L/kg/day)
CV = units conversion factor (1 mcg/1000 ng)

B. Hazard Quotient (HQ):

$$HQ = \frac{D}{MRL}$$

D = exposure dose (mcg/kg/day) MRL = Minimal risk level (mcg/kg/day)

C. Margin of Exposure (MOE):

 $MOE = \frac{Effect \ Level}{Estimated \ Ingestion \ Exposure \ Dose}$

Village of Hoosick Falls Public Water Supply Calculation of Noncancer PFOA Hazard Quotients

Highest Concentration = 983 ng/L

		Reasonable	Central							
		Maximum	Tendency							
		Exposure	Exposure							
		Drinking	Drinking	Reasonable	Central		Reasonable	Central	Reasonable	Central
		Water	Water	Maximum	Tendency		Maximum	Tendency	Maximum	Tendency
	Water	Consumption	Consumption	Exposure	Exposure	Minimal	Exposure	Exposure	Exposure	Exposure
	Concentration	Rate ¹	Rate ¹	Dose	Dose	Risk Level ²	Hazard	Hazard	Margin of	Margin of
Group	(mg/L)	(L/kg/day)	(L/kg/day)	(mg/kg/day)	(mg/kg/day)	(mg/kg/day)	Quotient ³	Quotient ³	Exposure ⁴	Exposure ⁴
0 to < 1	0.000983	0.1427	0.0646	1.40E-04	6.35E-05	3.0E-06	46.8	21.2	5.9	12.9
1 to < 2	0.000983	0.0783	0.0270	7.70E-05	2.66E-05	3.0E-06	25.7	8.9	10.7	30.9
2 to < 6	0.000983	0.0561	0.0216	5.52E-05	2.12E-05	3.0E-06	18.4	7.1	14.9	38.7
6 to < 11	0.000983	0.0442	0.0161	4.34E-05	1.58E-05	3.0E-06	14.5	5.3	18.9	52.0
11 to < 16	0.000983	0.0348	0.0112	3.42E-05	1.10E-05	3.0E-06	11.4	3.7	24.0	74.5
16 to < 21	0.000983	0.0341	0.0108	3.36E-05	1.06E-05	3.0E-06	11.2	3.5	24.5	77.7
<u>></u> 21	0.000983	0.0387	0.0153	3.80E-05	1.51E-05	3.0E-06	12.7	5.0	21.6	54.5
Pregnant						3 05 06				
Women	0.000983	0.0350	0.0120	3.44E-05	1.18E-05	3.0∟-00	11.5	3.9	23.9	69.6
Breastfeeding						3 0E 06				
Women	0.000983	0.0478	0.0222	4.70E-05	2.18E-05	5.02-00	15.7	7.3	17.5	37.6

¹Drinking water consumption rates are from the Exposure Factors Handbook [USEPA, 2011] and applied as recommended by ATSDR [ATSDR 2016]. ²Minimal Risk Level = 0.003 mcg/kg/day [ATSDR 2021a].

³Hazard quotient = exposure dose/minimal risk level.

⁴Margin of exposure = the difference between the exposure dose from drinking water and the exposure associated with health effects based off a human effect level from the lowest observable effect level (LOEL_{HED}) of 0.821 mcg/kg/day [ATSDR 2021a]

mg/L: milligrams per liter; L/kg-day: liters per kilogram per day; mg/kg/day: milligrams per kilogram per day