

REVISED REGULATORY IMPACT STATEMENT

Amendments to:

6 NYCRR Part 597

Hazardous Substances Identification, Release Prohibition, and Release Reporting

1. STATUTORY AUTHORITY

The State law authority that empowers the New York State Department of Environmental Conservation (Department) to create a list of hazardous substances is found in Title One of Article 37 of the Environmental Conservation Law (ECL), sections 37-0101 through 37-0111, entitled “Substances Hazardous to the Environment” (Article 37). The Department is authorized to adopt regulations to implement ECL provisions (ECL sections 3-0301(2)(a) and (m)). Moreover, section 37-0105 explicitly authorizes the Department to promulgate rules and regulations pertaining to the storage and prevention of releases of hazardous substances to the environment. Specifically, section 37-0103 directs the Department to create and maintain “a list of substances hazardous to the public health, safety or the environment,” including substances which, “because of their quantity, concentration, or physical, chemical or infectious characteristics cause physical injury or illness when improperly treated, stored, transported, disposed of, or otherwise managed” or “pose a present or potential hazard to the environment when improperly treated, stored, transported, disposed of, or otherwise managed.” The Department’s Article 37 list of hazardous substances and the rules and regulations pertaining to the prevention of releases are found at 6 NYCRR Part 597 (Part 597).

2. LEGISLATIVE OBJECTIVES

The legislative objectives underlying the above-referenced statutory authority are directed toward establishing a list of hazardous substances which pose a threat to public health or the environment. The legislative objectives of Article 37 include prevention of pollution, protection of natural resources such as

groundwater, and requiring safe storage and handling of hazardous substances in order to protect public health and the environment.

3. NEEDS AND BENEFITS

The purpose of this rule is to:

- Add perfluorooctanoic acid (PFOA-acid, Chemical Abstracts Service (CAS) No. 335-67-1), ammonium perfluorooctanoate (PFOA-salt, CAS No. 3825-26-1), perfluorooctane sulfonic acid (PFOS-acid, CAS No. 1763-23-1), and perfluorooctane sulfonate (PFOS-salt, CAS No. 2795-39-3) (also collectively referred to within as PFOA and PFOS) to the list of hazardous substances at 6 NYCRR Section 597.3 (Section 597.3);
- Allow continued use of firefighting foam that may contain PFOA or PFOS to fight fires (but not for training or any other purposes) on or before April 25, 2017 even if such use may result in the release of a reportable quantity (RQ), which is otherwise prohibited; and
- Correct the list of hazardous substances by providing units for RQs.

Need for and Benefit of Adding PFOA and PFOS to the List of Hazardous Substances

The Department concluded that these substances meet the definition of hazardous substances based upon the conclusion of New York State Department of Health (NYSDOH) that prolonged exposure to significantly elevated levels of these compounds can affect health and, consequently, pose a threat to public health in the State when improperly treated, stored, transported, disposed of, or otherwise managed. The Department also concluded that these substances meet the definition of hazardous substances based upon a Department ecotoxicologist's identification of these compounds as potential hazards to the environment. Proper management of these compounds is needed to protect public health and the environment, for reasons described below. These reasons are detailed further in NYSDOH's April 11, 2016 Health Hazard Review and two

October 7, 2016 Evaluations of Environmental Risk, all of which are attached to this Regulatory Impact Statement.

There is substantial concern across the globe regarding the toxicity of PFOA and PFOS. The United States Environmental Protection Agency (USEPA), the United States Agency for Toxic Substances and Disease Registry, Health Canada, the European Food Safety Authority, the European Chemical Agency, and the States of New Jersey, Minnesota, Michigan, and Maine have all conducted comprehensive evaluations of the human health effects of one or both of these chemicals. These evaluations show statistical associations between PFOA and PFOS exposure and an increased risk for adverse health effects in humans. The degree of increased risk depends on the route, frequency, duration, and degree of exposure.

As documented in NYSDOH's April 11, 2016 Health Hazard Review, appended to NYSDOH's April 20, 2016 letter requesting the Department's listing of PFOA and PFOS as hazardous substances and attached to this Regulatory Impact Statement, the combined weight of evidence from human and experimental animal studies indicates that prolonged exposure to significantly elevated levels of these compounds can adversely affect health and, consequently, pose a threat to the public. In addition, as documented by Department ecotoxicologist Timothy J. Sinnott in two Evaluations of Environmental Risk, attached to this Regulatory Impact Statement, each of these four compounds (PFOA-acid, PFOA-salt, PFOS-acid, and PFOS-salt) poses a potential hazard to the environment.

PFOA-acid and PFOA-salt (also known as C-8) are environmentally persistent chemicals that do not break down in the environment or in the human body and can be present in the blood for years after exposure. Human studies show associations between increased PFOA-acid and PFOA-salt exposure and increased risks for a number of health effects, including impacts on the liver, kidneys, immune system, thyroid gland, and cholesterol levels. Exposure to PFOA-acid and PFOA-salt is also associated with elevated blood pressure (including during pregnancy), high serum uric acid levels, kidney cancer, testicular cancer, ulcerative colitis,

and thyroid effects. Animal studies show that PFOA-acid and PFOA-salt exposure in animals caused cancer of the liver, pancreas, and testis, and caused liver toxicity, kidney toxicity, birth defects, delayed development, and immune system toxicity. Increased incidences in animals of testicular interstitial cell tumors, mammary fibroadenomas, liver adenomas, and pancreatic acinar cell tumors were identified. Developmental and hormonal impacts and reduced survival of female fish and offspring have also been observed.

