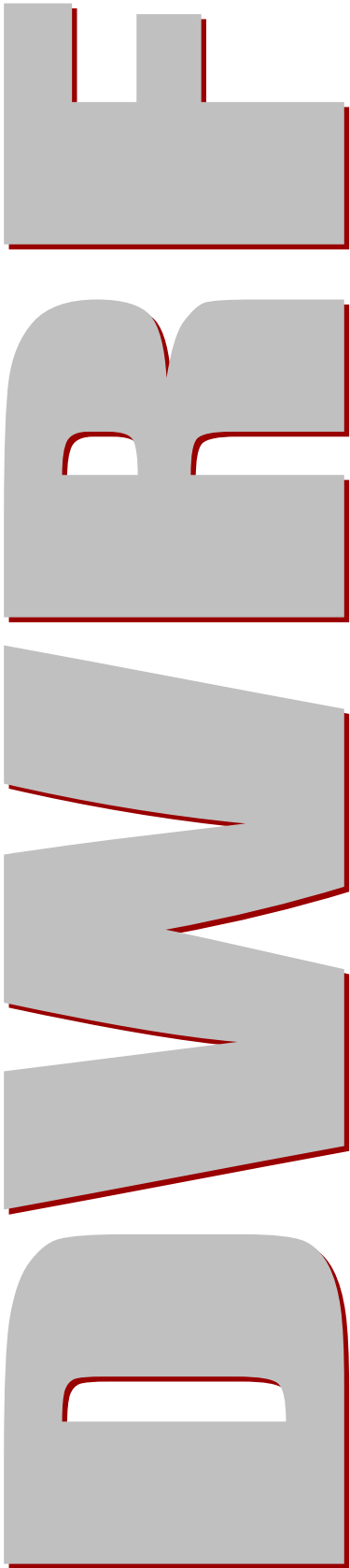


DRINKING WATER
RESEARCH FOUNDATION
ANALYSIS OF THE
FEBRUARY 1999
NATURAL RESOURCES
DEFENSE COUNCIL'S REPORT

JULY, 1999



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A TECHNICAL ANALYSIS OF THE NRDC REPORT ON BOTTLED WATER

EXECUTIVE SUMMARY

In February 1999, the Natural Resources Defense Council (NRDC) issued a report entitled “Bottled Water: Pure Drink or Pure Hype?” [hereafter “the NRDC Report”], which came to two basic conclusions:

- that bottled water is insufficiently regulated by federal and state government agencies and by the bottled water industry; and,
- that, based on an analytical product survey conducted by NRDC, bottled water “may not be as pure as we are led to believe” (NRDC Report, Executive Summary, p. vii).

The solution recommended in the NRDC Report is to overhaul the FDA’s regulatory regime for bottled water or to give the program to EPA, and to impose additional disclosure requirements on the bottled water industry.

The Regulatory Framework for Bottled Water Is Adequate to Ensure Safety

The NRDC Report contends that “federal bottled water regulation is weaker than the tap water regulations facing public water systems” because: (1) the FDA regulatory structure for setting allowable contaminant levels and associated monitoring and treatment requirements is not as stringent as EPA’s for tap water; (2) state programs are generally weaker than FDA’s; and, (3) neither FDA nor states have made bottled water regulation an enforcement priority. In addition, the NRDC Report devalues the contribution the International Bottled Water Association (IBWA) Model Bottled Water Code [hereafter, “Model Code”] makes in buttressing the federal/state system because not all bottlers belong to IBWA and the Model Code is not legally enforceable.

