

Attachment 2a: Agency Responses to Public Comments

Submitter	Comment	Agency Response
Anonymous Anonymous	The submitter commented on issues associated with the impacts of wildfire on wildlife.	The Agency appreciates the comments from the submitter. The comments are outside the scope of this docket.
Vicki Quint	The submitter commented on testing drinking water and groundwater for PFAS.	The Agency appreciates the comment from Vicki Quint. The exposure assessments focus on human exposure to PFAS from drinking water. While the presence of PFAS in groundwater indicates contamination, it does not necessarily signal that people have been exposed. The exposure assessments will investigate PFAS exposure among communities in which there is evidence of PFAS drinking water contamination. In addition, ATSDR will conduct drinking water testing at a subset of households to assess current levels of PFAS and advise appropriate mitigation, if necessary.
Vicki Quint	The submitter commented on issues associated with exposure of First Responders to PFAS during firefighting activities.	The Agency appreciates the comment from Vicki Quint. The Exposure Assessments are designed to characterize exposure to the general population rather than worker exposures. In order to generate results representative of the community, participants will be selected at random from all people in the defined study areas. Randomly selected individuals will be eligible to participate in the investigation if they meet all three inclusion criteria: are three years of age or older, have lived in the community for at least one year, and do not have a bleeding disorder and is not anemic. If first responders, including fire fighters, live in the study area and are selected through the random process, they will be included in the exposure assessment. In the current work we cannot target specific subpopulations (like first responders or fire fighters) and still generate results that will be valid for the community as a whole.
International Association of Fire Fighters	The submitter encouraged ATSDR to include fire fighters and other workers in its data collection to determine the relative risk to	The Agency appreciates the comment from the International Association of Fire Fighters. The Exposure Assessments are designed to characterize exposure to the general

	workers as opposed to other individuals at military bases.	population rather than worker exposures. In order to generate results representative of the community, participants will be selected at random from all people in the defined study areas. Randomly selected individuals will be eligible to participate in the investigation if they meet all three inclusion criteria: are three years of age or older, have lived in the community for at least one year, and do not have a bleeding disorder and is not anemic. If fire fighters live in the study area and are selected through the random process, they will be included in the exposure assessment. In the current work we cannot target specific subpopulations (like fire fighters) and still generate results that will be valid for the community as a whole.
Integral Consulting Inc.	The submitter requested that ATSDR release additional details on study design and protocol for public review and comment.	The Agency appreciates the comment from Integral Consulting, Inc. The document "Exposure Assessment Protocol: Biological and Environmental Sampling of Per- and Polyfluoroalkyl Substances (PFAS)" was submitted with the Federal Register Notice announcing the project and was available for review during the 60-day comment period. This document contains detailed information on the design of the exposure assessments.
Integral Consulting Inc.	The submitter requested that ATSDR conduct analysis and reporting of results on an individual basis, not just by composite summary statistics. The submitter requested that de-identified individual results (both questionnaire and biological sampling) be released to the public.	The Agency appreciates the comment from Integral Consulting, Inc. As described in the document, "Exposure Assessment Protocol: Biological and Environmental Sampling of Per- and Polyfluoroalkyl Substances (PFAS)," ATSDR will conduct individual-level analyses using biological, environmental, and questionnaire data to explore relative source contributions, including that of drinking water, as well as factors that might influence this relationship. Regarding data release, public health and scientific advancements are best served when data are shared for public health purposes while ensuring the privacy of participants is well protected. Investigators will comply with all applicable laws and regulations related to privacy protection and human subjects research protection such as the Privacy Act, the Common Rule at 45 CFR 46, etc. The investigators will also follow CDC/ATSDR's Policy on Public Health Research and Non-research Data Management and Access to make de-

		identified data available to external organizations and researchers at the appropriate access level(s) as approved in the study data management plan.
Diane Cotter	The submitter commented about concentrations of PFAS in fire fighter PPE.	The Agency appreciates the comments from Diane Cotter. The Exposure Assessments are designed to characterize exposure to the general population rather than worker exposures. In order to generate results representative of the community, participants will be selected at random from all people in the defined study areas. Randomly selected individuals will be eligible to participate in the investigation if they meet all three inclusion criteria: are three years of age or older, have lived in the community for at least one year, and do not have a bleeding disorder and is not anemic. If fire fighters live in the study area and are selected through the random process, they will be included in the exposure assessment. In the current work we cannot target specific subpopulations (like fire fighters) and still generate results that will be valid for the community as a whole.
Diane Cotter	The submitter commented about concentrations of PFAS measured in drinking water at fire training centers and fire stations across the United States. The submitter commented that with no regulations, the Department of Defense was able to advise Okinawa Prefecture Group they need not pursue PFOA/PFOS contamination any further as it was not regulated.	The Agency appreciates the comment from Diane Cotter. ATSDR is aware of concerns about PFAS contamination around fire training centers and fire stations. The 2018 National Defense Authorization Act requires no less than eight exposure assessments be conducted at current or former domestic military installations. ATSDR is considering locations for the exposure assessments on a site-by-site basis, taking into account a variety of factors. Because ATSDR and CDC are non-regulatory agencies, the comments regarding PFAS regulations are outside the scope of this docket.
Diane Cotter	The submitter attached a letter to her submitted comments dated September 12, 2018 and signed by Robert A. Bilott, Taft Stettinius & Hollister LLP.	Please refer to the Agency responses to comments submitted by Robert A. Bilott.
Robert A. Bilott, Taft Stettinius & Hollister LLP	Select comments from the submitted letter pertain to this docket, including the suggestion to include fire fighters in exposure assessments, the critique that the	The Agency appreciates the comments from Robert A. Bilott. The Exposure Assessments are designed to characterize exposure to the general population rather than worker exposures. In order to generate results