PFOS-acid and PFOS-salt are environmentally persistent chemicals that are bioaccumulative and toxic to mammalian species and that bioconcentrate in aquatic organisms. Human studies show associations between increased exposure and increased risk for adverse effects in humans, including increases in cholesterol, tryglycerides, and uric acid in the general population, and increases in the risk for low birth weight babies. Animal studies show that PFOS-acid and PFOS-salt exposure causes liver and thyroid cancer in rats, and caused adverse effects on the liver, immune system, cholesterol levels, and the developing nervous system, and reduced the survival rate in offspring born to rats. Exposures also caused an increased incidence of hepatocellular adenoma/carcinoma, and thyroid tumors. The offspring of fish exposed to PFOS showed significantly lower survival when exposed to the same or lower concentrations of PFOS in water than what the parents had been exposed to.

All four substances have been widely used by industry, including as a component of firefighting foam, stain resistant carpet, semiconductor coatings, and many other uses. In addition, the four substances have been detected in a number of U.S. cities in surface water and sediments. In their ionic forms, PFOA-acid and PFOS-salt are water soluble and can migrate readily from soil to groundwater, where they can be transported long distances (see “Emerging Contaminants-Perfluorooctane Sulfonate (PFOS-salt) and Perfluorooctanoic Acid (PFOA-acid)”, USEPA document EPA 505-F-14-001, March 2014).

There are at least three benefits of listing PFOA and PFOS as hazardous substances in Part 597. First, if a mixture containing PFOA or PFOS in concentrations of 1% or more is stored in an aboveground tank of

185 gallons or more or any size underground tank, the tank would be subject to the requirements of the Chemical Bulk Storage (CBS) regulations (6 NYCRR Parts 596 – 599). Among the goals of the CBS program are the prevention of and response to leaks and spills in order to protect public health and the environment. CBS facilities are periodically inspected by the Department for compliance with regulatory requirements. Second, this rule prohibits releases to the environment of an RQ of PFOA or PFOS, subject to the limited exceptions of 6 NYCRR 597.4(a). Any release of a listed hazardous substance at or above the RQ set forth in Part 597 (one pound for PFOA or PFOS) must be reported to the Department’s spill hotline (6 NYCRR 597.4(b)) to enable the Department to assess whether remediation of the release is appropriate. Third, if PFOA or PFOS is released into the environment, creating contamination that represents a significant threat to public health or the environment, resulting in the need for site cleanup, the Department is authorized to pursue clean-up of the contamination under one of the Department’s remedial programs (6 NYCRR Part 375 (Part 375)) and may expend funds under the State Superfund Program if a responsible party is unwilling or unable to undertake remediation. All of these benefits enhance protection of public health and the environment.

Need for and Benefit of Allowing Limited Continued Use of PFOA and PFOS in Firefighting

The release prohibition includes an exception allowing entities storing firefighting foam to use the foam to fight fires, but not for training or other purposes, on or before April 25, 2017 while they determine if the foam contains PFOA or PFOS. This exception is necessary in order to ensure the availability of materials to control fires effectively to benefit public safety. As discussed below, USEPA has taken some action to reduce the use of PFOA and PFOS. Nevertheless, many existing supplies of firefighting foam may contain PFOA and PFOS. Foams that may contain PFOA and PFOS include many Class B foams, some of which have a reported shelf life of up to 25 years.

Need for and Benefit of Correction of the List of Hazardous Substances

A correction is being made to the tables listing hazardous substances. After the 2015 rule making pertaining to 6 NYCRR Parts 596-599, it was determined that the units for RQs were inadvertently left out of the table causing some uncertainty regarding when a release would need to be reported. This rule adds units back to the column heading of the table so that it is clear that RQs are measured in pounds.

4. COSTS

Costs to Regulated Parties

Although PFOS-containing substances are reportedly no longer manufactured in the United States, USEPA's significant new use rules (SNUR) under the Toxic Substances Control Act (TSCA) allow for the continuation of a few limited, highly technical applications of PFOS-related substances where no known alternatives are available. Specifically, USEPA allows the use of PFOS-related substances in the photographic/imaging industry, semiconductor industry and the aviation industry. PFOS-related substances are also allowed to be used as intermediates to produce other chemical substances. As part of USEPA's PFOA-related substances stewardship program, eight manufacturers committed to phasing out the use and production of PFOA-related substances. The first commitment was to accomplish a 95% reduction (in comparison to 2000 levels) of (1) all PFOA-related substance emissions to the environment, (2) the use of precursor chemicals that break down into PFOA-related substances, and (3) the levels of PFOA-related substances in products. The second commitment was to phase out the production of PFOA-related substances by the end of 2015. Since production and importation of PFOA- and PFOS-related substances have been restricted, alternative substances have been developed to take the place of these hazardous substances for most uses. Although the production of PFOA and PFOS has been largely phased out, these substances have not been completely eliminated from the marketplace. PFOA- and PFOS-related substances continue to be stored and used in the State.

Costs Relating Primarily to Storage

The initial costs of complying with this rule are twofold: determining whether products containing PFOA or PFOS at concentrations of 1 percent or more are stored at each facility, and registering each facility with one or more regulated storage tanks that store these hazardous substances. Information regarding the presence and concentration of PFOA or PFOS in particular substances may be available free of charge through Safety Data Sheets prepared by chemical manufacturers, distributors, and importers or access to results of analysis undertaken by business consortiums or others. In the event laboratory analysis is necessary, the Department's experience is that the cost to analyze a sample to determine the presence and concentration of PFOA or PFOS is expected to be in the several hundred dollar range. Registration fees, set forth at 6 NYCRR Section 596.3(a), are determined by the number of regulated tanks and the capacity of each tank. The fees range from \$50 per tank for tanks with capacities less than 550 gallons to \$125 per tank for tanks with capacities greater than 1,100 gallons. Under 6 NYCRR Section 596.2(c), these registration costs recur every two years for as long as the entity continues to store hazardous substances listed in Section 597.3.

