

Human and Ecological Health Effects, Site Risk Assessment, Regulations, Risk Communication and Stakeholder Perspectives

This question and answer digest was prepared based on the Roundtable Session 4 event from June 10, 2021, including some additional questions that were submitted but not answered live on the roundtable. The information presented here is not a transcript of the session, but a summary of the information. Included in the answers below, the ITRC Technical and Regulatory Guidance Document, <https://pfas-1.itrcweb.org>, is abbreviated "Tech Reg." The user is encouraged to reference the Tech Reg document for more details. This digest represents an understanding of the state of the science as of the date of the roundtable.

The Roundtable was hosted through EPA Clu-In and promoted with the following information:

This fourth PFAS Roundtable Session offers a unique opportunity to interact directly with experts from the ITRC PFAS Team from around the country on several topics: *Human and Ecological Health Effects, Site Risk Assessment, Regulations, Risk Communication and Stakeholder Perspectives*. Participants were requested to submit questions in advance with registration for the event to be addressed during this Question and Answer discussion with expert panelists. The session was intended to be tailored to the specific needs of its participants, with the expectation that the participant have a basic understanding of these topics prior to attending the Roundtable Session.

Per- and polyfluoroalkyl substances (PFAS) constitute a large family of fluorinated chemicals, exceeding several thousand in commercial use or the environment that vary widely in their chemical and physical properties. The persistence and mobility of some PFAS, combined with decades of widespread use in industrial processes, certain types of firefighting foams, and consumer products, have resulted in their being present in most environmental media at trace levels across the globe. PFAS have relatively recently come to the attention of investigators and the public in large part due to the fact that until the early 2000s analytical methods to detect low levels of PFAS in the environment were available only in a few select research institutions. It was not until the early 2010s that these methods to detect a limited number of PFAS became widely available and had detection limits in water low enough to be commensurate with levels of potential human health effects. Toxicological studies have raised concerns regarding the bioaccumulative nature and potential health concerns of some PFAS. As a result, our understanding of PFAS and the risks they may pose is rapidly evolving.

This Roundtable Session is based on the following ITRC-produced resources:

- **A series of fact sheets** at synthesize key information about PFAS science. In particular for this webinar, the Regulations fact sheet, the Human and Ecological Health Effects and Risk Assessment fact sheet, the Risk Communication fact sheet, and the Stakeholder Perspectives fact sheet are available resources. The fact sheets were published in 2020.
- **A web-based technical and regulatory guidance document** published by the ITRC PFAS Team in April 2020, with updates published in September 2020, May 2021, and December 2021. The document presents the breadth and depth not given by the fact sheets, stakeholder points of view, technical challenges and uncertainties, risk communication strategies, and provides links to pertinent scientific literature. ITRC published a risk communication toolkit in June 2020. In 2022 and 2023, ITRC will continue its work, with plans to update the technical and regulatory guidance document with new information and regulatory approaches that become available to address the evolving understanding of these contaminants.
- **Online training materials** that convey the information presented in the technical and regulatory guidance document. Ten video training modules and brief introductory videos on the topics are posted on ITRC's YouTube channel. Additionally, the Team has provided in-person training workshops to approximately 2,500 attendees since 2018. The Team plans to continue to provide online and in person training resources. More information will be available on the ITRC Training page.

The target audience for this guidance and Roundtable Session is:

- state and federal environmental staff working on PFAS-contaminated sites
- Other project managers and decision makers
- Stakeholders who are involved in community engagement

ITRC PFAS Roundtable Webinar Session 4 *continued*

As a participant in this Roundtable Session you should learn more about:

- PFAS Regulations
- Human and Ecological Health Effects
- Site Risk Assessment
- Risk Communication
- Stakeholder Perspectives

Participants are highly encouraged to review the Guidance Document (<https://pfas-1.itrcweb.org> - specifically Sections 7, 8, 9, 12 and 14), the Water and Soil Values and Basis for PFOA and PFOS Values tabular summaries (<https://pfas-1.itrcweb.org/fact-sheets/>) and review the associated ITRC video training modules prior to attending the Roundtable Session:

- [ITRC Video Training Modules](#)

1 Roundtable Webinar Series Session 4 Panelists



Gloria B. Post, Ph.D., D.A.B.T. is a Research Scientist in the New Jersey Department of Environmental Protection (NJDEP) Division of Science and Research. She is a toxicologist with responsibility for human health risk assessment of contaminants found in New Jersey's environment. Since 2006, she has been a member of the NJ Drinking Water Quality Institute, an advisory body that recommends drinking water standards to NJDEP. Dr. Post has focused on the evaluation of PFAS in drinking water for more than 15 years, and she is the first author of five publications (including three critical reviews) and the co-author of three additional publications on this topic. She was a major contributor to the Human Health and Surface Water sections of the Interstate Technology & Regulatory Council (ITRC) PFAS Technical and Regulatory Document the Environmental Council of the States (ECOS) white paper on states' regulatory standards for PFAS, and she served on the National Academy of Sciences Planning Committee for the Workshop on Federal Human Health PFAS Research. She has been a Diplomate of the American Board of Toxicology since 1990. Dr. Post holds an A.B. with honors in Biochemical Sciences from Princeton University and a Ph.D. in Pharmacology from Thomas Jefferson University, with post-doctoral research at Duke University. gloria.post@dep.nj.gov.



Kevin Long, M.S. is a Principal Consultant in Terraphase Engineering Inc's Princeton, NJ office. He has more than two decades of experience in applying risk assessment and risk management strategies to support remedial action and closure of sites across the country. His work has included sites that have required the evaluation of unique exposure scenarios or exposure to complex and emerging chemicals, including PFAS. He has been a member of ITRC since 2011 and has supported the development of technical guidance and training regarding site risk assessment, bioavailability of contaminants in soil, and PFAS. Kevin earned BS and MS degrees, both in Civil and Environmental Engineering, from Princeton University in Princeton, NJ. kevin.long@terraphase.com



Chris McCarthy, M.S. is a nationally recognized ecological risk assessment expert with 24 years of experience. Chris has led risk assessments at sites around the U.S., Australia, Canada, and France. He directs teams in evaluating the likelihood and magnitude of adverse effects to human and non-human biota exposed to contaminants at hazardous waste sites and working with engineers on risk management strategies. Chris has been actively engaged in the thought leadership for PFAS ecotoxicity related work, leading toxicity studies with PFAS, and leading PFAS risk assessments at sites through the US and Australia. Chris regularly presents updates and gives training on the ecotoxicity and risk assessment of PFAS to audiences around the world. Chris is also an active member of the ITRC PFAS team including the regulations, toxicity, risk assessment, and surface water criteria subgroups. Chris earned a BS in Water Resources Management from University of New Hampshire and an M.S. in Biology from Minnesota State University. Chris.McCarthy@jacobs.com

ITRC PFAS Roundtable Webinar Session 4 *continued*



Linda C. Hall, Ph.D., is an environmental toxicologist based in California's San Francisco Bay Area. She holds a MS degree in Toxicology from California State University, San Jose and a PhD in Ecological Toxicology from University of California, Davis. She has actively followed the emerging science of PFAS toxicology and is in her fourth year as co-lead for the PFAS Regulations, Toxicity, and Risk Assessment Writing Subgroup for the Interstate Technology Regulatory Council (ITRC) PFAS Team. In that role, she coordinates, edits, and contributes to technical guidance on the human health, ecological toxicology, regulations, and risk assessment of PFAS. Dr. Hall's practice has focused on the toxicology and regulation of PFAS for many years. During that time, she has worked as a technical expert in toxicology on PFAS litigations involving aqueous film-forming foam (AFFF) contamination of drinking water; PFAS manufacturing releases to air and water at multiple sites, and the food chain transfer and potential health effects of PFAS in crops grown on soils amended with biosolids. She is a frequent presenter on PFAS at conferences and seminars. Prior to working as an environmental consultant, Dr. Hall was a Principal Investigator (PI) and co-PI for at the University of California and at Lawrence Livermore National Laboratory. lindachall@comcast.net



