Summary of Comments, Responses, and the Department of Health's Recommendations for the October 13, 2021 Public Hearing

Chapter 246-290 WAC Group A Public Water Supplies Rulemaking (WSR 21-16-095)

Department of Health

Contents

Purpose of Proposed Amendments to Chapter 246-290 WAC

The purpose of the proposal is to protect public health by establishing standards, or State Action Levels (SALs), for per- and polyfluoroalkyl substances (PFAS). PFAS are persistent, bioaccumulative, and toxic contaminants, or groups of contaminants, without an established federal standard, or maximum contaminant level (MCL).

The State Board of Health (board) and the Department of Health (DOH) are concerned because almost a dozen Group A public water systems (PWS) and over 200 private wells in five areas of the state are known to have PFAS contamination in their groundwater supplies above the Environmental Protection Agency (EPA) and other state's health advisory levels for these contaminants. There is currently no federal drinking water standard, or MCL, for PFAS.

This document is a concise summary of the comments received during the written public comment period, DOH summary responses, and DOH recommendations to the board regarding several technical, clarifying, or editorial rule language revisions in response to comments.

All recommended rule language revisions can be found below in the *Recommended Revisions to Proposed Rule Language* section of this document.

Summary of Comments and Responses by Section and *Summary of General Comments and Responses* contain the remaining summary comments and responses for which DOH is not recommending any rule language revisions.

Should the board adopt the rule proposal, with or without the recommended revisions included in this summary, DOH will send an electronic copy of the Concise Explanatory Statement to commenters and others who request a copy by emailing jocelyn.jones@doh.wa.gov.

More information, including the proposed rule language, can be found on the Rulemaking Activities for the Office of Drinking Water webpage.

Recommended Revisions to Proposed Rule Language

WAC 246-290-010 Definitions, abbreviations, and acronyms.

Comment Summary	(44) One commenter suggested that DOH change the definition of confirmation since it does not demonstrate the accuracy of the lab's analytical result. The commenter also recommended DOH define confirmation sample instead of confirmation.
Response Summary	DOH agrees that the definition of confirmation could use clarity.
Recommendation	DOH recommends the board adopt the following: (44) "Confirmation" means to demonstrate <u>that the result of a sample accurately represents the original</u> ~~the accuracy of results of a~~ sample <u>result</u> by analyzing another sample from the same location within a reasonable <u>given</u> period of time.~~, generally not to exceed two weeks. Confirmation is when analysis results fall within plus or minus thirty percent of the original sample results.~~, so that it reads as follows: "Confirmation" means to demonstrate that the result of a sample accurately represents the original sample result by analyzing another sample from the same location within a reasonable given period of time."

Comment Summary	(170) Commenter stated that the definition of PFAS is defined by use and suggested it would be more useful to base it on the chemical composition characteristics, while others said the definition was too broad and suggested changes that excluded gases and volatile liquids. And aqueous film forming "form" should be "foam" instead of "form".
Response Summary	PFAS were already defined in state law in 2019 based on their class-wide chemical characteristics. DOH recommends clarifying the definition by adding a reference to RCW 70A.350.010(8).
Recommendation	DOH recommends the board adopt an editorial change to correct the typo "~~form~~" with "<u>foam</u> and add "<u>and as referenced in RCW 70A. 350. 010(8)</u>" to the end of the definition in the proposal to be clearly and directly consistent with the state statutory definition and so that it reads as follows: "(170) "PFAS" means per- and polyfluoroalkyl substances, a group of man-made chemicals found in products such as aqueous film-forming foam used to suppress petroleum-based fires, nonstick cookware, stain-resistant fabrics and many other products and as defined in RCW 70A.350.010(8)."

WAC 246-290-130 Source approval.

Comment Summary	One commenter asked which contaminants with SALs were included in the requirements under WAC 246-290-130(g)(iv) and requested a cross reference to provide clarity.
Response Summary	DOH agrees that additional clarity would be helpful and will recommend the board adopt a clarification that cross references from this section to the monitoring requirements for 'contaminants with a SAL' found in WAC 246-290-300(10) and add subsection (h) to the WAC 246-290-300(10) already referenced in the proposal to specify where those provisions can be found.
Recommendation	DOH recommends the board adopt the following clarification to WAC 246-290-130(4)(g)(vi) so that it reads as follows: "Contaminants with a SAL <u>as required under WAC 246-290-300(10)</u>, except where waived or not applicable under WAC 246-290-300(10)<u>(h)</u>."

WAC 246-290-300 Monitoring requirements.

Comment Summary	DOH received a comment asking for clarification on which analytes were required per WAC 246-290-300(10)(b), was it the full list in WAC 246-390-075, Table 7, or was the full list limited to a complete test panel using EPA Method 533 or EPA Method 537. 1.
Response Summary	The proposed rule requires that one complete test panel—for either EPA method, 537.1 or 533—must be completed to be in compliance and not both test panels.
Recommendation	DOH recommends the board adopt a change in WAC 246-290-300(10)(b) for clarity to read, (b) Purveyors shall monitor for ~~the~~ PFAS contaminants <u>using an approved method in WAC 246-390-075(a) and all method specific contaminants as</u> listed ~~in~~ <u>on</u> Table 7 ~~under~~ <u>in</u> WAC 246-390-075, so that it reads as follows: "(b) Purveyors shall monitor for PFAS contaminants using an approved method in WAC 246-390-075(a) and all method specific contaminants as listed on Table 7 in WAC 246-390-075."

WAC 246-290-455 Operation of chemical contaminant treatment facilities.

Comment Summary	Two commenters stated that "with the inclusion of blending in this section, any system that blends sources prior to the entry point to the distribution system and has some detection of PFAS in any of those sources would inherently have to monitor quarterly."
Response Summary	DOH agrees this subsection could be clarified. DOH intended to require only purveyors that treat to remove, or blend to reduce, a contaminant *that exceeds the SAL* to conduct quarterly monitoring. It was not the intent of the proposal for all blended sources with

	detections below a SAL to monitor quarterly. DOH will recommend revising the proposed rule language to provide clarity.
Recommendation	DOH recommends the board make these clarifying changes to subsection (2) in this section: Purveyors that ~~using~~ treat~~ment or blending~~ to remove, or blend to reduce, a contaminant ~~with~~ that exceeds ~~a~~ the SAL, shall:", so that it reads as follows: "Purveyors that treat to remove, or blend to reduce, a contaminant that exceeds the SAL, shall..."

WAC 246-290-71006. [Now titled] Public notification for contaminants with a SAL

Comment Summary	Two commenters noted that Table 17 includes DCPA acid metabolites with an assigned tier level, but it is not included with an established SAL under table 9 of WAC 246-290-315(4)(a).
Response Summary	This was a drafting error which was to be removed.
Recommendation	DOH recommends the board adopt a technical correction and remove "DCPA acid metabolites" from Table 17, in this section.

WAC 246-290-72004 Report contents - Definitions

Comment Summary	Definition of SAL in subsection (5) of this section is not consistent with the definition in WAC 246-290-010(44); one says, "actions a purveyor takes", while the other says, "actions a water system must take".
Response Summary	DOH agrees that the definition could be more consistent and will recommend a slight revision. DOH does not recommend removing "must" or to include the WAC citations for the definition of SAL in the definition.
Recommendation	DOH recommends the board adopt the following changes to subsection (5), " State action level (SAL) means the concentration of a contaminant or group of contaminants, without an MCL, in drinking water established to protect public health and which, if exceeded, triggers actions a water system purveyor must take, so that it reads as follows: (5)"State action level (SAL) means the concentration of a contaminant or group of contaminants, without an MCL, in drinking water established to protect public health and which, if exceeded, triggers actions a water system purveyor must take.

WAC 246-290-72012 Regulated contaminants

Comment Summary	In the table description for the health effects of four PFAS, (PFOA, PFOS, PFNA, and PFHxS), a commenter found the following sentence to be ambiguous and confusing: "When water levels of [respective

	PFAS] are much higher than the SAL, shorter periods of exposure are of concern."
Response Summary	DOH agrees that this sentence could cause confusion when levels are low. DOH will work with PWSs to customize the message when levels are high. Because this statement is true for many of the contaminants listed in the table and those contaminants do not contain similar language, DOH will recommend removing the last sentence of the health effects language, which includes this phrase, for the four PFAS contaminants.
Recommendation	DOH recommends the board adopt the health effects language but remove the last sentence for PFOA, PFOS, PFNA, and PFHxS that says, "When water levels of [respective PFAS] are much higher than the SAL, shorter periods of exposure are of concern."

Summary of Comments and Responses by Section

WAC 246-290-010 Definitions abbreviations, and acronyms.

Comment Summary	(2) The definition for "adverse effect" is overly broad, could include adaptive changes and is not consistent with EPA.
Response Summary	The current rule definition for "adverse effect" is consistent with EPA as it comes directly from the EPA Integrated Risk Information System (IRIS) Program. DOH does not think the current definition is inclusive of clearly adaptive effects.
Recommendation	DOH recommends no change.