Non-registration storage-related costs of initial and continued compliance are expected to vary primarily based on quantity of hazardous substances stored at each facility. If a facility discontinues storage by April 25, 2018, when the storage and handling standards go into effect, there will be no regulatory costs associated with storage of these substances beyond the payment of the initial registration fee. If a facility continues to store these hazardous substances after April 25, 2018, costs associated with continued compliance will include costs of annual spill prevention reports and inspection of storage equipment every five years. The Department's experience with other CBS facilities suggests that these costs may range from hundreds to thousands of dollars. The Department is unable to provide a more complete estimate of costs because it is unknown how many facilities store these hazardous substances and costs will vary greatly by facility depending

on quantity of hazardous substances stored and whether professional services are utilized. The Department expects that costs will be reduced over time given the phase out of the manufacturing of the material and anticipated reductions in use.

Costs Relating Primarily to Release Prohibition

As noted above, USEPA previously restricted production and importation of PFOA- and PFOS-related substances. Alternative substances have been developed to take the place of these hazardous substances for most uses. Most of the PFOA- and PFOS-related substances that continue to be stored in the State are firefighting foams that were produced prior to 2016. Although not a cost of complying with this rule, some entities will likely incur costs to determine if stored foam contains one or more of these hazardous substances and/or to replace the foam if the use of the foam could result in the release of an RQ of a hazardous substance. The cost to replace firefighting foam, based on information gathered from firefighting foam suppliers, ranges from \$16 to \$32 per gallon; an entity's cost to replace firefighting foam depends on the amount and type of foam that is being replaced. For example, airports and major oil storage facilities have informed the Department that they may store 1,000 – 8,000 gallons of foam; hence, if their entire supply of foam needs to be replaced, their new foam could cost between \$16,000 and \$256,000. Utilities also may store significant supplies of firefighting foam. Since PFOA and PFOS have not been classified as hazardous wastes under the federal Resource Conservation and Recovery Act, older foams may be disposed of as a solid waste after solidifying the firefighting foam (i.e., mix with concrete) as follows:

- Individuals and institutions may dispose of the solidified foam in a permitted landfill.
- Generators of industrial wastes (e.g., factories and major oil storage facilities) must have a specific Department authorization to dispose of solidified foam in a permitted landfill and must contact the Department's Division of Materials Management prior to disposal.

Avoiding releases is not expected to present significant compliance costs because normal operations should not include releases of reportable quantities of hazardous substances. Costs of reporting any releases of an RQ of a hazardous substance, which are costs associated with noncompliance with the release prohibition, include the cost of determining whether a release of a reportable quantity of a hazardous substance has occurred (based on quantity released x known concentration) and the cost of notifying the Department of the release by calling the Spill Hotline. The costs are expected to be insignificant. Other costs associated with releases are discussed below under Costs Relating to Remediation.

Costs Relating to Remediation

Remediation costs are not costs of complying with this rule. However, as noted above, where PFOA or PFOS has been released into the environment, regulated entities may be subject to costs associated with remediation of these hazardous substances under Part 375. The costs of implementing a remedial program where PFOA or PFOS is a primary contaminant will vary widely as the costs depend upon many factors. These factors include the quantity released to the environment, the media contaminated (e.g., soil, groundwater, surface water, sediment, bedrock), the horizontal and vertical extent of contamination in each medium, the accessibility of the contamination, whether there are human or environmental receptors that must be protected while a remedial program is being undertaken, the difficulty of removing PFOA or PFOS from the contaminated environmental media, the future anticipated use of the area of contamination, and other factors. Because of the wide variety of scenarios, it is not possible to meaningfully estimate costs of remediation other than to note that remedial program costs for other hazardous substances have ranged from the thousands to millions of dollars on a case-by-case basis.

Costs to the Department, State, and Local Government

To the extent that government entities are regulated parties, these entities may be subject to the Costs to Regulated Parties, discussed above. Aside from potential costs as regulated parties, government entities, other

than the Department, are not expected to incur costs associated with implementation or continued administration of this rule. The Department will incur costs for implementation and administration of this rule. Government entities may choose to incur costs associated with public outreach and awareness. The Department also provides public outreach as discussed in the Rural Area Flexibility Analysis (RAFA) and Regulatory Flexibility Analysis for Small Businesses and Local Governments (RFASBLG).

Department Costs for Implementation and Continued Administration

The Department's CBS program was established in 1988; thus, the costs of implementing the CBS program were incurred prior to this rule making. Prior to this rule making, the CBS program regulated more than one thousand hazardous substances. Because this rule making adds only four substances to the list of hazardous substances regulated by the CBS program, this rule is not expected to create significant new costs associated with implementation or continued administration of the CBS program. Any costs associated with continued administration of the CBS program due to the addition of these four hazardous substances to the list will be at least partially offset through the registration fees discussed above under Costs Relating Primarily to Storage. The Department is unable to provide a more complete estimate of costs because the number of facilities that may enter and remain in the CBS program as a result of this rule is unknown.

Costs of responding to releases of PFOA and PFOS, including costs of determining whether remediation is required and costs of overseeing and/or conducting any required remediation of these hazardous substances, may be significant. The Department's release-related costs include costs of staff time and, in cases where a responsible party is unwilling or unable to undertake remediation, costs of the remediation itself (subject to efforts to recover the costs from responsible parties). As discussed above under Costs Relating to Remediation, it is not possible to meaningfully estimate costs of remediation other than to note that remedial program costs for other hazardous substances have ranged from the thousands to millions of dollars on a case-by-case basis.