Peter M. Strauss, M.S. is the sole proprietor of PM Strauss and Associates. With over 40 years of consulting experience, he has a demonstrated history of working with non-profit community organizations on RCRA, CERCLA and Brownfields projects for environmental remediation issues. Peter has been an active member and stakeholder lead in the ITRC PFAS team. Peter received an MS in Environmental Studies from State University of New York College of Environmental Sciences and Forestry. petestrauss1@comcast.net



Kerry Kirk Pflugh is the Director for Local Government at the New Jersey Department of Environmental Protection. She is the department's liaison between New Jersey's 565 Mayors, 21 counties and the 75 programs in DEP. She is responsible for troubleshooting, helping officials navigate the agency and identify the correct programs and people to resolve problems. She is also responsible for facilitating meetings between officials and agency personnel. Ms. Pflugh's area of expertise is strategic communication planning focusing on citizen participation in environmental management decision-making. She is the recipient of numerous awards including: Cabinet Liaison of the Year, New Jersey Conference of Mayors, April, 2019; George Hammell Cook Distinguished Alumni Award for Outstanding Achievement in Professional and Civic Endeavors, April 2017; and The Elizabeth River/Arthur Kill Watershed Association Appreciation Award, October 2016. Kerry earned a BA in Environmental Communication, Cook College, Rutgers University and an MS in Agricultural Journalism University of Wisconsin-Madison. Kerry is a co-lead for the ITRC PFAS Team Risk Communication writing subgroup.



Kristi Herzer is an Environmental Analyst and Technical Program Lead for the State of Vermont's Department of Environmental Conservation. Kristi is a project manager in the Brownfields Program and the Sites Management Section, and promotes the Vermont Brownfields Reuse and Environmental Liability Limitation Act (BRELLA) program. Kristi is the Division representative on VTDEC's Environmental Justice Team, an active member in a cross-agency PFAS workgroup, and co-author of multiple internal and external guidance documents for the regulated community. Since 2017, Kristi has served as a member and subgroup leader for the Sampling and Analysis section of ITRC's PFAS team, and most recently also serves as a subgroup leader of the PFAS Training team. Kristi holds a Bachelor's of Science in Physics and Biology from Guilford College and a Master's Degree in Environmental Engineering from the University of Vermont. kristi.herzer@vermont.gov

2 Q&A Digest

1. Can you please tell us what the ITRC PFAS Technical and Regulatory Guidance Document (otherwise referred to today as the Tech Reg) covers regarding Risk Communication related to PFAS, and what other Risk Communication Trainings might be out there?

[Pflugh] ITRC has developed three main resources to support risk communication efforts for state and federal environmental staff as well as for others. These include the Tech Reg Risk Communication Toolkit with PFAS-specific planning and outreach tools, and an explainer video. These resources include: the definition of risk communication, which scholars define as a science-based approach of communicating effectively in situations of high-risk high stress and controversy; the principles of risk communication, some of which include establishing dialogue early and continuing to resolution and listening acknowledging and following up on the concerns of the public; and the five key aspects of risk communication that should be built into any risk communication plan. These aspects include how communities see risk, building trust and credibility, releasing information effectively, interacting with communities, and explaining risk and management strategies.

One of the areas that the resources detail is “outrage factors” and how they impact the way a community may react to information or to your desire to engage them in the planning process in responding to a risk situation. These include risks that are perceived as either involuntary or involuntary, and with involuntary risks perceived to be much riskier.

The Toolkit includes a risk communication planning process that has several steps: (i) issue identification, (ii) development of SMART goals; (iii) identifying communities and constraints; (iv) audience assessment; (v) message mapping, (vi) method selection, (vi) strategy implementation, and (vii) concludes with evaluation and how to do any follow-up. There have also been, and will be, several training sessions offered by ITRC on Risk Communication which provide participants an opportunity to try their hand at some of the tools in the Toolkit. You can check out the ITRC website for dates and details for when those training sessions will take place.

2. What was the source of information in which you derived the list of stakeholder concerns in Section 13 of the Tech Reg?

[Strauss] There were several major sources, including: reviewing the websites listed in the Stakeholder Resources (Section 13.3 of the Technical and Regulatory Document); reviewing responses to a questionnaire to community activists asking them to inform me of their concerns; reviewing notes from the community meetings held by USEPA in 2018 (more information is in Risk Communication Section 14 of the Tech Reg); involvement with a local group that is made up of national and regional environmental groups in the San Francisco Bay area; and obtaining perspectives from an ITRC PFAS Team tribal representative, mostly regarding the Cherokee Nation.

3. In the absence of CERCLA (the Comprehensive Environmental Response, Compensation, and Liability Act) regulation and federal hazardous waste regulations, do states or other entities regulate PFAS as a hazardous waste?

[Hall] Yes, several states regulate certain PFAS as hazardous substances or as hazardous wastes (for example, Vermont, New York, New Jersey, Colorado, and Alaska), and regulations are under development in several other states. See the Tech Reg Section 8 for more information.

4. Why is there concern about PFAS in drinking water, particularly, from a human health viewpoint, and how do PFAS differ from other drinking water contaminants?

[Post] As discussed in Sections 7.1 and 17.2 of the Tech Reg, PFAS (especially long-chain PFAS) are of particular concern as drinking water contaminants because exposure to even low concentrations in drinking water (for example, below the USEPA Health Advisory of 70 nanograms per liter [ng/L] or parts per trillion [ppt]) can dominate other exposures from common sources such as the diet and consumer products. As described in Section 2 of the Tech Reg, long-chain PFAS are those with 8 or more carbons for carboxylates (for example perfluorooctanoic acid [PFOA] and longer) and 6 or more carbons for sulfonates (for example perfluorohexane sulfonic acid [PFHxS] and longer). Long-chain PFAS are excreted very slowly in humans with half-lives of several years. As such, they build up in the body from ongoing drinking water exposure and remain in the body for many years after exposure ends. This is of concern because low exposure levels of long-chain PFAS, even the levels found in the general population who do not drink contaminated water, are associated with several human health effects. Importantly, exposures to infants from PFAS in drinking water are much higher than in older individuals. This is particularly true in breastfed infants via

ITRC PFAS Roundtable Webinar Session 4 *continued*

transfer from the mother but also from formula prepared with contaminated water. These higher exposures to infants are of concern because infants are a susceptible subgroup for the effects of PFAS.

5. Has USEPA established toxicity criteria for PFAS which can be used to complete ecological risk assessments?

[McCarthy] No, USEPA has not established ecological risk assessment guidelines at this point. USEPA is currently evaluating aquatic toxicity data and conducting studies toward establishing some guidelines but the type of guidelines and for which PFAS is still under evaluation. For further information about USEPA's activities, see the USEPA's website (<https://www.epa.gov/pfas>).

6. Has the federal government established toxicity criteria for PFAS which can be used to complete human health risk assessments? Many PFAS might be or have been in use or released to the environment - but is it true that there are only limited toxicity criteria established by the federal government for just a few PFAS? Do these data include PFAS that are considered long chain, shorter chain, and/or replacement compounds?

