FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

December 17, 2019

Robert R. Hirst
Vice President
Education, Science and Technical Relations
The International Bottled Water Association
1700 Diagonal Road, Suite 650
Alexandria, VA 22314

Dear Mr. Hirst:

Thank you for your letter of November 8, 2019, requesting FDA to establish a standard of quality (SOQ) for per- and polyfluoroalkyl substances (PFAS) in bottled water. Specifically, you requested that FDA issue an interim final rule or direct final rule to establish a SOQ of 5 parts per trillion (ppt) for any single PFAS compound and 10 ppt total for multiple PFAS compounds. You requested that FDA apply the SOQ for PFAS substances to bottled water finished products (not source water) and to each type of bottled water but not each size of the same type of bottled water. You also requested that FDA specify the test frequency (annual) and methods (e.g., EPA Method 537 for 2019 and EPA Method 537.1 starting in 2020). You further requested that FDA's SOQ "include a provision that would ensure regulatory national uniformity."

In addition, you requested that prior to the publication of the SOQ interim final rule or direct final rule, FDA "prepare and distribute a letter to the relevant state agencies explaining how bottled water is regulated by FDA, including the requirements for testing finished product only and why testing the same product in multiple-size containers is unnecessary."

Request for the establishment of a SOQ for PFAS in bottled water

As background, FDA promulgated the bottled water SOQ regulation in 1973 based on the 1962 U.S. Public Health Service (PHS) Drinking Water Standard (38 FR 32558). When finalizing the SOQ regulation in 1973, FDA stated that the "compatibility of the bottled water standard with the drinking water standard will be maintained by revising the bottled water standard when the drinking water standard is revised." (38 FR 32558 at 32561). Over the years, FDA has revised the bottled water SOQ based on EPA's National Primary Drinking Water Regulations (NPDWR) (e.g., 74 FR 25651) or proposed revisions to the bottled water SOQ based on the PHS recommendation for public drinking water (e.g., 84 FR 12975).

In 2016, EPA established lifetime health advisories of 70 parts per trillion (ppt) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), the two most well-known and prevalent PFAS chemicals (81 FR 33250). Health advisories are not regulatory levels. In 2019, EPA announced that it is moving forward with the Maximum Contaminant Level (MCL) process for PFOA and PFOS[1]. EPA is also gathering and evaluating information to determine if regulation is appropriate for a broader class of PFAS[1]. While we do not object to IBWA's adoption of SOQs for its members, FDA believes it would be premature for the Agency to establish a SOQ for PFAS in bottled water at this time, given the ongoing activities at EPA addressing PFAS in public drinking water.
https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf

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In addition, FDA's testing show that bottled water generally has no detectable levels of PFAS. For example, in 2016, FDA analyzed 30 bottled water products collected at retail locations in the Washington, D.C. metropolitan area for PFAS. The samples included: purified, artesian, spring, mineral, and carbonated waters. None of the 30 samples had detectable levels of PFAS[2]. In addition, you stated in your letter that IBWA members are already testing for PFAS and the results, to date, have been overwhelmingly negative – i.e., PFAS compounds were not detected in bottled water products made by IBWA members at levels above what would be required by the states. Therefore, FDA believes that establishing a SOQ for PFAS in bottled water at this time would not significantly enhance FDA's mission of public health protection.

With regard to national uniformity, Section 403A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that: "… no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(1) Any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g) . . .." FDA has interpreted this provision to apply to standards of quality (21 CFR 100.1(c)(4)).

Request for a letter be sent by FDA to the relevant state agencies explaining how bottled water is regulated

As background, FDA regulates bottled water as food under the FD&C Act. In addition to regulations applicable to foods in general, bottled water is also subject to bottled water specific regulations, including the standard of identity regulation in 21 CFR 165.110(a), SOQ regulation in 21 CFR 165.110(b), and the current good manufacturing practice (CGMP) regulation for the processing and bottling of bottled drinking water in 21 CFR part 129.

FDA's CGMP regulation for bottled water includes testing requirements for contaminants in bottled water. Specifically, for chemical, physical, and radiological purposes, bottlers must take and analyze at least annually a representative sample from a batch or segment of a continuous production run for each type of the bottled drinking water produced during a day's production to assure compliance with the SOQ regulation for bottled water (21 CFR 129.80(g)(2)). FDA does not consider different bottle sizes to be different types of bottled water that would require separate testing under 129.80(g). However, the regulation requires testing of "a representative sample from a batch or segment of a continuous production run." Therefore, where a bottler has separate production runs for each size of bottled water, separate testing of each size would be required.

In addition, samples of source water from each source must be taken and analyzed as often as necessary but at a minimum each year for chemical contaminants (21 CFR 129.35(a)(3)). Bottlers that use a public water system for source water may substitute public water system testing results, or certificates showing full compliance with all provisions of EPA National Primary Drinking Water Regulations pertaining to chemical contaminants, for the testing requirements of 129.35(a)(3) (21 CFR 129.35(a)(4)(i)). https://www.fda.gov/media/130564/download

We note that the above bottled water regulations have not changed in recent years and the regulatory language is clear on the applicability of the SOQ regulation and the testing requirements. Therefore, FDA does not believe a letter is needed to explain how bottled water is regulated by FDA.

We hope this response provides clarification on how FDA regulates bottled water including the establishment of SOQ regulations.

Sincerely,

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and Applied Nutrition