The fact is that bottled water is among the most highly regulated “foods” by the Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (“FFDCA,” 21 U.S.C. s. 301 et seq.). Under FDA jurisdiction, bottled water is subject to extensive general food safety and labeling requirements which are not applicable to tap water, including prohibitions on misbranding and adulteration. The labeling (misbranding) and adulteration provisions of the FFDCA apply to all foods and are the cornerstone of the very safe food supply enjoyed in the United States. When applied to bottled water, the labeling requirements ensure that the source and purity of the bottled water are identified and that, if the label is false or misleading in any respect, the supplier is subject to civil or criminal sanctions for product “misbranding.” The adulteration prohibition ensures that no matter what is on the label, if the bottled water contains any “deleterious substance that may be injurious to health,” the product is adulterated and the supplier is also subject to criminal or civil penalties. In addition, misbranded or adulterated products are subject to FDA requests for product recalls where appropriate. There is no similar remedial action available in the tap water regulatory program.

Further, bottled water is the only food category which FDA also subjects to two additional sets of requirements specific to bottled water -- one prescribing Good Manufacturing Practices, and the other imposing specific identity and quality requirements. FDA’s GMPs for bottled water apply to every aspect of production, from source protection, all the way through processing, to finished water sampling for purity prior to final bottling. Over and above FDA’s fully protective requirements, IBWA’s Model Code provides detailed specifications for plant construction and design, sanitary facilities, equipment, process controls and operations, and personnel qualifications.

FDA Contaminant Standards for Bottled Water Are Commensurate with EPA’s for Tap Water

The NRDC Report alleges that bottled water “is not specifically required to meet treatment, contamination, or testing standards as strict as those applicable to city tap water” (NRDC Report, p. 41). And, the NRDC Report makes much of the fact that FDA over the years has been slow to conform its bottled water food quality standards to EPA’s

tap water quality standards as required by law.

Section 410 of the FFDCFA requires that FDA review all new EPA regulations for tap water and determine whether they are applicable to bottled water. In 1996, that section was amended to add time frames to FDA's review. Now, if the tap water regulations are applicable, FDA must propose regulations for bottled water within 180 days after the effective date of EPA's tap water standards. In the absence of action by FDA, the tap water standard automatically applies to bottled water. Today, there are very small discrepancies between EPA and FDA's contaminant limit regulations.

Close scrutiny of the water quality standards for chemical contaminants reveals that FDA bottled water quality standards are the same as EPA's tap water standards for 62 out of 71 chemical substances highlighted in Table 6 of the NRDC Report. For lead, copper, and fluoride, FDA standards are stricter than EPA's. For three of the remaining contaminants -- asbestos, acrylamide, and epichlorohydrin -- FDA has determined, as the law allows it to do, that establishing specific standards for bottled water is unnecessary. Asbestos contamination is a feature of tap water resulting from transport through some asbestos-containing municipal distribution systems. Acrylamide and epichlorohydrin occur as a function of the chemicals used to treat public water systems. These same chemicals are not used in the treatment of bottled water. In all these cases, to the extent a bottler utilizes municipal water, it is reasonable to expect that the source meets EPA standards. The fourth chemical contaminant, phthalates, is under regulatory consideration at FDA and is already controlled by FDA as an indirect food additive.

With regards to microbiologic issues, a combination of the FDA and IBWA Model Code results in a system that is similarly comparable, and in many cases more stringent, than EPA's. The FDA, like EPA, requires monitoring and specific testing for total coliforms (21 CFR 165.110(b)(2)). The IBWA Model Code sets a zero tolerance for total coliform, as adopted by EPA. IBWA also calls for weekly monitoring of product and operations water for microbial contaminants similar to EPA's requirement.

A comparison of the monitoring frequency for total coliform required for tap water in contrast with bottled water shows that there is substantially more monitoring conducted on bottled water on a delivered water basis. For example, a typical bottled water purveyor producing 250,000 gallons of water per day conducts approximately 30 analyses for total coliform each day. A public water system producing a similar quantity of water is only required to analyze 2 samples for total coliform per month. The absence of any incidence of *E. coli* in NRDC's own survey results supports the proposition that the current system is adequately controlling microbiologic contamination in bottled water.

The NRDC Report's lengthy discussion of heterotrophic plate count (HPC) bacteria is both misleading and completely irrelevant to the safety of bottled water. HPC is found in all water and many food products, and has been studied extensively by EPA and FDA. FDA has concluded that in the absence of pathogenic bacteria, HPC bacteria are part of the normal flora of bottled water and do not pose a health risk.