[Post] Regarding long-chain PFAS, the USEPA Office of Water developed toxicity values (Reference Doses) for PFOA and PFOS that were used in the Drinking Water Health Advisories issued in 2016. In 2021, ATSDR (the Center for Disease Control's Agency for Toxic Substances and Disease Registry) finalized toxicity values (Minimal Risk Levels; MRLs) for PFOA and PFOS that are 7 to 10 times lower than the USEPA Reference Doses, as well as MRLs for perfluorononanoic acid (PFNA) and PFHxS. We understand that USEPA Office of Water is currently evaluating more recent toxicology data for development of Maximum Contaminant Levels Goal (health-based drinking water values) for use in developing MCLs (drinking water standards) for PFOA and PFOS. USEPA also recently issued a final Reference Dose for perfluorobutane sulfonic acid (PFBS), a short-chain PFAS, and is working on a Reference Dose for GenX (HFPO-DA), a short-chain replacement PFAS, for which a draft document was issued in 2018. The USEPA IRIS program is developing risk assessments for 5 PFAS, including two short-chain (perfluorobutanoic acid [PFBA], perfluorohexanoic acid [PFHxA]) and three long-chain (PFNA, perfluorodecanoic acid [PFDA], PFHxS). IRIS released draft systematic review protocols for these assessments for comment in November 2019.

7. Is there an estimate of how the recent changes for PFBS might impact site risk assessment?

[Long] In April 2021, USEPA released its final Human Health Toxicity Values for PFBS. They included both chronic and subchronic oral reference dose, which can be used for non-cancer calculations. The chronic oral reference dose for PFBS is about an order of magnitude less stringent than that used by USEPA for PFOS and PFOA. The availability of toxicity values for PFBS fills a gap in our ability to do site risk assessment and allows us to quantify the significance of potential exposure for this chemical which can help reduce the uncertainty in risk assessment and use the risk assessment in support of site risk management decisions. The USEPA's PFBS assessment is available the USEPA webpage (<https://www.epa.gov/pfas>).

8. How does the USEPA regulate PFAS?

[Hall] The USEPA regulates PFAS under the Safe Drinking Water Act (SDWA), the Toxic Substances Control Act (TSCA), and the Toxic Release Inventory (TRI), and in the future, it is anticipated that USEPA may regulate PFAS under the Clean Air Act, Clean Water Act (CWA), and CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act, also known as "Superfund"). For more information about USEPA's activities, see the USEPA's website (<https://www.epa.gov/pfas>). In summary, as of the date of this roundtable:

- The USEPA has not yet developed enforceable drinking water standards for any PFAS. However, under the SDWA, the USEPA has the authority – among other things, to develop legally enforceable Maximum Contaminant Levels (MCLs). The USEPA also uses the Unregulated Contaminants Monitoring Rule (or UCMR) program to require public water systems to periodically test for certain chemicals in drinking water that are not otherwise regulated. UCMR provides occurrence data needed by USEPA to decide whether there is a need to regulate the contaminants. The first time PFAS were sampled for in US drinking water pursuant to the UCMR was in 2013-2015 under UCMR3. UCMR5 sampling, planned for 2023-2025, will require municipal water systems that serve more than 3,300 customers to sample for 29 PFAS and will use lower reporting limits than available for UCMR3 sampling.
- The USEPA develops non-regulatory drinking water Health Advisories based on Health Effects Assessments, develops toxicity data on PFAS for the Integrated Risk Assessment Program (IRIS), and develops and

ITRC PFAS Roundtable Webinar Session 4 *continued*

validates analytical methods that are used for regulatory purposes, including two drinking water methods that encompass 29 PFAS and is working toward validating methods for other environmental media.

- Under TSCA, the USEPA has now promulgated five Significant New Use Rules (or SNURs), with the most recent SNUR passed in 2020. In general, these SNURs limit the manufacture, use, and import of certain PFAS, especially long chain sulfonates and carboxylates, and certain precursors to perfluoroalkyl acids (PFAAs). For more information about PFAS groupings and naming conventions, refer to Section 2 of the Tech Reg.
- The USEPA also has the authority to allow (or not allow) new PFAS into commerce and uses the USEPA's New Chemicals Program (NCP) to do this. USEPA's review of alternatives to PFAS has been ongoing since 2000.
- The USEPA also regulates the reporting of 175 different PFAS under the Toxic Release Inventory, where reporting is required if emissions are 100 pounds or more.

Follow up: Do other federal agencies regulate PFAS?

[Hall] Yes. PFAS are also regulated by the US Food and Drug Administration (USFDA), which evaluates and may authorize or deny the use of different PFAS for use in Food Contact Materials (FCM). Additionally, as mentioned earlier, the CDC's Agency for Toxic Substances and Disease Registry (ATSDR), while not a regulatory body, studies, and funds studies of PFAS exposure and health effects in several US communities. ATSDR has finalized Minimal Risk Levels (MRLs) for four PFAS. MRLs are toxicity values used to evaluate potential risks of exposure to contaminants at hazardous waste sites.

9. Are there any federal developments related to human health effects studies? Are PFAS risks to human health based on results derived from mice studies?

[Post] Information on federal human health effects studies is included in Sections 7.1 and 17.2 of the Tech Reg, and additional recent information will be added in the upcoming update. The National Toxicology Program (NTP) recently completed important 28-day rat studies of seven PFAS and a two-year chronic rat study of PFOA, and NTP and USEPA are currently conducting some focused rodent studies which provide very valuable information. Also, NTP and USEPA are currently pursuing a research program to develop high throughput testing toxicity testing methods, such as cell culture assays and zebrafish studies, to rapidly evaluate the toxicity of large numbers of PFAS. This is important because it is not feasible to conduct studies in rodents or other mammals for all PFAS of potential concern.

As discussed in Section 7.1 and 17.2 of the Tech Reg, PFAS risk assessments developed by US federal and state agencies are based on animal toxicology studies, usually in rats or mice. This is also true of most human health risk assessments for other environmental contaminants developed by these agencies. In human health risk assessment, the toxic effects observed in animal studies are evaluated to determine whether they occur through biological processes that are also present in humans. If it is determined that the toxic effect occurs through a process that is present in humans, it is assumed that the toxicity seen in the animals is relevant to human health risks.

10. Are there any federal developments related to ecological effect studies?

[McCarthy] Yes there are, many summarized in Section 9.2 of the Tech Reg. In particular, the Strategic Environmental Research and Development Program (SERDP) (<https://www.serdp-estcp.org/Featured-Initiatives/Per-and-Polyfluoroalkyl-Substances-PFASs>) has been funding research to evaluate ecological effects of a number of classes of organisms (mammals, fish, reptiles) since 2016.

USDOD continues to fund research that supports developing PFAS guidelines, and the US Air Force Civil Engineer Center has an initiative to develop a set of screening values for 4-, 6-, 8-, 9-, and 10-carbon linear perfluorocarboxylic acids (PFCAs) and the 4-, 6-, and 8-carbon linear perfluorosulfonic acids (PFSAs). Navy is also funding some marine aquatic toxicity research.

However, there are several reports, including two recent reports funded by the USDOD, that provide the data needed to complete ecological risk assessments within most regulatory frameworks here in the U.S. These efforts and the available reports are highlighted in the Section 9.2 of the Tech Reg.

11. Based on information we just heard, are the toxicity data adequate to evaluate risks to potential human or ecological receptors?

[Long] To support site risk management decision-making (for example, cleanup, IC/ECs), we have adequate information to evaluate and characterize the potential risks to human health and the environment. That's not to say

that there aren't some uncertainties that can have an impact in our ability to characterize the risk, but for the most part the current state of the science allows us to evaluate and characterize potential risks to receptors, especially since we are often performing these risk calculations in a manner that is conservative to account for these uncertainties.

Critical uncertainties, for example, include our understanding of the toxicity and physical chemical properties for these chemicals. Toxicity is important because we need to understand and quantify the dose-response relationship. Physical chemical properties are important so that we can model the fate and transport of these chemicals to evaluate possible future risks. In the absence of perfect information, risk assessors have to accommodate for the uncertainty when quantifying risk. This is the case with PFAS but it's also the case with other chemicals too where we don't have all of the answers. That doesn't mean that we don't have adequate information to evaluate the potential significance of the problem.