Comment Summary	(238) State Action Level (SAL) is not consistent between WAC 246-290-010 and WAC 246-290-72004; if a SAL is exceeded one indicates "actions a purveyor takes", while the other indicates, "actions a water system must take".
Response Summary	The definition in WAC 246-290-010 does not use the word "must" because the bill drafting guide states not to use a definition to specify a requirement. The definition in WAC 246-290-72004 is slightly different for use in communicating to the public in a community water system's Consumer Confidence Report (CCR) so it is clear that a water system must take actions.
Recommendation	DOH recommends no change to the definition of State Action Level (SAL) in this section. See WAC 246-290-72004 in this summary for a recommended rule language change related to this definition.

WAC 246-290-130 Source approval.

Comment Summary	One commenter suggested that requiring PFAS testing at source approval per WAC 246-290-130(4)(g)(vi) was out of place because it indicated that SALs must be met at source approval.
Response Summary	Samples must be taken per WAC 246-290-130(4)(g)(vi), but WAC 246-290-130(4)(h) only refers to meeting the standards in WAC 246-290-310 not the SALs listed in WAC 246-290-315. This section does not state that a system must meet the SALs, only that they must submit the results as part of the source approval process. It is important for both the PWS and DOH to understand the quality of water prior to approval.
Recommendation	DOH recommends no change.

WAC 246-290-300 Monitoring requirements.

Comment Summary	DOH received multiple comments asking to require "transient, non-community water systems" (TNC) be monitored more broadly. The requests ranged from requiring all TNCs to test at least once to ensure they do not contain PFAS to placing the same requirements on all TNC systems as this rule does for Community and Nontransient Noncommunity systems (NTNC).
Response Summary	The proposed rule requires TNC systems that are near known or suspected PFAS contamination to collect PFAS samples for analysis as well. If PFAS is detected in the sample, TNC systems must also comply with the follow-up requirements in WAC 246-290-320(8).
Recommendation	DOH recommends no change.

Comment Summary	DOH received multiple comments urging that monitoring should be required as soon as the rule is effective instead of establishing the compliance cycle of January 2023 through December 2025.
Response Summary	DOH set up the monitoring to align with other federal monitoring time frames for synthetic organic contaminants. This also aligns the testing with EPAs Fifth Unregulated Contaminant Monitoring Rule (UCMR 5), allowing systems to take advantage of federal funding for UCMR 5 testing. In addition, DOH is offering to pay for PFAS samples for PWSs starting in 2021 to encourage early monitoring. PWSs that sample before January 2023 may be allowed to use their samples to meet the initial monitoring requirements.
Recommendation	DOH recommends no change.

Comment Summary	DOH received several comments related to the proximity of the PWSs water supply to a known PFAS contamination. In general people

	wanted to ensure DOH would consider proximity to a known or suspected PFAS source in the prioritization of testing for Community and NTNCs in the same way it would be considered for TNC systems. One commenter recommended DOH consider sources susceptible due to approved stormwater injection wells permitted under a National Pollution Discharge Elimination System (NPDES) permit.
Response Summary	Proximity to a known or suspected source of PFAS contamination is part of the vulnerability determination already considered in WAC 246-290-300(10)(b)(ii). DOH will consider including NPDES stormwater injection well locations in the prioritization process for testing.
Recommendation	DOH recommends no change.

Comment Summary	Several commenters suggested that DOH not require PFAS testing of sources that were not downgradient of known or suspected PFAS contaminant sites, or that DOH limit testing to only groundwater sources.
Response Summary	DOH will not know for certain where PFAS may be found until the initial statewide sampling is complete. Other states have detected PFAS in both surface and groundwater supplies for drinking water. If DOH finds, after the initial round of testing, that specific areas or surface water supplies in the state are not at risk for PFAS contamination, they may be eligible for less monitoring and possibly a waiver.
Recommendation	DOH recommends no change.

Comment Summary	DOH received requests to require PWS with wells in shared aquifers, or shared water via interties, to use the same labs and same methods. The commenter was concerned that if different laboratory methods were used there may be detections that are not in the same panel chosen by either PWS.
Response Summary	The rule currently allows for two methods, for which there are 14 of the same contaminants analyzed using the same state detection reporting limits (SDRL). Some diversity may allow for a greater range of results representing the additional 15 PFAS contaminants. In addition, aquifer determinations don't necessarily represent contaminant plume impacts. PWS may coordinate with each other to sample at the same time or using the same lab and method if they continue to meet the requirements of this rule.
Recommendation	DOH recommends no change.

Comment Summary	Several commenters were concerned about the use of DOH-approved methods in WAC 246-290-300(1)(c), "The analyses must be performed by a laboratory accredited by the state using EPA-approved methods or other department-approved methods"
Response Summary	This provision allows flexibility to respond to future unregulated contaminants that don't have an EPA-approved method. EPA has two approved methods for PFAS in drinking water so there is no "other department-approved method" for PFAS at this time.
Recommendation	DOH recommends no change.

Comment Summary	One commenter indicated that a full PFAS panel was required for a PWS to qualify for a future waiver.
Response Summary	PWS must analyze a full test panel to get credit for meeting the requirements of the rule, not simply for waiver eligibility. Either EPA approved method may be used.
Recommendation	DOH recommends no change.

Comment Summary	One commenter was concerned that the acceptable methods for PFAS analysis and the resulting analytes which would be reported are not listed in chapter 246-290 WAC but only in chapter 246-390 WAC.
Response Summary	Chapter 246-390 WAC is the appropriate rule to provide information regarding analytical methods. There may be more than one method that a water system may choose to use. Methods may also change over time, which would be updated in chapter 246-390 WAC. DOH will provide guidance to PWS.
Recommendation	DOH recommends no change.

Comment Summary	Some commenters requested that the rule require additional monitoring for total PFAS (total organic fluorine or TOF) or other expanded analyses for PFAS in drinking water such as the total oxidizable precursors (TOP) assay. Some commenters asked if these can't be added at this time, that they be added as soon as practical.
Response Summary	The TOP assay and TOF do not have an EPA approved drinking water method at this time. The Lab rule requires that laboratories seek accreditation for an EPA approved drinking water method if the lab is running drinking water compliance samples for the state of Washington. Part of this accreditation process requires that laboratories demonstrate annual proficiency by analyzing blind samples and submit the results to a third-party proficiency provider. The lab must also demonstrate the capability to achieve the state detection reporting limit stated in the Lab rule. As EPA approves new

	drinking water methods DOH will consider their use for monitoring compliance or supplemental data collection.
Recommendation	DOH recommends no change.

Comment Summary	DOH received several comments regarding the use of confirmation samples. Some commenters were concerned about public notification (PN) being required without a confirmation sample; others were concerned that all confirmation samples would be averaged.
Response Summary	DOH believes that confirmation samples should be collected prior to conducting PN, as required for other federally regulated contaminants where PN is required after one sample, such as coliform and nitrate. DOH would require a confirmation sample under most circumstances prior to requiring PN. If a sample is collected in an area of known contamination, a purveyor may choose not to collect a confirmation sample prior to conducting PN. A water system that fails to collect a required confirmation sample within ten business days, per WAC 246-290-315(4)(b), may be required to conduct PN without a confirmation sample. WAC 246-290-300(10)(e) allows for both averaging of the original sample result with the confirmation results or invalidation of obvious errors. This reduces the potential for PN associated with human error when confirmation results are incongruent and suggest a potential error.
Recommendation	DOH recommends no change.

WAC 246-290-315 State action levels (SALs) and state maximum contaminant levels (MCLs)

Comment Summary	Some commenters recommended that instead of a SAL, the rule establish a maximum contaminant level (MCL) as a more appropriate approach to addressing PFAS. The MCL should include a rigorous cost-benefit analysis to ensure that risk reduction is optimized for communities with limited resources.
Response Summary	One of the reasons the board directed DOH to first develop SALs for PFAS is as an interim step towards that goal. Setting SAL requirements for initial testing, follow-up monitoring, and results reporting will allow for the collection of data needed to conduct the cost-benefit analysis required to set an MCL. In the meantime, the SAL provides public health guidance for PWS that exceed a SAL. The PN requirement ensures that the public is informed about results, knows the steps that their PWS is taking, and knows how to take action to protect themselves and their families if their water contains PFAS above a SAL.
Recommendation	DOH recommends no change.

Comment Summary	Many commenters prefer that the regulations require removal of PFAS from the water when present above a SAL.
Response Summary	Treatment to remove PFAS would require the enforceable limit of an MCL. The SAL is an interim step to an MCL and will collect the data needed to develop an MCL. In the meantime, PWS can take voluntary action.
Recommendation	DOH recommends no change.

