

ISSUE BACKGROUNDER

BROMATE and the FDA DISINFECTANT/DISINFECTION BYPRODUCTS DIRECT FINAL RULE December 7, 2005

About this Paper

The purpose of this paper is to provide IBWA members with a resource when addressing issues related to the FDA/EPA Disinfectant/Disinfection Byproducts (D/DBP) Rule, including the resulting bromate Standard of Quality (SOQ) of 10 parts-per-billion (ppb). This paper provides you a brief background on the issue, sample Question and Answers and issue talking points being used by IBWA.

This document does not provide legal advice and companies should consult with their individual counsel to address company-specific matters or how they may utilize this information. This document provides examples as to how IBWA may address this topic based on a number of general inquiries. IBWA may be a resource to members for media inquiries on the topic as a general matter. IBWA does not provide comment on company-specific matters.

For IBWA more information on this and other bottled water industry topics, please visit the Members Only section of the IBWA web site at www.bottledwater.org.

IBWA addresses this issue as simply one regulation in a comprehensive set of standards designed to help ensure consumers enjoy safe, high-quality bottled water products. There are no immediate adverse health affects from drinking bottled water produced either before or after the Rule's compliance date and there is no looming health threat faced by bottled water consumers.

Background and Key Facts

The bromide ion is a natural and harmless element found in some bottled water source waters that, when exposed to the disinfection process of ozonation, may form a byproduct called bromate. Not all source waters for bottled and other water contain the bromide ion. Therefore, water not containing the bromide ion will not undergo conversion to bromate when ozonated. **As important, not all finished waters contain bromate, even if the source water contained the bromide ion.**

The level of bromate that may form in water depends on the concentration of bromide in the source water, the amount of ozone contact time, and a variety of water chemistry factors including pH, organic material, hardness and alkalinity.

Ozonation is one aspect of a multi-barrier approach used to help ensure the safety and quality of bottled water products. Ozonation is often preferred over chlorination to disinfect water because it does not leave a residual taste, color or odor in the water. While chlorination is primarily used for disinfection in public water systems, a number of U.S. public water systems use ozone. Ozonation has been used extensively for public water utilities in Europe for many years.

In the early 1990's, the U.S. Environmental Protection Agency (EPA) began to look at the health effects of byproducts formed by drinking water disinfection methods including chlorine and ozone. In December 1998, EPA issued a rule for "Disinfectants and Disinfectant Byproducts (D/DBPs)." That rule contained a new standard of 10 parts-per-billion (ppb) for bromate, with a compliance date of January 1, 2002 for large municipal systems and January 1, 2004 for smaller systems. There is no actual evidence that exposure to bromate in drinking water presents a health risk to humans. Because of the very conservative way EPA conducted its risk evaluation for bromate, there may be no actual health risk to humans from bromate in drinking water. Although EPA has estimated a cancer potency value for bromate, the health protective methods used to determine cancer potency mean that the true risk is likely to be lower than predicted and could even be zero (0). There are no studies indicating that ingestion of bromate in water has caused adverse health effects in humans.

By law, FDA must adopt standards for bottled water comparable to EPA's standards within 180 days after EPA's rules take effect. On March 28, 2001, FDA published in the *Federal Register* a D/DBP Direct Final Rule with standards analogous to the EPA rule and standards and with a compliance date of January 1, 2002.

In anticipation of that rule, IBWA amended the IBWA Bottled Water Code of Practice to require member bottlers to begin monitoring for bromide in source waters in 2001 and was further amended to require compliance with a 10 ppb bromate standard starting January 1, 2002. In developing its new rule, FDA indicated that it did not want to increase the potential risks to bottled water consumers that might be caused if producers reduced disinfection levels in an effort to reduce bromate levels.

Questions and Answers

Q) What are the rules and when did they take effect?

- A) In the early 1990's, the U.S. Environmental Protection Agency (EPA) began to look at the health effects of byproducts formed by drinking water disinfection methods, including chlorine and ozone. In December 1998, EPA issued a new rule for "Disinfectants and Disinfectant Byproducts (D/DBPs)." That rule contained standards for disinfection byproducts from both chlorination and ozonation.

By law, the FDA must adopt standards for bottled water comparable to EPA's standards within 180 days after EPA's rules take effect. On March 28, 2001, FDA published in the *Federal Register* a D/DBP Direct Final Rule with standards analogous to the EPA rule and standards with a compliance date of January 1, 2002. The FDA rule applies to bottled water produced and bottled on or after January 1, 2002.