Overall, while there still is some uncertainty, the current state of the knowledge regarding PFAS toxicity and fate and transport, is at a level that can be used to complete risk assessments and help support decisions regarding how to protect public health and the environment.

12. Please discuss the USEPA's progress towards establishing MCLs for PFOA and PFOS.

[Hall] USEPA is using the same process for PFOA and PFOS as USEPA would take to establishing any MCL. This process was established by Congress in the 1996 Amendments to the Federal Safe Drinking Water Act. The process for USEPA to establish an MCL is long and complex. The USEPA first lists a chemical on a drinking water "Contaminant Candidate List" or CCL which is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations but are known or anticipated to occur in public water systems. After a final CCL is published in the Federal Register, the USEPA then decides whether to proceed with making a "Regulatory Determination" which is a formal decision on whether USEPA should initiate a process to develop a national primary drinking water regulation for a specific contaminant. The USEPA has listed PFOA and PFOS on the CCL4, and in February 2021, USEPA made a Final Regulatory Determination for PFOA and PFOS, and the agency is moving forward to implement the national primary drinking water regulation development process (in other words, MCLs) for these two PFAS. The agency must propose a drinking water standard within two years of the regulatory determination and finalize it within 18 months of the proposed regulation (although a 9-month extension is allowed). We have a way to go yet, but that is where we stand with PFOA and PFOS MCL development. More information about USEPA's work on PFAS is available on their website (<https://www.epa.gov/pfas>).

13. Why is there such a wide range of Human Health Risk Assessment acceptable PFAS criteria out there when comparing, US, European, Australian, etc. criteria. Europe is traditionally more conservative than the US, but not so with PFAS?

[Post] Criteria for PFAS established by nations other than the U.S. are included in the ITRC PFAS Team's Tables of PFAS Water and Soil Regulatory Values which is updated approximately monthly. Most current European PFAS criteria are similar or lower than USEPA Reference Doses and Health Advisories – they are not substantially less stringent. The European Union's European Food Safety Authority (EFSA) recently adopted a Tolerable Daily Intake for the total of four long-chain PFAS (PFOA, PFOS, PFNA, PFHxS) that is lower than the toxicity values developed by USEPA, ATSDR, or U.S. States. While all U.S. values are based on animal toxicology data, the EFSA value is based on human epidemiology data, specifically PFAS exposure in a mother that results in decreased vaccine response in the breastfed child at age one year. The UK recently (2021) updated its drinking water guidelines for PFOA and PFOS – with tiered action levels that are substantially lower or slightly higher than the USEPA Health Advisory (depending on the tier). German values for PFOA, PFOS, PFHxS are close to, but slightly higher, than the USEPA Health Advisory and the German value is slightly lower for PFNA. Other countries' criteria that apply to the total of multiple PFAS in water (Denmark – total of 12 PFAS; Sweden – total of 7 PFAS) are close to but slightly higher than the USEPA Health Advisory. The Australian PFOS drinking water value is identical to the USEPA Health Advisory, and their PFOA value is higher because of a difference in interpretation of the toxicology study that was used as the basis for both countries.

14. How much do the uncertainty and safety factors play into the low values for drinking water and groundwater?

[Post] Uncertainty factors are used in human health risk assessments for non-cancer effects to account for factors such as potentially greater sensitivity of humans than animals and for sensitive human subpopulations, among other considerations. The total uncertainty factor used in federal, and state PFAS risk assessments is in the 30 to 300

range. This is within the lower range of the maximum total uncertainty factor of 3,000 that is recommended in USEPA risk assessment guidance, and risk assessments for many other contaminants use higher total uncertainty factors.

There are two reasons why the drinking water and groundwater values for PFAS are relatively low compared to values for most other contaminants: First, there is a need to account for the much slower excretion rates, or, in other words, the much longer half-lives, for PFAS in humans as compared to laboratory animals. This means when you give a human and an animal the same dose of a PFAS, the human will have much a higher blood level than the animal. This is discussed in detail in Sections 7.1 and 17.2 of the Tech Reg. Second, very low levels of PFAS can be reliably quantified in water and removed from water. For some other contaminants with low health-based levels similar to those for PFAS, the regulatory standard must be set higher than the health-based level because they cannot be reliably measured or removed to concentrations as low as the health-based levels.

15. Are replacement PFAS acutely toxic?

[Post] In general, the doses of PFAS (whether legacy or replacement) that cause acute toxicity are not low compared to some other chemicals that are highly acutely toxic, although PFAS can cause toxicity and death in acute animal studies if given at relatively high doses. The major concern for PFAS is toxicity from the levels of PFAS that build up in the body from repeated, ongoing exposures. As explained in Section 7.1 and 17.2 of the Tech Reg, most PFAS replacements have shorter chain lengths than the long-chain PFAS that they replace, and these shorter chain PFAS replacements are generally excreted more rapidly and bioaccumulate to a lesser degree. In general, they cause similar types of toxicity as the long-chain PFAS, but usually, although not always, at higher doses. The dose needed to cause toxicity is usually higher for shorter-chain PFAS because of less bioaccumulation. However, some replacement PFAS are not short-chain and are equally or more bioaccumulative as the long-chain PFAS that they replaced. These PFAS can be equally or more toxic as the phased-out long-chain PFAS.

16. Can the MCL values be used in site risk assessment for sites where there isn't any drinking water exposure?

[Long] In conducting site risk assessments, it is important to understand what groundwater exposures are relevant based upon a review of current and reasonably expected future land and groundwater use. Drinking water standards, like MCLs, can be used to help evaluate the potential significance of groundwater concentrations. As with any values used for such a purpose, it is critical to understand what the values represent and what they don't represent. For example, in the case of the MCLs, what they are based upon, how they are derived, and what the values represent. This would include having an understanding for how the non-zero MCLGs are calculated, what the zero MCLGs mean, and how some of the final MCLs are based upon levels that are as close to the MCLGs as feasible given best available treatment technology. Such values are also often used as cleanup goals for programs such as CERCLA.

17. How many states have established enforceable PFAS standards, or have established screening values, and for what types of PFAS (just PFOA/PFOS, or replacements, precursors, short chain, other)?

[Hall] At this time, 17 states currently have at least one type of promulgated (legally enforceable) standard for at least one PFAS in water, and these standards may apply to more than one PFAS. Several states have promulgated standards for PFAS in multiple different environmental media. For example, Michigan has promulgated standards for PFAS in surface water, drinking water, and groundwater. New Jersey also has separate promulgated standards for PFAS in drinking water and in groundwater.

In addition to those legally enforceable standards, 15 States have advisory levels for PFAS. Most of these regulatory criteria (both enforceable and advisory) focus on perfluoroalkyl acids (PFAAs), such as PFOA, PFOS, and PFNA. But certain states have criteria for GenX (HFPO-DA, a perfluoroalkyl ether carboxylic acid), and Wisconsin has proposed groundwater standards for 22 PFAS including 4 PFOS precursors. Hawaii just proposed regulatory criteria for 16 PFAS which include the PFOS precursor, PFOSA.

While there are more state standards developed for long-chain PFAAs, some states also have standards or guidelines for short-chain PFAAs, most commonly PFBS, but also PFBA and PFHxS. ITRC maintains an on-line table of promulgated standards and other regulatory criteria for PFAS in water and soil in the US and internationally. The table is updated on an approximately monthly basis and is your best resource to obtain current information on the regulation of PFAS in the US. The table is available from: <https://pfas-1.itrcweb.org/>.

18. In some cases, it seems that the officials at state and federal levels use different language and display a different sense of urgency about PFAS, which leads to confusion with the public. What strategies should be used to address this issue? For example, one participant asked about DoD sites and how the public can

encourage the DoD to follow state regulations which are more stringent (and sometimes federal standards are nonexistent).

