USEPA updated PFAS health advisories: What do you need to know?

On 15 June 2022, the US Environmental Protection Agency (USEPA) released updated or new drinking water Health Advisories (HAs) for four per- and polyfluoroalkyl substances (PFAS): perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorobutane sulfonic acid (PFBS) and its potassium salt, and hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (referred to as "GenX chemicals" or "GenX").

PFAS touches multiple types of companies, public entities and business sectors, and many are asking what the new HAs mean and what implications they may have.

This Client Alert provides a summary to address these and other questions clients are asking.

Highlights of the new HAs

HAs are non-enforceable, informational guidelines issued for certain chemicals that are not subject to National Primary Drinking Water Regulations. HAs are intended to correspond to levels of exposure at or below which human health effects are not anticipated.

According to USEPA, HAs provide information to help guide the operation of drinking water systems and for addressing emergency spills and other contamination situations.

However, the toxicity values used by USEPA to calculate HAs may also be cited in other circumstances, such as the evaluation of chemicals in consumer articles, the conduct of human health risk assessment, or litigation regarding potential human health effects.

Substantially more stringent HA levels

The interim updated HAs recently published by USEPA for PFOA and PFOS are substantially more stringent than the previous HA of 70 parts per trillion (ppt) for PFOA and PFOS combined, which was issued by USEPA in 2016. The interim updated HA for PFOA has been lowered to 4 parts per quadrillion (0.004 ppt) – a 17,500-fold reduction. The HA for PFOS was lowered to 20 parts per quadrillion (0.02 ppt) – a 3,500-fold reduction.

Levels so low they can't currently be measured reliably

The interim updated HAs for PFOA and PFOS are below current analytical detection limits, and also below some background concentrations reported for rainwater, surface water, and residential wastewater samples.

The interim updated HAs are so low that current USEPA-approved analytical methods are not able to reliably detect or measure PFOA or PFOS at or below these concentrations.

In addition, water treatment technologies to remove PFAS are not routinely designed or operated to reach the new PFOA and PFOS HAs. Validating compliance with such low levels is challenging when they cannot be reliably measured.

Final HAs issued for other PFAS for the first time

In addition to the interim updated HAs for PFOA and PFOS, for the first time USEPA also issued final HAs for two additional PFAS: PFBS and GenX. While these compounds have generally not been detected in the environment as frequently as PFOA and PFOS, it is likely that the existence of the HAs for PFBS and GenX will lead to expanded testing and possibly treatment for these PFAS in drinking water systems.

Ultimate takeaway from HAs

While HAs are non-enforceable and pertain directly only to drinking water, these new criteria demonstrate that USEPA is moving forward in implementing its PFAS Strategic Roadmap. They also indicate that USEPA will continue to expand beyond its initial focus on PFOA and PFOS to include not only PFBS and GenX, but potentially additional PFAS as well.

Implications of the updated HAs

On the following pages, Ramboll experts have provided some insights based on questions from clients in areas where PFAS can have significant and diverse implications.

We cover:

- Water
- Mergers & acquisitions, and transactions
- Site investigation and remediation
- Litigation
- Health impacts - toxicology
- Health impacts - epidemiology
- Product liability
- Natural resource damage
- Air

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Actions to consider:

1. Evaluate the potential for PFAS to impact your operations, sites, concerns, and third parties under current and anticipated near-term regulations.
2. Perform a comprehensive PFAS-based risk assessment for your situation, including operational, financial, business, and reputational risk.
3. Seek professional guidance on the breadth and depth of advisory services that may be required for your situation such as environmental, legal, financial, and risk communication.

For more specific advice relative to your situation, contact Ramboll:
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Water

Bill Meinert
Water Market Director

Is it likely that public water utilities in some jurisdictions will look to enhance treatment to attain the new HAs, even though USEPA has not established them as enforceable standards?

Probably not in the near term especially since attaining the new HAs cannot be achieved with current analytical techniques.

Many public water utilities have detected PFAS at concentrations exceeding the interim updated HAs for PFOA and PFOS, and nearly all public water systems will be required to analyze their water for a wide range of PFAS under the upcoming Unregulated Contaminant Monitoring Rule (UCMR) 5 program.

It is likely that new treatment technologies and analytical methods will need to be developed if USEPA develops significantly lower, enforceable maximum contaminant limits (MCLs) based on the HAs.