Comment Summary	Several commenters recommended that DOH regulate PFAS as a class, establish a limit for total PFAS in drinking water, or consider another way to address PFAS mixtures, as soon as practical.
Response Summary	DOH considered a class-wide approach for regulating PFAS but did not find adequate data to support this type of approach. For most PFAS there are limited mechanistic data to support a toxic equivalency approach and multiple mechanisms appear to be involved in some health endpoints. Additionally, DOH sees substantial differences between members of the PFAS class in terms of their adverse effects, potential pathways of exposure, clearance rates from the body, and potential to bioaccumulate. If we collapse all mixtures into a single class approach (e.g., by regulating total organofluorine) we will miss characterizing real differences in risk posed by different constituent profiles. DOH is hopeful that with additional research underway now at EPA and National Institute of Environmental Health Sciences, that a subclass or grouped approach may be possible in the future. Should such an approach be developed, DOH will consider its application in future development of drinking water standards for PFAS. Until then, DOH is recommending action levels for the five PFAS with sufficient toxicological information. When treatment technology is applied to drinking water sources for these five PFAS, it is generally effective at removing many PFAS.
Recommendation	DOH recommends no change.

Comment Summary	WA should develop more SALs to address other PFAS in drinking water. (e.g., Washington should consider setting SALs for all 29 of the PFAS in the UCMR 5).
Response Summary	DOH developed SALs for the PFAS already known to be in Washington state drinking water supplies if they also had sufficient toxicological information. The comprehensive testing required by this rule is intended to significantly expand our understanding about the prevalence of specific PFAS. Once DOH has that information, DOH can consider adding

	SALs provided there is enough toxicological data available for SAL development.
Recommendation	DOH recommends no change.

Comment Summary	Several commenters suggested that the proposed SALs for Washington state are less protective than health recommendations made by another state or organization. Commenters asked us to consider the enforceable MCLs in Massachusetts and Vermont which limit the sum of five or six PFAS chemicals to no more than 20 parts per trillion; Consumer Reports recommendation of no more than 5 ppt for any one PFAS chemical and 10 ppt for two or more; and the Environmental Working Group recommendation of no more than 1 ppt of total PFAS in drinking water.
Response Summary	DOH used protective assumptions and are confident that, based on available data, the SALs are low enough to protect health across a lifetime of drinking water consumption, including in sensitive groups. Lower numbers are not necessarily more protective. All the examples provided were grouped approaches that assume that the sum of the included PFAS can be compared to a single health protective value. This value may be tied to one of the PFAS in the mixture and assumed to apply to all others in the mixture. Since individual PFAS may vary in their health risk, DOH set individual standards based on the scientific evidence for each of five SALs.
Recommendation	DOH recommends no change.

Comment Summary	Two industry commenters did not think the proposed SALs were derived using the best available science. "There are many deficiencies and unduly conservative and scientifically flawed assumptions associated with these proposed SALs." Most of the detailed critiques submitted in support of this claim pertained to the critical studies selected and other decisions made by EPA, Agency for Toxic Substances and Disease Registry (ATSDR), and states during development of the reference doses and minimal risk levels that Washington State relied on.
Response Summary	Although Washington state did not develop our own reference doses, DOH did review the critical studies and methods used by science teams at the EPA, ATSDR, and several other U. S. states that developed these health protective values. EPA and ATSDR assessments went through extensive scientific review and public comment periods before they were finalized in 2021. Numbers derived by the Minnesota Department of Health were adopted by other states and have also been through public comment periods associated with rulemaking in Michigan and New Hampshire. Many of the same detailed critiques from industry about flawed science were submitted during these public comment periods

	and answered by EPA, ATSDR, and MI, NH, and NJ risk assessors. DOH reviewed these responses and found them to be reasonable. DOH clearly explained the scientific rationale for the SAL values in a 100-page support document (Pub # 331-673). In addition to this general response, DOH summarized and responded to the main industry critiques for each SAL below.
Recommendation	DOH recommends no change.

Comment Summary	Two commenters said that the critical study selected by ATSDR to derive a minimal risk level for PFOA was flawed and lacked fundamental scientific rigor (small number of animals, a single treatment dose, etc.). As such the ATSDR minimum reporting levels (MRL) do not provide adequate support for the DOH proposal.
Response Summary	Similar comments were submitted to ATSDR. ATSDR responded[1] that "The small number of animals evaluated in the Koskela et al. (2016) is a limitation; however, support for the finding comes from the consistency of the findings at 13 and 17 months of age, the reduced bone ossification observed in the Lau et al. (2006) study and in vitro studies conducted by Koskela et al. (2016) finding alterations in osteoclast and osteoblast cells."(page 121) "The use of a single PFOA dose group is a limitation of the Koskela et al. (2016) study; however, the extensive database provides dose-response support for the selection of the POD." (page 88) DOH concurs that the single dose (0.3 mg/kg-day) tested by Koskela et al. 2016 adds an important observation below the Lowest Observed Adverse Effect Level (LOAEL) from Lau et al. 2006 and contributes to the dose-response evident in the database as a whole. Lau et al. 2006, the critical study for the 2016 EPA RfD, reported a LOAEL for skeletal effects in mouse pups (reduced ossification of proximal phalanges) at 1 mg/kg-day with more serious skeletal defects at 5 mg/kg-day. No NOAEL was established. Van Esterik et al. 2016 also reported reduced bone density and altered functional properties in adult mice following developmental exposure to PFOA. The study authors derived benchmark dose (BMD) levels for reduced femur weight and functional characteristics of the tibia (reduced bending strength and torsion resistance) that ranged from 0.88 – 0.98 mg/kg-day PFOA. Koskela et (2016) also included in vitro experiments that show alterations in osteoclast and osteoblast cells and support the observations of the in vivo study. Mineral density represents a sensitive indicator for bone effects and is a precursor to serious bone

[1] Agency for Toxic Substances and Disease Registry (ATSDR) Disposition of Public Comments for Toxicological Profile for Perfluoralkyls. January 2020

	diseases, such as osteoporosis and osteopenia. Evidence for the potential human relevance of skeletal effects is limited but expanding (see the discussion on page 31 and page 35 of Pub# 331-673).
Recommendation	DOH recommends no change.

Comment Summary	One commenter wrote that "Koskela et al. also appeared to have conducted their statistical analysis on a per-fetus basis, rather than per-litter as advised by USEPA's guidelines for assessing developmental toxicity, which has been widely critiqued as a study deficiency in the past."
Response Summary	ATSDR responded[2] that "[t]he results of the Koskela et al. (2016) study were based on an individual animal basis rather than a litter basis. ATSDR did not consider this to be a limitation since the effects were examined when the offspring were 13 and 17 months of age." (page 107). DOH concurs that skeletal effects measured in adult mice at two time points more than a year after birth are not likely to be biased by litter effects.
Recommendation	DOH recommends no change.

Comment Summary	With respect to the PFOS SAL, one commenter stated: "The immune system effects in mice reported by Dong et al. (2011), that are the basis of the SAL, conflict with the findings reported by other researchers. In addition, the decision to focus on immune effects as the basis for its proposed SAL runs directly counter to the specific concerns expressed about these data by both USEPA and Health Canada…"
Response Summary	DOH acknowledges that opinions differ among some government risk assessors about which endpoint is the most suitable to use in deriving health guidelines for PFOS. However, all the health protective values (reference doses, toxicity values, acceptable daily doses) developed independently by U. S. states consider decreased antibody response to a foreign antigen in mice either as the critical effect (MN,NH,MI,NJ,NY,CA) or through a database uncertainty factor for more sensitive effects (MA).[3] In addition, the ATSDRs Minimal Risk Level for PFOS (2 ng/kg-day) applied a modifying factor of 10-fold to their developmental POD to address the apparently more sensitive critical effect of immunotoxicity as observed in Dong et al 2009 and 2011, Peden-Adams et al. 2008 and Guruge et al. 2009. In support of this 10-fold modifying factor ATSDR

[2] Agency for Toxic Substances and Disease Registry (ATSDR) Disposition of Public Comments for Toxicological Profile for Perfluoralkyls. January 2020.

[3] Post, Gloria (2021) Recent US State and Federal Drinking Water Guidelines for Per- and Polyfluoroalkyl Substances. Environmental Toxicology and Chemistry 40 (3):550–563.

	calculated a "candidate MRL" of 3 ng/kg-day based on the NOAEL for immune toxicity in Dong et al 2011. Use of the immunotoxicity endpoint is also supported by a systematic review conducted by the National Toxicology Program (NTP 2016)[4] which concluded that PFOS should be presumed to be an immune hazard to humans. The European Food Safety Authority's (EFSA 2020)[5] also recently based their tolerable daily intake for the sum of 4 PFAS based on their careful review of evidence of immune effects in laboratory animals and epidemiological studies.
Recommendation	DOH recommends no change.
Comment Summary	One commenter said the Minnesota Department of Health (MDH) analysis relies on a flawed study, as there was a technical omission by Dong et al. (2011) that critically impacts the point of departure (POD). DOH should not accept the no observed adverse effect level (NOAEL) as the POD since the Dong et al. (2011) study presented an incomplete dataset in the published manuscript. Furthermore, DOH should acknowledge that because of the numerous technical deficiencies in the Dong et al. study, it does not provide any robust or compelling scientific evidence to support the claim that PFOS is associated with immune suppression in mice. DOH should review the information provided by Dong, the study author, that completes the dataset for the study at issue.
Response Summary	The Dong et al. 2011 study was published in a peer-reviewed journal and the authors were apparently responsive to the peer review. DOH declines to second-guess the reason that a journal reviewer identified the highest dose data point as problematic during the peer-review process. Including it does not affect the LOAEL or NOAEL from the experiment. Reduced immune response has been selected as the critical effect by independent risk assessors in NJ, NH, MN, NY, and MI in their state-based drinking water standards and advice for PFOS. All selected a NOAEL rather than a BMD as points of departure for reduced IgM in Dong et al 2011 or reduced IgM dependent plaque forming cell response in Dong et al 2009. The Dong research group published three 60-day gavage studies in male mice investigating PFOS immunotoxicity in the same strain (C57BL6) of mice (Dong et al. 2009, 2011, 2012)[6]. A number of the shortcomings cited of Dong et al. 2011 are addressed when the findings are considered as a

[4] NTP (National Toxicology Program). 2016. Monograph on Immunotoxicity Associated with Exposure to Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). Research Triangle Park, NC: National Toxicology Program.