[Pflugh] One of the components of the Risk Communication planning process is audience assessment. In answering questions like this from the public, it is important to know your audience and the case and the circumstances that have caused the situation. This information is gathered in the audience identification and assessment step of the risk communication planning process. This will guide you in understanding how best to deliver information to your community that is needed by them and in the form needed. With respect to discussing standards, it is best to use the guidance that has been adopted by your state to use. Explain why you are using it and not something else; acknowledge the uncertainty surrounding PFAS; and explain that this selection is based on the best available science for this situation as indicated by the experts. It is also safe to indicate to your community that there are ongoing conversations between federal agencies and the States.

19. What are some strategies for a municipality to be more involved with site assessment and remediation decisions for PFAS contamination?

[Pflugh] Municipal officials are key leaders within a community in delivering information to residents. It is important to develop a relationship with them as soon as possible. It is important to determine what information they need and in what form to act as a liaison to residents and as partners in helping find a solution to a problem, and how best to communicate within the community. Examples of partnerships include shared websites, sharing documents and reports in advance of public release, having them sponsor listening sessions and public meetings, and making joint presentations.

20. What are the sources of the human health toxicology data that are used? How much confidence is there in the research and papers that support these topics?

[Hall] The sources of health effects data used in federal and state risk assessments for PFAS are peer reviewed studies published in the scientific literature, toxicology studies conducted by the National Toxicology program or similar laboratories in other countries, and, in some cases, studies sponsored by industry that are conducted in contract laboratories that meet certain regulatory requirements. The numerical basis for current state and federal PFAS risk assessments is animal toxicology data, with human epidemiology studies and other types of studies such as cell culture studies providing supporting information. These are the same types and quality of data that are considered in evaluating the human health risks of environmental contaminants in general, so they are not specific to PFAS. The data from such studies are generally considered to be reliable by the scientific and regulatory community.

21. For ecological health, what are the sources of toxicity data used? How much confidence is there in the research and papers that support these topics?

[McCarthy] The sources of toxicity data for ecological risk are similar to those described earlier. A difference is that tests are performed on an expanded set of organisms and the types of effects that are studied for ecological risk purposes can differ. For ecological risk, the focus is usually on measures that are tied to protecting populations of organisms with a focus on reproduction, growth, and mortality. Most of the toxicity data is from laboratory tests with single chemicals. There is confidence with how the data were generated. And in most cases, efforts to develop thresholds from the data have produced similar results: PFOS is the most toxic PFAS for most ecological receptors studied. Where confidence decreases is understanding whether these data and resulting guidelines are reflective of environmentally relevant concentrations which occur as mixtures that vary significantly by site. Another area of lower confidence is with the understanding of pre-cursors of PFAS or PFAS that are present but are not detected by standard methods.

22. When both ecological and human health receptors are present, can ecological risk drive the site remediation scenario?

[Long] Given their physical chemical properties, including their bioaccumulation potential, it is very possible for ecological risk to end up driving site remedial action decisions, especially when you are dealing sites that are in proximity to an aquatic environment. Currently there aren't any case studies in the Tech Reg that illustrate this concept, but we will query the team and find examples to illustrate this condition. There is a case study in the Tech Reg now that was used for evaluation of concentrations in fish and resulting decisions were based upon limiting human exposure through fish consumption advisories.

23. There are several papers and other discussions that propose managing and regulating PFAS as a class of chemicals - is there any regulatory framework that either currently addresses this issue or is considering addressing it in the future?

[Hall] Proponents of regulating PFAS as a class tend to support this idea because there is little or no health effects information on many PFAS that are used in commerce and that may be present in the environment. Support for regulating PFAS as a class is also since it is not feasible to perform toxicology studies, develop chemical-specific risk assessments, and develop regulations for each individual PFAS, as this type of chemical-by-chemical evaluation takes years and extensive resources. Much of the support provided for regulating PFAS as a class is based on persistence as a common characteristic of PFAS as a class, and also because of the fact that the PFAS studied to date, have exhibited toxicity in either in vitro (cell culture) or whole animal experiments.

To address the part of the question whether there is any regulatory framework that addresses this, there are a couple of examples. The State of California's Department of Toxic Substances Control is regulating PFAS as a group in consumer products and is working to ban the sale of certain products - like carpets, or plant-based food containers that contain any PFAS - if there are viable, functional alternatives. California's approach is based on both the persistence and health hazard of PFAS and is a regulatory strategy that may not be available in other states. Vermont recently completed a comprehensive analysis regarding the feasibility of regulating PFAS as a class in drinking water and determined that it was not possible at this time due to inadequate toxicologic data, insufficient analytical data, and other factors.

If states or municipalities make a policy decision to regulate PFAS as a class in commerce, it may be possible in practical terms to do so. In contrast, it may be more difficult to regulate PFAS in environmental media "as a class" since the PFAS that are known to be present in an environmental sample are dependent on the analytical method used. Current analytical capabilities do not support an evaluation of all possible PFAS in the environment. In other words, one cannot know if all PFAS present in the environment have been identified and addressed. The being said, the use of methods such as Total Oxidizable Precursor Assay and Total Organic Fluorine to estimate targeted PFAA precursors or total PFAS in environmental media is a step in that direction, and USEPA is currently evaluating these methods.

24. Do human health studies look at PFAS individually, or are PFAS grouped?

[Hall] The update to the Human Health sections of the Tech Reg document will review available information on the toxicity of mixtures of PFAS. There are very few animal toxicology studies of mixtures of PFAS and more research on PFAS mixtures is needed. In contrast, humans are exposed to multiple PFAS that may be present in drinking water, food, or consumer and industrial products, and multiple PFAS are detectable in the blood serum of almost all residents of the U.S. and many other countries. One of the challenges in interpreting the results of epidemiology studies that associate PFAS exposure with human health effects is that exposure to multiple PFAS is often correlated. This can create challenges for epidemiologists who try to understand whether to attribute a human health effect to exposure to a specific PFAS.

25. Given that PFAS and closely related compounds often present together in the environment, is there any understanding of combination effects?

[McCarthy] There is no definitive understanding. An overview of this topic is found in the Tech Reg Document Section 9.2 and in more detail in a recent journal article by McCarthy, Roark, and Middleton (2021). There have been several recent published toxicity studies looking mostly at binary mixtures – typically PFOS and one other PFAS – to try to get some preliminary indications of whether the effects may be additive, synergistic, or antagonistic. These studies have been with amphibians, fish, aquatic insects, birds, and reptiles. Some of the preliminary studies have shown potential additivity or synergism. Mixture studies are very complex even with chemicals that have been studied for decades. There are a lot of different approaches to conducting risk assessments with mixtures or performing laboratory studies. A multi-pronged approach is likely to be the optimal approach used for PFAS.

26. Are risks being calculated using total PFAS, and if so, which PFAS are included in total?

[Long] Risk assessment typically includes assessing the cumulative effects of exposure to multiple chemicals. Cancer risks due to exposure to carcinogens are typically combined into a total cumulative cancer risk while hazard quotients due to exposure to noncarcinogens are combined for those chemicals with the same effect or mechanism of action. With consideration for PFAS exposure, decisions regarding the need for risk management are mostly driven by noncancer adverse effects. Current toxicological information suggests that the effects or mechanisms of action for

several PFAS are the same and thus their individual chemical-specific hazard quotients would be combined in order to calculate a hazard index for a particular exposure scenario. The Tech Reg provides a table (Table 9.2) summarizing the potential noncancer health effects of various PFAS and includes 14 chemicals. As shown on this table, 13 of the 14 chemicals seems to have overlapping noncancer health effects and it may then be appropriate to combine HQs estimated for exposure to these PFAS. That's not to say that the HQ from all PFAS should necessarily be combined but you may see such an approach be used currently as a conservative approach in order to accommodate for some uncertainty. Also, remember that the toxicity or dose-response for individual PFAS can be different so there may be situations where it wouldn't be appropriate to calculate a total PFAS concentration and calculate a noncancer HQ assuming a receptor's exposure to this concentration using the dose-response (or toxicity value) for one particular PFAS (say PFOA).