Given these facts, the NRDC Report's conclusion that bottled water is "not necessarily any better regulated, purer, or safer than most tap water" is groundless. FDA has made a public policy decision not to promote the fact that bottled water is "safer" and has instead concluded that:

[I]n general, adopting EPA's standards for chemical contaminants as allowable levels in bottled water is appropriate because it will protect the public health, maintain consistent standards for identical contaminants in bottled and tap water, prevent duplication of efforts between FDA and EPA in evaluating the effects of contaminants in drinking water, prevent public confusion concerning the significance of different standards for bottled water and public drinking water and not foster public perception that bottled water is required to be of better quality than tap water.¹

NRDC Offers Scant Evidence for Bottled Water Contamination

In an attempt to document contamination, NRDC conducted an extensive survey of

bottled water gathered over several years. To dramatize the limited and unremarkable results its survey produced, NRDC devotes many pages in the report describing adverse health effects information associated with a variety of chemicals at levels well above those found (and in some cases not found) in its survey. Nonetheless, when the NRDC results are critically reviewed, rather than demonstrating serious or even worrisome contamination, the result that emerges is far better than the NRDC Report's concession that "most bottled water is of good quality" (p. 35).

NRDC surveyed more than 1,200 bottles of bottled water, looking for roughly 57 contaminants. Throughout all of their analysis, NRDC found not one instance of contamination that would raise a legitimate health concern. Indeed, the survey could find only four results where federal health standards were exceeded. Closer inspection reveals that the two results charged by the NRDC Report to exceed total coliform standards, were in fact quite likely false positives because they could not be replicated in subsequent tests as required by federal standards. The other two exceedances were for a fluoride standard so narrow, and with such limited application, as to be irrelevant to public health. In fact, the levels found in the bottled water are below the EPA health-based fluoride standard for public water systems.

The allegation that arsenic exceeds California's Proposition 65 (Safe Harbor Limits) resulted from a policy-based extrapolation of questionable relevance to bottled water. In addition to these, the NRDC Report discusses the presence at very low levels of other trace compounds, which have no regulatory or health import, but provide the opportunity for the NRDC Report to alarm the reader by discussing a myriad of adverse health outcomes which have been associated with these compounds only when tested in animals at high levels of exposure.

In a similar effort to enhance its case for concern about potential microbiologic contamination in bottled water, the NRDC Report elaborates on a number of pathogens, viruses and bacteria, without any linkage to actual cases of contamination or reported

¹ 59 Fed. Reg. 61529, 61531.

illness associated with bottled water. The NRDC Report is replete with anecdotal reports of contaminated water related illnesses, notably the *Cryptosporidium* episode that killed 100 people in Milwaukee in 1993 -- but this is from tap water. The only instance where a public health problem has been attributed to bottled water in the U.S. is an outbreak that occurred in 1994, in the unique setting of Saipan, a U.S. Territory of the Northern Mariana Islands. In this case, treated well-water was bottled because the tap water is generally too salty to drink. The actual source of the contamination was never confirmed (*Centers for Disease Control and Prevention Surveillance Summaries, Morbidity and Mortality Weekly Report*, vol. 45 no. 55-1, April 12, 1996).

Indeed, nothing in the NRDC Report can equate the bottled water track record to that for tap water. As reported by EPA in its “1996 National Annual Public Water System Compliance Report” (September, 1998, B-1), approximately ten percent of the public water systems in the U.S. were cited in 1996 for maximum contaminant level (MCL) violations for either total coliforms or chemicals. The number of MCL violations cited nationwide during that year exceeded 14,000.

