

~~Draft Deliberative Document—Do not cite, quote, or disseminate—This draft document is solely for the purpose of public comment. It does not represent and should not be construed to represent any Agency determination or policy until it is finalized.~~

USEPA Draft Interim Recommendations to Address Groundwater Contaminated with Perfluorooctanoic Acid and Perfluorooctane Sulfonate

PURPOSE

This guidance provides interim recommendations for addressing groundwater contaminated with perfluorooctanoic acid (PFOA) and/or perfluorooctane sulfonate (PFOS) at sites being evaluated and addressed under federal cleanup programs, including the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund),¹ ~~and corrective action under the Resource Conservation and Recovery Act (RCRA).~~ In addressing PFOA and PFOS contamination, EPA's ~~responses~~ statutory and regulatory authorities provide the Agency with flexibility in how it ensures protectiveness of human health and the environment. Depending on site-specific circumstances, a CERCLA response action may be appropriate (including an interim action, interim measure, or an early action to abate releases and limit exposure, as discussed in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) (e.g., 40 CFR 300.430 (e) and (f), 40 C.F.R. 300.415(b)(2)(ii) and associated provisions), and existing EPA guidance), ~~as well as the use of various enforcement tools (including enforcement or a settlement agreement or an order under the Resource Conservation and Recovery Act (RCRA) section 7003, or Safe Drinking Water Act section 1431).~~ The information and recommendations in this guidance may also be useful for state, tribal, or other regulatory authorities (e.g., federal facility cleanup programs, approved state RCRA corrective action programs).

Broadly, this guidance provides interim recommendations for screening levels, ~~factors to consider when evaluating whether there is an appropriate basis for taking a CERCLA response action; removal management levels (RMLs);~~ and preliminary remediation goals (PRGs) to inform final cleanup levels for PFOA and/or PFOS contamination of groundwater that is a current or potential source of drinking water. The recommendations in this document are ~~based on~~ consistent with existing EPA guidance and standard practices, in addition to applicable statutes and regulations. ~~For groundwater contaminated with PFOA or PFOS, Regions should consult on a case-by-case basis with the Office of Land and Emergency Management (OLEM) prior to using the Fund and the Office of Enforcement and Compliance Assurance (OECA) prior to taking enforcement action.~~²

INTERIM RECOMMENDATIONS

As explained more fully below, this guidance recommends the following:

¹ ~~Consistent with CERCLA, the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), and Executive Order 12580, Federal agencies are responsible for cleaning up groundwater and other contamination at their facilities.~~

² This guidance does not apply to emergency orders issued under the Safe Drinking Water Act (SDWA).

~~Draft Deliberative Document—Do not cite, quote, or disseminate. This draft document is solely for the purpose of public comment. It does not represent and should not be construed to represent any Agency determination or policy until it is finalized.~~

- ~~• Setting 40 ng/L or parts per trillion (ppt) as a Regional Screening Levelsites using a screening level set to a Hazard Quotient³ of 0.1 for PFOA or PFOS individually; which is currently 40 ng/L or parts per trillion (ppt);~~
- ~~• Using the PFOA and PFOS Lifetime Drinking Water Health Advisory (HA) HAs of 70 ppt (individual or combined concentration of PFOA and PFOS) as an appropriate basis for taking a response action to address PFOA/PFOS contamination in as the PRG for groundwater that is a current or potential source of ~~drinking water;~~~~
- ~~• Using the PFOA and PFOS HA of 70 ppt as a PRG for drinking water, where no state or tribal MCL or other applicable or relevant and appropriate requirements (ARARs) exist; ;~~
- ~~• The U.S. Environmental Protection Agency (EPA) may use an RML of 400 ppt (individual or combined concentration of PFOA/PFOS) to inform decisions to undertake removal actions under CERCLA;~~
- ~~• At sites that are not on the National Priorities List and where no viable private, federal, or state potentially responsible party (PRP) exists and where PFOA/PFOS levels are between 70 ppt and 400 ppt, EPA will work with those states, tribes, and local governments addressing PFOA and PFOS contamination using relevant state, tribal, and local government authorities.~~
- In situations where groundwater is being used for drinking water, EPA expects that responsible parties will address levels of PFOA and/or PFOS over 70 ppt.