5. LOCAL GOVERNMENT MANDATES

No county, city, town, village, school district, fire district, or other special district or local government is required to institute any program, service, duty, or responsibility as a result of this rule, except as a regulated party (to the extent applicable). This is not a local government mandate.

6. PAPERWORK

This rule contains no substantive changes to existing reporting and record keeping requirements. Existing reporting and record keeping requirements include: registration forms, spill prevention reports, reporting of releases above an RQ or other standard, and record keeping for inspection of storage equipment.

7. DUPLICATION

Under TSCA, USEPA completed a Significant New Use Rule (SNUR) to limit the production and importation of PFOS-related substances in 2002. USEPA worked with industry to voluntarily phase out the use of PFOA-related substances by December 2015, and proposed a SNUR to limit production and importation of PFOA-related substances in anticipation of the phase-out deadline (80 FR 2885; January 21, 2015).

Additionally, under the Safe Drinking Water Act (SDWA), the federal government requires that entities supplying drinking water to 10,000 people or more test their drinking water supplies for PFOA, PFOS, and other substances.

The listing of PFOA-acid, PFOA-salt, PFOS-acid, and PFOS-salt as hazardous substances in Part 597 causes no duplication, overlap, or conflict with the above-mentioned provisions of TSCA and SDWA or any other state or federal government programs or rules.

8. ALTERNATIVES

The only alternative to listing PFOA-acid, PFOA-salt, PFOS-acid, and PFOS-salt as hazardous substances considered by the Department, the no action alternative, was not taken. The Department declined to take no action because, as determined by NYSDOH and the Department, the combined weight of evidence from human and experimental animal studies indicates that prolonged exposure to significantly elevated levels of these compounds can affect health and, consequently, pose a threat to public health in the State when improperly treated, stored, transported, disposed of, or otherwise managed, and because each of these substances poses a potential hazard to the environment when improperly treated, stored, transported, disposed of, or otherwise managed.

9. FEDERAL STANDARDS

Listing PFOA-acid, PFOA-salt, PFOS-acid, and PFOS-salt as hazardous substances exceeds the current federal approach, as USEPA has not listed PFOA-acid, PFOA-salt, PFOS-acid, or PFOS-salt as hazardous substances under the federal Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. Section 9601, *et seq.*, or under the applicable regulation, 40 CFR Part 302 (“Designation, Reportable Quantities, and Notification”).

10. COMPLIANCE SCHEDULE

Registration

A facility that stores PFOA or PFOS that is subject to the CBS registration requirements is required to submit its registration application to the Department and pay the commensurate fee when it becomes subject to regulation. The registration requirements became effective on April 25, 2016. The Department issues a registration certificate to each registered facility; the registration certificate must be displayed in a conspicuous

location at the facility. The Department estimates that it should take approximately one hour of effort for an applicant to complete the registration application and approximately one week after submission of the registration application for the applicant to receive the registration certificate from the Department.

Handling and Storage Requirements

Facilities with existing storage are not required to comply with the handling and storage requirements for hazardous substances until April 25, 2018 (6 NYCRR 598.1(h)). The Department expects that facilities that currently store PFOA or PFOS will phase out storage of the substance prior to April 25, 2018, and, therefore, will not have significant CBS compliance requirements beyond the registration requirements. For those facilities that continue to store PFOA or PFOS, adequate preparatory time has been provided to achieve compliance with the storage and handling requirements, which may take up to several months depending on the quantity of hazardous substances stored and storage equipment used.

Release Prohibition

Part 597 prohibits the release of an RQ of a hazardous substance to the environment unless a release is authorized or is continuous and stable and reported to the Department (6 NYCRR 597.4(a)). As noted above, the release prohibition includes an exception allowing entities storing firefighting foam to use the foam to fight fires, but not for training or other purposes, on or before April 25, 2017 to allow time to determine if the foam contains PFOA or PFOS. The Department estimates that it may take up to one month or longer to determine whether foam contains PFOA or PFOS, depending upon laboratory availability. The Department has not authorized and is not aware of any continuing releases of PFOA or PFOS.



Department of Health

ANDREW M. CUOMO
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Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

April 20, 2016

Honorable Basil Seggos
Acting Commissioner
NYS Department of Environmental Conservation
625 Broadway
Albany, New York 12233

Dear Acting Commissioner Seggos:

The New York State Department of Health (Department) requests that the New York State Department of Environmental Conservation (DEC) list perfluorooctanoic acid (PFOA, including the free-acid form, Chemical Abstract Services (CAS) Registry number 335-67-1 and the ammonium salt form, CAS Registry number 3825-26-1) and perfluorooctane sulphonic acid (PFOS, including the free-acid form, CAS Registry number 1763-23-1, and the potassium salt form, CAS Registry number 2795-39-3) as hazardous substances, pursuant to 6 NYCRR Part 597. The Department has evaluated evidence for human health effects of these compounds. DEC proposes to issue an Emergency Rule and Proposed Rule Amendments to 6 NYCRR Part 597 to list these four compounds as hazardous substances.

There is substantial concern across the globe regarding the human toxicity of PFOA and PFOS. The United States Environmental Protection Agency, the United States Agency for Toxic Substances and Disease Registry, Health Canada, the European Food Safety Authority, the European Chemical Agency, and the States of New Jersey, Minnesota, Michigan, and Maine have all conducted comprehensive evaluations of the human health effects of one or both of these chemicals. These evaluations show statistical associations between PFOA and PFOS exposure and an increased risk for several adverse health effects in humans. The degree of increased risk depends on the route, frequency, duration, and degree of exposure. As documented in the attached Health Hazard Review, prepared by the Department and dated April 11, 2016, the combined weight of evidence from human and experimental animal studies indicates that prolonged exposure to significantly elevated levels of these compounds can affect health and, consequently, pose a threat to public health in New York State when improperly treated, stored, transported, disposed of or otherwise managed.

