PFOS and PFOA in Drinking-water: Background document for development of WHO Guidelines for Drinking-water Quality

Background

In view of the public health concerns of per- and polyfluoroalkyl substances (PFAS), the World Health Organization (WHO) initiated the development of a background document for the Guidelines for drinking-water quality (GDWQ) on PFAS in drinking-water with a focus on perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA). The process was initiated in 2017. Preliminary drafts were discussed at numerous consultations with the authors and the chemical working group, including in July 2018, April 2019, March 2021 and October 2021. The document also went through a peer review process in 2021, with the feedback provided considered by the chemical working group. As part of this process, the draft background document was offered for public consultation from 29 September to 11 November 2022, during which 25 sets of comments were received from different stakeholders.

WHO's responses to the most common comments received during the public consultation period

Comment*: The WHO's conclusion that the scientific uncertainties are too significant to derive a health-based value for PFOS and PFOA is incorrect. Addressing scientific uncertainty is inherent to the practice of risk assessment and is not a justifiable reason for not establishing a health-based guideline value.*

> **Response**: The derivation of health-based guideline values for PFOS and PFOA is technically possible and is not necessarily precluded by scientific uncertainty. The uncertainty in this case refers principally to a lack of consensus on key issues raised below, rather than uncertainty which could be characterized. The draft background document cites health-based values derived by multiple authoritative agencies, including: Health Canada, U.S. Environmental Protection Agency, European Food Safety Authority, U.S. Agency for Toxic Substances and Disease Registry, and others. The draft document also points out that health-based values established previously span orders of magnitude. Therefore, recognizing that multiple health-based values for PFOA and PFOS have already been established, and further recognizing the lack of scientific consensus on the key end point and risk assessment approach for these compounds, WHO proposed for its draft background document, a provisional guideline value based on technical achievability, while emphasizing the need to achieve contamination levels as low as reasonably practical. In parallel the background document emphasized the need to prevent contamination of water sources and to stop non-essential uses of PFAS.
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> However, in response to multiple requests from stakeholders, recognizing the value of assessing the evidence beyond PFOS and PFOA and to ensure that the latest evidence is taken into account since the background document was drafted, WHO will be undertaking a more comprehensive review on PFAS that will include further examination of whether international health-based guideline values can be established.

Comment: *The provisional guideline value of 100 ng/L for PFOA and PFOS proposed in the WHO draft background document is not sufficiently health-protective because it is significantly higher than other health-based values recently derived by other agencies. Further, treatment technologies are available to achieve much greater removal efficiencies than those suggested in the draft document.*

Response: The provisional guideline value of 100 ng/L for PFOA and PFOS proposed in the draft background document is not a health-based value and the draft background document does not suggest this is a safe level of exposure. Therefore, the WHO's proposed provisional guideline value should not be compared to health-based values established by other agencies.

The draft background document found that high pressure membrane processes, adsorption and ion-exchange can reduce PFOS and PFOA contamination levels by ≥ 90%, and that these technologies can consistently and reliably reduce PFAS-contaminated waters to below 100 ng/L. However, the draft background document did not intend to suggest that these technologies *couldn't* reduce PFOS and PFOA contamination to concentrations lower than 100 ng/L. Therefore, the provisional guideline value should not be interpreted as the lowest concentrations of PFOA and PFOS that can be achieved with available treatment technologies; in fact, it is expected that well-operated treatment processes designed for PFAS removal are able to achieve concentrations well below this value.

Instead, the provisional guideline value of 100 ng/L was proposed recognizing that achieving lower levels is unlikely to be feasible globally, especially for resource limited countries and contexts that do not have these systems in place or do not have the ability to consistently operate them effectively. WHO guideline values are developed to inform the establishment of national standards and regulations, and therefore take into account that there is limited benefit in establishing requirements that cannot practically be achieved. It should also be noted that WHO guideline values usually consider "reasonably practicable treatment", where this is usually interpreted as conventional water treatment (coagulation, flocculation, filtration and chlorination). Nevertheless, the draft document emphasizes that the provisional guideline values "should not be considered as licenses to allow contamination (up to these levels)", and further advises that Member States "should strive to achieve concentrations that are as low as reasonably practical, even when lower than the provisional guideline value."

It is recognized that this is an area of active research with new data continuing to emerge and therefore WHO will keep the state of science on treatment achievability under review.

Comment: *The WHO draft background document did not incorporate a systematic review of the literature, and therefore attempts to draw conclusions on health effects without considering all the relevant data.*

Response: WHO's draft background document was prepared in line with WHO's Policies and procedures manual for developing the Guidelines for drinking-water quality. In preparing chemical background documents for the Guidelines for drinking-water quality, WHO does not usually carry out stand-alone systematic reviews. Instead, the background documents, including the drinking-water guideline values are, where possible, based on up to date assessments carried out by WHO (e.g. monographs in the Environmental Health Criteria or CICAD series). In the absence of a suitable WHO assessment, the background documents may instead be based on one or more recent high-quality peer-reviewed national assessments. Accordingly, in the absence of a WHO assessment on PFAS, the background document

considered the evidence reviews conducted by multiple national and regional agencies, providing a summary of the literature for each health endpoint of concern with details on a subset of the data. This intent was stated in the background document; for example, in section 4 on human health effects, it states: "Although this section highlights several studies related to the toxicological effects of PFOA and PFOS exposure in humans as illustrative examples, it is not intended to be a comprehensive summary of all the data available."

