

WAC 246-290-460, Drinking Water Fluoridation
Summary SBOH Positions on Rule Revision Requests and Comments
Fluoride Petitions 1-17

From	Request or Comment	Discussion	SBOH EH Committee Recommendation	SBOH Position Taken
William Osmunson, President of Washington Action for Safe Water (petition #1, May 2010)	Only FDA has authority to approve use of fluoride compounds for therapeutic purposes such as reducing tooth decay. FDA has authority over compounds used, concentration, and labeling through 1938 Food Drug and Cosmetics Act new drug approval provisions. This should be done through FDA's Center for Drug Evaluation and Research (CDER).	FDA has deferred regulation of tap water to EPA through an MOU. FDA has adopted regulatory concentrations for naturally occurring and additive levels of fluoride in bottled water. FDA regulations for bottled water are consistent with fluoride levels formerly (pre-2011) recommended by divisions of the U.S. Department of Health and Human Services (HHS).	SBOH cannot make a federal agency regulate something it does not want to. FDA regulatory levels of fluoride in bottled water appear to indicate the agency has reviewed the safety of the levels of fluoridation formerly recommended by HHS.	Denied petition. FDA maintains it does not regulate additives in drinking water. The Board cannot make a federal agency act, and cannot adopt rules that countermand state statutes. The Board has no authority to consider the changes you have requested.
"	The MOU between FDA and EPA is illegal. FDA cannot disregard its statutory responsibility.	FDA continues to claim no jurisdiction over fluoridation of tap water.	SBOH cannot make a federal agency regulate something it does not want to.	Denied Petition. The concentration range is below the primary and secondary safety standards set by EPA and within the range recommended in guidance posted by CDC. The Board cannot force a federal agency to act and cannot adopt rules that countermand state law.

“	The Safe Drinking Water Act prohibits federal rules requiring tap water additives intended for preventive health purposes unrelated to contamination.	No federal agency requires the fluoridation of drinking water. The decision to fluoridate in the State of Washington falls under water systems own statutory authority.	SBOH does not require fluoridation of tap water. Its rule is intended to help assure fluoridation levels are within the range recommended by CDC if a water system chooses to fluoridate.	Not pertinent to SBOH rule.
“	A group of EPA scientists is opposed to water fluoridation because they think risk is too high compared with benefits.	Labor-employer dispute involved. It is unclear whether this group reflects the majority opinion of EPA scientists.	There might be internal disagreement at EPA, but SBOH rule is based on HHS recommendation.	Not pertinent to SBOH rule.
“	Washington State Board of Pharmacy has jurisdiction over fluoride when used with the intent to prevent disease.	Board of Pharmacy letter dated June 4, 2009 to Dr. Osmunson says that board does not have jurisdiction over drinking water additives. It says RCW 57.08.012 supersedes its authority under chapter 69.41 RCW.	Board of Pharmacy claims it does not have jurisdiction over fluoridation of tap water.	SBOH agrees with the Board of Pharmacy’s position.
“	Requiring FDA approval is reasonable and legal.	FDA claims no jurisdiction over fluoridation of tap water.	SBOH cannot make a federal agency do something it has declined to do.	Not pertinent to SBOH rule. SBOH cannot make a federal agency do something it has declined to do.
“	EPA allows more fluoride in water than FDA-required warnings on toothpaste tubes would indicate are appropriate.	SBOH regulatory levels for systems that choose to fluoridate are based on HHS recommendations. HHS re-evaluated recommendation in 2011.	SBOH relies on HHS recommendation because neither it nor the Washington State Department of Health (DOH) has the capacity to	Base SBOH rule on most current HHS recommendation.