We expect that many water industry groups will advocate for a sound science approach and encourage USEPA to consider the practical aspects of treatability, waste management, and cost effectiveness in evaluating appropriate performance criteria for public water supplies utilizing established treatment technologies.

We expect public water utilities will assess the alternatives and potential cost for enhanced treatment, while they await USEPA's decision on enforceable MCLs.

What can public water utilities do proactively, prior to USEPA setting enforceable limits on PFAS?

Public water utilities can prepare themselves by performing a survey of potential PFAS sources in their watershed and completing a source control assessment. A proactive PFAS survey and assessment can be a valuable first step in charting a long-term strategy for addressing potential PFAS in drinking water.

Development of such a strategy, including data development, should be undertaken after consultation with a qualified environmental consultant experienced with PFAS.

How are the new HAs likely to affect industrial and commercial dischargers that have PFAS in their wastewater or stormwater?

According to the USEPA Strategic Roadmap, PFAS monitoring will be required at industrial facilities where PFAS are expected or suspected to be present in wastewater and stormwater discharges. USEPA will likely use this effluent monitoring data to inform which industrial categories USEPA should study for future effluent limitations guidelines (ELG) actions to restrict PFAS in wastewater or stormwater discharges.

We expect many industries to detect PFOA and PFOS at concentrations greater than the HAs in their wastewater and/or stormwater, thus increasing the probability of affecting more industrial categories than before.

Mergers & acquisitions, and transactions

Sarah Stoneking
Principal

Will the HAs have an impact on PFAS risk for mergers and acquisitions(M&A) or transactions?

Although the new (2022) ASTM Standard for Phase I Environmental Site Assessments includes PFAS as a non-scope consideration, those involved in M&As or transactions would be well advised to consider evaluating PFAS risk as part of environmental due diligence.

The lower HAs suggest that careful consideration of current and historical site and surrounding property use may be warranted in many cases. This can assist in identifying sources of PFAS while accounting for background conditions and facilitate an understanding of the likelihood of future regulatory requirements to test for PFAS at the target site(s). For some portfolios, a level of review beyond that required under ASTM may be appropriate.

Further understanding of PFAS risk during environmental due diligence can be achieved through robust document review, development of environmental liability cost estimates for known or potential impacts (including natural resource damage (NRD)), and through the conduct of screening level product safety reviews to understand whether PFAS may be present in consumer products or product packaging, and whether the target company is in compliance with consumer product safety regulations.

If an intrusive investigation is implemented as part of environmental due diligence, any detection of PFOA or PFOS may be interpreted as "unacceptable" because USEPA-approved analytical techniques are not able to reliably achieve detection limits at or below the updated interim HAs for PFOA and PFOS.

When analytical data are available, a thorough review should consider background contributions and quality assurance/quality control during data collection.

When acquiring sites with known PFAS contamination issues, should site owners/operators be concerned about "re-openers": the regulatory requirement for re-evaluation of sites that previously received regulatory closure, or sites that have entered into a monitoring-only phase under a federal or state regulatory program?

Before characterizing a site as "low risk", because it was previously investigated and remediated and/or has entered into a monitoring-only phase, potential purchasers should consider PFAS risk. The new HAs introduce regulatory uncertainty and may result in greater environmental liabilities.

A robust evaluation of PFAS risk in the context of environmental due diligence and M&A/transactions is best achieved by an experienced team with expertise in all areas of PFAS risk as estimation of potential PFAS liability can differ significantly from traditional environmental due diligence.

Site investigation and remediation

Jaana Pietari
Senior Managing Consultant

Will the new HAs affect site investigation and remediation decisions?

We can expect that upcoming PFAS standards and guidelines, whether related to drinking water, groundwater, soil or other environmental media, may be substantially lower than current state and federal values. This could result in greater financial liabilities for sites with PFAS contamination as well as lead to the identification of more potential sources of PFAS.

The new HAs also introduce regulatory uncertainty as they are based on a much more conservative evaluation of the potential toxicity of PFAS than existing environmental regulatory criteria. As an example, USEPA's current Regional Screening Levels (RSLs) for PFOA, PFOS, PFBS and GenX, in tap water[1] are substantially higher (i.e., less stringent) than the updated HAs for the same compounds. While RSLs are not cleanup standards, they are often relied on in some jurisdictions to determine the need for and extent of further site investigation or remediation.

It is possible that the new HAs, and eventually MCLs, should USEPA propose them as part of future PFAS drinking water regulations anticipated this fall, may be considered in site-based decisions, potentially resulting in more extensive investigations and remediation, and will lead to increases in the timeframes required to achieve cleanup criteria.