For these reasons, the Department requests that DEC amend 6 NYCRR Part 597 to list both free-acid and salt forms of PFOA and PFOS as hazardous substances.

Sincerely,

Howard A. Zucker, M.D., J.D.
Commissioner of Health

Attachment

Health Hazard Review for PFOA and PFOS
April 11, 2016

Health Hazard Summary

Perfluorooctanoic Acid

Chemical Abstract Services Registry Number 335-67-1 (free acid), 3825-26-1 (ammonium salt)

Perfluorooctanoic acid (PFOA¹, C8, or perfluorooctanoate) is an environmentally persistent anthropogenic chemical that is primarily used as a reactive intermediate in the production of PFOA salts, which are used as processing aids in the production of fluoropolymers and fluoroelastomers (HSDB, 2014; US EPA, 2005a). PFOA is also used in fire-fighting foams, cosmetics, greases, lubricants, paints, polishes, and adhesives, which contribute to its release into the environment through various waste streams (HSDB, 2014). PFOA is released into the environment from fluoropolymer manufacturing or processing facilities, effluent releases from wastewater treatment plants, landfill leachates, and from degradation/transformation of PFOA precursors (EC/HC, 2012).

The toxicity of PFOA and its salts has been reviewed and summarized by authoritative bodies (ATSDR, 2009; EC/HC, 2012; MDH, 2008, 2009; NJ DEP, 2007; US EPA, 2005, 2006, 2014a). These summaries identify important studies on the health effects associated with exposure to PFOA and its salts, including studies on chronic, developmental, and reproductive effects observed in humans and animals.

PFOA does not readily break down in the environment, and therefore is extremely persistent. Furthermore, studies show that human exposure to PFOA is widespread and that most people have PFOA in their blood. Fetal exposure can occur via the placenta, and infants can be exposed via mother's breastmilk. PFOA does not break down in the human body and can be present in blood for years after exposure (US EPA 2014a).

Human studies show associations between increased PFOA exposure and an increased risk for several health effects. These include effects on the liver, immune system, thyroid gland, cholesterol levels, pre-eclampsia (a complication of pregnancy that includes high blood pressure), and kidney and testicular cancer. Exposure has also been associated with high serum uric acid levels, which may be associated with an increased risk of high blood pressure. Recent studies have reported positive associations between PFOA serum levels and chronic non-cancer effects (e.g., kidney effects, ulcerative colitis, thyroid effects, and pregnancy-induced hypertension) among workers and/or community residents in the Ohio River valley (Darrow et al., 2013; Steenland et al., 2012, 2013; Winqvist, Steenland, 2014). None of the studies provided any estimates of the daily intakes (doses) associated with the measured serum levels. Barry et al. (2013) reported positive associations between PFOA serum levels and kidney and testicular cancer among the general population of communities within the Ohio River Valley, but did not provide any estimates of the daily intakes (doses) associated with the measured serum levels. Overall, human PFOA studies show statistical associations between measures of PFOA exposure and various health outcomes. However, these study results do not support causal inferences because of study limitations such as lack of control for other competing exposures and conflicting statistical results among different study populations.

¹ This document uses PFOA to refer to both the free acid (CAS # 335-67-1) and PFOA salts. The most common commercially-produced form of PFOA is the ammonium salt (CAS # 3825-26-1).

Exposure to PFOA has also been shown to cause several adverse health effects in animals. PFOA caused cancer of the liver, pancreas, and testis in male rats exposed for their lifetimes. Non-cancer health effects caused by PFOA exposure in animals include liver toxicity, kidney toxicity, developmental toxicity (birth defects, delayed development), and immune system toxicity (ATSDR, 2009; 2015). In a two-year dietary study of Sprague-Dawley rats exposed to ammonium perfluorooctanoate (APFO), dose-related increased incidences of Leydig cell tumors (also called testicular interstitial cell tumors) in males and mammary fibroadenomas in females were observed (Sibinski, 1987, cited in US EPA, 2005a). In a single-dose two-year dietary study, APFO induced Leydig cell tumors, liver adenomas, and pancreatic acinar cell tumors in male Sprague-Dawley rats (Biegel et al., 2001). The results of toxicology studies in experimental animals inform qualitative assessment of potential health effects from exposure. However, there are substantial differences in factors that could influence susceptibility to PFOA toxicity between laboratory animals and humans. Therefore, results of animal toxicity studies cannot be directly extrapolated to predict human health outcomes.

Short-term *in vitro* assays of PFOA or APFO in bacteria and mammalian cells and *in vivo* studies of rats and mice showed mixed results, but overall, results indicate that PFOA compounds are not mutagenic (EC/HC, 2012). It has been hypothesized (e.g., US EPA, 2005, 2006) that PFOA induces liver tumors via a receptor based mode-of-action (MOA) involving peroxisome proliferator-activated receptors (PPAR)². In addition, PFOA induces a “tumor triad” (i.e., liver, Leydig cell tumors, and pancreatic acinar cell tumors), which is characteristic of PPAR-alpha agonists³ (US EPA, 2005). However, in its review of the U.S. Environmental Protection Agency’s (US EPA) “*Draft Risk Assessment of Potential Human Health Effects Associated with Perfluorooctanoic Acid (PFOA) and Its Salts*” (US EPA, 2005), the majority of the Scientific Advisory Board (SAB) expert panel concluded that there is insufficient evidence to support a conclusion that PPAR-alpha is the sole MOA for liver tumors⁴ or to determine the carcinogenic MOA for Leydig cell tumors, pancreatic acinar cell tumors, and mammary gland tumors (US EPA, 2006).