[5] Risk to human health related to the presence of perfluoroalkyl substances in food. EFSA Panel on Contaminants in the Food Chain (EFSA CONTAM Panel) ADOPTED: 9 July 2020 EFSA Journal 2020;18(9):6223.

[6] Dong et al. (2009) Arch Toxicol (2009) 83:805–815; Dong et al. (2011) Arch Toxicol (2011) 85:1235–1244; Dong et al. (2012) Toxicol and Appl Pharmacol 264: 292–299.

	whole. For example, PFOS treated mice in this model showed dose-dependent reductions in relative thymus and spleen weights; reduced splenic and thymic cellularity, altered subpopulations of lymphocytes in serum, spleen and thymus; altered lymphocyte proliferation responses, and increased production of pro-inflammatory cytokines by peritoneal and splenic cells. The most sensitive immune effect was a dose-related decrease in specific IgM antibody production as measured in serum by ELIZA kit (Dong et al. 2011) and by the PFC assay in spleen cells (Dong et al. 2009). Two shorter duration studies in mice also observed suppression of plaque forming cell response following PFOS exposure (Zheng et al. 2009 and Peden-Adams et al. 2008). Antigen-specific IgM measured in the PFC is a response to a T-cell-dependent antigen (e. g. sheep red blood cells). While immune function can be evaluated with multiple assays, the T cell-dependent antibody response (TDAR) is considered a "gold standard" by regulatory agencies for evaluation of immunotoxic potential and is reportedly the most sensitive functional assay for evaluating immunosuppression (Dewitt et al. 2019)[7].
Recommendation	DOH recommends no change.

Comment Summary	One commenter shared that "The National Toxicology Program's (NTP) systematic review of the animal immunotoxicity data concluded that it cannot be confident in the outcome assessment of the Dong et al. study that is the basis for the proposed SAL. NTP's lack of confidence is supported by the inability of BMD modeling of the plaque-forming cell response data to provide an acceptable fit to any of the dose-response models included in USEPA's BMD software. The inability of BMD modeling to yield a valid point of departure suggests that the response data reported by Dong et al. are not sufficiently robust to use for risk assessment.
Response Summary	DOH did not see any comment in NTP's 2016 monograph[8] about lack of confidence in Dong et al. 2011 nor did the NTP comment on lack of fit in BMD modeling. Instead, NTP concluded that "There is high confidence that exposure to PFOS is associated with suppression of the antibody response in animals based on consistent suppression of the primary antibody response in mice." (pg 63) The monograph specifically mentions Dong et al. 2011 along with other studies as showing "consistent evidence that PFOS exposure results in suppression of the primary antibody response as determined by antigen-specific IgM antibody

[7] Dewitt, J et al. (2019) Exposure to per- and polyfluoroalkyl substances leads to immunotoxicity: Epidemiological and toxicological evidence. J Expo Sci Environ Epidemiol. 29(2): 148–156.

[8] NTP (National Toxicology Program). 2016. Monograph on Immunotoxicity Associated with Exposure to Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). Research Triangle Park, NC: National Toxicology Program.

	production to single challenge with T-cell specific antigens (SRBC) in male and female mice (Keil et al. 2008, Peden-Adams et al. 2008, Dong et al. 2009b, Zheng et al. 2009, Qazi et al. 2010b, Dong et al. 2011, Vetvicka and Vetvickova 2013) with support from a study in chickens (Peden-Adams et al. 2009) (Figure D8) at oral doses from 0. 00166 to 40 mg/kg/day. Antibody suppression in the lower dose range (0. 00166 to 5 mg/kg/day PFOS) takes place without changes in body weight, spleen or thymus cellularity, or other signs of overt toxicity." (Page 62). "Not only is there high confidence in the body of evidence from animal studies that PFOS suppresses the antibody response, but the animal data also demonstrate suppression at PFOS serum levels that are relevant to general human exposure levels. The serum PFOS levels in mice associated with the lowest dose that suppressed the antibody response [92 ng/ml PFOS (Peden-Adams et al. 2008)] are below occupational exposure levels (range 145 to 3490 ng/ml PFOS) (Olsen et al. 2007a) and approximately 3x higher than the upper end of serum PFOS levels of the general population (range 4. 3 to 36. 9 ng/ml PFOS) (Olsen et al. 2007b)." (page 82)
Recommendation	DOH recommends no change.

Comment Summary	Regarding PFNA, one commenter noted that recent studies have reported reductions of testosterone in animal studies, but the effects do not appear to have impacted fertility. Moreover, it is not clear that a lowering of testosterone levels is a more sensitive endpoint than the liver and developmental effects reported in other studies as the NOAELs and LOAELs are similar or higher.
Response Summary	To be clear, WA based its SAL on developmental effects of PFNA. However, the database uncertainty factor considers emerging rodent data on altered hormone levels and damage to reproductive tissue. A 90-day study by Singh and Singh 2019 did show reduced number of pups per litter when unexposed females were mated to male mice that had been exposed to 0. 5 mg/kg-day PFNA for 90 days. This reduced fertility was plausibly due to the reduced sperm motility, viability and sperm counts observed in this group of treated male mice. The NOAEL for this study was 0. 2 mg/kg-day: nearly 10 times lower than the NOAEL in Das et al. 2015. (see page 57-58 of Pub# 331-673).
Recommendation	DOH recommends no change.

Comment Summary	Regarding PFNA, one commenter questioned the relevance to humans of developmental effects in rodents mediated by PPARα-dependent mechanisms. Related to this, they questioned the use of a 10-fold database uncertainty factor given this lack of relevance.

Response Summary	DOH addressed the concern about human applicability of PPARα-dependent responses in rodents on page 58-59 of Pub# 331-673. "Human liver has lower expression of PPARα compared to mouse liver and is not as prone to proliferative changes mediated by PPARα. [56, 144, 184] … The evidence underlying this argument is specific to liver responses and does not extend to the many other tissues in the human body that express PPARα and other PPARs that may be minor targets of PFAS. PPARα and PPARγ are centrally involved in lipid and glucose regulation in a number of other tissues and are widely expressed in immune cells, endocrine organs, and reproductive tissue including the placenta. [272, 273] As such, a PPARα-mediated pathway of developmental effects in rodents should be considered potentially relevant to human reproduction and fetal and child development."
Recommendation	DOH recommends no change.

Comment Summary	One commenter recommended that the DOH defer development of a SAL for PFNA until EPA IRIS program releases its evaluation of PFNA.
Response Summary	DOH welcomes the publication of EPA's IRIS assessment on PFNA. Unfortunately, if the EPA assessment of PFBS and GenX are any indication, DOH may not have a finalized toxicity value until 2025. In the meantime, DOH will use the data we have to advise the public on how to protect themselves when there is PFNA in their drinking water.
Recommendation	DOH recommends no change.

Comment Summary	One commenter noted the paucity of laboratory data for PFHxS and questions why the WA analysis does not consider the study by Butenhoff et al. (2009) which has been used by other groups for assessing the health effects of PFHxS. "The Department's supporting document also does not address the suggestion by Butenhoff et al that thyroid effects (such as those reported in the NTP study) may be related to hepatocellular hypertrophy caused by PPARα activation leading to hyperplasia of the thyroid that is likely not relevant to human health risk."
Response Summary	The ATSDR assessment was based on Butenhoff et al. 2009 and DOH did evaluate that assessment. However, DOH also evaluated several high-quality rodent studies that have been published since and three 2019 state health assessments (MDH, NHDES, MSAW) which used these newer studies as their critical study (See pages 63-68 of pub # 331-673). The "thyroid effects" the commenter refers to in Butenhoff et al. 2009 are increased hypertrophy and hyperplasia in thyroid follicular cells in male rats at the two highest PFHxS doses. The Butenhoff study did not measure thyroid hormones T4 or T3 and thus did not suggest a possible causal link between reduced levels of thyroid hormones (reported in the

	NTP 2019 study) and hepatocellular hypertrophy observed in the liver. The SAL is based on a health protective value derived from a more sensitive endpoint in the 28-day rat study of PFHxS conducted by the National Toxicology Program (NTP 2019). This study had the advantage of testing a number of PFAAs with the same protocol. The consistency of the observed effects on thyroid hormones across PFAAs adds to confidence in the finding. PFHxS also produced reduced thyroid hormones in a second rat study (Ramhoj et al. 2018).
Recommendation	DOH recommends no change.