In particular, EPA set a standard for bromate of 10 ppb for public water systems and requires large public water systems to be in compliance by January 1, 2002 and small municipal utilities to be in compliance by January 2004 which is most relevant to bottled water. FDA adopted a similar standard for bottled water.

In anticipation of that rule, IBWA amended the IBWA Bottled Water Code of Practice to require member bottlers to begin monitoring for bromide (a naturally occurring element) in source waters in 2001 and further amended the IBWA Bottled Water Code of Practice to require member compliance with a 10 ppb bromate standard starting January 1, 2002.

FDA has indicated that it does not want to increase the risk of illness due to reduced or new disinfection levels.

Q) What is bromate? How may it get in my water?

- A) The bromide ion is a natural and harmless element found in some bottled water source waters that, when exposed to the disinfection process of ozonation, may form a byproduct called bromate. Not all source waters for bottled and other water contain the bromide ion. Therefore, water not containing the bromide ion will not undergo conversion to bromate when ozonated. **As important, not all finished waters contain bromate, even if the source water contained the bromide ion.**

The level of bromate that may form in water depends on the concentration of bromide in the source water, the amount of ozone contact time, and a variety of water chemistry factors including pH, organic material, hardness and alkalinity.

FDA requires bottled water producers to provide a microbiologically safe product to consumers, as EPA requires public drinking water suppliers to do the same. Both agencies acknowledge that applying disinfectants may result in the presence of disinfection byproducts, using current technology. Therefore, the importance of safeguarding the microbiological quality of bottled water outweighs the minimal risks associated with bromate that may be present in the finished product.

Ozonation is one aspect of a multi-barrier approach used to help ensure the safety and quality of bottled water products. Ozonation is often preferred over chlorination to disinfect water because it does not leave a residual taste, color or odor in the water. While chlorination is primarily used for disinfection in public water systems, a number of U.S. public water systems use ozone. Ozonation has been used extensively for public water utilities in Europe for many years.

Q) What are the health effects?

A) There is no actual evidence that exposure to bromate in drinking water presents a health risk to humans. Because of the very conservative way EPA conducted its risk evaluation for bromate, there may be no actual health risk to humans from bromate in drinking water.

Q) Is it unsafe to drink water containing bromate?

A) No. Although EPA has estimated a cancer potency value for bromate, the health protective methods used to determine cancer potency mean that the true risk is likely to be lower than predicted and could even be zero (0). There are no studies indicating that bromate in drinking water has caused adverse health effects in humans.

EPA and FDA have concluded that an individual consuming two (2) liters of water per day containing the maximum level of bromate (10 ppb) over their entire lifetime would be safe.

Q) Should I stop drinking water with bromate?

- A) Consumers should not be alarmed about the presence of bromate in water. If the presence of bromate were an imminent health risk, EPA would not have allowed public water systems up to five years from the rule's effective date to meet the new standards. At this writing some small community water systems are still not required to comply with a 10 ppb bromate standard and the smallest of systems may be permanently exempted, as are private wells. The benefits of water consumption outweigh the minimal – possibly zero – risk of consuming water that adheres to the bromate and other standards.

EPA and FDA have concluded that an individual consuming two (2) liters of water per day containing the maximum level of bromate (10 ppb) over their entire lifetime would be safe.

Q) How does the industry meet the DBP standards and reduce bromate?

- A) Bottlers that must do so are likely to employ a variety of methods to meet the standards due to the fact that each situation is unique. The industry, through the International Bottled Water Association (IBWA) is reviewing a number of approaches designed to reduce or eliminate bromate in water and at the same time maintaining the current high levels of protection and the natural characteristics of the water.

These approaches include trying to eliminate bromide in the water source, altering the ozonation process, and identifying and/or enhancing other technologies and approaches other than ozonation. These include micro and nano-filtration, ultraviolet light, application of plant zoning principles, enhanced maintenance and cleaning/sanitizing operations, further attention to personnel training, control procedures, and corrective actions.

FDA requires bottled water producers to provide a microbiologically safe product to consumers, as EPA requires public drinking water suppliers to do the same. Both agencies acknowledge that applying disinfectants may result in the presence of disinfection byproducts, using current technology. Therefore, the importance of safeguarding the microbiological quality of bottled water outweighs the minimal risks associated with bromate that may be present in the finished product.

Q) Why doesn't the bottled water industry simply stop using ozone for disinfection and do something else?