² PPAR-alpha is one of the three members, along with PPAR-delta and PPAR-gamma,, are part of the subfamily of PPARs.

³ An agonist is a chemical that binds to some receptor of a cell and triggers a response by that cell. Agonists often mimic the action of a naturally occurring substance.

⁴ A recent study (Filgo et al. 2014) showed that PFOA developmental exposure induced liver lesions, including adenoma, in two strains of mice lacking the PPAR-alpha receptor. This evidence liver toxicity in PPAR-alpha knockout mice warrants further investigation into PPAR-alpha independent toxicological pathways.

Health Hazard Summary

Perfluorooctane Sulfonic Acid

Chemical Abstract Services Registry Number 1763-23-1 (free acid), 2795-39-3 (potassium salt)

Perfluorooctane sulfonic acid (perfluorooctane sulfonate, PFOS⁵) is an environmentally persistent anthropogenic chemical that is no longer manufactured in the U.S., but can be imported and used for specific limited uses. Past uses of PFOS were similar to PFOA, including in fire-fighting foams, as an intermediate in chemical synthesis, and in surfactant applications. It is chemically and biologically stable in the environment, and can be found in air, soil, groundwater, and food. PFOS is also persistent, bioaccumulative, and toxic to mammalian species (ATSDR, 2009; OECD, 2002). PFOS is released into the environment from fluoropolymer manufacturing or processing facilities, effluent releases from wastewater treatment plants, landfill leachates and from degradation/transformation of PFOS precursors (HC, 2006).

The toxicity of PFOS has been reviewed and summarized by several authoritative bodies (ATSDR, 2009; EFSA, 2008; HC, 2006; OECD, 2002; US EPA, 2005, 2009, 2012, 2014b). These reviews identify important studies on the health effects associated with exposure to PFOS, including studies on chronic, developmental, and reproductive effects observed in humans and animals.

PFOS does not readily break down in the environment, and therefore is extremely persistent. Furthermore, studies show that human exposure to PFOS is widespread and that most people have PFOS in their blood. PFOS is the most dominant of all the perfluoroalkyl chemicals detected in human blood (Olsen et al, 2008). Fetal exposure to PFOS can occur via the placenta, and infants can be exposed via mother's breastmilk. PFOS does not break down in the human body and can be present in blood for years after exposure (US EPA, 2014b).

Human studies show associations between increased PFOS exposure and an increased risk for several health effects, including increases in total serum cholesterol, triglycerides, and uric acid in the general population. General population studies of effects on reproduction and development have shown increases in the risk for low birth weight. Epidemiological studies of workers or the general population have not provided convincing evidence of increased cancer risk from PFOS exposure (ATSDR, 2009; EFSA, 2008; US EPA, 2014b). The results of one study in occupationally exposed workers showed an association between PFOS exposure and increased incidence of bladder cancer; however, the results were considered inconclusive due to the limited size of the population (Alexander and Olsen, 2007; CA EPA, 2010; EFSA, 2008, OECD, 2002). Overall, human PFOS studies show statistical associations between measures of PFOS exposure and various health outcomes. However, these study results do not support causal inferences because of study limitations such as lack of control for other competing exposures and conflicting statistical results among different study populations.

PFOS exposure has also been shown to cause several adverse health effects in laboratory animals. PFOS caused liver and thyroid cancer in rats exposed for their lifetimes. PFOS also causes several non-cancer health effects in animals, including adverse effects on

⁵ This document uses PFOS to refer to both the free acid (CAS # 1763-23-1) and PFOS salts. The most common commercially-produced form of PFOS is the potassium salt (CAS # 2795-39-3).

the liver, immune system, cholesterol levels, and the developing nervous system, and reduces survival in offspring born to rats (ATSDR, 2009; 2015). In a two-year study (OECD, 2002),⁶ male and female rats were fed diets containing four different concentration of PFOS.⁷ A recovery group was fed diets containing the highest PFOS concentration in the main study group for 52 weeks and was observed until death. PFOS increased the incidence of hepatocellular adenoma/carcinoma in high-dosed male and female rats in the main study group, and increased the incidence of thyroid tumors in male rats in the recovery group. PFOS also increased the incidence of mammary tumors in female rats without a clear dose-response effect (Butenhoff et al., 2012; OECD, 2002). Based on the results of this study, several agencies consider PFOS to be carcinogenic in animals (EFSA, 2008; HC, 2006; OECD, 2002). The results of toxicology studies in experimental animals inform qualitative assessment of potential health effects from exposure. However, there are substantial differences in factors that could influence susceptibility to PFOS toxicity between laboratory animals and humans. Therefore, results of animal toxicity studies cannot be directly extrapolated to predict human health outcomes.

Most of the evidence from short-term *in vitro* assays suggest that PFOS is not active in short-term tests indicative of direct genotoxicity potential (EFSA, 2008; HC, 2006; OECD, 2002). However, a few recent studies have shown limited positive evidence of PFOS direct interaction with DNA, such as adduct formation in calf thymus DNA (Lu et al., 2012) as well as DNA damage (comet assay) and micronucleus formation in rat bone marrow (Celik et al., 2013).

Conclusions

Concern about the health effects of PFOA and PFOS in humans is not limited to the New York State Department of Health. There is a substantial concern across the globe regarding the human toxicity of these chemicals. The United State Environmental Protection Agency, the United States Agency for Toxic Substances and Disease Registry, Health Canada, the European Food Safety Authority, the European Chemical Agency, and the States of New Jersey, Minnesota, Michigan, and Maine have all conducted comprehensive evaluations of the human health effects of PFOA, PFOS, or both. The California Environmental Protection Agency has initiated the evaluation of PFOA and PFOS as developmental/reproductive toxicants under the state Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Proposition 65), and the National Toxicology Program of the United States Department of Health and Humans Services has initiated a review of the immunotoxicity of PFOA and PFOS. The International Agency for Research on Cancer has identified PFOA as possibly carcinogenic to humans.

