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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) and corrective action under the Resource Conservation and Recovery Act (RCRA). In addressing PFOA and PFOS contamination, EPA's 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. 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, 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 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.¹

INTERIM RECOMMENDATIONS

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

- Screening sites using a screening level set to a Hazard Quotient² of 0.1 for PFOA or PFOS individually, which is currently 40 ng/L or parts per trillion (ppt);
- Using the PFOA and PFOS HAs of 70 ppt as the PRG for groundwater that is a current or potential source of drinking water, where no state or tribal MCL or other applicable or relevant and appropriate requirements (ARARs) exist.

¹ This guidance does not apply to emergency orders issued under the Safe Drinking Water Act (SDWA).

² 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.

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- 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. 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; metals; and for specialized applications, such as fire suppression for hydrocarbon fires. PFOA and PFOS are resistant to metabolic and environmental degradation; and 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 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 HAs based upon the Agency's assessment of the best-available peer-reviewed science.³ 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 WITH 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).⁴

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

³ 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.

⁴ 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).

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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 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) 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. The EPA's reference doses (RfD), which were used to derive the HAs for PFOA and PFOS (USEPA 2016 c,d), when put into Superfund risk equations (USEPA, 1989) for a HQ of 0.1, yield a recommended screening value of 40 ppt for each chemical.⁵

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 (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).

Preliminary Remediation Goals

PRGs⁶ 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

⁵ 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.

⁶ 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)

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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 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 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 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 could lead to a different cleanup level.

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.

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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