The Bottled Water System under FDA Is Not Broken

The NRDC Report proposes to fix the “bottled water problem” either by altering FDA’s regulations for bottled water to look like EPA’s regulation of tap water, or by turning bottled water regulation over to EPA entirely. A more balanced review of the tap water and bottled water programs clearly supports maintaining the current system. In fact, many of the benefits that accrue because bottled water is a FDA-regulated food product would be lost through a transfer to EPA. Under the FDA regime, bottled water labels must inform the consumers and may not be false or misleading. Any bottled water found to be adulterated or otherwise to exceed federal safety standards and pose a risk to health, is subject to regulatory enforcement action which may include immediate removal from the market through either a court-order seizure or injunction or a voluntary recall carried out at the request of FDA or initiated by a company. EPA offers no such mechanisms.

The NRDC Report is plainly an effort to sensationalize a non-issue. The validity of the allegations against bottled water must be judged on the basis of its safety record, which is that bottled water must be considered one of the safest food products on the market today. The motivation for attacking an industry with an exemplary public health record remains a mystery. The only reasonable conclusion is that the NRDC Report is a solution in search of a problem and should be dismissed.

I. Introduction

In February 1999, the National Resources Defense Council (NRDC) issued a report entitled “Bottled Water: Pure Drink or Pure Hype?” [hereafter “the NRDC Report”], which compares the regulatory system that governs bottled water in the U.S. with the regulatory regime for tap water. The NRDC Report contends that: (1) the FDA regulatory structure for setting allowable contaminant levels and associated monitoring and treatment requirements are not as stringent as those EPA applies to tap water; (2) FDA does not adequately enforce the regulations it has; and, (3) states in general are not equipped or inclined to fill in the gaps. Based on this assessment, NRDC’s regulatory analysis concludes that “federal bottled water regulation is *weaker* than the tap water regulations facing city water supplies.”

To support its contention, NRDC conducted a bottled water quality and compliance survey and concluded that some bottled water “contains contamination...and should not automatically be assumed to be purer or safer than most tap water.” As a result, the NRDC Report advocates that FDA should either change its bottled water regulatory system to more closely parallel EPA’s for tap water; or, in the alternative, regulation of bottled water should be moved to EPA.

The following analysis is designed to address the concerns expressed in the NRDC Report. This assessment will show that:

- the regulatory system in place for bottled water protects public health;
- the FDA regulatory scheme supported by the International Bottled Water Association (IBWA) Bottled Water Model Code [hereafter IBWA “Model Code”] is not only remarkably similar to EPA’s in providing for contaminant control, but also incorporates additional safeguards that are unique to regulation of bottled water as a food; and,

- the incidents of contamination which the NRDC bottled water survey documents are few and well within the bounds of acceptability from a public health perspective.

A close comparison of the FDA and EPA regulatory requirements reveals that they are not as different as the NRDC Report maintains. Indeed in all but a few cases, which can be readily explained, FDA bottled water standards of quality and EPA maximum contaminant levels (MCLs) for tap water are identical. Moreover, the FDA regulatory program for bottled water is among the most stringent applied to foods. When this fully protective Federal regulatory regime is combined with the IBWA “Model Code,” the regulatory framework that emerges is even more comprehensive and overall subjects bottled water to equivalent, and in some cases more stringent, requirements than those applied to tap water. Moreover, the bottled water safety track record speaks for itself -- it is exemplary. Even the NRDC Report is forced to concede that “most bottled water apparently is of good quality.”

II. Bottled Water is Highly Regulated as a Food

A. The FDA/ FFDCCA Regulatory System Is Appropriate For Bottled Water

The system for regulating bottled water is fundamentally different than for tap water in that bottled water is regulated as a “food” by the Food and Drug Administration under the Federal Food, Drug and Cosmetic Act (FFDCA, 21 U.S.C. s 301 et seq.), while tap water is controlled by the Environmental Protection Agency (EPA) in accordance with the Safe Drinking Water Act (SDWA, 42 U.S.C. s 300f et seq.). All foods under FDA’s jurisdiction are subject to the labeling (misbranding) and purity (adulteration) requirements of the FFDCA; there are no such requirements for tap water in EPA’s system. Moreover, within the universe of foods regulated by FDA, bottled water is the only one subjected to two additional sets of regulations. The first prescribing Good

Manufacturing Practices (GMPs, 21 CFR 129) which aim to ensure the quality of the “source” water intended to be bottled, and the integrity of the manufacturing process; and the other, imposing specific quality and safety requirements as well as labeling provisions that are unique for finished bottled water products (21 CFR 165.110).