Comment Summary	One commenter objected to a 10-fold database uncertainty factor in the PFHxS reference dose developed by the Minnesota Department of Health and used by WA to derive a SAL. "The lack of a two-generation study would justify the use of a 3-fold uncertainty factor, based on USEPA guidance. Concern about early-life sensitivity is addressed by Chang et al. who reported no treatment-related effects on postnatal survival of development in offspring exposed in utero through PND 36. Although limited, Butenhoff et al. did not find evidence of immunotoxicity in rats exposed to up to 10 mg/kg per day by gavage for up to 56 days."
Response Summary	DOH disagrees that Chang et al. or Butenhoff et al. 2009 included the types of observations needed to address the concern about developmental effects of thyroid hormone disruption during sensitive periods of early life or address immunotoxicity. Although DOH would prefer to have these data gaps filled before establishing health advice, DOH has been asked work with the available information in protecting Washington state residents when PFAS occur in their drinking water.
Recommendation	DOH recommends no change.

Comment Summary	One commenter shared that "for short-chain PFAS like PFBS, use of the default approach of body-weight scaling to estimate the human equivalent dose is consistent with USEPA guidance and the state of the science in the use of body weight allometric scaling."
Response Summary	EPA received many comments on this issue in public comments on their 2018 draft PFBS toxicity assessment. They considered the two approaches and adopted the dosimetric adjustment factor (DAF) approach in their final PFBS assessment. This was partly due to new studies on clearance rates in rodents and in humans which informed the final assessment. DOH concurs that default allometric body weight scaling approaches should be superseded when more detailed information on tissue dosimetry can be developed. PFBS is cleared from blood serum more rapidly that the other four PFAS with SALs; serum

	half-life of PFBS in studies in exposed workers was estimated to be 27 - 44 days. (see Pub# 331-673)
Recommendation	DOH recommends no change.

Comment Summary	Other commenters "recognize and appreciate the efforts made by DOH staff to examine and incorporate the best available science in developing this regulation."
Response Summary	n/a
Recommendation	DOH recommends no change.

Comment Summary	Evaluating Exposures for Assessing Developmental Effects The SALs proposed for three of the five PFAS (PFOA, PFNA, and PFBS) are based on reports of effects in animals exposed during gestation. Although the studies chosen for these three substances are discussed later in this comment, ACC/CPTD wishes to provide a general comment on DOH's approach to estimating exposures. In each case, DOH uses the water intake model developed by the Minnesota Department of Health which includes both pre- and post-natal exposures – even though the offspring in the studies were exposed in utero. For the purposes of evaluating many developmental effects, estimates of exposures should be limited to prenatal exposure which can be based on serum levels of the mother. Including post-natal exposures significantly increases the estimate of internal dose (Figure 1). Figure 1. Simulated plasma PFOA concentrations in human mother/child.
Response Summary	DOH agrees that postnatal exposure can significantly increase internal exposure of infants. DOH was not comfortable ignoring this exposure in a potentially sensitive population without supporting data. The three critical studies that served as the basis for PFOA, PFNA and PFBS health protective values administered the PFAS to pregnant mice but allowed the pups to nurse. The offspring's exposure was not strictly in utero and the experiments don't rule out that lactational exposure contributed to the developmental delays and effects observed at postnatal timepoints in these studies at the same LOAELs. A number of experiments have demonstrated that lactational exposures may contribute to effects on postnatal growth and developmental of reproductive tissues. For example: • Wolf et al. 2006[9] a cross fostering experiment that showed that lactation exposure contributed to effects observed in mice but to a lesser extent than in utero exposure.

[9] https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NHEERL&dirEntryId=140739

	• White et al. 2009[10] Cross fostering experiment that showed mammary development was affected by lactational only exposure to PFOA in mice. • Yu et al. 2009[11] a cross fostering experiment with PFOS on rat development showed that prenatal PFOS exposure and postnatal PFOS exposure induced hypothyroxinemia in rat pups to a similar extent. The 2019 Goeden model of life stage-specific exposure has been adopted by several groups of risk assessors (MI, NH, MN, WA) because infancy is a potentially sensitive life stage for developmental toxicants that affect thyroid hormones and/or because infants sustain greater exposure to these PFAS in drinking water compared to adults sharing the same household tap. The breastfeeding pathway is particularly important to capture when PFAS are in drinking water since the PFAS exposure via breastmilk appears to significantly contribute to children's PFAS serum level well into childhood (Mondal et al. 2014; Kingsley et al. 2018)[12] Secondary pathways of drinking water exposure for infants have not been modelled for PFBS. Still, EPA in their 2021 Assessment of Human Health Toxicity Values for PFBS identified "early life stages" as potentially susceptible to PFBS. CA OEHHA and Michigan Science Advisory Workgroup used the same data set as EPA to identify health protective drinking water levels for PFBS – both used infant consumption of drinking water in their equations.
Recommendation	DOH recommends no change.

Comment Summary	One commenter did not think that the minimum SAL setting criteria were met: "At a minimum, the criteria require that DOH determine that the Proposed Regulated PFAS be "known or likely to occur . . . at levels of public health concern" and have a "possible adverse effect on health of persons exposed based on peer-reviewed scientific literature or government publications . . . " The UCMR 3 data, scientific literature, and other information upon which DOH relies does not support such conclusions.
Response Summary	DOH disagrees. The five PFAS proposed for regulation with a SAL are known to occur in Washington state drinking water at levels above EPA health advisories for (PFOA and PFOS) and are known or likely to occur above the proposed SALs (for the other three PFAS (see figure 1, pub # 331-673 and Table 68 in the final Washington PFAS Chemical

[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3477546/

[11] https://pubmed.ncbi.nlm.nih.gov/19924978/

[12] Mondal et al 2014, doi.org/10.1289/ehp.1104538; Kingsley et al. 2018, doi: 10.1016/j.envres.2018.04.033.

	Action Plan[13], or CAP). Specifically, PFAS have been identified in drinking water in the Lower Issaquah Valley aquifer, and in private wells and PWSs at or near four military bases: Naval Air Station (NAS) Whidbey Island, Fairchild Air Force Base, Joint Base Lewis-McChord, and Navy Base Kitsap-Bangor. EPA, ATSDR, and other federal health agencies have concluded that these contaminants have possible adverse effects on the health of persons based on evidence of toxicity in laboratory animals and supporting epidemiological data. They have developed human health protective values to help define the threshold of human health concern. These government assessments are reviewed in the technical support document for the SAL values (Pub# 331-673).
Recommendation	DOH recommends no change.

Comment Summary	One commenter recommended that DOH delete the reference to state assessments as a source of information when developing SAL values or clarify that any government assessments must have rigorous external peer review. They also recommend that the reference to USEPA guidelines for exposure assessments be deleted since it is unlikely to provide insight into adverse effects for individual PFAS.
Response Summary	Some states such as California, Minnesota, and New Jersey have dedicated teams of scientists that develop drinking water standards for emerging contaminants. Other states have devoted resources to address a specific contaminant. For example, Michigan hired some of the top national PFAS experts to develop the Michigan Science Panel report and to support the Michigan Science Advisory Workgroup. These may be the only assessments available for emerging contaminants. DOH doesn't see a reason to exclude these assessments from information considered in the evaluation. To clarify, the reference to EPA Exposure guidelines was not meant to be a sole source of assessment information but rather a resource for standard exposure assumptions to use when developing standards.
Recommendation	DOH recommends no change.

Comment Summary	Two commenters claim that "The body of scientific evidence does not show adverse effects in humans" from PFAS and "the vast body of scientific evidence does not show that the proposed regulated PFAS cause adverse health effects in humans." They submitted numerous examples to support this claim.

[13] Per- and Polyfluoroalkyl Substances Chemical Action Plan, Washington State Department of Ecology Olympia, Washington; 2021

Response Summary	DOH disagrees with the first statement. DOH described epidemiological data that supports human relevance of animal toxicity endpoints in the technical support document. While the epidemiological data is not conclusive, DOH also did not find sufficient epidemiological data to exclude or rule-out the endpoints from animal testing that the selected reference doses relied on. The first claim is in contrast with a number of federal and state health agencies that have reviewed the breadth of evidence available including the toxicity of these 5 PFAS in laboratory animals (e. g. , mice, rats, monkeys), mechanistic studies to understand the biological interactions that underlie observed toxicity, gene expression studies to understand cellular responses, in vitro and other high-throughput studies, and epidemiological studies in populations of workers, the general population, and communities with elevated exposure through drinking water. Based on that review, they have recommended that people reduce their exposure to these PFAS to protect their health and have provided health-based values to guide exposure reduction by public health officials. The available evidence, taken together, meet the criteria of a "possible adverse effect in humans". The second statement implies incorrectly that a SAL requires proof that PFAS cause human health effects and that available evidence must meet the high evidentiary bar of a proven causal relationship. Again, the SAL criteria require “a possible adverse effect in humans.”
Recommendation	DOH recommends no change.