27. What kinds of concerns have stakeholders expressed about regulating PFAS individually or as a group?

[Strauss] To put the question in perspective, when the ITRC PFAS Team was formed in 2017, the Team was discussing approximately 4,000 known PFAS; now we discuss 5,000 to 6,000 compounds, with some estimates exceeding 10,000 PFAS. The universe is growing and not yet settled. As discussed in Section 13.1.2, several environmental organizations have petitioned USEPA to classify PFAS as a group. Many stakeholders believe that PFAS should be treated as a class of chemicals, like how PCBs or dioxin are currently regulated. Given the lack of toxicological information for the vast majority of PFAS, when even less is known about the potential additive and synergistic effects associated with PFAS mixtures, many stakeholders support using a method that tests for total PFAS. Another petition in New Hampshire requested that PFAS in drinking water be regulated as a group with a treatment technique drinking water standard, which might be described as a performance standard or treatment technology. There are two other active petitions under RCRA: one asking that long-chain PFAS be grouped as a class, and another requesting that all PFAS be regulated as a group and become a listed hazardous waste. Many stakeholders have the goal of regulating PFAS as a class, although as acknowledged by others in this roundtable, current science is unclear about how to do this.

28. What is the best way to handle the precursors from a risk assessment standpoint?

[Long] Precursors should be considered in the risk characterization, especially in conducting the calculations for potential future exposure concentrations. The Tech Reg (Section 10.4.4) includes methods that can be used to understand and quantify precursor transformation rates. This includes reviewing concentration ratios of precursor and daughter end products in groundwater samples from monitoring wells located along the center line of a plume, looking at concentration trends along the center line of a plume, and using information from published studies regarding precursor transformation mechanisms and rates due to particular site geochemistry.

29. As PFAS are considered "forever chemicals", what has been identified as the most problematic exposure pathway over the long-term?

[Long] From a site investigation, risk management action standpoint, the most significant exposure pathways (those that typically drive the need for risk management action) are ingestion of groundwater impacted by PFAS (for example, potable groundwater use) and consumption of aquatic life impacted by PFAS (for example, fish consumption). Exposure routes like inhalation and dermal contact are expected to be smaller sources of exposure. If we're talking about exposure pathways beyond the site risk management context, then exposure via contact with PFAS in the workplace, ingestion of food, and exposure to consumer products may be of interest.

30. How do we more effectively communicate long-term health risks associated with PFAS?

[Pflugh] With any type of risk communication, it is always best to meet people where they are. The audience assessment step helps to learn what people know and understand. Build from what they know. Hear what the concerns are and start there. Provide all the information you know about what is known and explain what is still unknown. Explain that guidance is provided using the best available science and what is most protective of their health.

31. Are there any state regulatory or screening values proposed or in use for surface water, sediment, or soil - and if so, what studies identify the negative ecological effects that support these values?

[McCarthy] Yes, a small, but growing number of states have developed final or draft screening values for freshwater and soil. These are mostly for PFOS and sometimes PFOA. Minnesota developed surface water values over 10 years ago and Michigan developed values around 2018. Florida and Hawaii have some draft values. Wisconsin has been developing surface water values. And a few other states are planning to do so.

ITRC PFAS Roundtable Webinar Session 4 *continued*

In California, the San Francisco Bay Regional Water Quality Control Board (SFB RWQCB) has released Interim Final Environmental Screening Levels (ESLs) for PFOS and PFOA including soil and for groundwater protective of freshwater and saltwater organisms and wildlife. These are based off a variety of sources including 2020 Reports from DoD and CRC CARE. This information is referenced in Section 9.2 in the Tech Reg document. A tabular summary of available soil and water regulatory values are updated by the ITRC PFAS Team approximately monthly, and available on the ITRC PFAS webpage.

32. Have any surface water standards been developed?

[Hall] Surface water criteria for ecological receptors was just addressed. With respect to human health, seven states currently have regulatory criteria for surface water: AK, CO, CT, FL, MI, MN, and OR. Surface water criteria for PFOA and PFOS are under development in Wisconsin. Not all these surface water criteria are enforceable, some are advisory - see the ITRC Water and Soil values table to determine which surface water criteria are enforceable and which are advisories. There are additional technical challenges in developing surface water criteria that are different from developing drinking water criteria, including the limited availability of bioaccumulation factors (BAFs). The ITRC PFAS Team and USEPA are engaged in important efforts to gather and review information relevant to PFAS BAFs.

The Tech Reg has a new comprehensive section on PFAS in Surface Water (Section 16). To develop this section, the ITRC PFAS Team surveyed states to gain insight into how they were regulating - or planned to regulate - PFAS in surface water. The ITRC PFAS Team understands that USEPA is currently assessing whether there is sufficient data to develop human health and aquatic life criteria for PFOA and PFOS under the Clean Water Act, and the agency is also evaluating potential approaches for developing their own criteria. Note that one of the important distinctions when we talk about surface water criteria for PFAS is whether we are discussing human health criteria or criteria for the protection of aquatic life. Most of the surface water criteria developed to date are focused on the protection of human health. The number of states that have established values for protection of aquatic life is small and currently includes Michigan and Florida. A tabular summary of available soil and water regulatory values are updated by the ITRC PFAS Team approximately monthly, and available on the ITRC PFAS webpage.

33. Has ITRC published bioconcentration or bioaccumulation factors (BCF or BAF) for any PFAS? If not, is ITRC planning to incorporate this information with references to supporting studies, in future documents?

[McCarthy] Bioconcentration is referring to the direct uptake of PFAS by an organism from the water column (through the gills), measured as the ratio of the concentration in an organism to the concentration in water (typically measured in the laboratory, units typically in liters per kilogram [L/kg]). Bioaccumulation refers to the amount of PFAS taken up from bioconcentration plus the contribution of PFAS in the diet of the organism (can be measured in the laboratory or field, typically unitless).

Biomagnification refers to an increase in tissue concentration as one moves up the food chain based on a predator/prey relationship (always measured in the field, typically unitless), often defined as the concentration of chemical in an organism divided by the concentration of chemical in its food.

ITRC has a lengthy discussion of bioconcentration and bioaccumulation of PFAS in Section 5.5 of the Tech Reg Document, and there is a new comprehensive review of the literature values compiled in a table that will be published later this year. Two SERDP reports published last year (Divine et al. 2020 and Conder et al. 2020) also provide tables of these values and break them out by groupings reflective of animals' diets - for instance aquatic invertebrates, aquatic plants, fish, etc. There is wide variability with some of these data and a difference between those determined in a lab versus measured in the field.

34. Have stakeholders expressed concern about PFAS-contaminated sediments?

[Strauss] Although the Tech Reg has not identified sediments as a media that stakeholders are typically concerned about, sediment concerns are implied in Sections 13.1.3 and 13.1.6. These concerns are related to a lack of ecological guidelines and the fact that there is only one national health advisory, which deals exclusively with drinking water. Stakeholders are concerned with the entire food chain and ecosystem, and benthic organisms that live in sediments are crucial for many species of birds and fish.

35. Are there any studies regarding minimum concentrations of PFAS in soils that will result in negative ecological effects?

[McCarthy] There are no federal, and very few state, criteria for soil that are intended to be protective of ecological health. Available values are summarized in Section 9.2 of the Tech Reg. There have been a few laboratory exposure

ITRC PFAS Roundtable Webinar Session 4 *continued*

tests with plants and invertebrates exposed to spiked soils. And last year SERDP funded two reports (Divine et al. 2020 and Conder et al. 2020) that provided the data to develop soil values protective of ecological health, identified exposure factors and physical and chemical properties affecting bioavailability like organic carbon, and even provided some soil screening values. These reports are summarized in Section 9.2.