A) While some bottlers are choosing to eliminate the use of ozonation, others are able to adjust processes and control use of ozonation in concert with other steps to continue to provide a safe, high quality bottled water product. For those bottlers that continue to utilize ozonation, they are able to do so for several reasons. First, not all source waters contain the bromide ion and will not undergo conversion to bromate when ozonated. Since ozonation remains an effective disinfection method, bottlers are likely to continue to use this method. Second, ozonation may be managed or used in concert with other processes to help ensure that bromate is contained within allowable limits, or does not form at all. **As important, not all finished waters contain bromate, even if the source water contained the bromide ion.**

Ozonation is a proven means of disinfecting bottled water in the United States and has been used safely for over 30 years and is an important measure for some bottlers as part of the bottled water industry's multi-barrier approach, which helps ensure safe, high quality bottled water products. The U.S. Food and Drug Administration (FDA), which regulates bottled water as a packaged food product, lists ozonation as Generally Recognized As Safe (GRAS) as a disinfection method for foods, including bottled water, when used in conformity with FDA regulations. Moreover, ozonation has been widely used as a disinfection method in European public water systems for nearly 70 years and has come into use in many public water systems in the United States.

The bottled water industry uses ozonation as a treatment method because of its effectiveness and safety as a disinfectant. Ozonation is capable of disinfecting water at a faster rate than chlorine and, once it passes through water, ozone undergoes a complete conversion to oxygen within a few hours. And since it leaves no residual in the container, there is no detectable taste in the water. Other commonly used disinfectants such as chlorine and iodine leave a residual taste that many consumers find objectionable.

Q) Why has XYZ Company stopped using ozonation?

A) While I cannot comment on the actions of any one bottler, I am confident that the company has adopted processes that ensure compliance with the new bromate standard based on their specific circumstances, while at the same time continuing to provide a safe, high quality product. To achieve FDA standards and IBWA Code of Practice requirements, IBWA member bottlers employ a multi-barrier approach to help assure safe, high-quality bottled water products.

A multi-barrier approach may include two or more of the following: source protection, source monitoring, reverse osmosis, distillation, micron filtration, ultraviolet (UV) light, and ozonation.

Q) Is there a risk of drinking water containing even 1 ppb or any bromate below the 10 ppb standard?

A) Consumers should not be alarmed about the presence of bromate in water. If the presence of bromate were an imminent health risk, EPA would not have allowed public water systems up to five years from the rule's effective date to meet the new standards; at this writing some small community water systems are still not required to comply with a 10 ppb bromate standard and the smallest of systems may be permanently exempted, as are private wells. The benefits of water consumption outweigh the minimal – possibly zero – risk of consuming water that adheres to the bromate and other standards.

EPA and FDA have concluded that an individual consuming two (2) liters of water per day containing the maximum level of bromate (10 ppb) over their entire lifetime would be safe.

Q) I thought bottled water was supposed to be pure and, at the least, could not possibly have adverse health affects. If there is any question as to its safety, why should I pay for this product?

A) Bottled water sold in the United States must meet very strict standards for quality and safety, standards that have undergone intensive research, testing and analysis. Bottled water is subject to great care and technologies that help ensure a consistently safe, high quality product. Producing such a product that meets stringent federal, state and industry standards requires significant capital investment and utilization of people, technology and equipment to bring this high quality, safe product to consumers.

Q) If my bottled water was so pristine and pure, why did the company have to “disinfect” it and, by doing so, add contaminants or carcinogens?

A) Disinfection and sanitization are used to help further ensure high bottled water quality. Although bottled water plants must follow general food Good Manufacturing Practices (GMPs) and bottled water-specific GMPs, bottlers employ all known technological measures and take advantage of every precaution to ensure the safety and quality of the finished bottled water product.

As well, a small percentage of bottled water is sourced from municipal systems. Disinfection/sanitization is a key part of the additional care given to further purify these waters using methods dictated in a multi-barrier approach to render a finished bottled water product that is distinctly different from the original tap water source.

Q) Is tap water safer than bottled water?

A) No. Tap water is required by EPA to comply with the same bromate standard of 10 ppb. In addition, tap water is required to meet a host of other standards tied to disinfection byproducts that result from the use of chlorine for disinfection as well as standards for other contaminants. Bylaw, FDA bottled water standards must be as stringent and protective of public health as EPA tap water standards. But that is just a starting point on top of which FDA general food and bottled water-specific regulations and standards apply.