			evaluate the raw science.	
“	Many people are ingesting too much fluoride because it is in many products and dose is cumulative.	EPA recently evaluated relative source contribution and released report in late 2010. HHS has considered this report for its 2011 recommendation.	SBOH relies on HHS and other federal agencies to evaluate the raw science.	Base SBOH rule on most current HHS recommendation.
“	Research shows water fluoridation has no significant benefit in preventing cavities.	HHS has evaluated benefit vs. harm and still recommends fluoridation.	SBOH relies on HHS and other federal agencies to evaluate the raw science.	Base SBOH rule on most current HHS recommendation.
“	Drinking water fluoridation is unethical because it constitutes experimental research without the consent of those affected.*	Public water systems may choose to fluoridate under their own statutory authorities.	SBOH does not require fluoridation. Its rule sets a standard, based on HHS recommendation, to help prevent over-fluoridation by those water systems that choose to fluoridate.	Keep a regulatory level based on most current HHS recommendation.
William Osmunson (petition #2, August 2010)	SBOH has responsibility to regulate safety of public drinking water. Cumulative consumption of fluoride in water along with that in food and various products adversely affects some people. Some research literature indicates water fluoridation at current levels in the SBOH rule adversely affect some people. Change the rule to specify a concentration range of 0.001 – 0.08 mg/L in systems that choose to fluoridate.	Individual research papers about water fluoridation levels might be inconsistent. EPA has set regulatory maximum concentration levels of fluoride in water based on safety. CDC, part of HHS, has a recommended level for artificial fluoridation of drinking water. The HHS recommended level is less than the EPA regulatory level. FDA has regulatory maximum	SBOH is not a research agency, does not have the capacity to evaluate the raw research about fluoride, and relies on federal agencies for guidance. Recommend that the rule not be opened until EPA changes its safety standards and CDC changes its recommendations for artificially fluoridating water, or FDA changes its	Denied Petition. Base SBOH rule on most current HHS recommendation.

		<p>levels of fluoride in artificially fluoridated bottled drinking water equivalent to the range formerly recommended by HHS for tap water.</p> <p>* HHS responded to this assertion by looking at legal challenges to CWF and found that the courts have viewed CWF as a proper means of furthering public health and welfare.</p>	standards for fluoride in bottle water.	
William Osmunson & James Robert Deal (petition #3, September 2010)	Fluoridating water contributes to an increase in arsenic, lead, and other contamination in the water either through leaching of plumbing materials or direct contamination from impurities. Water systems that fluoridate should be required to provide a notice to customers explaining the potential sources of lead in the water system; the corrosivity of the water; steps being taken to mitigate lead exposure; and a specific statement that silicofluorides contain lead and increase leaching of lead from plumbing.	Many chemicals added to water for various purposes can increase corrosivity of the water. EPA regulations for public drinking water require water purveyors to monitor the corrosivity of the water, whether natural or due to additive chemicals; control for it; monitor for lead and copper in the distribution system; and provide an advisory to the public if lead and copper levels exceed certain standards.	SBOH delegated authority to DOH in 2009 to update chapter 246-290 WAC to add provisions of EPA's 2007 revision of its lead and copper rules. The petitioners could provide input to that rule-making process, which was still in progress in late 2010.	Petition denied. Suggested that the petitioner contact DOH because the Board has delegated rulemaking to adopt the EPA's 2007 revision of lead and copper rules. EPA's lead and copper rules have extensive notification requirements and this request is best addressed through that rule update.

<p>William Osmunson & James Robert Deal (petition #3, September 2010)</p>	<p>Silicofluorides should be disallowed as fluoridation materials because they contain lead contaminants and increase leaching of lead from plumbing.</p>	<p>CDC and EPA publications contend that silicofluorides added in appropriate concentrations for water fluoridation do not have an appreciable effect on lead content of drinking water.</p>	<p>Disagree with comment.</p>	<p>Disagree with comment.</p>
<p>William Osmunson (petition #4, October 2010)</p>	<p>Mother's milk is the perfect formulation for infants. Drinking water used to mix formula should not have fluoride levels greater than mother's milk. Add a requirement that water systems with average fluoride levels above 0.01 ppm, or that lack the ability to measure low concentrations of fluoride, include a warning statement in each water bill to avoid using the water for infant drinking or infant formula preparation.</p>	<p>Infants drink more liquid in proportion to body weight than do older children or adults. The CDC and the American Dental Association (ADA) recommend using fluoride-free or low-fluoride water to mix with powdered or concentrated infant formula to reduce the potential for dental fluorosis, a cosmetic condition. CDC guidelines state there is low risk for fluorosis using water with less than 0.7 ppm fluoride for infant formula. Most water systems in Washington have natural fluoride above 0.01 ppm.</p>	<p>Support recommendations from CDC and many other health-related organizations that mother's milk is the best choice for infants. Support recommendations from CDC and ADA, which are used by DOH, that infant formula should be prepared using fluoride-free or low-fluoride water. The specific rule revision requested is not appropriate. An educational approach is more appropriate.</p>	<p>Denied petition. The Board favors an educational approach of CDC and the American Dental Association for informing the public about the risk of mild fluorosis from giving infants fluoridated water and that this approach is adequate without the Board changing the rules.</p>
<p>William Osmunson (petition #5, October 2010)</p>	<p>Add a phrase to WAC 246-290-460 in two subsections: "...with the intent to prevent dental caries..."</p>	<p>The concentration range of fluoride specified by WAC 246-290-460 is intended to be consistent with CDC recommendations for the</p>	<p>The intent of fluoridation to prevent dental caries is self-evident and does not warrant the expenditure of public resources to make</p>	<p>Petition Denied. The Board follows CDC guidelines for setting an appropriate level of fluoride in drinking water for those</p>