36. In the absence of a state or federal lookup table of standards or guidance - and in the absence of EPA-approved analytical methods for these matrices - how are PFAS soil/sediment/groundwater/surface water threshold limits for a site investigation determined?

[Long] The process would be no different for PFAS than for any other chemical. Determination of the relevant exposure scenarios, compilation of relevant exposure factors for these scenarios, compiling physical/chemical properties for each chemical as needed to support fate and transport calculations, compiling toxicity values to quantify the dose-response relationship, and selecting what “target risk/HQ levels” to use (for example, target cancer risk level of 1E-6 and noncancer HQ of 1). A lot of these inputs may be jurisdictionally specific and should be taken into consideration as part of the process.

In the absence of widespread regulation, how are site risk assessments considering the soil to groundwater pathway - aka the leaching of PFAS from soil to groundwater?

In the absence of chemical/physical properties that can be used to model leaching to groundwater, our understanding is a little more limited, but there are various methods that can be considered to evaluate the exposure scenario including developing screening levels. This includes mass-limited calculations (see USEPA 1996) or laboratory leach testing (for example, SPLP). Another approach would be to use empirical information and install monitoring wells if such a concern is present.

37. Have any biosolids standards been developed?

[Hall] The USEPA does not regulate PFAS in biosolids; however, USEPA is reportedly developing a screening tool and probabilistic risk assessment framework that will help the agency assess risks from PFAS and numerous other substances that have been detected in biosolids that are used as fertilizer or land applied. A number of states have looked at regulating PFAS in biosolids. Maine is currently the only state to have concentration-based screening levels for PFAS in biosolids (2.5 and 5.2 parts per billion (ppb) for PFOA and PFOS, respectively, and 1,900 ppb for PFBS).

38. Are there stakeholder concerns about transitions from AFFF to Fluorine Free Foam? Are there any resources to which a stakeholder can refer to learn more about these issues?

[Strauss] – The Tech Reg does not identify this type of concern. Many stakeholder groups have supported the 2020 National Defense Authorization Act, which provides that the military will transition to an alternative to AFFF in as few years. They will still use AFFF aboard ships, where the risk of a fuel related fire could be catastrophic. There are not a lot of resources that I am aware of that address foam transitions, although there is at least one resource developed by the Foam Exposure Committee and distributed by Fire Department Service Announcements (codepfas@gmail.com).

39. Can you provide some examples of community-level risk communication?

[Pflugh] Addressing community risk communication should consider the risk communication planning approach that we talked about earlier. Each community will have unique ways they communicate with each other, which is why audience assessment is so important to understand how people receive information. Some examples of local efforts are listening sessions, drop in sessions, media boards, community forums, festivals, churches, school meetings, etc. Always remember why you are communicating: Is it to report back results of testing? Is it to establish dialogues? Is it to obtain information? Is it to build consensus? This will help determine the best way to talk with the public. Above all, it is important to not leap right away to methods and outreach techniques before you understand your community, issues, and how the community is interpreting the information they are receiving.

40. Given that some industrial facilities have been identified as the source of widespread community impact via an air emissions pathway, what is the state of the practice to assess risks from deposition to soils, sediments, and surface water? Do these risk assessments consider impacts to particulates, water vapor and aerosols?

[Long] Site risk assessments that are used for risk management decision-making should consider and detail the scenarios for potential human and ecological exposure in the conceptual site model. This would include noting sources of potential contamination, release mechanisms, fate and transport in the environment and subsequently

ITRC PFAS Roundtable Webinar Session 4 *continued*

exposure media, pathways, and routes. Such fate and transport pathways very well could be relevant when working to characterize current and potential future risk due to releases to the environment.

41. Are regulators looking at PFAS in air?

[Hall] The USEPA has the authority to regulate PFAS emissions to air under the Clean Air Act, and that Act applies to discharges of PFAS to air under National Emission Standards for Hazardous Air Pollutants or NESHAPs; however, there are no federal air emission standards for PFAS at this time.

A couple of states have been active in regulating PFAS in air. Texas has regulatory concentrations for certain PFAS in air known as Protective Concentration Limits. New Hampshire and North Carolina have required permits of certain industrial facilities to limit their release of PFAS to air. And although other states such as California are beginning to look at regulating PFAS in air, further development of commercially available analytical methods that have been validated by the USEPA to support the measurement of PFAS in air are necessary to understand and/or limit emissions.

42. Are there data to support evaluation of a vapor intrusion risk for PFAS?

[Hall] PFAS that are acids such as perfluoroalkyl carboxylates and sulfonates (for example, PFOA, PFOS, and related PFAS with different chain lengths) are not volatile (at environmentally relevant concentrations), not are other types of PFAS that are acids - for example, GenX - HPFO-DA which is a perfluoroalkyl ether carboxylic acid. Some other types of PFAS are volatile, for example fluorotelomer alcohols (FTOHs). The ITRC PFAS Team was not able to identify toxicity values for the volatile PFAS for inclusion in the Tech Reg at this time, and the USEPA has not yet published validated analytical methods for PFAS in air.

43. What are the federal rules about destruction and disposal of treatment media [and other PFAS wastes]?

[Hall] Currently, there are no final federal rules or guidance on the destruction and disposal of PFAS. As of December 2020, USEPA published interim guidance on PFAS destruction and disposal, but that guidance has not been finalized.

44. What kind of concerns are stakeholders expressing about landfill leachate and wastewater treatment plant discharges?

[Strauss] PFAS containing material is placed in landfills, and landfills and leachate are discussed in Section 13 of the Tech Reg. Landfill leachate (in general, water that flows through a landfill) is usually collected and stakeholders are concerned that PFAS-containing leachate might be discharged directly to ground or open waters. Although leachate is commonly sent to a wastewater treatment plant (WWTP), WWTPs influents have not been historically tested for PFAS and stakeholders are concerned about two potential PFAS-contaminated outputs: solids called sludge and "clean" liquid effluent. Historically some sludge drying beds had liquids that seeped into the ground. The "clean" liquid effluent from WWTPs has been discharged to evaporation ponds, rivers, or water bodies typically without treatment for PFAS because WWTPs have not historically been equipped to reduce PFAS levels in liquid effluent or sludges. In some cases, treated sludge (referred to as biosolids) can be sold or given away as fertilizer or compost. Stakeholders are concerned these WWTP outputs containing PFAS will enter the food chain for humans and wildlife. For an example, PFAS-containing sludge generated in the state of Washington had been managed in a manner that resulted in contamination of ground and surface water used for drinking and fishing.

45. Have any landfill leachate standards been developed?

[Hall] The Tech Reg does not currently address landfill leachate standards. However, one of our ongoing updates is to develop a table that documents current state, federal, and international regulations, and standards. When complete, this table will be a resource to answer this question and available on the ITRC PFAS webpage (<https://pfas-1.itrcweb.org/>).

46. In site risk assessment, is there a standard approach to handling non-detects for PFAS - especially given the potential range in detection limits that might have been reported over the years (for example, for sites that first started sampling in 2016, there may be higher reporting limits for many compounds as compared to today's analytical capabilities).

[Long] The question of how to handle non-detect results is not just an issue for PFAS. This can be a challenge for many environmental contaminants, but there is guidance navigating this challenge. For example, USEPA's Risk Assessment Guidance for Superfund provides specific guidance for how to handle non-detect chemicals in performing risk assessment. In general, if chemicals are not detected in an environmental media across an entire site, then it would not

ITRC PFAS Roundtable Webinar Session 4 *continued*

be necessary to account for the chemicals in the quantitative risk characterization. However, if a chemical was detected in an environmental media, then it may be appropriate to consider their presence when estimating exposure.