1. The FDA Mandates Labeling and Misbranding Provisions

The FFDCFA requires a food label to provide the name of the manufacturer, and the weight and ingredients of the contents. A food product is deemed “misbranded” if the label is “false or misleading” (FFDCA S. 403(a) *et seq.*). The food is “adulterated” if it contains a “poisonous or deleterious substance that may render it injurious to health,” contains any “filthy” or “putrid” substance, has been prepared, packaged, or held in unsanitary conditions, or if its container is composed of any substance that may render it injurious to health (FFDCA S. 402(a)(1) *et seq.*). The FDA’s specific regulations for bottled water amplify these requirements, calling for explicit labeling if the water does not meet stated microbiological, chemical, physical and radiological limits, even when the substance is present at a level not “considered injurious to health” (21 CFR 165.110(c)). The regulations further explicitly state that bottled water containing a deleterious substance, at levels considered injurious, would be deemed adulterated (21 CFR 165.110 (d)).

FDA regulations also specify that bottled water labels identify whenever the water came from a “community” or “municipal” source, unless the water has been treated, in which case the label must identify the treatment used, *e.g.*, distillation, deionization, reverse, osmosis, sterilization (21 CFR 165.110(a)(3)(ii), and (a)(2)(iv) and (vii)). Violations of any of these requirements by a bottled water supplier are subject to civil and criminal penalties.

2. New Federal Right-To-Know Labeling Mandates Are Inappropriate and Unnecessary

The NRDC Report advocates the need to “[e]stablish the public’s right-to-know for

bottled water as now required for tap water” (p. 11). This statement ignores the fact that bottled water producers are already required to provide information about product source, manufacturer, and contents, under the FDA’s labeling requirements. Moreover, bottled water consumers can obtain additional information about product composition, including detailed product analyses and product quality information, upon request of the manufacturer who is identified with necessary contact information on the product label.

The NRDC Report contends that “water bottlers were successful at killing a measure that would have required... right-to-know information from bottlers to be provided to consumers” (p. 69) and asks “why, if bottled water is as pure as bottlers say, they are so afraid of a right-to-know requirement” (p. 11). Obviously, given the FDA labeling requirements and their own voluntary disclosure program, bottled water manufacturers are already providing information in response to consumer requests. It is unnecessary for any food product, including bottled water, to provide the type of information that the NRDC Report recommends. Furthermore, in the absence of any semblance of a safety problem with bottled water or of discontent among bottled water consumers, there do not appear to be any benefits in mandating additional labeling and disclosure mandates.

3. Good Manufacturing Practices Ensure High Quality Bottled Water

FDA Good Manufacturing Practices (GMPs) for bottled water specify that all product water must be obtained from a source that has been approved. To achieve approval, the source water must be “inspected and the water sampled, analyzed and found to be of a safe and sanitary quality according to applicable laws and regulations of state and local government agencies having jurisdiction (29 CFR 129.3(a)).”

The NRDC Report describes these FDA source water protection requirements as “sketchy” and “essentially meaningless” because there are no guidelines directing the content of state and local rules and no indication of what should be done if there are no active state or local programs (p. 50). NRDC maintains that the program is deficient

because, for example, “[t]here are no specific requirements in FDA rules for protection of bottled water sources from pollution sources (such as setbacks from hazardous-waste dumps, industrial facilities, septic tanks, or underground gasoline storage tanks), nor are there any specific rules for disapproval of sources once they become contaminated.” Instead, NRDC prefers EPA’s approach, established by the 1996 amendments to the SDWA, which obligates states to conduct a source-water assessment which delineates the boundaries of the assessment area that supplies the water and to evaluate known or suspected sources of contamination.