[1]RSLs refer to "tap water", which is equivalent to "drinking water".

If USEPA proposes MCLs, it is expected that states will follow with similar or possibly even lower state-specific treatment and cleanup criteria.

Comparison of New and Revised Health Advisories (June 2022) to Current USEPA Regional Screening Levels for Tap Water (May 2022)

Chemical	Lifetime Health Advisory (ppt)	Regional Screening Level (ppt)
PFOA	0.004 (Interim)	60
PFOS	0.02 (Interim)	40
PFBS	2,000 (Final)	6,000
GenX	10 (Final)	60

What about cleanup liabilities for sites with PFAS contamination – how will they be affected by the new HAs?

The HAs are very low for PFOA and PFOS, below even some literature-reported background levels. This suggests potential contributions from non-point anthropogenic sources could become more significant – for example, when evaluating the presence of PFAS in groundwater or in other environmental media.

Evaluating the range of potential PFAS sources, including background contributions, can be very important in defining site boundaries, identifying the extent of cleanup needed, and are expected to in determining cleanup liabilities.

This is likely to be even more critical with lower cleanup goals if they are developed based on the new HAs.

Conducting studies to determine background contributions may add complexity and cost to site investigations but, in the long term, may be valuable in developing and implementing feasible PFAS remediation plans, and in properly allocating the costs of such remediation.

What other potential regulatory changes may affect sites that have been impacted by PFAS?

In addition to the new HAs and potential development of MCLs for PFOA and PFOS, the anticipated proposed regulations designating PFOA and PFOS as Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) hazardous substances and designating PFOA, PFOS, PFBS and GenX as Resource Conservation and Recovery Act (RCRA) hazardous constituents are expected to have significant implications for site investigations and remediation, as well as for associated liabilities.

It is possible that the updated HAs, potential future MCLs, and CERCLA and RCRA designations, may impact or serve to reopen existing "closed" RCRA and CERCLA sites, potentially leading to more extensive, complex and costly investigations and response actions.

Litigation

Steve Washburn
Senior Advisor

How will the updated HAs affect drinking water and groundwater litigation?

Municipalities needing to meet the much more stringent HAs are likely to pursue potential PFAS sources to cover increased treatment costs. Suits are also likely to be filed against potential sources (and also possibly the municipalities) on behalf of people who have been, or continue to be, provided drinking water with PFAS concentrations above the new HAs. Groundwater with PFOA, PFOS, PFBS and GenX concentrations above the new HAs are likely to fuel toxic tort, nuisance, and NRD claims. Defendants will likely look to insurers to cover costs for claims brought against them which will increase disputes over coverage.

Will the updated HAs affect litigation involving exposures other than drinking water?

The updated toxicity evaluations that underly the new HAs – the reason they are so much more stringent for PFOA and PFOS – may be applied by plaintiffs in claims of health effects from exposures through a wide range of pathways, including those related to PFAS in consumer articles. Plaintiffs may claim damages, including the cost of medical monitoring, for alleged exposures to much lower levels of PFOA and PFOS based on the more stringent toxicity evaluations.

In evaluating such claims, it will be important to understand the specific health endpoints on which the updated HAs are based, and how they may (or may not) relate to the health effects that are alleged.

Health impacts - Toxicology

Bob DeMott
Principal

Why are the new interim HAs for PFOA and PFOS so much lower than the 2016 HAs? What has changed? What health outcomes are being considered with regard to PFAS?

In essence, we appear to be in the midst of a USEPA changeover where extrapolations from quantitative toxicology testing results are being replaced with judgements about the relevance of observations from human populations (epidemiology). However, the appropriate steps for calculating health-based standards based on the results of epidemiological studies continue to be debated and are under development.

While information directly from human experience can help mitigate uncertainties in toxicity testing, the computations used by USEPA to extrapolate down to standards are still fundamentally built around adjusting results from toxicity tests.

When these extrapolation methods are used in conjunction with epidemiology studies, it is possible that, for some chemicals, USEPA will calculate "safe" drinking water levels that are impractical as standards – as is apparently the case with PFOA and PFOS. In addition, it is not clear that the very conservative approach applied by USEPA in this instance is necessary to protect public health.

Getting more useful outcomes will require updating the approaches and models that go into low-dose extrapolation.