Comment: *The names and affiliations of those who contributed to the document are not transparent and there is concern about potential conflict(s) of interest.*

The development of the document was overseen by an expert working group and included an external peer review process. All peer reviewers, working group members, and contributing authors were required to declare any potential conflicts of interest and signed a declaration of interest form. None of these individuals disclosed any interests that precluded their involvement in the development of the background document. Traditionally, WHO has published the names of all those who are involved in preparation of a background document for the Guidelines for drinking-water quality only in the final background document. In response to concerns raised post the public review process, WHO has made available the names of key contributors to the background document. Specifically, the names of the lead authors, chemical working group members who guided document development and peer reviewers are included on the WHO webpage: PFOS and PFOA in drinking-water: background document for development of WHO Guidelines for drinking-water quality. As noted on the webpage, these contributors disclosed interests related to PFAS and it was determined that no interests were declared that precluded involvement in development of the draft background document.

WHO will continue to only engage experts in its work on PFAS, including the wider assessment on PFAS, who have signed WHO's declaration of interest form and have been determined to not have any conflicts that would preclude involvement. Furthermore, the names of all experts who will be involved in the wider WHO assessment on PFAS will be posted on WHO's website throughout the development process.

Additional information

The draft background document mentions chemical guideline values. What are those?

A guideline value normally represents the concentration of a constituent that does not result in any significant risk to health over a lifetime of consumption. The health effects information in the chemical background documents, including guideline values, are usually based on international chemical risk assessments (e.g. from WHO's chemical safety team). In the absence of a suitable WHO assessment, guideline values may be based on one or more recent high quality, peer reviewed national or regional assessments.

In certain cases, WHO recommends a provisional guideline value that is higher than the health-based value (i.e. based on a chemical risk assessment). The provisional guideline value takes into account practical issues, including those associated with the feasibility of

monitoring or treating the contaminant[1]. WHO has established a number of provisional guideline values at concentrations that are reasonably achievable through practical treatment approaches or that are detectable by standard analytical methods.

Chemical guideline values should be adapted in national standards and regulations, including establishing stricter values in national standards compared to the provisional guideline values, when resources are available.

Who were the experts who participated in developing the GDWQ?

The contributors included the **experts from the Guideline Development Group** and working groups for the Guidelines for drinking-water quality: Fourth edition incorporating the first and second addenda, who formulate the recommendations related to chemical, microbial or protection and control aspects based on the evidence. Their names can be found in the Acknowledgement section of the Guidelines.

Additional contributors provide expertise and comments for all WHO assessments of drinking-water contaminants, including for PFOS and PFOA. For the PFOS and PFOA document, their names will be included in the final background document. As of 29 September 2022, contributors include:

- Dr Ruth Bevan, independent consultant, United Kingdom; Mr Brad Lampe, WHO Collaborating Centre NSF International; Professor Peter Jarvis, Cranfield University, United Kingdom; and Professor John Fawell, Cranfield University, United Kingdom prepared the initial drafts of the background document, under the coordination of WHO and its experts from the chemical working group.
- Experts from the chemical working group of WHO's Guidelines for Drinking-water Quality guided the development of this document: Dr Mari Asami, National Institute of Public Health, Japan; Mr Richard Carrier, Health Canada, Canada; Dr Joseph Cotruvo, Joseph Cotruvo & Associates, United States of America; Dr David Cunliffe, South Australian Department of Health, Australia; Dr Alexander Eckhardt, Umweltbundesamt (Federal Environment Agency), Germany; Dr Akihiko Hirose, National Institute of Health Sciences of Japan, Japan; Dr Peter Marsden, formerly Drinking Water Inspectorate, United Kingdom; Dr Ed Ohanian, Environmental Protection Agency, United States of America; Professor Choon Nam Ong, National University of Singapore, Singapore; Dr Betsy Behl, Environmental Protection Agency, United States of America; and Dr Emanuela Testai, National Institute of Health, Italy.
- Peer reviewers included Antonia Calafat, CDC, United States of America; Milou Dingemans, KWR Water Research Institute, the Netherlands; Dr Michael Dourson, Toxicology Excellence for Risk Assessment, United States of America; Nick Fletcher, Food Standards Australia New Zealand, Australia; Tony Fletcher, London School of Hygiene and Tropical Medicine, United Kingdom; Philippe Grandjean, University of Southern Denmark and Harvard T.H. Chan, School of Public Health, Denmark and United States of America; Roberta Hoffman-Caris, KWR Water Research Institute, the

[1] An example of a provisional guideline value is the value established for lead at 10 µg/L. Although there is no apparent safe level of lead, this value takes into account difficulties in achieving lower values where lead-containing materials are used in water systems.

Netherlands; Philip McCleaf, Uppsala Vatten Och Avfall AB, Sweden; Katie Pelch, University of North Texas Health Science Center, United States of America; Marc-Andre Verner, University of Montreal, Canada; Graham White, formerly Health Canada, Canada; and additional experts from the Environmental Protection Agency, United States of America.

- WHO Unit on Water, Sanitation, Hygiene and Health provided coordination, strategic direction and liaison with the WHO Unit on Chemical Safety and Health.

Did the experts and contributors declare their conflicts of interest?

All authors, chemical working group members and peer reviewers have disclosed circumstances that could give rise to actual or ostensible conflicts of interest and have signed a Declaration of Interest form. No authors, working group members or reviewers declared any interests that were considered by the WHO Secretariat to preclude their involvement in development of the draft background document.