This guidance is based on EPA’s current scientific understanding of the toxicity of PFOA and PFOS, and is consistent with other relevant EPA guidance. ~~EPA~~For these reasons, EPA considers the recommendations to be interim and may revise this guidance’s recommendations as new information becomes available.

BACKGROUND

PFOA and PFOS are synthetic fluorinated organic chemicals belonging to a large group commonly referred to as per- and poly-fluoroalkyl substances (PFAS). Manufacturers have produced PFAS for a variety of industries and products, including surface treatments for soil/stain/water resistance; ; surface treatments of textiles; ; paper, ~~and;~~ ; metals; and for specialized applications, such as fire suppression for hydrocarbon fires. PFOA and PFOS are resistant to metabolic and environmental degradation; ; and ~~are~~ therefore, are highly persistent in the environment and can bioaccumulate in humans.

In 2009, EPA developed provisional HAs for PFOA and PFOS in response to concerns about drinking water contamination. Subsequently, EPA conducted a thorough evaluation of literature on human

³ A hazard quotient is considered by EPA to be the ratio of the potential exposure to the substance and the level at which no adverse effects are expected.

~~Draft Deliberative Document—Do not cite, quote, or disseminate—This draft document is solely for the purpose of public comment. It does not represent and should not be construed to represent any Agency determination or policy until it is finalized.~~

health effects associated with PFOA and PFOS and issued draft health effects support documents in 2014 for public comment and independent panel peer review. In 2016, EPA finalized a lifetime drinking water HA of 70 ppt, for the individual or combined concentrations of PFOA and PFOS (USEPA, 2016a,b).

EPA established the PFOA and PFOS HAHAs based upon the Agency's assessment of the best-available peer-reviewed science.⁴ These advisories are non-enforceable, non-regulatory values, which provide technical information to federal, state, and tribal agencies, and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination (USEPA, 2016a,b). The HAs may change as new information becomes available (USEPA, 2016a,b).

ADDRESSING GROUNDWATER CONTAMINATED GROUNDWATERWITH PFOA AND PFOS

Role of Screening and Screening Levels

Cleanup programs, including Superfund and RCRA corrective action, typically use a risk-based approach to determine when contaminants present at a site may warrant further investigation or cleanup. EPA has developed several guidance documents and tools to support these efforts, including regional screening levels (RSLs).⁵

Consistent with EPA *Soil Screening Guidance: User's Guide* (USEPA, 1996) and other guidance, "screening" generally refers to the process of identifying and defining areas, contaminants, and conditions, at a particular site, that may warrant further attention. Under CERCLA, RCRA, and other regulatory programs, at sites where contaminant concentrations are below risk-based screening levels, no further action or study is generally warranted. It is important to note that screening levels are not the same as cleanup levels. Screening a site for further evaluation does not necessarily indicate that additional response action is appropriate beyond assessing the actual or potential risk posed by releases or threatened releases at the site. A decision to take further response remedial cleanup action typically is based on the results of a baseline risk assessment performed following the recommendations provided in existing EPA guidance, which typically considers the risks posed by all contaminants at a site (e.g., USEPA, 1991).

For non-cancer effects, the Superfund program typically uses a hazard quotient (HQ)⁶ of 1.0 for screening when there is a single contaminant and 0.1 when more than one contaminant is present. A HQ of 0.1 is recommended for screening PFOA and /or PFOS for several reasons, including: (1) the specific and limited purpose of a screening level; (2) the additive toxicity of PFOA and PFOS; and (3) the possibility that other PFAS compounds, which may be toxic but for which toxicity values may not currently be available, may be co-located with PFOA and /or PFOS. Using a HQ of 0.1 is recommended to ensure that PFOA- and PFOS-contaminated sites are further evaluated rather than prematurely screened out. Using The EPA's reference doses (RfD), which were used to derive the HAs for PFOA and

⁴ This guidance is focused on PFOA and PFOS, however, EPA recognizes that toxicity information is being developed on additional PFAS and will consider that information as it becomes available.