	<p>exposure assessments will not enroll sufficient numbers of participants to derive conclusions about health effects, and whether data from the exposure assessments would be combined with data from the proof of concept study.</p>	<p>representative of the community, participants will be selected at random from all people in the defined study areas. Randomly selected individuals will be eligible to participate in the investigation if they meet all three inclusion criteria: are three years of age or older, have lived in the community for at least one year, and do not have a bleeding disorder and is not anemic. If fire fighters live in the study area and are selected through the random process, they will be included in the exposure assessment. In the current work we cannot target specific subpopulations (like fire fighters) and still generate results that will be valid for the community as a whole. Regarding the comment on numbers of participants in the exposure assessments hindering an analysis of health effects, the exposure assessments are not intended to study exposure-outcome relationships. Lastly, given that data from the exposure assessments will not include information on health outcomes, combining it with health-related data from the proof of concept would not yield additional insights on exposure-outcome relationships. The remaining comments in the letter are outside the scope of this docket.</p>
<p>Stephen Risotto, American Chemistry Council</p>	<p>The submitter requested that ATSDR: release additional details on study design and protocol for public review and comment; explain the approach taken to choose sites; list the PFAS species that will be analyzed; explain the use of questionnaire and laboratory data to estimate exposure; increase dust and tap water collection to 100% of households; and release de-identified, individual-level data.</p>	<p>The Agency appreciates the comments from Stephen Risotto. The document “Exposure Assessment Protocol: Biological and Environmental Sampling of Per- and Polyfluoroalkyl Substances (PFAS)” was submitted with the Federal Register Notice announcing the project and was available for review during the 60-day comment period. This document contains detailed information on the design of the exposure assessments and the planned data analyses. ATSDR is in the process of evaluating sites for inclusion in the exposure assessments. ATSDR is considering locations on a site-by-site basis, taking into account a variety of factors. The approach taken will be shared publicly once the selections have been made. Though collection of environmental samples from 100% of households would increase statistical power, the decision to sample a 10% subset was informed by logistics and resource availability. Regarding data release,</p>

		<p>public health and scientific advancements are best served when data are shared for public health purposes while ensuring the privacy of participants is well protected. Investigators will comply with all applicable laws and regulations related to privacy protection and human subjects research protection such as the Privacy Act, the Common Rule at 45 CFR 46, etc. The investigators will also follow CDC/ATSDR's Policy on Public Health Research and Non-research Data Management and Access to make de-identified data available to external organizations and researchers at the appropriate access level(s) as approved in the study data management plan.</p>
<p>Jessica Bowman, FluoroCouncil</p>	<p>The submitter commented that collecting data on flooring type is immaterial to estimates of PFAS exposure through drinking water and recommended removing questions about flooring from the questionnaire. The submitter recommended that individual-level and paired data be analyzed to understand 1) relative source contributions, and 2) human elimination kinetics and human serum to water slope factors.</p>	<p>The Agency appreciates the comments from Jessica Bowman. Information on flooring type will help ATSDR accomplish its third objective, as defined in the document "Exposure Assessment Protocol: Biological and Environmental Sampling of Per- and Polyfluoroalkyl Substances (PFAS)": to investigate environmental determinants of PFAS concentrations in blood and urine. There is reasonable evidence to suggest that flooring type might impact PFAS dust levels (Wilkins, K. et al. Environ Int. 2018 Oct; 119:493-502). ATSDR will conduct individual-level analyses using biological, environmental, and questionnaire data to explore, when feasible, relative source contributions, elimination kinetics, and serum to water slope factors. Regarding data release, public health and scientific advancements are best served when data are shared for public health purposes while ensuring the privacy of participants is well protected. Investigators will comply with all applicable laws and regulations related to privacy protection and human subjects research protection such as the Privacy Act, the Common Rule at 45 CFR 46, etc. The investigators will also follow CDC/ATSDR's Policy on Public Health Research and Non-research Data Management and Access to make de-identified data available to external organizations and researchers at the appropriate access level(s) as approved in the study data management plan.</p>