In light of the public health concerns associated with PFOA and PFOS it is essential to list both as hazardous substances under 6 NYCRR Part 597, making both hazardous wastes pursuant to Environmental Conservation Law Section 27-1301, in order to enable the NYS Department of Environmental Conservation to expend funds from the Hazardous Waste Remedial Fund to clean up these contaminants where they pose a significant public health threat.

⁶ This study was conducted by the 3M Company in 2002 and was made publically available via a report by Thomford (2002) prior to publication in Butenhoff et al. (2012).

⁷ Dietary concentrations correspond to oral doses of 0, 0.024, 0.098, 0.242, and 0.984 mg/kg-day in males and 0, 0.029, 0.120, 0.299, and 1.25 mg/kg-day in females.

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Evaluation of Environmental Risk: PFOA
Ammonium Perfluorooctanoate (PFOA-salt) and Perfluorooctanoic Acid (PFOA-acid)

PFOA is an industrial chemical used in a variety of applications, including fire-fighting, cosmetics, greases and lubricants, paints, polishes and adhesives (HSDB 2012). After reviewing environmental toxicity and fate data, it is my assessment that PFOA poses a potential hazard to the environment.

PFOA can be formulated as an ammonium, sodium, potassium, or silver salt. However, PFOA is a strong acid, and when discharged to water with a pH of between 5 - 8, salt formulations will disassociate into the anionic (acid) form (Nielsen, 2012).

PFOA is extremely resistant to degradation, and can adsorb to aquatic sediment (HSDB, 2012). If released into water, PFOA will persist indefinitely, with no clear degradation pathway.

In the water, PFOA is not acutely toxic (i.e., lethal in a few days or less) to fish and aquatic invertebrates, unless present in very high concentrations of greater than 100 mg/L (parts per million, or PPM) or more. PFOA in the water is chronically toxic to fish and aquatic invertebrates at moderate concentrations of < 3-12 mg/L (PPM). Chronic toxicity means that when an organism is exposed to PFOA for a longer period of time, the organism's ability to survive, grow, or reproduce is likely to be harmed. At low concentrations in the water, that is, <1 mg/L (PPM), a trend of reduced female fish survival was observed, although the results were not statistically significant over the 28 day term of the experiment. Alterations in hormonal and developmental processes were observed in fish eggs and larvae exposed to 0.1 mg/L (PPM) PFOA for up to 49 days, although the consequence of those alterations were reserved for future study. Finally, the offspring of fish exposed to PFOA showed significantly lower survival when exposed to the same or lower concentrations of PFOA in the water than the parents had been exposed. For example, Medaka exposed to 0.1 mg/L (PPM) PFOA showed about 80% survival, but the offspring of those fish, when themselves were exposed to 0.1 mg/L (PPM) PFOA showed slightly less than 60% survival.

Based on aquatic acute toxicity data alone, PFOA might not appear to be a potential hazard to the environment. However, PFOA is chronically toxic. Because of its extreme resistance to environmental degradation, aquatic organisms could be exposed for considerable periods of time, up to and exceeding complete life cycles. This continuous persistence and potential for continuous lifetime exposure combined with the documented potential for developmental and hormonal impacts, and the observed reduced survival of female fish and offspring at low concentrations, together indicate that PFOA presents a real hazard to the environment. The following table is a synopsis of the most important chronic toxicity data that I reviewed in making this assessment.

Table 1. Synopsis of important chronic toxicity studies with PFOA

Species	Test	Results	Citation
<i>Daphnia magna</i>	21 day, chronic life cycle test	LOEC *= 12.5 mg/L NOEC** = 6.25 mg/L for days to first brood	Ji, et al. 2008
Daphnid <i>Moina macrocopa</i>	7 day chronic life cycle test	LOEC = 6.25 mg/L NOEC = 3.125 mg/L for number of young per adult and number of young per brood.	Ji, et al. 2008
Medaka <i>Oryzias latipes</i>	28 day Multigenerational exposure	Offspring of fish exposed to PFOA showed significantly lower survival when exposed to the same or lower concentrations of PFOA than what the adults had been exposed to.	Ji, et al. 2008
Medaka <i>Oryzias latipes</i>	Early Life Stage (ELS) 14 day test	LOEC = 0.1 mg/L Female survival reduced but was not statistically significant	Li, et al. 2009
Atlantic salmon (<i>Salmo salar</i>) eggs and larvae	49 day exposure to 0.1 mg/L PFOA to evaluate changes in endocrine signaling, growth, and development.	Alterations observed in all the investigated gene transcripts. decreases in weight observed after the observation period.	Sprachmo and Arukwe 2012

*LOEC means Lowest observed effects concentration, or the lowest concentration tested in which effects were observed.

**NOEC means No observed effects concentration, or the highest concentration tested in which effects were not observed.



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**Evaluation of Environmental Risk: PFOS
Perfluorooctane Sulfonate (PFOS-salt) and Perfluorooctane Sulfonic Acid (PFOS-acid)**

PFOS is an industrial chemical used in a variety of applications, including as a surfactant in fire fighting foam, surfactant for alkaline cleaners, emulsifier in floor polish, mist suppressant for metal plating baths, surfactant for etching acids for circuit boards, and a pesticide active ingredient for ant bait traps (HSDB 2012). After reviewing environmental toxicity and fate data, it is my assessment that PFOS poses a potential hazard to the environment.