⁵ RSLs generally are generic screening levels based on default exposure parameters and factors that represent reasonable maximum exposure (RME) conditions for long-term/chronic exposures and normally are based on the methods recommended in EPA's Risk Assessment Guidance for Superfund, Part B Manual (USEPA 1991) and Soil Screening Guidance documents (USEPA, 1996 and 2002).

⁶ A hazard quotient is considered by EPA to be the ratio of the potential exposure to the substance and the level at which no adverse effects are expected.

~~Draft Deliberative Document—Do not cite, quote, or disseminate. This draft document is solely for the purpose of public comment. It does not represent and should not be construed to represent any Agency determination or policy until it is finalized.~~

~~PFOS (USEPA 2016 c,d), when put into Superfund risk equations (USEPA, 1989) for a HQ of 0.1 yields, yield a recommended screening value of 40 ppt- for each chemical.~~⁷

For carcinogenic effects, the Superfund program generally uses a one-in-a-million excess cancer risk as the screening level. Under the EPA 2005 cancer guidelines, the evidence for the carcinogenicity of PFOA and PFOS is considered *suggestive* (USEPA 2016 c,d). In the case of PFOS, the existing evidence does not support a strong correlation between the tumor incidence and dose to justify a quantitative assessment (~~ibid~~USEPA 2016 c,d). For PFOA, the data are sufficient for a quantitative analysis to provide a sense of the magnitude of potential carcinogenic risk for comparison with the noncancer risk. This analysis showed that the equivalent drinking water concentration derived from the RfD for noncancer effects of PFOA is lower than the concentration associated with a one-in-a-million risk, indicating that a screening value derived from the developmental endpoint for the RfD will be protective for the cancer endpoint as well (USEPA 2016 c,d).

Action Determination

~~The Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions (USEPA, 1991a) guidance recommends that action is generally warranted when addressing contaminated groundwater where maximum contaminant levels (MCLs) or non-zero maximum contaminant level goals (MCLGs) are exceeded. In addition, the guidance states that “[o]ther chemical-specific ARARs may also be used to determine whether a site warrants remediation.” Currently, there are no federal MCLs for PFOA or PFOS, or any other PFAS.~~

~~EPA’s remedy selection guidance for Superfund (USEPA, 1997) recommends considering the following factors when evaluating whether there is an appropriate basis for taking a CERCLA response action:~~

- ~~1.—The cumulative excess carcinogenic risk to an individual exceeds 1×10^{-4} (using reasonable maximum exposure assumptions for either the current or reasonably anticipated future land use);~~
- ~~2.—The non-carcinogenic hazard index (HI)⁸ is greater than one (using reasonable maximum exposure assumptions for either the current or reasonably anticipated future land use);~~
- ~~3.—Site contaminants cause adverse environmental impacts; or~~
- ~~4.—Chemical-specific standards or other measures that define acceptable risk levels are exceeded and exposure to contaminants above these acceptable levels is predicted for the reasonable maximum exposure. Examples include: drinking water standards that are exceeded in groundwater when that groundwater is a current or potential source of drinking water; or water~~

⁷ ~~The screening value of 40 ppt was derived using the process described in the Regional Screening Level User’s Guide and is based on the same RfDs (0.00002 mg/kg/d) that EPA used to calculate the HAs. Because of differences in processes used to address risk from combined exposure to multiple chemicals the RSL values for PFOA and PFOS are not identical to the drinking water HAs. RSL values are calculated for each chemical and to account for co-exposures to multiple chemicals the recommended Hazard Quotient is reduced by an order of magnitude, leading each individual chemical to an HQ of 0.1. For the HAs, the value of 70 ppt is compared to the total concentration of PFOA and PFOS.~~

⁸ ~~A hazard index is considered by EPA to be the sum of hazard quotients for substances that affect the same target organ or organ system.—~~

Draft Deliberative Document—Do not cite, quote, or disseminate—*This draft document is solely for the purpose of public comment. It does not represent and should not be construed to represent any Agency determination or policy until it is finalized.*

quality standards that are exceeded for designated uses of those waters (e.g., support aquatic life).