Comment Summary	A commenter shared that an Australian Expert Health Panel concluded that “after considering all of the evidence, . . . the evidence does not support any specific health or disease screening or other health interventions for highly exposed groups in Australia, except for research purposes.”
Response Summary	Drinking water regulations are set to protect health at the community level. Protective values that are set to minimize adverse responses across a population are different than recommended clinical screening practices for individuals. For example, a compound that increases the rate of thyroid disease in a community from 15% to 18% might not change the clinical screening criteria for thyroid disease in this population but might impact hundreds of additional people in that community depending on the size of the water system. In addition, federal and state health experts in the U. S. generally acknowledge that the evidence supports possible health effects in people. For example,

	EPA states "There is evidence that exposure to PFAS can lead to adverse health outcomes in humans."[14]
Recommendation	DOH recommends no change.

Comment Summary	One commenter objected to DOH information on the "C8 Health Project" as this is outdated. They shared that "in 2020, scientists and collaborators who had formed the "C8 Science Panel" reviewed the current literature with respect to each of the health conditions potentially linked to PFOA. These scientists concluded that epidemiological evidence remains limited and question the broader implications drawn from their prior work, noting that their work assessed a single population and that additional studies would be expected to vary." The commenter then presented the updated findings with respect to six conditions linked to PFOA exposure in 2012: increased blood cholesterol, ulcerative colitis, thyroid disease, testicular cancer and kidney cancer.
Response Summary	DOH is aware of this 2020 paper and included it in the discussion of human relevance of PFOA endpoints in the revised technical document (Pub# 331-673, pages 34-36). DOH disagrees that our discussion is misleading or outdated. DOH fails to see the relevance of the updated epidemiological evidence provided on these six conditions as none are developmental endpoints and DOH did not use any of these human health endpoints to derive the SAL for PFOA.
Recommendation	DOH recommends no change.

Comment Summary	With regard to PFHxS, one commenter suggests that, "even if a potential mechanism of action included possible competition of PFHxS with T4 for binding to transthyretin (a main carrier protein of thyroid hormone in mammals), observational (community epidemiology) studies do not suggest this effect occurs at relevant human exposures, either in the mother or infant."
Response Summary	DOH agrees that there is only limited evidence for PFHxS-associated thyroid hormone effects in human populations, however the literature is still sparse. The EPA recently based their final toxicity assessment of PFBS on reduced thyroid hormone levels in rodents reasoning that thyroid hormone levels are critical to neurodevelopment of developing human fetus and neonate (EPA 2021)[15]. DOH will continue to review data that become available, but DOH has been asked to use the data

[14] EPA webpage https://www.epa.gov/pfas/basic-information-pfas

[15] (EPA 2021) U.S. Environmental Protection Agency. Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3). EPA Office of Research and Development Washington, DC 20460. EPA Document Number: EPA/600/R-20/345F. APRIL 2021

	we have to provide protective public health advice to communities impacted by PFAS in their drinking water.
Recommendation	DOH recommends no change.

Comment Summary	There is insufficient evidence in the literature to conclude that an association between thyroid disease and exposure to PFAS exists in humans.
Response Summary	DOH based two SALs on altered thyroid hormone levels in rodents. None were based on thyroid disease. DOH discussed the epidemiological evidence for PFHxS and PFBS and effects on thyroid or thyroid hormones on pages 69-70 and pages 78-79 of Pub# 331-673. For PFBS, DOH relied on EPA's recent weight-of-evidence review which concluded that the evidence in animals for thyroid effects "supports a hazard" and that the thyroid is a potential target for PFBS toxicity in humans (EPA, 2021). For PFHxS DOH concluded that "overall, there is limited evidence for PFHxS-associated thyroid hormone level perturbations in human populations."
Recommendation	DOH recommends no change.

Comment Summary	The levels of PFOS or PFOA causing a potential reproductive or developmental toxicity in rodents are several orders of magnitude higher than the levels experienced by the general human population, demonstrating an ample margin of safety.
Response Summary	A number of studies have shown that communities with high levels of PFOA or PFOS in their drinking water have serum levels of these two PFAS that are much higher than the general population and higher than reference serum levels derived by U. S. federal health agencies to provide a margin of safety for developmental toxicity. (for references see Pub# 331-673 pages 27-49)
Recommendation	DOH recommends no change.

Comment Summary	The evidence from two meta-analyses now indicate a non-causal association with lower birthweight for PFOA (Steenland et al. 2018) and PFOS (Dzierlenga et al. 2020) as it is likely due to confounding related to the maternal timing of the blood measurement and the physiological changes in pregnancy between first and second/third trimesters as related to the glomerular filtration rate. The short-term study needs to be carefully evaluated prior to any meaningful risk assessment for humans.
Response Summary	DOH agrees that confounding by glomerular filtration rate (GFR) appears to explain some of the epidemiological associations between PFOS and PFOA exposures and lower birth weights. DOH disagrees

	that it explains all the associations reported. See discussion of additional studies that support this opinion on page 34 (PFOA) and page 46 (PFOS) of Pub# 331-673.
Recommendation	DOH recommends no change.

Comment Summary	Two commenters submitted detailed critiques of the epidemiological evidence for immune toxicity of PFOS and other PFAAs. They highlighted potential sources of bias and confounding in specific studies and inconsistencies across different study results. Based on this evidence, they do not agree that the evidence supports human health standards based on this endpoint.
Response Summary	DOH agrees that there is some inconsistency in epidemiological data on this endpoint and briefly reviewed some of the key studies on pages 45-46 of Pub# 331-673. DOH also notes that other authoritative sources such as the European Food Safety Administration (EFSA) have conducted a careful review of the evidence and come to a different conclusion based on a weight-of-evidence approach (EFSA 2020).[16] ATSDR's response to similar comments was reasonable "Although there are inconsistencies in the epidemiological data, ATSDR considers the data to be suggestive of an association between serum PFOS and decreased response to antibodies." WA state did not derive a SAL from these epidemiological studies. Rather, the evidence was used to show potential relevance to human populations of reduced immune response to antigens in laboratory animals.
Recommendation	DOH recommends no change.

Comment Summary	Develop supporting toxicological assessments applicable to all people in a community. This will enable development of applicable risk communication materials for all community members and support informed decisions regarding the removal of a water source from use, or investment in treatment, if feasible.
Response Summary	The SAL is intended to protect the entire community served by a public water system including sensitive groups. It is not specific to certain subgroups.
Recommendation	DOH recommends no change.

Comment Summary	SALs are premature as the process and criteria for adopting SALs were not yet finalized prior to proposing the SALs.

[16] Risk to human health related to the presence of perfluoroalkyl substances in food. EFSA Panel on Contaminants in the Food Chain (EFSA CONTAM Panel) ADOPTED: 9 July 2020 EFSA Journal 2020;18(9):6223.

Response Summary	DOH and the board have indicated that setting the SAL criteria and SALs in the same rulemaking is acceptable because the criteria being established in the proposal is being used to set the SALs.
Recommendation	DOH recommends no change.

Comment Summary	SALs should be reviewed and updated regularly given the emerging science.
Response Summary	DOH agrees that new data may inform SAL values, indicate the need for new SALs, or make possible more comprehensive regulatory approaches to PFAS in drinking water. A natural time point for this re-evaluation will be in 2025, when DOH evaluates the data collected in the first round of testing.
Recommendation	DOH recommends no change but agrees with commenter and recommend the board and DOH stay current with the emerging science and revise the rule as necessary to protect public health.

WAC 246-290-320 Follow-up action.

Comment Summary	DOH received numerous comments requesting that DOH and the board require PWS to install treatment or otherwise mitigate when they exceed any SAL.
Response Summary	Action to address water treatment would be required under an MCL. A SAL is a bridge to an MCL, which the board may determine is necessary in the future. The proposed rule includes the process for promulgating a state MCL in this rule.
Recommendation	DOH recommends no change.

Comment Summary	Several commenters requested DOH to develop consistent language and guidance for PFAS-related PN. Provide different notice language based on the range and relative health risk of PFAS measured in the water source.
Response Summary	DOH is developing PN for a PWS exceeding a SAL and for PWS with significantly higher results. DOH is also developing a PN guidance document for PWS.
Recommendation	DOH recommends no change to the rule language and will develop guidance.

Comment Summary	One commenter was concerned that the proposed rule would require a PWS to conduct environmental analysis of the contamination where "investigate the cause of contamination within the purveyor's control" is used.

Response Summary	Investigating the cause of contamination is limited to what is under the purveyor's control. If the purveyor determines that the contaminant is in the aquifer, then the investigation is considered complete. DOH recommends that the purveyor work with Ecology in these circumstances, so Ecology can determine the source of the environmental contamination within the aquifer and identify potentially liable parties.
Recommendation	DOH recommends no change.

Comment Summary	Commenters were concerned about the phrase "Take action as directed by the department." Commenters wanted an explanation of all potential actions that may be required, or a specific concentration where a water system would be required to mitigate. Commenters were especially concerned that take action as directed means that DOH would require all systems which exceed a SAL to install treatment.
Response Summary	There may be individual situations where a water system's PFAS results are very high and pose an immediate public health threat. In those unique situations DOH, the water system, and the local health jurisdiction will work together to take actions to protect public health, as they would in the event of any known or unregulated contaminant. If supported by the facts and emerging science, the local health officer and/or DOH has authority to order a water system to take action to remedy a public health emergency under its general authority to regulate drinking water systems, including RCW 70A.125.030(1); RCW 70.05.070; RCW 43.70.130(7). This would be a case-by-case decision, not a requirement of general application under this rule.
Recommendation	DOH recommends no change.