		“optimal” concentration to help prevent dental caries.	the rule change to add the recommended phrase.	systems that fluoridate. CDC counts fluoridation as the single most effective public health measure to prevent tooth decay. The Board supports this position. It is not an efficient use of public resources to initiate and complete a rule making process to add the language requested by the petitioner. Rule change is not warranted.
William Osmunson (petition #6, October 2010)	EPA publications regarding review of literature on the safety of fluoride in drinking water at the Recommended Maximum Contaminant Level (RMCL) are flawed. The harm from fluorosis to children is under appreciated. Cumulative expositors to fluoride are increasing. Add a requirement that water systems with average fluoride levels above 0.01 ppm, or lacking the ability to measure low concentrations of fluoride, include the following notice with each customer’s water bill: “The Washington State Board of Health recommends no more than one glass of water for children from 6 months	A 2006 report to EPA by the Committee on Fluoride in Drinking Water, National Research Council, recommended EPA consider lowering the RMCL closer to 2 ppm than 0.01 ppm. Most water systems in Washington have natural fluoride above 0.01 ppm.	Because SBOH is not a research agency, it relies on recommendations from federal agencies. Also, the rule change requested does not appear to be consistent with the majority of scientific opinion.	Petition Denied. Disagrees with petitioners assertions. SBOH looks to the U.S. Environmental Protection Agency (EPA) for standards and recommendations regarding the safety of drinking water. EPA standards allow fluoride concentrations in water more than a hundred times greater than 0.01 ppm and consider the water to be safe for consumers without such an advisory statement as recommended by the petitioner. The rule petition is

	to 4 years of age and no more than two glasses of this water before the age of 8. Use non-fluoridated water for additional drinking and cooking.”			also not supported by recommendations of the 2006 report of the Committee on Fluoride in Drinking Water, National Research Council. The Board believes the rule requested change is not consistent with the majority of scientific opinion at this time.
William Osmunson (petition #7, October 2010)	Exposure to fluoride has been associated with reduced IQ scores by researchers. FDA letter to Representative Ken Calvert of December 2000 stated fluoride used for prevention of a disease is a drug and is subject to FDA regulation. Reiteration of comments in petition #1 about drug laws applying to drinking water fluoridation. Add a requirement that water systems with average fluoride levels above 0.01 ppm, or lacking the ability to measure low concentrations of fluoride, include the following notice with each customer’s bill: “The Washington State Board of Health finds the fluoride level in this water may contribute to lower IQ and an increase in mental retardation.”	The research cited is not consistent regarding controls and effects from fluoride in drinking water at levels similar to those in WAC 246-290-460. Some of the Chinese studies indicate coal burning is a significant source of fluoride exposure. There is no generally recognized threshold concentration of fluoride in drinking water considered unsafe regarding lower IQ or mental retardation. The 2006 report to EPA by the Committee on Fluoride in Drinking Water, National Research Council, recommended EPA consider lowering the RMCL closer to 2 ppm than 0.01 ppm. Most	Because SBOH is not a research agency, it relies on recommendations from federal agencies. Also, the rule change requested does not appear to be consistent with the majority of scientific opinion.	Petition Denied. Disagree with requested rule change. The petition is not supported by recommendations of the 2006 report of the Committee on Fluoride in Drinking Water, National Research Council, and is not consistent with the majority of scientific opinion at this time.