The perception of a deficiency in the FDA source water protection and monitoring scheme is misguided particularly when viewed in conjunction with the relevant provisions of the IBWA Model Code. Rule 4 of the IBWA Model Code calls for a field inspection by a qualified professional hydrogeologist to demonstrate the integrity of the source; evaluation of the chemical, physical, microbiological and radiological characteristics of the source; a report on the geology of the site surrounding the sources; a report detailing development of the source such as catchment and intake structures, etc.; a watershed survey of the recharge area or zone of influence which identifies actual and potential sources of contamination which is updated every three years; and a plan for special monitoring and preventive action for any significant contaminant source identified.

To maintain source water quality, the FDA requires a minimum of yearly monitoring for chemical contaminants, weekly monitoring for microbiologic contaminants when the water source is not a public water system and monitoring every four years for radiological contaminants (21 CFR 129.35 (a) (3)). In a step beyond these federal requirements, the IBWA Model Code provides a “multi-barrier” approach to bottled water protection which promotes the use of sources protected from surface contamination. If the source water is not protected, then treatment is automatic. Rule 3(j) of the IBWA Model Code specifically requires that “bottled water that originates from a source which is not protected from surface contamination shall be subjected to “ozonation, filtration rate at one micron, or another effective process which removes or

destroys the cysts of the parasite *Giardia lamblia* and *Cryptosporidium*.” Rule 3(e) of the Model Code adds that total coliform analysis of all source water be performed at least once a week by an approved laboratory, and daily microbial sampling and analysis be performed in the plant.

B. Other Unique FDA Features Enhance the Regulation of Bottled Water

1. Recalls

The NRDC Report reviews EPA’s regulations requiring tap water providers to report violations of water quality standards, and is concerned that “FDA rules include no provision obligating a bottler to notify FDA or a state of test results, contamination problems, or violations, even in the case of contamination that could pose a serious health threat” (p. 52). This concern is misplaced because in fact the FDA general food regulations at 21 CFR 7.40 - 7.59 provide guidance for product recalls which accomplish precisely the goals the NRDC Report advocates. Further, should a company decline to recall a product that FDA determines is a serious health threat, it can ask the court to have such product removed from the market. This combination of activities provides a stronger system of regulatory controls to ensure that unsafe food products are not consumed.

FDA guidelines recommend that all food producers, including bottled water companies, have a written recall plan in the event products must be withdrawn from the market because they are adulterated or misbranded. A recall plan includes a list of people who will be involved in the recall and their specific responsibilities, and an outline of proposed strategies depending on the seriousness of the recall. The regulations identify three classes of recall, each with differing requirements for the depth of recall, the degree of public warning, and the need for verification of recall. The most serious is Class I in which there is a reasonable probability that the product may cause death or illness. A Class I recall would go to the consumer and require individual consumer notification through media and 100% effectiveness. A Class II recall would be used where the health

consequences expected are less serious and the supporting activities would be dictated by the situation. Class III is the least serious, and may only extend to the wholesale level.

Under the FDA product recall program, a recall can be initiated when a firm believes a product may be in violation of FDA standards. In such a case, the firm should notify FDA and provide information on: (1) the identity of the product; (2) the reason for the recall and when the problem was discovered; (3) evaluation of the risk involved; (4) time and amount of production; (5) total amount in and nature of distribution; (6) a copy of any recall communication already done or proposed; (7) proposed strategy for the recall; and, (8) the name and coordinates of a company contact (21 CFR 7.46). Upon review of this information the, FDA assigns a recall classification for the ensuing action.

Generally, the FDA relies upon voluntary action by bottlers to effect recalls. The policy guidance in the regulations observes that a recall is “generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed” (21 CFR 7.40 (c)). However, in the event a company refuses to undertake a recall when required by FDA, or the recall is determined to be ineffective, the FDA may intervene to direct the company to act. If a company is non-compliant, FDA may request that the Justice Department institute a civil seizure or injunction action on the company. Thereafter, the FDA may seek criminal penalties as well.

