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Paul South, PhD
Director, Division of Plant and Beverage Products
Office of Food Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Re: Request that FDA Establish a Standard of Quality for PFAS in Bottled Water

Dear Dr. South:

As we have previously discussed, the International Bottled Water Association (IBWA) has taken several actions concerning the issue of per- and polyfluoroalkyl substances (PFAS) as it relates to bottled water. IBWA requires its members to test their finished bottled water product types annually for PFAS. In addition, IBWA has adopted a standard of quality (SOQ) for the 14 PFAS compounds listed in US EPA Method 537. The IBWA SOQ is 5 parts per trillion (ppt) for one PFAS compound and 10 ppt for multiple PFAS compounds. Beginning January 1, 2020, IBWA will require its members to use EPA Method 537.1 for PFAS testing, which will increase the number of target PFAS compounds from 14 to 18.

Considering the increased number of public water systems throughout the country that have experienced PFAS contamination, and the resulting media attention, IBWA believes that it is important for the U.S. Food and Drug Administration (FDA) to issue a bottled water Standard of Quality for these substances. That will provide consumers; federal, state, and local governments; and emergency relief personnel further assurance that bottled water products are safe for everyday use and in times of need when tap water is compromised.

In the absence of FDA regulations for PFAS in bottled water products, or U.S. Environmental Protection Agency (EPA) PFAS standards for public water systems, several states have established their own PFAS rules for drinking water. This has led to a patchwork of laws and regulations that are not consistent from state-to-state. Nor are they consistent with how FDA has traditionally addressed SOQs for chemical contaminants. We therefore think that it is important for FDA to take action to issue a PFAS Standard of Quality that would ensure regulatory uniformity for bottled water products sold throughout the U.S.

Like other Standards of Quality for bottled water, IBWA requests that FDA apply the SOQ for PFAS substances to bottled water finished products (not source water), to each type of bottled water (e.g., spring water, artesian water, purified water) but not each size of the same type of bottled water, and specify the acceptable test method (e.g., EPA Method 537 for 2019, EPA Method 537.1 starting in 2020) to be utilized annually.

Provided below is further support for our request.

State Efforts to Regulate PFAS in Drinking Water

PFAS contamination of public waters systems around the country has caused many states to establish their own PFAS quality and monitoring requirements. This is due primarily to the lack of any federal regulation of PFAS in drinking water beyond the US Environmental Protection Agency's current health advisory limit of 70 ppt. This has led to a patchwork of regulations that are not consistent from state to state. For example, New Jersey has established maximum contaminant levels and monitoring requirements for PFNA for public water systems and bottled waters effective in early 2019. The state plans to add PFOA and PFOS in 2020, and additional PFAS compounds beyond 2020. Many other states, including Vermont, New York, Massachusetts, Connecticut, New Hampshire, and California, have either established MCLs and monitoring requirements or are taking action to do so.

Impact of State Regulation of PFAS on the Bottled Water Industry

Different state PFAS regulations are not an issue for public water systems because they only provide water to consumers in one state. However, the different state PFAS requirements are becoming a significant burden to the bottled water industry since many companies sell their products in several states. Moreover, such multiple regulation is unnecessary because 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. ^{1/}

IBWA members are being subjected to many different state approaches to regulating PFAS in bottled water, which in many cases has also become an unnecessary financial burden. For example, bottled water companies doing business in Vermont recently received a letter from the Agency for Natural Resources (VT ANR) requiring them to test finished products, sources, and every container size for PFAS using EPA Method 537.1 for five specific PFAS compounds and report the results to the VT ANR by January 13, 2020. Since most of our members have already completed the IBWA-mandated testing this year using EPA Method 537, and VT ANR has repeatedly stated that they will only accept data generated by EPA Method 537.1, it has

^{1/} IBWA is aware of one non-member bottled water company in Massachusetts whose water tested positive for PFAS but, to the best of our understanding, that company is no longer selling bottled water.

become a huge financial burden for our members to retest their products. To date, most states have focused on the 14 target analytes in EPA Method 537.

The lists of analytes regulated also varies. New Jersey currently regulates PFNA but intends to add PFOA and PFOS in 2020. Connecticut has published a plan to legislate 5 PFAS compounds and New York has published a proposed rule to regulate two PFAS compounds.

Request for FDA Action

IBWA respectfully requests that CFSAN adopt a PFAS Standard of Quality for bottled water of 5 ppt for single PFAS compound detections and 10 ppt for multiple PFAS compound detections. As with other FDA-required testing, the frequency of such testing should be annual. That action will provide consumers; federal, state, and local governments; and emergency relief personnel further assurance that bottled water products are safe for everyday use and in times of need when tap water is compromised. We also request that FDA's Standard of Quality include a provision that would ensure regulatory national uniformity and eliminate the patchwork of state regulation. We note that FDA's Standards of Quality for bottled water products under 21 CFR 165.110(a) are issued under the Standard of Identify provision of the Federal Food, Drug, and Cosmetic Act ("the Act") which carries with it a mandate for national uniformity. See Section 403A of the Act, 21 U.S.C. 343-1(a)(1). 2/

We understand that the US EPA is in the process of formulating a PFAS regulation for public water systems. FDA has traditionally waited for EPA to issue a Maximum Contaminant Level for a substance before issuing a bottled water Standard of Quality for that same substance. However, final EPA action on a PFAS standard for tap water could take several years and our need is much more urgent. We therefore urge FDA to issue an interim final rule or direct final rule for bottled water as soon as possible.

Although it would be more expeditious than a proposed/final rule, an interim final rule or direct final rule will require some time to accomplish. As an interim step, we request that 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. We hope that the letter would support national regulatory uniformity, for reasons that include providing consistent messaging to consumers, preventing disparities of varying regulations by the states, and reducing the regulatory and financial burdens on the bottled water industry.

2/ Specifically, under Section 403A of the Act, states may not "directly or indirectly establish . . . any requirement for a food which is the subject of a standard of identity under section 341 of this title that is not *identical* to such standard of identify. . . ." 21 U.S.C. 343-1(a)(1)(emphasis added). FDA's standard of quality regulations for bottled water are promulgated under the standard of identity provision at 21 CFR 165.110(a). Notably, the regulations were promulgated pursuant to Section 341 of Title 21 of the U.S. Code (the Standard of Identify provision) and therefore embody the preemptive effect of Section 403A.

We hope CFSAN will favorably consider our requests. IBWA stands ready to assist and support FDA's actions on this important issue.

If I can answer any questions or provide additional information, please do not hesitate to contact me at (703) 647-4611 or bhirst@bottledwater.org.

Respectfully,

INTERNATIONAL BOTTLED WATER ASSOCIATION

A handwritten signature in black ink that reads "Robert R. Hirst". The signature is written in a cursive, flowing style.

Robert R. Hirst

Vice President – Education, Science and Technical Relations

C: Joe Doss, IBWA President/CEO
Dr. Yinqing Ma, CFSAN
Dr. Henry Kim, CFSAN