In setting HAs, a critical point to bear in mind is that USEPA is not attempting to determine an upper limit above which effects are anticipated. It is instead attempting to account for all identifiable uncertainties in extrapolating downward to a number it will stand behind as not having the potential to produce any type of adverse effects for any human population.

The HAs are projected to be "safe", but they are not intended to serve as an indicator for toxicity or adverse health effects.

Health impacts - Epidemiology

Linda Dell
Principal

Why are the new interim HAs for PFOA and PFOS so much lower than the 2016 HAs? What has changed? What health outcomes are being considered with regard to PFAS?

The updated interim HAs for PFOA and PFOS are based on recent reviews of the science on human health effects. Since the USEPA established the 2016 HAs, there have been hundreds of epidemiological studies on PFAS in blood and health effects or health-relevant biomarkers. Examples of health-relevant biomarkers include cholesterol, thyroid hormones, antibodies and other biomarkers of immune function.

The USEPA has conducted the recent reviews on human health effects as part of its stated goal to set enforceable national primary drinking water regulations for PFOA and PFOS. The low HA levels for PFOA and PFOS are below the current limits of detection, signaling that USEPA does not believe that it can identify a reliably measurable "safe level" for these compounds based on currently available information (at the same time recognizing that USEPA does not necessarily consider concentrations above the new HAs to be "unsafe").

The updated interim HAs for PFOA and PFOS are derived based on critical effects observed in human epidemiological studies. This is a change from the 2016 HAs, which were derived using critical effects in animal studies. The critical effect for the updated interim HAs for PFOA and PFOS is decreased antibody response to tetanus vaccine and diphtheria vaccine, respectively, in 7-year-old children in relation to PFAS in blood measured two years earlier (at age 5 years).

Antibodies are biomarkers relevant to health but relying on them as the critical effect is not without controversy. There is a large variation in the magnitude of vaccine response and in the decay rate of vaccine response among individuals. There has been inconsistent information regarding PFOA or PFOS exposure and impaired resistance to infectious diseases, even among those with decreased antibodies. Additional research is necessary to make sense of the variable pattern of potential immunological associations and whether these change actual health outcomes.

In the meantime, USEPA has decided to move forward in establishing the HAs based on a conservative assessment of the available data. Epidemiological studies have also reported associations between exposure to PFOA or PFOS and increases in cholesterol, decreases in birth weight, and certain cancers. USEPA reported that it did not find any epidemiological studies of GenX chemicals and described the results from epidemiological studies of PFBS as equivocal.

Product liability

Bob DeMott
Principal

What do the new HAs mean for PFAS in products?

Firstly, having environmental target levels in the part per quadrillion range creates an interest for parties to identify additional products and uses of PFAS that could be contributing to widespread background levels. Pressure for cleanup and treatment system performance to these types of levels will enhance the attention on background levels and corresponding sources.

Establishing that local background conditions are a constraint to reaching target levels will require expanded testing and that will direct attention toward non-point source contributions and the activities that produce them.

We routinely see statements along the lines that PFAS are ubiquitous, but the generalized sources are not well understood. The cost for cleanup or system performance to much lower levels creates a substantial incentive to investigate background contributions and shift attention toward an expanded set of products and uses.

Secondly, the lowest common denominator just got a lot lower when PFAS are considered as a group. Product restriction initiatives try to group PFAS broadly to simplify the message, then rely upon information from the individual chemicals considered likely to have health effects at the lowest levels in order to support protective approaches.

Agency endorsement of the studies and levels used in calculating the HA for PFOA creates a new floor to represent the lowest common denominator among PFAS. And, since the resulting HAs are so low, the perceived potential for health effects from the entire group of PFAS will be promoted in efforts to expand product restrictions.

Due to the interpretations accepted for calculating the HAs, a large number of fluorine-containing products that were not considered PFAS are now going to be characterized by analogy to PFOA as potentially having properties not yet understood but warranting restrictions.

Natural resource damage

John Newsted
Technical Manager

What do the new HA values mean for natural resource damage assessments (NRDA)?

CERCLA defines “natural resources” broadly to include “land, fish, wildlife, biota, air, water, ground water, drinking water supplies, and other such resources”. Thus, NRDA address impacts to both ecological resources (such as habitat and food chains) and human resources (such as groundwater used as a drinking water supply and recreational use of surface water) as well as fish and wildlife resources that are consumed by humans.