		<p>water systems in Washington have natural fluoride above 0.01 ppm.</p> <p>The December 2000 FDA letter to Rep. Ken Calvert also contained the statement: "As you know, the Environmental Protection Agency regulates fluoride in the water supply."</p>		
<p>William Osmunson (petition #8, February 2011)</p>	<p>Reiteration of comments in petition #1 regarding only FDA having authority to authorize fluoridation. Fluoride is used as a drug when added to water. Serving fluoridated water is human subject research and requires informed consent. Add the following statement to WAC 246-290-460: "...Where fluoride substances which are unapproved by the FDA CDER are added to water systems, the Washington State Board of Health recommends Public Water Systems make application for IRB (Institutional Review Board) approval."</p>	<p>Letter from Washington State Institutional Review Board (WSIRB) of February 2011 states fluoridation by local water districts is not human subject research. Water systems fluoridate under their own authority.</p>	<p>FDA has stated it has no intent to regulate fluoridation of tap water. Addition of fluoride to tap water is not a research investigation appropriate for IRB review.</p>	<p>Petition denied. Board does not expect the fluoride additives used will be approved by the U.S. FDA CDER because, according to FDA, it has no intention of regulating fluoride additives in tap water. The Board recommends petitioner direct his request to federal authorities. Institutional review boards evaluate proposals for human subject research to assure the rights and welfare of human subjects are protected. IRBs evaluate research project protocols. Adding fluoride to drinking water does not constitute a research investigation by either the water purveyor or this Board.</p>

				The Board considers it inappropriate to recommend water purveyors apply for IRB approval.
William Osmunson (petition #9, February 2011)	Fluoride compounds have been shown to affect thyroid function. The 2006 report to EPA by the Committee on Fluoride in Drinking Water, National Research Council, recommended this association be researched further. Reiteration of comments about only FDA having authority to evaluate and approve the use of fluoride in water to help prevent cavities. Add a requirement that water systems with average fluoride levels above 0.01 ppm, or lacking the ability to measure low concentrations of fluoride, include the following notice with each customer's bill: "The Washington State Board of Health finds the fluoride level in this water may contribute to thyroid damage, diabetes and/or obesity. Pregnant mothers, infants and those at risk of thyroid damage are advised to drink water containing less fluoride."	The 2006 NRC report did recommend more research about fluoride's effect on thyroid function, but it did not recommend a maximum concentration of fluoride in drinking water. There is no scientific agreement on whether fluoridation levels recommended by CDC are harmful to thyroid function. Most water systems in Washington have natural fluoride above 0.01 ppm.	Because SBOH is not a research agency, it relies on recommendations from federal agencies. Also, the rule change requested does not appear to be consistent with the majority of scientific opinion. Recommend he send comments to EPA and HHS, which announced on January 7, 2011 they are considering changing their standards and recommendations regarding fluoride in drinking water.	Petition Denied. When setting standards in state rule, this Board relies on existing federal standards and recommendations. The request is not consistent with standards and recommendations of either EPA or HHS. EPA and HHS announced they are reviewing their standards and recommendations for fluoride. Board suggests the petitioner direct comments, and review of the research literature, toward those agencies.
William Osmunson (petition #10,	EPA analyses of the safety of fluoride in water have focused on non-cancer effects. Its December 2010 reports	The research on a potential association between fluoride and cancer appears to be	Because SBOH is not a research agency, it relies on recommendations from	Denied petition. Disagree with requested rule change-- The many confounding factors in

