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FDA should adopt Maximum Contaminant Level Goals as enforceable, health-based standards for contaminants in bottled water

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Regarding proposed amendment of 21 CFR Parts 129 and 165
Docket No. FDA-2008-N-0446

Environmental Working Group (EWG) is a non-profit health and environmental research and advocacy organization based in Washington, DC. We focus much of our research on potential health risks from exposures to hazardous chemicals that contaminate food, water and the environment, or that may be found in consumer products. This letter provides our comments on a proposed Food and Drug Administration (FDA) amendment of its bottled water regulations for microbiological contamination of ground water sources for bottled water production (FDA 2008).

For the past two years EWG has conducted studies of bottled water quality, which revealed that bottled water can be contaminated with a range of chemical and microbiological pollutants (EWG 2008). A summary of EWG findings and all test data can be found at http://www.ewg.org/reports/bottledwater. The study included ten popular brands of bottled water, purchased from grocery stores and other retailers in nine states and the District of Columbia. The ten brands contained 38 chemical pollutants altogether, with an average of eight contaminants in each brand. Four brands were also contaminated with bacteria, including coliform bacteria in one brand.

EWG research highlighted that under the current FDA regulations, consumers are not receiving the uniform quality and purity they expect from bottled water. FDA regulation of bacterial contamination of source water is woefully insufficient and does not provide the same level of public health protection as set by the Environmental Protection Agency (EPA) for public drinking water. For example, surface or ground water used as a source for bottled water production is supposed to be analyzed for microbiological contaminants once a week, yet up to now FDA has not defined an appropriate standard of microbiological purity of source water. The proposed amendment fails to ensure purity and safety of bottled waters with respect to microbiological contamination. EWG is very concerned that with this new rule FDA is continuing its track record of merely carrying over the municipal water standards and applying them to bottled water (FDA 2002) instead of setting health-protective standards on the basis of best available scientific evidence. As a result of this FDA policy, bottled water is not necessarily safer

than tap water even though bottled water costs much more than tap water on a per gallon basis (US EPA 2007).

The proposed rule (73 Fed. Reg. 53,775 Sept 17, 2008) incorporates several elements: a) mandatory testing of source ground water for total coliform; b) if any coliform organisms are detected, bottled water manufacturers must conduct follow-up tests for the bacterium *Escherichia coli* (*E.coli*); c) bottled water containing *E. coli* would be considered adulterated, and source water containing *E. coli* would not be considered to be of a safe, sanitary quality; d) bottlers would be required to eliminate *E. coli* contamination in source water and keep records of such actions.

EWG agrees with the proposed rule on points (a) and (b) above and commends the Agency for its plan to develop a better microbiological quality standard for bottled water. In contrast, the plan for the enforcement of the new standard, as summarized in points (c) and (d) above, contains gaps that would likely weaken the proposed amendment. According to the new rule, bottled water drawn from fecally contaminated sources must be labeled with a statement of substandard quality. Yet, FDA notes that "a statement of substandard quality only prevents bottled water that exceeds an allowable level for a contaminant from being misbranded with regard to that contaminant; it does not prevent the water from being adulterated or otherwise misbranded" (FDA 2008). Clearly, the proposed rule is not sufficient to guarantee bottled water quality, especially when considered in light of the hands-off approach FDA has historically taken with respect to bottled water quality regulation.

The enforcement gap is further compounded by the lack of transparency in the correction steps bottlers need to take once *E.coli* contamination is detected. Absent from the proposed rule is a requirement for bottlers to make the results of their tests public. The EPA ground water rule describes specific conditions under which municipalities need to notify the public of potential fecal contamination in the sources of tap water (U.S. EPA 2006). None of these provisions exist in the FDA amendment, so that consumers are left in the dark about potential pollution problems and the presence of contaminants that may affect bottled water quality.

In order to make bottled water truly safe, EWG urges FDA to strengthen the proposed amendment on three essential counts:

- FDA should adopt EPA's Maximum Contaminant Level Goals (MCLGs) as enforceable standards for chemical and microbiological contaminants in bottled water.
- FDA should require bottled water companies to fully disclose all test results to the public.
- FDA should require companies to disclose source and treatment information on bottled water labels.

Details of these recommendations are outlined below.

FDA should adopt EPA's Maximum Contaminant Level Goals (MCLGs) as enforceable standards for chemical and microbiological contaminants in bottled water.

FDA should use this meaningful opportunity to set in practice public health goals for stringent regulation of contaminants in drinking water. Bottled water contaminants may originate from source water, treatment and bottling processes, or packaging. While a number of these contaminants are unregulated, for many others both health standards (MCLGs) and legal limits (Maximum Contaminant Levels, or MCLs) have been defined (US EPA 2008). Tap water MCL standards have been developed as a compromise between protecting public health and the treatment costs potentially incurred by public utilities for lowering contaminant levels in municipal water systems. None of these cost considerations apply to bottled water companies. Thus, bottlers can and should produce bottled water of quality and purity that will fully protect consumer health.

