

RECOMMENDATIONS FOR WATER BOTTLERS AND VENDORS THAT ADD FLUORIDE TO BOTTLED WATER



On April 27, 2015, the U.S. Public Health Service (PHS) issued a new recommendation for the optimal fluoride level in drinking water to prevent tooth decay. The new recommendation is for a single level of 0.7 mg of fluoride per liter of water. It replaces the previous PHS recommended range of 0.7 to 1.2 mg per liter (mg/L). In order to be consistent with the new PHS recommendation, the U.S. Food and Drug Administration (FDA) recommends that bottled water manufacturers do not add fluoride to bottled water at concentrations greater than maximum final concentrations of 0.7 mg/L. The details of the FDA recommendation can be downloaded at the agency's website link.

Existing regulations (21 CFR 165.110(b)) include a quality standard for bottled water and provides for different allowable levels for added and naturally occurring fluoride, as well as for imported and domestic products. Under this quality standard, for bottled water with added fluoride, domestic bottled water can contain between 0.8 and 1.7 mg/L fluoride, depending on annual average air temperatures at the location where the bottled water is sold at retail, and imported bottled water cannot contain more than 0.8 mg/L fluoride. FDA's recommendation -- that bottled water manufacturers do not add fluoride to bottled water at concentrations greater than a maximum final concentration of 0.7 mg/L -- does not affect the current allowable levels of fluoride in bottled water specified in 21 CFR 165.110(b). FDA has indicated that they intend to modify this quality standard in the near future to conform to the revised PHS recommendation.