February 2011)	<p>were limited to dental and skeletal fluorosis. EPA analysis is flawed because it does not address other possible effects. EPA should support studies on the relationship of fluoride exposure and concentrations in various body tissues, especially serum and urine. Some studies report an association between higher fluoride intake and a higher rate of bone cancer in animals and young men.* Reiteration of comments about only FDA having authority to evaluate and approve the use of fluoride in water to help prevent cavities.</p> <p>Add a requirement that water systems with average fluoride levels above 0.01 ppm, or lacking the ability to measure low concentrations of fluoride, include the following notice with each customer's bill: "This water contains fluoride which may contribute to cancer and tumors for at risk persons."</p>	<p>minimal. The 2006 NRC report recommended more such studies. Most water systems in Washington have natural fluoride above 0.01 ppm.</p> <p>* The HHS report cites a later study showed "no significant association between bone fluoride levels and osteosarcoma risk."</p>	<p>federal agencies. Recommend he send comments to EPA and HHS, which announced on January 7, 2011 they are considering changing their standards and recommendations regarding fluoride in drinking water</p>	<p>research on cancer causation make requiring a statement suggesting any definitive link to fluoride levels commonly found in drinking water problematic. The request is not consistent with standards and recommendations of either EPA or HHS. EPA and HHS announced they are reviewing their standards and recommendations for fluoride. Board suggests the petitioner direct comments, and review of the research literature, toward those agencies. FDA claims a role in regulating fluoride only in bottled water (21 CFR 165.110) and not in tap water. Board does not require fluoridation of tap water. That is determined by water system under their own authorities.</p>
William Osmunson (petition # 11, May 2011)	<p>Reiterates comments in petition #1 that fluoride must either be considered a poison or regulated as a prescription drug. Monitoring serum fluoride levels would more accurately measure exposures to fluoride from</p>	<p>Board of Pharmacy letter dated June 4, 2009 to Dr. Osmunson says that board does not have jurisdiction over drinking water additives. It says RCW 57.08.012</p>	<p>SBOH has authority to regulate what is in drinking water and does not appear to have authority to require water systems to monitor serum fluoride</p>	<p>Denied petition. The Board considers your proposal to require water systems to monitor blood serum to be inconsistent and unworkable. The Board does not consider</p>

	<p>many sources. Require water systems that fluoridate to maintain concentrations in water below 0.7 ppm and human serum fluoride levels below 0.02 ppm or 0.01 ppm [inconsistent maximum serum concentrations proposed].</p>	<p>supersedes its authority under chapter 69.41 RCW. FDA says it does not intend to regulate fluoride in tap water.</p>	<p>levels in consumers. The proposal to do so is unworkable and inconsistent. Comments received will be considered input as part of rule making process started by SBOH filing CR-101 on May 13, 2011 to revise WAC 246-290-460 based on anticipated revised recommendation from HHS for water fluoridation at 0.7 ppm.</p>	<p>its statutory authority for regulating water systems to include requiring monitoring blood serum fluoride concentrations of consumers. Petitioners request to require water systems to randomly monitor blood serum concentrations in consumers is unworkable due to medical information privacy laws. Base SBOH rule on most current HHS recommendation.</p>
<p>William Osmunson (petition #12, May 2011)</p>	<p>Reiteration of comments in petition #1 about only FDA having authority to regulate fluoride added to water to prevent cavities. EPA's proposed reference dose (RfD) for maximum daily fluoride exposure of 0.08 mg/kg/day is explained not to be adequately protective for children under 7 years old. In order to protect young infants from fluorosis, require water systems that fluoridate to maintain fluoride levels in water below 0.15 ppm.</p>	<p>FDA has said it does not intend to regulate fluoridation of tap water. EPA's mission to set a regulatory maximum level of fluoride in tap water is different from HHS' goal of setting an optimal level. EPA's current and likely future regulatory level will be higher than an HHS guideline.</p>	<p>SBOH assumes HHS will consider guidelines from EPA and various parts of its own agency when finalizing a new recommendation for fluoridation of tap water. Comments received will be considered input as part of rule making process started by SBOH filing CR-101 on May 13, 2011 to revise WAC 246-290-460 based on anticipated revised recommendation from HHS for water fluoridation at 0.7 ppm.</p>	<p>Denied Petition. Plan to move ahead with rulemaking to base the rule on most current HHS recommendation.</p>