Given that they are based on potential human health effects, the updated HAs for PFOA, PFOS, PFBS and GenX will not have a direct impact on NRDA for ecological aspects in aquatic and terrestrial ecosystems. However, in a separate program, the USEPA is currently deriving ambient surface water quality criteria for PFOA and PFOS in both freshwater and marine systems, which could be used in future NRDA.

In contrast, the new HAs are very likely to have a significant impact on NRDA elements that focus on human resources, especially those that are related to exposures to PFAS in the environment. For example, some states have been pursuing NRD cases where groundwater has been impacted by PFAS and other compounds. In these instances, if the new, extremely low HAs are used as groundwater criteria, then the number and extent of groundwater systems that come under scrutiny during the NRDA process could increase dramatically, particularly for PFOA and PFOS.

In addition, the human health reference doses (RfDs) that have been used as the basis for the new HAs could be used by regulatory agencies to derive fish and wild game consumption advisories at both the state and federal level. Depending on PFAS concentrations detected in terrestrial and aquatic biota at a site, damages could be assessed if concentrations exceed such new numerical criteria, which would be much lower than those previously developed.

Matt Traister
Principal

Is it only a matter of time before air emissions of PFAS begin to be regulated?

It is very likely that USEPA will propose to regulate several PFAS as hazardous air pollutants (HAPs) under the Clean Air Act. It will likely take several years, however, to develop emission standards for affected source categories that emit PFAS, so the prospect of having to reduce PFAS air emissions from industrial and commercial sources to meet USEPA regulations is a longer-term concern.

A more likely near-term outcome is that states with existing air toxic rules will implement restrictions through their respective programs, and that emissions measurements and, perhaps, monitoring for PFAS will become more routine for some industrial sources. The frequency of site-specific risk assessments involving PFAS emissions will also likely increase.

Should companies prepare now for the eventual regulation of PFAS in air?

Yes. USEPA is expected to significantly broaden the Toxic Release Inventory (TRI) reporting requirements for PFAS, perhaps as soon as for the 2022 calendar year report (due in July 2023).

These changes may include reductions in the de minimis concentrations in raw materials that require reporting, a reduction in the annual threshold amount that triggers PFAS reporting – potentially requiring all PFAS usage to be reported, and perhaps more enforcement actions centered around the supplier notifications required under TRI regulations.

We also expect that regulations that limit PFAS releases will be developed and refined over the next several years. Potentially affected parties would be wise to pay close attention to the development of those regulations.

The new HAs target PFAS concentrations in the US's drinking water supplies. What impact, if any, do these changes have on the air emissions pathway?

The significance of the reduction in the HAs will result in an increased focus on PFAS air emission sources and the fate and transport of these compounds on surface water bodies and other drinking water resources (including deposition in areas of municipal wellfields, for instance).

Unlike some other chemicals, some PFAS have been shown to reach substantially elevated concentrations in groundwater (for example, well above the HAs) after having been emitted to air and then deposited onto soil.

As parties dealing with investigations and cleanup for water resources demonstrate that background contributions above the HAs preclude meeting these targets, attention will turn to the airborne transport aspect of background concentrations.

Acronym summary

PFAS - per- and polyfluoroalkyl substances
PFOA - perfluorooctanoic acid
PFOS - perfluorooctane sulfonic acid
PFBS - perfluorobutane sulfonic acid and its potassium salt
HFPO-DA - hexafluoropropylene oxide dimer acid
GenX chemicals or GenX - HFPO-DA and its ammonium salt
BAT - best achievable technologies
CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act
ELG - effluent limitations guidelines
HAP - hazardous air pollutant
HA - Health Advisory
MCL - maximum contaminant limit
NRD - natural resource damage
NRDA - natural resource damage assessments
PPQ - parts per quadrillion
PPT - parts per trillion
RCRA - Resource Conservation and Recovery Act
RfD - reference dose
RSL - regional screening level
TRI - toxic release inventory
UCMR - Unregulated Contaminant Monitoring Rule 5 program
USEPA - US Environmental Protection Agency

Providing expert solutions to PFAS challenges for more than 20 years

For more than two decades, Ramboll has helped clients around the world resolve their most critical PFAS issues. Our multi-disciplinary expertise and experience has been instrumental in assisting clients in reducing a wide range of risk and liabilities related to PFAS source treatment and control, site remediation, product safety and stewardship, regulatory compliance and environmental due diligence.

For more information on Ramboll's experience and capabilities, see **www.ramboll.com/pfas**

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