In addition, states and tribes often have an important role in helping to frame EPA's approach to groundwater characterization and remediation under Superfund or other cleanup programs. For example, states and tribes may have MCLs or other drinking water standards, antidegradation regulations, or other standards and requirements that may be potential ARARs. They may also have other relevant guidance and policies, such as aquifer classifications.

Where no state or tribal regulations qualify as ARARs,⁹ EPA recommends consideration of the 1991 guidance on the role of baseline risk assessment and the NCP's risk-based approach, as appropriate, as well as the following factors when evaluating whether the use of CERCLA response authority is warranted:

1. Additive toxicity of PFOA and PFOS;
2. Bioaccumulation;
3. Persistence in the environment;
4. Ubiquity in the environment;
5. Likelihood of other PFAS being present for which toxicity values may not be presently available, which may have the potential to be present at concentrations that could contribute to harmful effects to human or environmental receptors;
6. Presence of PFAS precursors (such as fluorotelomer-based polymers, acrylates, alcohols, amides, etc.) that can degrade into perfluoroalkyl acids;
7. Likelihood of drinking water contamination; and
8. Likelihood of complete exposure pathways to receptors.

In consideration of the contaminant-specific factors and the conditions outlined in the guidance above, the 70 ppt Drinking Water HA for PFOA and PFOS can be an appropriate basis for taking a response action to address contaminated groundwater that is a current or potential drinking water source.

Preliminary Remediation Goals

⁹ Currently, PFAS are not listed as CERCLA hazardous substances. Where PFAS contamination at a site is not commingled with known CERCLA hazardous substances, CERCLA section 104(a)(1) authorizes EPA and other federal agencies to respond to releases or threatened releases of pollutants or contaminants when the release or potential release "may present an imminent and substantial danger to the public health or welfare." When evaluating whether use of CERCLA response authority is warranted at a site where there is no commingling of PFASs with CERCLA hazardous substances, EPA project managers should consider the circumstances at each site and determine whether the actual or potential release may present an imminent and substantial danger to public health or welfare. If there is a release of both hazardous substances and pollutants/contaminants, there normally would be no need to make the endangerment determination. CERCLA section 104(e) provides broad authority to investigate a site to determine whether hazardous substances, pollutants or contaminants have been or may be released into the environment, and what risks to human health and the environment may be posed by the site.

~~Draft Deliberative Document—Do not cite, quote, or disseminate. This draft document is solely for the purpose of public comment. It does not represent and should not be construed to represent any Agency determination or policy until it is finalized.~~

PRGs¹⁰ are used to set initial targets for cleanup, which can be adjusted on a site-specific basis as more information becomes available during the remedial investigation/feasibility study (RI/FS) process. Groundwater cleanup levels under CERCLA, and similar programs, are often established based on chemical-specific promulgated standards (e.g., federal or state MCLs, or other standards found to be ARARs) (USEPA, 2009). In situations where ARARs are not available or are not sufficiently protective, EPA generally establishes site-specific, risk-based cleanup levels for: (1) carcinogens at a level that represents an excess upper bound lifetime cancer risk to an individual of between one-in-ten-thousand to one-in-a-million excess cancer risk (denoted as 10^{-4} to 10^{-6}); and (2) non-carcinogens such that the cumulative risks from exposure ~~will not~~would not reasonably be expected to result in adverse effects to human populations (including sensitive sub-populations) that may be exposed during a lifetime or part of a lifetime, incorporating an adequate margin of safety (USEPA, 2011). These risk-based concentrations are typically derived from recommended equations ~~discussed in EPA guidance and~~ that utilize available exposure and toxicity information, ~~as discussed in EPA CERCLA risk assessment guidance (e.g., Risk Assessment Guidance for Superfund; Role of Baseline Risk Assessment guidance USEPA, 1991a,b).~~

As the remedial investigation proceeds and information from the baseline risk assessment becomes available, PRGs ~~may be~~are often modified. Modification can be based on several factors, including consideration of site/aquifer-related exposure through multiple exposure pathways or exposure to multiple chemicals—either of which may raise the cumulative risk of site-related chemicals out of the acceptable exposures and risk range. It is also possible that other site-specific considerations ~~would~~could lead to a ~~higher~~different cleanup goallevel.