By adopting MCLGs as enforceable standards for bottled water, FDA would provide consumers with access to water that is truly safe. Under current FDA regulations, bottled water drinkers can only expect that their water is no worse than tap water. The new standard for microbiological quality of bottled water, as proposed by FDA, would be "no less protective of the public health" compared to EPA municipal water regulations, but not any better. Considering that bottled water is hundreds or even thousands of times more expensive than municipal water (EWG 2008; Food and Water Watch 2007), consumers deserve much greater health protection from toxic contaminants in bottled water.

As summarized in Table 1 below, with respect to microbiological pollution, MCLG guidelines recommend zero total coliform, and zero concentration of other pathogens, such as *Cryptosporidium*, *Giardia lamblia*, *Legionella*, and viruses (US EPA 2008). These standards of microbiological quality should be applied to bottled water. Moreover, the same public health consideration needs to be adopted for chemical pollutants, especially for cancer-causing chlorination byproducts, arsenic, lead, pesticides, and radioactivity.

Table 1: Summary of regulated drinking water contaminants with Maximum Contaminant Level Goal of zero.

Contaminant	Potential health effects (US EPA 2003)	EPA-recommended safety standard (level of contaminant that avoids any human health risk) (US EPA 2008)	FDA bottled water standard (FDA 1995)
Microbiological contaminants			
Cryptosporidium	Gastrointestinal illness	0	no standard
Giardia lamblia	Gastrointestinal illness	0	no standard
Legionella	Legionnaire's Disease, a type of pneumonia	0	no standard
Total Coliforms (including fecal coliform and *E. Coli*)	Indicator of fecal contamination in water	0	Less than 2.2 organisms in 100 ml

Viruses	Gastrointestinal illness	0	no standard
Disinfection byproducts			
Bromate	Increased risk of cancer	0	10 parts per billion (ppb)
Bromodichloromethane	Liver, kidney, or central nervous system problems; increased risk of cancer	0	no standard
Bromoform	Liver, kidney, or central nervous system problems; increased risk of cancer	0	no standard
Dichloroacetic acid	Increased risk of cancer	0	no standard
Inorganic chemicals			
Arsenic	Skin damage, circulatory problems, increased risk of cancer	0	10 ppb
Lead	Infants and children: delays in physical or mental development; adults: kidney problems, high blood pressure	0	5 ppb
Organic chemicals and pesticides			
Alachlor	Eye, liver, kidney or spleen problems; anemia; increased risk of cancer	0	2 ppb
Benzene	Anemia; decrease in blood platelets, increased risk of cancer	0	5 ppb
Benzo(a)pyrene (PAHs)	Reproductive difficulties; increased risk of cancer	0	0.2 ppb
Carbon tetrachloride	Liver problems; increased risk of cancer	0	5 ppb
Chlordane	Liver or nervous system problems; increased risk of cancer	0	2 ppb
1,2-Dibromo-3-chloropropane (DBCP)	Reproductive difficulties; increased risk of cancer	0	0.2 ppb
1,2-Dichloroethane	Increased risk of cancer	0	5 ppb
Dichloromethane	Liver problems; increased risk of cancer	0	5 ppb
1,2-Dichloropropane	Increased risk of cancer	0	5 ppb
Di(2-ethylhexyl) phthalate	Reproductive difficulties; liver problems; increased risk of cancer	0	no standard
Dioxin (2,3,7,8-TCDD)	Reproductive difficulties; increased risk of cancer	0	$3x10^{-5}$ ppb
Epichlorohydrin	Increased cancer risk, and over a long period of time, stomach problems	0	no standard
Ethylene dibromide	Problems with liver, stomach, reproductive system, or kidneys; increased risk of cancer	0	0.05 ppb

Heptachlor	Liver damage; increased risk of cancer	0	0.4 ppb
Hexachlorobenzene	Liver or kidney problems; reproductive difficulties; increased risk of cancer	0	1 ppb
Polychlorinated biphenyls (PCBs)	Skin changes; thymus gland problems; immune deficiencies; reproductive or nervous system difficulties; increased risk of cancer	0	0.5 ppb
Pentachlorophenol	Liver or kidney problems; increased cancer risk	0	1 ppb
Tetrachloroethylene	Liver problems; increased risk of cancer	0	5 ppb
Toxaphene	Kidney, liver, or thyroid problems; increased risk of cancer	0	3 ppb
Trichloroethylene	Liver problems; increased risk of cancer	0	5 ppb
Vinyl chloride	Increased risk of cancer	0	2 ppb
Radioactive pollution			
Alpha particles	Increased risk of cancer	0	15 picocuries/liter (pCi/L)
Beta particles and photon emitters	Increased risk of cancer	0	4 millirems per year, equivalent to 50 pCi/L
Radium 226 and Radium 228	Increased risk of cancer	0	5 pCi/L
Uranium	Increased risk of cancer, kidney toxicity	0	30 ppb

As demonstrated by the data in this table, health standards of zero contamination are recommended by EPA for 36 pollutants, including five types of microbiological pollutants; four especially hazardous disinfection byproducts; two metals, lead and arsenic, that are well known for their toxicity; 21 synthetic organic chemicals; and four types of radioactive pollutants (US EPA 2008). Among these 36 pollutants, 30 are associated with an increased risk of cancer; many are also toxic to the developing fetus. Presence of these contaminants in drinking water at levels above zero cannot be considered completely safe. It is unjustifiable for bottled water industry to sell products that do not adhere to these health-protective guidelines. FDA should ensure that MCLG safety standards apply to all bottled waters, thus providing consumers with drinking water whose purity corresponds to public health goals as defined by decades of scientific research on health effects of water pollution.