Comment Summary	Two commenters asked questions about the frequency of increased monitoring, both about the necessity and benefit of increased quarterly monitoring, and a request for increased monitoring without the complication for monitoring based upon the detected concentrations.
Response Summary	This rule is intended to address monitoring for both current and future SALs. It also addresses other unregulated contaminants with established health advisory levels. It was structured to minimize rule language and future changes necessary as new SALs may be developed, and to reduce monitoring costs associated with detections well below established risk levels. DOH created publication #331-668 to help clarify these requirements.

	DOH does not have sufficient data yet to indicate that PFAS will be steady and not fluctuate seasonally. Quarterly monitoring would be the frequency for confirming whether or not quarterly PN is still appropriate, especially for results that are around the SALs (greater than 80 percent).
Recommendation	DOH recommends no change.

Comment Summary	One commenter recommended DOH change the SDRLs to match the MRLs established by EPA under UCMR 5. The commenter thought using something other than the measurements specified by USEPA jeopardizes the defensibility, consistency, and quality of the information reported to DOH. This commenter quoted USEPA's definition of MRL in the federal register for including UCMR 5 as follows, "MRL as the minimum quantification level that, with 95% confidence, can be achieved by capable analysts at 75% or more of the laboratories using a specified analytical method. (86 Federal Register 13846, March 11, 2021)."
Response Summary	While EPA does set standards nationally for labs participating in UCMR, this is not necessarily indicative of what all labs can achieve. DOH set the SDRLs based on the capabilities of the labs which are accredited in Washington State. Laboratories accredited by the Department of Ecology have confirmed Washington accredited labs can achieve the SDRLs identified in the proposed rule.
Recommendation	DOH recommends no change.

Comment Summary	A commenter stated concerns about the 20 percent of a SAL "trigger" being below EPA's MRL for UCMR 5 (For PFOA, PFOS, PFNA, and PFHxS) and its use by DOH to determine the number of increased samples required under the proposal.
Response Summary	Twenty percent of the SAL isn't the only "trigger" for increased monitoring. Any PWS required to test for PFAS under this chapter, with a detection above an SDRL, is "triggered" to collect additional samples. DOH used a tiered approach to monitoring requirements. If a PWS chooses to use their UCMR 5 data to meet requirements of the rule, and the lab reports a "j" flagged detection below the UCMR 5 established MRL, DOH would require one additional sample if that detection was greater than the SDRL. If such a reported result was below the SDRL, DOH would not require additional monitoring.
Recommendation	DOH recommends no change

WAC 246-290-480 Recordkeeping and reporting.

Comment Summary	One commenter was concerned that by requiring purveyors to maintain records of actions taken to address exceedances of a SAL for ten years, that remedial action to address a SAL exceedance is required.
Response Summary	PWSs must keep records of any actions they take to mitigate or address a contaminant including PFAS, whether they were required by DOH or based upon purveyor choice.
Recommendation	DOH recommends no change.

Comment Summary	One commenter felt that it would be inappropriate to require PWS to inform DOH within 24 hours of their being notified of a SAL exceedance result because the SAL is not an MCL.
Response Summary	Consistent with the federal rule, the proposal requires 48-hour notification to DOH of an exceedance of a contaminant with a SAL, unless it's an acute risk. PWS are required under WAC 246-290-480 to report any violation of an acute risk contaminant under the National Primary Drinking Water regulation within 24 hours, including monitoring violations. DOH aligned the rule so that an exceedance of any acute risk SAL contaminant would require a 24-hour notification to the DOH. WAC 246-290-480 addresses reporting to DOH and does not address PN.
Recommendation	DOH recommends no change.

WAC 246-290-71006. [Now titled] Public notification for contaminants with a SAL

Comment Summary	One commenter recommended that in addition to the current required public postings in the media and in the annual reports, notification with exact levels of PFAS in water samples exceeding the standards should be provided as soon as possible to each consumer by direct mail or a water bill insert.
Response Summary	DOH aligned the PN requirements with those in the federal rule for other contaminants based on the acute (tier 1) or chronic (tier 2) nature of the exposure risk. For PFAS, the proposed rule does require customers receive direct PN as soon as possible, but no more than 30 days after the exceedance is reported.
Recommendation	DOH recommends no change to the rule. DOH is working on guidance for electronic delivery options for PN.

Comment Summary	One commenter expressed concern about the need for quarterly PN when a SAL was exceeded. The commenter expressed concerns over the high costs (over $100,000 per year) to meet the direct mailing

	costs in order to reach all customers, not just billed accounts. The commenter didn't feel the PN requirements other than an annual CCR were justified, except for notifying following the first exceedance and notifying new water customers at the time of initiating service. The commenter thought that contrary to the intent, constant repeated notifications, particularly without new information, can create confusion, clutter, and loss of audience attention.
Response Summary	DOH set the SALs at the levels established to ensure public health is not significantly impacted. While the proposal doesn't require treatment, it does require PN, so individuals may take action to protect their health. The quarterly PN would include updated information regarding results of quarterly sampling, at a minimum. DOH aligned the requirements for PN with the federal rule for other tier 2 notification, which require quarterly PN to all affected consumers. Any contaminant that exceeds a public health-based standard, except for copper, requires a minimum of quarterly notification and in notice in the CCR. The CCR rule now requires large utilities to provide CCR updates two times per year. It is possible that a PWS may include ongoing PN as part of their CCR to meet one or two of the quarterly notification requirements, provided all elements of PN notification were included in the CCR.
Recommendation	DOH recommends no change. DOH is working on guidance for electronic delivery options for PN.

Comment Summary	DOH received several questions regarding quarterly PN as it related to quarterly sampling. One commenter was concerned that quarterly PN would be required when a PWS wasn't required to sample quarterly.
Response Summary	PN is only required when a PWS source has a result above a SAL regardless of the monitoring frequency. This situation would also simultaneously require ongoing quarterly monitoring. PN would not be required in any quarter in which the source results were below the SAL, although the PWS might want to communicate such results to their customers.
Recommendation	DOH recommends no change.

Comment Summary	One commenter said the co-mingling of SALs and MCLs in this table, alongside Maximum Contaminant Level Goals (MCLG) may be misleading to some readers. The commenter was concerned that development document for the PFAS SALs explicitly states that the derived values are based on the MCLG model, and they believed it would therefore be more transparent and accurate to list SALs with MCLGs than with MCLs.

Response Summary	Since a SAL must consider additional criteria (e. g., technical feasibility) and the board is proposing to regulate contaminants with SALs, they are closer to an MCL than an MCLG. DOH did not need to, nor did we, adjust the SAL values based on technical feasibility criteria, so in the case of the five proposed PFAS SALs, the same value could also be entered into the MCLG column in this table. It is important to note that for most EPA MCLs established for chemical contaminants based on non-cancer health risks, the MCL is equal to the MCLG.
Recommendation	DOH recommends no change.

Comment Summary	One commenter was concerned that health effects language required for PN listed effects other than those for which the SAL was derived.
Response Summary	The simplified health effects language covers any potential health effects of exposures including exposures above a SAL. Although the PFAS SALs are derived from developmental, immune, and thyroid endpoints, there are other health endpoints of concern to human health that are relevant to potential drinking water exposures.
Recommendation	DOH recommends no change.

Summary of General Comments and Responses

General Support

Comment Summary	Many commenters: • Thanked the board and the DOH for setting SALs for drinking water. • Recognized the state as a national leader in its efforts to curtail the use of PFAS but some also highlighted it was a first step. • Expressed their support for even more protective standards, including those that would require treatment and cleanup. • Supported including TNCs if they are located near a known area of contamination; however, some would like them to have same requirements as Community and NTNCs. • Support for federal MCL superseding a state SAL or less protective state MCLs. • Expressed appreciation for how the proposal allows the board and DOH to address future unregulated contaminants and not just PFAS. • Urged the board to take immediate action and adopt the proposed rules.
Response Summary	Thank you for your comments and support for the proposed amendments to the Group A Public Water Supplies rule. The board

	and DOH agree. The proposal is a good first step toward protecting public health from PFAS contamination in the drinking water supplies. The proposed rule provides a pathway to potential next steps in what will be ongoing efforts to protect public health from PFAS contamination. The requirement to treat and cleanup PFAS contamination is outside the scope of this rulemaking. DOH will, as always, work with PWS and local health jurisdictions in their efforts to address the needs of the communities they serve as they determine the necessary next steps. DOH supports the work being done by the Department of Ecology to adopt a CAP for PFAS contamination and will continue to work with them to protect public health from PFAS contamination.
Recommendation	Adopt the rule, with the changes recommended by DOH, continue to follow the evolving science and adapt the standards, as supported by the best available science and needed to protect public health.