As a product, PFOS is usually formulated as a lithium, potassium, ammonium, diethanolamine (DEA) or other organic salt (OECD 2002). However, PFOS is a strong acid, and when discharged to water with a neutral pH, salt formulations will disassociate into the anionic (acid) form (Beach, et al. 2006).

PFOS is persistent in the environment. It does not hydrolyze, photolyze or biodegrade under environmental conditions and is not expected to volatilize from water (OECD 2002). If released into water, PFOS will persist indefinitely, with no clear degradation pathway. PFOS will adsorb strongly to aquatic sediment (HSDB 2012). Although PFOS itself does not degrade, it appears to be the ultimate degradation product of other commercially used perfluorinated compounds (Beach, et al. 2006).

There is a plethora of data available regarding the toxicity of PFOS to aquatic organisms. The EPA ECOTOX database, when searched in September 2016, contained over 600 records of toxicity data for PFOS for over 25 species of aquatic animals and plants. Both short and long-term toxic effects were documented at concentrations of PFOS in water ranging from 0.0001 mg/L (parts per million or PPM) for genetic impacts to African clawed frogs to over 200 mg/L (PPM) for lethality to an aquatic snail (ECOTOX 2016).

One of the most useful compilations of toxicity data for PFOS is the Organization for Economic Co-operation and Development's (OECD) Hazard Assessment of Perfluorooctane Sulfonate; the development of which was led jointly by the US and UK (OECD 2002). This document provides detailed reviews of individual studies from both US and European sources, including proprietary studies submitted to the EPA for review.

OECD (2002) reports that PFOS is moderately acutely toxic (i.e., lethal from short term exposure) to aquatic organisms. The lowest LC₅₀¹ for PFOS in water to fish is a 96-hour LC₅₀ of 4.7 mg/l for the fathead minnow. For aquatic invertebrates, the lowest EC₅₀² for PFOS for

¹ The LC₅₀ is the concentration of a toxicant in water that is lethal to 50% of the exposed organisms

² An EC₅₀ is the concentration of a toxicant in water that causes a specific effect to 50% of the exposed organisms. In *Daphnia* studies, the toxic effect is immobilization, because it can be difficult to determine if the animals were killed or immobilized.

freshwater species is a 48-hour EC50 of 27 mg/l for the waterflea *Daphnia magna*. For saltwater species, the 96-hour LC50 value for PFOS was 3.6 mg/L (PPM) for the Mysid shrimp.

OECD (2002) also reported long-term, or chronic toxicity data for fish and aquatic invertebrates. The Lowest Observed Effects Concentration (LOEC)³ for fish exposed to PFOS was a 42 day LOEC for survival of 0.6 mg/L (PPM) in an early life stage test with fathead minnows. The lowest LOEC for PFOS with saltwater aquatic invertebrates is a 35-day LOEC of 0.55 mg/l for Mysid shrimp for growth and reproductive effects. Freshwater invertebrate species appear to be less sensitive. The 28-day EC50 for PFOS for *Daphnia* reproduction was 11.4 mg/L (PPM), and the NOEC³ for reproductive effects of PFOS was 7 mg/L (PPM).

The offspring of fish exposed to PFOS showed significantly lower survival when exposed to the same or lower concentrations of PFOS in the water than what the parents had been exposed to. For example, Medaka exposed to 0.1 mg/L (PPM) PFOS showed about 35% survival, but the offspring of those fish, when they themselves were also exposed to 0.1 mg/L (PPM) PFOS, showed about 10% survival.

PFOS has been shown to bioconcentrate in the tissues of fish (OECD 2002). In bluegill sunfish, the concentration of PFOS in fish tissue was between 1,100 and 4,000 times higher than the PFOS concentration in the surrounding water (bioconcentration factor, or BCF value). When fish were placed in clean water without PFOS, it disappeared slowly, with up to 116 days needed to reduce the PFOS concentration in fish by half (50%). In carp, BCF values were determined to be between 200 and 1500.

Table 1, below, summarizes the most important toxicity data that I reviewed for PFOS.

³ The Lowest Observed Effects Concentration (LOEC) is the lowest concentration of a toxicant tested in which a toxic effect was observed. The No Observed Effects Concentration (NOEC) is the highest concentration of a toxicant tested in which a toxic effect was observed.

Table 1. Summary of acute and chronic toxicity studies with PFOS

Species	Test	Results	Data source*
Acute toxicity – freshwater			
Fathead minnow	96 hour LC50	LC50 = 4.7 mg/L	EPA review of a study by 3M Company, Environmental Laboratory, St. Paul, MN, 3/25/94.
Waterflea (<i>Daphnia magna</i>)	48 hour EC50 for immobilization	EC50 = 27 mg/L	EPA review of a study by 3M Company, Environmental Laboratory, St. Paul, MN, 1984
Acute toxicity – saltwater			
Mysid shrimp	96 hour LC50	LC50 = 3.6 mg/L	EPA review of a study by Wildlife International Ltd., Easton, MD, 1999
Chronic toxicity – freshwater			
Fathead minnow	42 day Early Life Stage study	LOEC = 0.6 mg/L	EPA review of a study by Wildlife International Ltd., Easton, MD, 1999
Waterflea (<i>Daphnia magna</i>)	28 day life cycle study	EC50 = 11.4 mg/L NOEC = 7 mg/L	EPA review of a study by 3M Company, Environmental Laboratory, St. Paul, MN, 1984
Chronic toxicity – saltwater			
Mysid shrimp	35 day life cycle study	LOEC = 0.55 mg/L	EPA review of a study by Wildlife International Ltd., Easton, MD, 1999

*EPA summary reviews of original studies compiled in OECD 2002.



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