FDA should require bottled water companies to fully disclose all test results to the public. EWG urges FDA to further develop the new amendment so as to require manufacturers to release the test data on chemical and microbiological contaminants in source water and in packaged bottled water. According to FDA's public health mandate, the Agency may issue a regulation

establishing a standard of quality when "such action will promote honesty and fair dealing in the interests of consumers" (21 U.S.C. 341). Unlike the situation with tap water, where consumers are provided with test results every year or more frequently (US EPA 2006), the bottled water industry is not required to disclose the results of contaminant testing. As uncovered by EWG investigation, bottled waters do not provide consistent quality to consumers: different brands and even different samples of the same brand purchased in various locations throughout the country may contain a diverse mixture of both regulated and unregulated pollutants (EWG 2008). Lack of uniformly applied standards of practice and lack of transparency affect consumers' right-to-know and does not guarantee purity and safety of bottled waters on the market.

This unsupportable situation can be rectified by a provision for mandatory public disclosure of all test results for both source water and packaged bottled water. The finalized FDA rule should include a provision for public notification as found in EPA tap water regulations. EPA requires public water systems that use ground water to notify the public if monitoring samples are positive for a fecal indicator or if appropriate water protection measures have not been taken in a timely manner. In contrast, the new amendment of bottled water standards does not require the same level of transparency, limiting itself to the provision that bottlers maintain records of corrective measures. These records would then be available for a review by an FDA inspector. However, as the Agency acknowledges, bottled water plants generally are assigned low priority for inspection (FDA 2002). And while some manufacturers conduct contaminant testing and publish the results on their websites (Nestle Waters 2008; Poland Spring 2007), public disclosure has not yet become a uniform standard in the field. As a result, records of recurring violations, even if collected, would likely remain hidden from both public scrutiny and FDA oversight. Thus, the proposed FDA amendment urgently needs to be strengthened by ensuring release of testing records in a way that is readily available to the public.

FDA should require companies to disclose source and treatment information on bottled water labels.

Current FDA labeling requirements fail to ensure complete disclosure by bottled water manufacturers. For example, while manufacturers are required to notify shoppers via appropriate information on the label if bottled water has been derived from municipal water sources (21 CFR 165.110(a)(3)(ii)), this requirement is easily circumvented when bottler proposes to use a purification treatment, even though the results of the treatment are very rarely monitored by FDA. EPA recommends that "consumers who choose to purchase bottled water should carefully read its label to understand what they are buying, whether it is a better taste, or a certain method of treatment" (US EPA 2007). Yet, if manufacturers are not including the information on the label, consumers' right-to-know is severely compromised. EWG urges FDA to close all loopholes for evading disclosure and insist on manufacturers' responsibility for providing the information consumers need. FDA should require that all relevant data be always listed on the label, including the location of the source water and purification techniques.

Ground water sources supply water for 70 to 75 percent of all U.S. bottled water products (FDA 2008). Some underground aquifers have been fouled by decades of pollution, whereby fecal contamination reaches ground water sources from improperly stored or managed manure, runoff from land-applied manure, leaking sewer lines or failed septic systems. Considering many potential pathways of contamination and severe health consequences from exposure to bacterial and viral pathogens in fecally contaminated or at-risk ground water sources, stringent enforcement provisions are necessary to protect the health of municipal water users (U.S. EPA 2006). A 2005 EWG study found nearly 300 contaminants in drinking water all across the country (EWG 2005). These pollutants are now present in both surface and ground waters and some of them have been detected in bottled water (EWG 2008).

Picturesque labels on water bottles seldom include information about precise location of the water withdrawal site; moreover, these labels never list information about potential contamination of source water or pollutants that may be present in the bottle. Public disclosure of this information, on the principal display panel or panels of the bottle label, will provide consumers with the evidence on which to make the decision to purchase the product that would best suit their needs and the needs of their families. The new amendment to bottled water regulations would remain incomplete and ineffective unless FDA would require bottled water manufacturers to disclose source and treatment information on bottled water labels.

In conclusion, EWG urges FDA to use this meaningful opportunity to provide consumers with bottled water quality they can trust. Health-based standards for bottled water contaminants, better monitoring for microbiological purity, full disclosure of test results for all contaminants, and disclosure of source and treatment of bottled waters are urgently needed in order to safeguard the interests of consumers and protect public health as outlined in the mandate of the Agency.

With best regards,

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