Q) Is processed water safer than natural or spring water?

A) No. All bottled water sold in the United States must meet stringent FDA/federal and state quality and safety standards. In addition, IBWA members must adhere to the IBWA Bottled Water Code of Practice, a set of strict standards and processes that, in some cases, are more stringent than FDA and state regulations. Consumers can get an IBWA member brand list by calling 1-800-WATER11 or logging on to the IBWA web site at www.bottledwater.org.

Q) How extensive is bromate in bottled water?

A) IBWA does not maintain data on individual bottlers and only tracks compliance with FDA, IBWA and state regulations. Compliance is verified through FDA and state bottled water plant inspections and the unannounced plant inspections conducted as a requirement of the IBWA Bottled Water Code of Practice. Again, not all source waters contain bromide and therefore are not affected by bromate, and many finished products do not contain bromate. Compliance with bromate, and all other standards, is both an FDA requirement and a requirement for IBWA membership in good standing.

Q) How can I tell which brand is safer?

A) Bottled water that meets FDA standards is considered safe for human consumption. Further, IBWA members must adhere to the IBWA Bottled Water Code of Practice, a set of strict standards and processes that, in some cases, are more stringent than FDA and state regulations. Consumers can get an IBWA member brand list by calling 1-800-WATER11 or logging on to the IBWA web site at www.bottledwater.org.

Q) How much water can I safely drink?

- A) Consumers should feel comfortable drinking as much water as they please. The EPA standard for bromate was based on worst-case and very conservative assumptions. Because of the very conservative way EPA conducted its risk evaluation for bromate, there may be no actual risk – even zero (0) - from 10 ppb of bromate in drinking water.

Q) Why doesn't EPA regulate bottled water?

- A) FDA has regulated bottled water since 1938 as a packaged food product because it is produced specifically and only for human consumption. Because of this, the product and the processes used to guide the water from its source to the packaged finished product must meet or surpass food standards. These standards also apply to the container, cap, closure and the equipment and plants where bottled water is packaged. EPA regulates tap water and, even though the tap water may have many industrial, residential, commercial and personal uses, it must be potable and meet standards as dictated by the EPA Maximum Contaminant Levels (MCL).

Q) How is bottled water regulated?

- A) Bottled water is a highly regulated product, subject to federal, state, and industry standards. Bottled water is regulated as a food product by FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA). This includes packaged water sold in smaller containers at retail outlets as well as larger containers (e.g., three and five gallon) distributed to the home and office markets.

Bottled water is subject to FDA's extensive food safety and labeling requirements, and water is subject to FDA's:

- food adulteration and misbranding provisions;
- nutritional labeling provisions;
- general Good Manufacturing Practices (GMPs);
- bottled water GMPs;
- the bottled water standard of identity; and
- the bottled water standard of quality (which is as stringent as EPA's standards for public water systems).

The bottled water industry is further regulated on two additional levels: state and industry trade association. Many states maintain their own bottled water standards at least equivalent in stringency to those of FDA. In addition, members of the International Bottled Water Association (IBWA) are required to undergo an unannounced third-party annual plant inspection and product

analysis to assure compliance with IBWA standards that are more stringent than FDA requirements. In addition, products imported from outside the U.S. must meet all U.S. regulations in addition to standards established by the exporting country.

FDA regulations, combined with state and industry standards, offer consumers assurance that the bottled water they purchase is stringently regulated, tested, and of the highest quality. The IBWA has been a long-standing proponent of additional federal regulations for bottled water, and is active at all levels of local, state, and federal government assisting in the development of such regulations.

Q) What is IBWA?

A) The International Bottled Water Association (IBWA) is the authoritative source of information about all types of bottled waters. Founded in 1958, IBWA's membership includes U.S. and international bottlers, distributors and suppliers. IBWA is committed to working with the U.S. Food and Drug Administration (FDA), which regulates bottled water as a packaged food product, and state governments to set stringent standards for safe, high quality bottled water products. In addition to FDA and state regulations, the Association requires member bottlers to adhere to the IBWA Bottled Water Code of Practice, which mandates additional standards and practices that in some cases are more stringent than federal and state regulations. A key feature of the IBWA Bottled Water Code of Practice is an annual, unannounced plant inspection by an independent, third-party organization. Consumers can contact IBWA at 1-800-WATER-11 or log onto IBWA's web site (www.bottledwater.org) for more information about bottled water and a list of members' brands.

###