47. How does the identification of certain PFAS on the Stockholm Convention and the identification of continued uses impact regulation in the US?

[Hall] PFOS, its salts, and PFOSF, or perfluorooctane sulfonyl fluoride; as well as PFOA, its salts, and "related compounds", have been designated as persistent organic pollutants (POPs) under the Stockholm Convention. As of 2009, PFOS, its salts, and PFOSF uses are restricted under the Convention. In 2019, PFOA and its salts and "related compounds" were banned (with some exemptions) under the Convention - an act which gives countries that have ratified the Convention 12 months to enact the ban. A global ban on PFHxS has also been recommended by the Stockholm Convention. The US is not a signatory to the Stockholm Convention, so the restrictions and/or bans on these PFAS do not apply to regulation here in the United States.

48. How does Canada regulate PFAS?

[Hall] Water and soil regulatory values in Canada are summarized on the PFAS Water and Soil Values Table Excel file available on the ITRC PFAS website (<https://pfas-1.itrcweb.org/>). Other PFAS regulations tracked by the ITRC PFAS Team are primarily focused in the US. That said, there are a few mentions in the Tech Reg of activities in Canada - for example, prohibition of certain substances and links to ecological risk studies. ITRC is developing a table that documents current state, federal, and international regulations, and standards. When released, it will include information on PFAS regulation in Canada and available on the ITRC PFAS webpage (<https://pfas-1.itrcweb.org/>).

The following questions were not answered during the live session as there were more questions asked than could be answered in the time allotted.

49. Do federal or state regulations require or establish funding for assessment and remediation of PFAS?

There are some federal programs that have established funding for assessment and remediation of PFAS-contaminated sites. There are also some individual states that have established PFAS funding for contaminated sites, but generalizations about these programs is difficult. However, one of our ongoing updates is to develop a table that documents all current state, federal, and international regulations, and standards. When complete, this table will be a resource to answer this question and available on the ITRC PFAS webpage (<https://pfas-1.itrcweb.org/>).

50. Does eco risk address impacts to honeybees (and resulting honey for human consumption) or maple trees (for maple sap harvesting and syrup production)?

There was a study published in 2001 looking at acute oral exposure to honeybees. These data, included in Section 7.2 of the Tech Reg, can be used to assess potential effects to bees at a specific site. Both no effect levels and lowest effect levels were published. Vermont Department of Environmental Conservation studied the potential for PFOA uptake into maple trees and transfer to maple syrup and concluded in the area tested, where PFOA in drinking water was high, that maple syrup was not contaminated.

51. What do we know about the ecological effects of low level, chronic PFAS exposure in terrestrial freshwater ecosystems?

If we focus just on PFOS, the chemical with the most ecological effects data, environmentally relevant concentrations seem to be below concentrations that result in toxicity to animals at the base of the food web –invertebrates, plants, forage fish. Published lab studies on birds suggest that some sites have environmental concentrations that warrant further evaluation. There have been a few field studies with birds looking at reproductive effects in areas with known PFAS and the results have varied with some showing a potential reduced reproductive capacity and others not showing a potential effect. The jury seems to still be out because there is not enough data to draw a conclusion one way or the other. Most recent papers discussing the needs for ecological effects due to PFAS indicate that more field studies are needed to link with the laboratory studies that have been conducted.

52. Are you aware of any ecological studies on PFAS effects on mussels?

A recent study by the US Navy looked at mussels exposed to PFAS. However, there are not many published studies looking at adverse effects in mussels exposed to PFAS. There are also little or no published field studies that looked at the same question.

53. Given the widespread use of PFAS, how does one determine if your detections are from an actual release at the property? What does the data mean on a lab report with respect to a Phase II Environmental Site Assessment (ESA) or Remedial Site Inspection or Site Investigation (SI)?

Section 10.5 of the Tech Reg provides guidance on how to approach source identification and distinguish between sources of PFAS. Source identification uses the evaluation of both typical and advanced chemical analyses to identify and differentiate among sources and age-date release events. Advanced techniques can include chemical fingerprinting, signature chemicals, isotopic fingerprinting, contaminant transport models, molecular diagnostic ratios, radionuclide dating, and microscopic analysis. Overall, multiple lines of evidence may be needed to distinguish between two or more sources of PFAS contamination.

54. Are there regulations that require companies to report the use of PFAS - so that communities can know who might be using and releasing PFAS near them?

Under the Toxic Release Inventory, or TRI, the USEPA regulates the emission of 175 different PFAS. Companies that release 100 pounds or more of any of these PFAS to air, per year, are required by law to report these emissions to the USEPA. These reports are publicly available. In addition, some states have reporting requirements for chemicals designated as Hazardous Substances; these requirements vary among states.

55. Are there any known Endangered Species Act considerations regarding ecological risk posed by PFAS?

There is concern with Threatened and Endangered species exposure to PFAS, as there is with any contaminant. Specific lab and field studies are limited. The USDOD has funded several projects to develop methods to assess threatened and endangered species exposure to PFAS, including exposure and effects data that could be used, and spatial techniques for prioritizing and focusing efforts. These projects and reports are summarized in Section 9.2 of the Tech Reg.

56. Given that PFAS are used for life and property saving efforts for firefighting, and used as protective coatings and in medical devices, but that the regulatory standards for drinking water exposure are relatively low compared to other chemicals, how do we provide a balanced communication about the risk between use and exposure?

It is best to avoid discussions of cost benefit and risk comparisons. Remember it is the public not you that determines what they value and what is important to them. Focus on the risk of PFAS and let them decide what is most important to them.

57. Are stakeholders identifying a desire to make PFAS a RCRA Hazardous Waste to improve protection of human and ecological health?

Stakeholders have petitioned USEPA to classify certain PFAS compounds as RCRA Hazardous Wastes. If approved, this creates an incentive not to use materials that would leave a hazardous waste that requires special disposal.

58. Does the USEPA PFAS Action Plan describe how USEPA regulates PFAS, and do you know when the next update will be issued?

The USEPA's PFAS Action Plan (issued in 2019 and updated in 2020) describes regulatory initiatives and goals for PFAS, such as their work on MCLs; on UCMR5; on developing Toxicity Assessments for a number of PFAS, developing additional SNURs under TSCA, and on including PFAS under TRI. The USEPA has completed - or is in the process of completing many of the initiatives/goals set out in the original Plan. For further information about USEPA's activities, see the USEPA's website (<https://www.epa.gov/pfas>)

59. Which States require PFAS testing of public water systems and what are the testing parameters (types of systems that are required to test, frequency, testing protocol, etc...)?

The Tech Reg does not currently address individual state requirements for testing of water systems for PFAS. However, one of our ongoing updates is to develop a table that documents current state, federal, and international regulations, and standards. When complete, this table will be a resource to answer this question and available on the ITRC PFAS webpage (<https://pfas-1.itrcweb.org/>).

ITRC PFAS Roundtable Webinar Session 4 *continued*

60. Are there other state regulations about PFAS? More specifically, are there regulations about use of certain sampling equipment, well construction materials, etc. to avoid cross contamination? Do any states have regulations that don't allow for them to develop PFAS regulations?

The Tech Reg does not currently address individual state requirements for sampling equipment, well construction materials, or similar information. However, one of our ongoing updates is to develop a table that documents all current state, federal, and international regulations, and standards. When complete, this table will be a resource to answer this question and available on the ITRC PFAS webpage (<https://pfas-1.itrcweb.org/>).

3 References and Acronyms

The references cited in this digest, and further references can be found at <https://pfas-1.itrcweb.org/references/>.

The acronyms used in this digest and the Guidance Document can be found at <https://pfas-1.itrcweb.org/acronyms/>.