In circumstances where a groundwater cleanup program is addressing PFOA and/or PFOS contaminated groundwater, and where no state, or tribal laws or regulations qualify as ARAR, EPA recommends using the HA of 70 ppt for the combined concentration of PFOA and PFOS as the PRG, or equivalent preliminary cleanup goal for other programs. Where state or tribal laws or regulations qualify as ARARs for PFOA or PFOS, those standards should be used to develop PRGs.

At Superfund sites, final remediation goals and remedy selection decisions should be made consistent with CERCLA, the NCP (e.g., 40 CFR 300.430 (d), (e)), and (f) and associated provisions), and existing EPA guidance.

Removal Management Levels

~~By definition, a removal action would not be used to address groundwater cleanup. It could, however, be an appropriate response action if the groundwater is, or could potentially be, used as drinking water. Removal management levels (RMLs) are a tool to help make a determination when an EPA removal~~

¹⁰ PRGs “are concentrations of contaminants for each exposure route that are believed to provide adequate protection of human health and the environment based on preliminary site information. These goals are also used to assist in setting parameters for the purpose of evaluating technologies and developing remedial alternatives. Because these preliminary remediation goals typically are formulated during project scoping or concurrent with initial RI [remedial investigation] activities (i.e., prior to completion of the baseline risk assessment), they are initially based on readily available environmental or health-based ARARs (e.g., [MCLs]), ambient water quality criteria and other criteria, advisories, or guidance (e.g., reference doses (RfDs)). As new information and data are collected during the RI, including the baseline risk assessment, and as additional ARARs are identified during the RI, these preliminary remediation goals may be modified as appropriate to ensure that remedies comply with CERCLA’s mandate to be protective of human health and the environment and comply with ARARs.” (NCP; 55 FR 8666, 8712)

~~Draft Deliberative Document—Do not cite, quote, or disseminate *This draft document is solely for the purpose of public comment. It does not represent and should not be construed to represent any Agency determination or policy until it is finalized.*~~

~~action is warranted. RMLs are chemical- and media-specific concentrations that may be used to support a decision for EPA to undertake an action using CERCLA authority and funding (USEPA, 2018). The purpose of the RMLs is to help define areas, contaminants and conditions that may warrant a removal action at a site; they do not cover every conceivable situation that EPA might need to address in the remedial phases of a cleanup. Sites where contaminant concentrations fall below RMLs are not necessarily “clean,” and further action or study may be warranted under the Superfund program (USEPA, 2018). For example, the NCP states that “actual or potential contamination of drinking water supplies or sensitive ecosystems” is one factor to consider in determining the appropriateness of a removal action, which could be “any appropriate removal action to abate, prevent, minimize, stabilize, mitigate, or eliminate the release or threat of release.” 40 CFR 300.415(b). On a case-specific basis, EPA may need to take action because of combinations of chemicals, chemical-specific factors, unusual site-specific circumstances, the finding of a public health hazard by the Agency for Toxic Substances and Disease Registry (ATSDR), ecological risk, or other case-specific considerations (USEPA, 2018).~~

~~RMLs are typically derived in the same way as RSLs using default exposure parameters and factors that represent reasonable maximum exposure (RME) conditions for long-term/chronic exposures and normally are based on the methods recommended in EPA's Risk Assessment Guidance for Superfund, Part B Manual (USEPA, 1991) and Soil Screening Guidance documents (USEPA, 1996 and 2002). RMLs generally differ from RSLs in the selection of a HQ or HI. Whereas RSLs are typically calculated for a HQ of 0.1 or 1.0; RMLs are typically calculated for a HQ of 1.0 and 3.0. In consideration of the contaminant-specific factors and the conditions outlined in the section above, EPA is recommending using a HI of 1.0 for PFOA and PFOS. Using EPA's RfDs for PFOA or PFOS (USEPA 2016 c,d), an HI of 1.0 yields an RML of 400 ppt.~~