William Osmunson (petition #13, July 6, 2011)	Compares water fluoridation with discredited public health experiments without informed consent and comparison with experimentation on slaves, prisoners, or institutionalized individuals.	Comparison of water fluoridation with examples of discredited experimentation is inflammatory rhetoric. SBOH rules do not require fluoridation.	Adding fluoride to water is not an experiment.	Denied petition on same grounds as earlier petitions.
“	Asserts data does not demonstrate that water fluoridation has a significant beneficial effect. Examples of problems with and disagreements in research conclusions. Reiterates that monitoring serum fluoride levels would more accurately measure exposures to fluoride from many sources.	SBOH assumes HHS will consider breadth of research and public comments regarding research conclusions.	SBOH is not a research agency and relies on advice of federal agencies regarding water fluoridation.	Base SBOH rule on most current HHS recommendation.
“	Asks SBOH to require water systems that fluoridate to maintain concentrations in water below 0.7 ppm and human serum fluoride levels below 0.02 ppm; monitor serum concentrations in at least five volunteers monthly; decrease fluoride concentration in water by 0.1 ppm in each month serum fluoride concentrations exceed 0.02 ppm.	Proposal is similar to petition #11, with similar problems.	SBOH does not appear to have authority to require water systems to monitor serum fluoride levels in consumers. The proposal to do so is unworkable.	Base SBOH rule on most current HHS recommendation.
William Osmunson (petition #14,	Consumed fluoride is not eliminated well by individuals with kidney disease and may cause further injury	Petitioner does not provide support for 0.3 ppm being trigger for kidney health risk.	Proposal is not appropriate for WAC 246-290-460 and concerns could be handled	Denied petition. The Board follows US EPA and HHS recommendations for safe

August 10, 2011)	to kidneys. Asks SBOH to require water purveyors supplying water with average fluoride concentration above 0.3 ppm to place notice in water bills warning of health risks for those with kidney problems.	A lot of water systems in Washington have natural fluoride above 0.3 ppm, as well as those that fluoridate. This proposal is not consistent with MCL for fluoride or consumer confidence report requirements set by EPA.	better by advice from health care providers to kidney patients.	levels of fluoride and consumer advisory information. The petition is not consistent with these standards and recommendations.
William Osmunson (petition #15, August 28, 2011)	NSF Standard 60 does not assure each batch of fluoridation chemicals has a safe concentration of impurities such as lead and arsenic. Asks SBOH to require water purveyors that fluoridate to only use fluoridation chemicals for which each batch has been assayed for composition and labeled with concentration at the recommended dilution in water.	SBOH has adopted in WAC 246-290-220 requirements for all drinking water treatment chemicals to meet NSF Standard 60. EPA supports NSF Standard 60 without the proposed requirements.	WAC 246-290-460 is inappropriate rule section for requested change. SBOH relies on advice from EPA for approval of water treatment chemicals.	Denied petition. Disagree with requested rule change. The Board follows US EPA and HHS recommendations and standards. Current requirements are adequate for fluoridation.
James Deal (Petition September 2, 2015)	Fluoride additives do not comply with the toxicological testing requirements listed in NSF standard 60 and are, therefore, no longer approved for use in Washington until the toxicological tests have been performed and verified by DOH as NSF 60 compliant.	SBOH has adopted in WAC 246-290-220 requirements for all drinking water treatment chemicals to meet NSF Standard 60. The NSF approval process for Fluoride additives is well documented and uses the requirements as published in NSF Standard 60.	SBOH rules already require NSF Standard 60 certification for all water treatment chemicals (except commercially retailed hypochlorite compounds). Mr. Deal's representation of NSF requirements is inaccurate; the contention that fluoride additives do not	Denied petition. Disagree with contention that Fluoride additives do not comply with NSF Standard 60; the requested rule change is not needed to protect public health.

			meet NSF Standard 60 requirements is also inaccurate.	
Gerald Steel (Petition October 2, 2015)	Adopt a new rule to only permit fluoride additives that do not add any lead or arsenic.	NSF Standard 60 has a method in place of accessing trace levels of contaminants in water treatment chemicals. This standard is applied to fluoridation additives. Some batches of fluoridation additives do have trace amounts of lead and arsenic. These levels in finished water are far below NSF allowable levels for these contaminants.	Washington State Drinking water rules, Federal Safe Drinking Water Act, EPA's Primary Drinking Water Standards, and NSF Standard 60 requirements provide adequate protection. These rules and standards apply uniformly to drinking water contaminants and all water additives not just fluoridation additives.	Denied Petition. The regulatory framework provided in Washington State statute and rule is sufficient to protect the public health and provide safe and reliable drinking water without adopting the requested rule.