Comment Summary	During comment period a request was made for an extension of the comment period.
Response Summary	DOH staff reached out to the commenter by telephone. Assured them if their comments were received before or at the public hearing on October 13, 2021 that DOH and the board would consider them. The commenter ultimately submitted comments within the published comment period.
Recommendation	DOH recommends no change.

Preliminary Significant Analysis

Comment Summary	Several comments asked clarifying questions about the Preliminary Significant Analysis (SA) and what the cost estimates in Table 3 included.
Response Summary	On Page 11 – WAC 246-290-300 Monitoring – "Costs: A total of 109 Group A water systems provided costs to collect and ship water quality samples for testing. Table 3 below shows the estimate for one sample from one location. Sample costs include travel time, labor to collect sample, and shipping costs."
Recommendation	DOH recommends no change and encourages commenters with questions not answered in this summary to reach out to DOH to discuss their questions with their DOH regional office.

Comment Summary	A commenter disagreed with the statement in the SA, "PFAS contamination of groundwater is likely to be a localized problem", stating that it is an assumed statement based on limited sampling

	around the state and requested that this language be removed from the preliminary SA.
Response Summary	The statement that PFAS contamination of drinking water is likely to be localized is based upon limited sampling in Washington state and on results from more comprehensive testing of drinking water supplies in other states that were conducted with lower analytical detection limits. For example, in 2018, Michigan tested 1,744 PWSs for PFAS. 1,565 had no detectable levels of any PFAS. The leading potential sources of drinking water contamination identified in the Washington state's PFAS CAP appear to be industrial sites that use or make PFAS, military bases and airports where aqueous film forming foam, or AFFF, was used or trained with, and certain waste streams such as landfills and wastewater treatment plants.
Recommendation	DOH recommends no change.

Comment Summary	A commenter stated that the analysis ignores any costs associated with long-term impacts of the SALs despite DOH stating that the SALs can serve as the foundation for future MCLs or remediation cleanup standards.
Response Summary	DOH disagrees. The statement in the SA "there are no known or anticipated direct compliance costs associated with the board establishing the SALs in the Rule" is accurate. The aim of this rulemaking is to understand the burden of PFAS in drinking water, not to remedy it. DOH did not include the costs of these because there is no way to know the cost as DOH does not yet know the full burden of PFAS contamination in Washington state, nor the plan to remedy it. The Administrative Procedures Act (APA) requirements in RCW 34.05.328 stipulate what must be analyzed for the SA. The SA does analyze and include the costs associated with annual monitoring costs for PFAS as well as providing PN as required in the rule. DOH also included the benefits of PFAS monitoring and PN requirements, which are what this rule specifically directs and directly impacts. The board focused the benefit throughout the SA on the value of providing information so that consumers can make informed decisions about their health and safety, which is a direct benefit of the requirements of this rule. The board does correctly include potential long-term benefits based on actions consumers could take if they know the level of PFAS in their water system. Costs associated with establishing an MCL would be addressed in a future board rulemaking should a state MCL ever be proposed. This rule does not set standards for remediation or cleanup of PFAS contamination and it would be premature to speculate on potential

	costs as there are still too many unknowns. If a cleanup standard should be proposed in the final PFAS CAP, as DOH presumes may happen in the SA, WAC 173-333-420(3) directs Ecology to identify the probable benefits and costs of implementing the recommendations in the PFAS CAP.
Recommendation	DOH recommends no change.

Rule Process

Comment Summary	One commenter requested that the state conduct statewide testing first, outside of the required monitoring in the rule proposal, to understand the prevalence and occurrence of a contaminant prior to implementing a rule that they believe will erode public confidence.
Response Summary	DOH disagrees. DOH and the board would be remiss in not informing the public of a known drinking water contamination that may impact public health. The approach taken in the proposed rule accomplishes both the collection of occurrence data and informing the public should a SAL exceedance occur.
Recommendation	DOH recommends no change.

Comment Summary	One commenter noted that no specific actions are required for an MCLG exceedance. They recommended that DOH either not compare a SAL to an MCLG or change the requirements for a SAL exceedance to be similar to an MCLG exceedance at the federal level.
Response Summary	In the communications about how DOH derived the SAL values, DOH explained that the derivation process was analogous to deriving the health protective values called MCLGs under the SDWA. The SAL itself is a regulatory instrument that carries requirements and is not the same as an MCLG. A SAL has requirements for initial testing, ongoing monitoring, and PN, where as an MCLG does not. The same could be said for the many MCLs that are set at the MCLG for regulated contaminants. The values are the same but an MCL is a regulatory instrument that carries with it specific requirements.
Recommendation	DOH recommends no change.

Readability

Comment Summary	Several questions were submitted asking for clarity and suggestions were made to improve formatting to increase the rules readability, such as a request that we used more indentations and bullets.
Response Summary	Much of the formatting and layout is determined by the Code Revisers Office, who disallow the use of bullets in Bill Drafting Guidance. Additionally, DOH wants to keep the focus and attention

	on the important work of establishing the five PFAS SALs and the subsequent monitoring, follow-up, and PN requirements necessary to protect public health. DOH has staff who provide technical assistance and the Water Quality Monitoring Schedule (WQMS) for the PWS to help them understand and remain compliant with the rules.
Recommendation	DOH recommends no change.

Water Rights

Comment Summary	Concerns over water rights being in jeopardy if a drinking water source is taken offline due to PFAS contamination…resulting in no daily average consumption which the commenter states is necessary to maintain their water rights.
Response Summary	DOH appreciates the comments and understands the concerns, however, water rights are outside the scope of this rulemaking. That said, DOH is working with Ecology on several issues related to municipal water rights and will continue to do so.
Recommendation	DOH recommends no change.

Availability of PFAS Monitoring Data

Comment Summary	DOH received comments requesting that all PFAS data be publicly available as soon as possible.
Response Summary	DOH will maintain all PFAS results in the publicly accessible database, Sentry internet, as DOH does for all other drinking water results. The database is updated twice a week.
Recommendation	DOH recommends no change.

Comment Summary	DOH received two comments requesting that DOH provide healthcare providers in Washington State relevant communication and messaging so that they may appropriately respond to potential patient concerns following any required PN.
Response Summary	Information and resources for healthcare providers can be found on DOH's PFAS-Resources for Healthcare Providers webpage. DOH also works with health care providers at the Region 10 Pediatric Environmental Health Specialty Unit to provide outreach to clinicians in impacted areas.
Recommendation	DOH recommends no change.

Federal Action/MCL

Comment Summary	The current proposed SAL may result in circumstances where purveyors could be required to construct and operate PFAS removal

	treatment plants which at a future date may be rendered unnecessary as a result of the proposed rules defaulting to a federal MCL.
Response Summary	In general, these proposed values have been dropping over time (see Post et al 2021). When or if, EPA sets an MCL for two or more PFAS, the board will adopt the federal MCL, but will keep the SALs that lack a federal MCL. DOH has this process outlined in the proposal to set a stricter state MCL if the federal MCL is not deemed sufficiently protective.
Recommendation	DOH recommends no change.

Comment Summary	Commenter recommends that DOH delay the rulemaking and develop a UCMR like testing process so not only PFAS, but also future contaminants of concern can be evaluated to determine contaminant prevalence to aid in the rulemaking. Also suggested the board and DOH let EPA complete its work to set MCLs.
Response Summary	DOH disagrees. Instead of waiting for EPA to complete the federal rulemaking process which can take several years, this proposal allows us to get started identifying drinking water supplies with PFAS, developing funding sources to help address it, and mitigating exposures to people.
Recommendation	DOH recommends no change.

Cost/Funding

Comment Summary	Many commenters expressed concern about funding for treatment and cleanup saying that Washington should explore state funding and technical support for PWS and well owners with water levels that exceed the SALs. Some are concerned about the potential that only larger and more affluent cities/water systems will enact the costly treatment resulting in inequitable protection from contaminated water across the state.
Response Summary	The board and DOH understand the concerns for costs of impacts associated with PFAS contamination. Likewise, DOH is keenly concerned with the real potential for inequities. However, the rule proposal requirements for PN of a SAL exceedance provides most PWS consumers with information to help them make decisions that affect their health and that of their families. Ultimately, it will be the communities and the PWS that decide what is best for their community's health and safety—should testing show an exceedance of the state standards proposed in this rulemaking. DOH will work with local health jurisdiction, PWS, and the community on next steps should they be necessary—as DOH would in the case of any other drinking water contamination.

	Meanwhile, DOH has taken several steps to help mitigate costs for PWS who move forward with PFAS treatment. DOH has worked with Ecology to ensure SAL values are taken into consideration when determining groundwater cleanup standards. This will enable PWS to be reimbursed by responsible parties under applicable laws. Additionally, DOH has made PFAs treatment an eligible funding criterion under the Drinking Water State Revolving Fund loan program. DOH has also supported PWS by providing corroborating information to the legislature on the requests for state funding for treatment.
Recommendation	DOH recommends no change. DOH remains committed to the ongoing efforts to address the public health impacts of PFAS contamination and will explore what additional actions the state could take to help mitigate the cost impacts to PWS and the communities they serve.