~~Exceeding an ARAR, such as an MCL, does not necessarily trigger a removal action, however, once EPA has determined the need for a removal action under CERCLA, ARARs should be attained to the extent practicable during the removal action considering the exigencies of the situation. In determining whether attaining ARARs are practicable, the Agency may consider appropriate factors including the urgency of the situation and the scope of the removal action to be taken. For further information on ARARs in the removal action process, please refer to the *Superfund Removal Procedures: Guidance on the Consideration of ARARs During Removal Actions* (USEPA, 1991c).~~

~~At those sites without a PRP where EPA may expend Superfund dollars for removal actions, the application of the guidance results in an RML of 400 ppt (individual or combined concentration of PFOA/PFOS). At sites where PFOA/PFOS levels are between 70 ppt and 400 ppt (particularly at non-NPL sites where no viable private, federal, or state PRP exists), EPA will work with those states, tribes, and local governments addressing PFOA and PFOS contamination using relevant state, tribal and local government authorities.~~

~~Draft Deliberative Document—Do not cite, quote, or disseminate—This draft document is solely for the purpose of public comment. It does not represent and should not be construed to represent any Agency determination or policy until it is finalized.~~

REFERENCES

USEPA, 1991a. Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions. OSWER Directive 9355.0-30. <https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=910165CR.TXT>

USEPA, 1991b. Risk Assessment Guidance for Superfund: Volume 1 – Human Health Evaluation Manual (Part B, Development of Risk-Based Preliminary Remediation Goals). EPA/540/R-92/003. <https://www.epa.gov/risk/risk-assessment-guidance-superfund-rags-part-b>

USEPA, 1991c. Superfund Removal Procedures: Guidance on the Consideration of ARARs During Removal Actions. EPA/540/P-091/011. <https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=10001YMN.TXT>

USEPA, 1994. National Oil and Hazardous Substances Pollution Contingency Plan; Final Rule. 59 FR 47384. <https://www.govinfo.gov/content/pkg/CFR-2015-title40-vol28/xml/CFR-2015-title40-vol28-part300.xml>

USEPA, 1996. Soil Screening Guidance: User's Guide. <https://www.epa.gov/superfund/superfund-soil-screening-guidance>

USEPA, 1997. The Rules of Thumb for Superfund Remedial Selection. <https://www.epa.gov/superfund/key-principles-superfund-remedy-selection>

USEPA, 2009. Summary of Key Existing CERCLA Policies and Groundwater Restoration. OSWER Directive 9283.1-33. <https://semspub.epa.gov/work/HQ/175202.pdf>

USEPA, 2011. Groundwater Road Map: Recommendation Process for Restoring Contaminated Groundwater at Superfund Sites. OSWER Directive 9283.1-34. <https://semspub.epa.gov/work/HQ/174480.pdf>

USEPA, 2016a. Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA). EPA 822-R-16-005. https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final_508.pdf

USEPA, 2016b. Drinking Water Health Advisory for Perfluorooctanoic Sulfonate (PFOS). EPA 822-R-16-004. https://www.epa.gov/sites/production/files/2016-05/documents/pfos_health_advisory_final_508.pdf

USEPA, 2016c. Health Effects Support Document for Perfluorooctanoic Acid (PFOA). EPA 822-R-16-003 https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_hesd_final_508.pdf

USEPA, 2016d. Health Effects Support Document for Perfluorooctanoic Sulfonate (PFOS). EPA 822-R-16-002. https://www.epa.gov/sites/production/files/2016-05/documents/pfos_hesd_final_508.pdf

~~USEPA, 2018. Removal Management Levels (RMLs) Frequently Asked Questions. <https://www.epa.gov/risk/regional-removal-management-levels-rmls-frequently-asked-questions> Accessed August 2018.~~