UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
LAND AND EMERGENCY
MANAGEMENT

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MEMORANDUM

SUBJECT: Interim Recommendations to Address Groundwater Contaminated with Perfluorooctanoic Acid and Perfluorooctanesulfonate

FROM: Peter C. Wright
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TO: Regional Administrators

PURPOSE

This guidance[1] provides interim recommendations for addressing groundwater contaminated with perfluorooctanoic acid (PFOA)[2] and/or perfluorooctanesulfonic (PFOS) at sites being evaluated and addressed under federal cleanup programs, including programs for cleanup under 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 protection of human health and the environment. Depending on site-specific circumstances, a CERCLA response action may be appropriate (including an interim action, 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 CFR 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).

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[1] This guidance document presents interim recommendations of the U.S. Environmental Protection Agency (EPA) based on our current understanding of how to address groundwater contaminated with PFOA and PFOS. This guidance document does not impose any requirements and shall not by itself be considered binding on any party. Rather, the sources of authority and requirements for addressing groundwater contamination regarding a particular situation are the relevant statutes, and as appropriate, regulations. This guidance is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. EPA decision-makers retain the discretion to adopt or approve approaches on a case-by-case basis that differ from this guidance document, where appropriate.

[2] PFOA, PFOS, and their associated salts are expected to disassociate under most environmental conditions and are expected to be present as anions.

Broadly, this guidance provides interim recommendations for screening levels and preliminary remediation goals (PRGs) to inform the development of 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 Superfund trust fund resources and with the Office of Enforcement and Compliance Assurance (OECA) and OLEM prior to taking enforcement action.[3]

INTERIM RECOMMENDATIONS

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

- Screening sites using a recommended groundwater screening level based on a target Hazard Quotient[4] 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 Advisories (HAs) of 70 ppt (combined or individually) as the recommended Preliminary Remediation Goal (PRG)[5] 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) are available or sufficiently protective.

- In situations where groundwater is currently 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 considers the recommendations to be interim and may revise this guidance's recommendations as new information becomes available. For example, if the Agency promulgates a federal ARAR, such as a national drinking water standard, for PFOA or PFOS this guidance would be revised, replaced, or rescinded.

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

[4] A hazard quotient is considered by EPA to be the ratio of the potential substance exposure to the level at which no adverse non-cancer effects are expected, i.e. a reference dose (RfD), for a similar exposure period.

[5] 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., maximum contaminant levels [MCLs]), ambient water quality criteria (AWQC) and other criteria, advisories, or guidance (e.g., 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 PRGs 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; March 8 1990)

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, surfactants, 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 and animals.

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.[6] 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 risks, analytical methodologies, and treatment technologies associated with drinking water contamination (USEPA, 2016a,b). EPA and its sister federal agencies, as well as some states, continually review and develop new scientific information; 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.[7]

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 remedial cleanup action typically is based on the results of a baseline risk

[6] 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.

[7] Screening levels are typically 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 1991b) and Soil Screening Guidance documents (USEPA, 1996 and 2002).

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, 1991a).

For non-cancer effects, the Superfund program typically uses a target HQ of 1.0 for screening when there is a single contaminant and a target HQ of 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 potential additive or multiplicative toxicity of PFOA and PFOS; and (3) the possibility that other chemicals (including 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 RfDs, 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, yields the currently recommended screening level of 40 ppt for each chemical.[8] The EPA regularly updates screening levels for Superfund in accordance with agency policy when new scientific information becomes available.

For carcinogenic effects, the Superfund program typically derives screening levels based on an individual excess lifetime cancer risk of one-in-a-million. 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 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 screening level 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 level derived from the developmental endpoint for the RfD will be protective for the cancer endpoint as well (USEPA 2016 c,d).

Preliminary Remediation Goals (PRGs)

PRGs generally 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, 2017). Where state regulations qualify as ARARs for PFOA and PFOS, the remediation goals established to ensure protectiveness of human health and the environment normally should be developed considering the state regulations that qualify as ARARs, as well as other factors cited in the NCP (*see* 40 CFR 300.430(e)(2)(i)). Final remediation goals and remedy decisions generally are made in accordance with 40 CFR 300.430 (e) and (f) and associated provisions.

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[8] The screening levels of 40 ppt were derived using the process described in footnote 5 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 screening levels for PFOA and PFOS are not identical to the drinking water HAs. The screening levels are calculated for each chemical. To account for co-exposures to multiple chemicals the recommended HQ 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 combined concentration of PFOA and PFOS.

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). A final remedy must be protective of both cancer and non-cancer health effects posed by all chemicals of concern at a site.

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-specific 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 individual or combined concentration of PFOA and PFOS as the PRG, or equivalent starting point for determining 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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