The NRDC Report references FDA’s decision not to establish specific recall procedures in the bottled water Good Manufacturing Practices (21 CFR 129). However, the FDA previously reviewed this matter in promulgating bottled water regulations, and could find no “circumstances that establish that there is a unique problem with recalls of bottled water.” FDA therefore has concluded that “the guidelines for recall procedures for foods are adequate” (60 Fed. Reg. 57076, 57118). Given the established safety record of bottled water, it would seem appropriate to rely on FDA’s expertise and experience with recalls.

2. Inspections

Pursuant to Section 704 of the FFDCA, FDA may inspect without notice any food manufacturing facility, including a bottled water plant. FDA can conduct spot checks on bottled water and make results public, similar to EPA's program to perform spot checks on public water systems.

As with any food establishment, states can also perform unannounced inspections. Some states also have annual inspection programs. Backstopping this system, IBWA currently contracts with third party, independent inspection services to conduct annual, unscheduled inspections for compliance with FDA's GMPs and IBWA's Model Code. Continued membership in IBWA is contingent upon successful completion of an IBWA inspection every year.

III. Standards of Quality for Bottled Water Are Comparable to Tap Water

Bottled water manufacturers must ensure that their products meet FDA standards of quality as specified by regulation in 21 CFR 165.110(b). These standards of quality establish allowable levels for substances including microorganisms such as coliform, physical parameters such as turbidity, color and odor, and radiological quality for such substances as radium 226. There are also limits specified for individual chemicals, including metals, inorganics, volatile organics, pesticides, trihalomethanes, and fluoride. FDA's standards of quality also set out testing time frames for the various categories of contaminants and specify the methodologies required for conducting the analysis, and the records bottlers must maintain.

Historically, the FFDCA required that, whenever EPA prescribed an interim or revised drinking water regulation, FDA was to consult with EPA, and within 180 days after promulgation of such drinking water regulations, either adopt a comparable regulation or publish a reason(s) for not doing so. In 1996, the FFDCA requirement was strengthened

such that if FDA fails to act within the time provided, the drinking water regulation will automatically become applicable to bottled water (FDCA § 410, 21 U.S.C. 349).

A point that is stressed repeatedly in the NRDC Report is that the FDA's chemical contaminant limits do not parallel EPA's drinking water standards in terms of stringency and specific chemicals addressed. The NRDC Report compares FDA and EPA's allowable limits for chemical, radiologic and microbiologic compounds in drinking water in an effort to establish that FDA's regulatory apparatus is weaker and must be radically altered or abandoned to the presumably more rigorous enforcement oversight of EPA. Unfortunately, the NRDC Report fails to acknowledge that FDA bottled water standards are identical to EPA's tap water standards in all but a few cases, and for these few, the difference is readily justifiable.

A. Chemical Contaminant Limits

A careful comparison of the FDA and EPA organic and inorganic contaminant limits reveals that there are only four instances where EPA has adopted a chemical standard for a public water system and there is no corresponding standard for bottled water. For 62 of the 71 contaminants identified in the NRDC Report Table 6, FDA's standards are equal to those established by EPA. For three additional chemical contaminants -- fluoride, lead, and copper -- the FDA standards are more stringent than EPA's. Of particular significance is the lower lead standard of 0.005 mg/l which FDA set "because bottlers do not use the public water distribution systems to deliver their finished products, and because source waters for bottling generally are free of significant lead contamination" (59 Fed. Reg. 61530).

For haloacetic acids, it is premature to compare FDA's standard to EPA's because the EPA standard for haloacetic acids is not yet enforceable and will not be until the year 2001 at the earliest. Thus, as discussed above, any FDA standard of quality for haloacetic acids must be finalized by then, or the EPA standard will automatically apply. Similarly for trihalomethanes (TTHMs), NRDC's charge that EPA standards are more

stringent than FDA's is misleading because, today, the enforceable EPA and FDA standards are the same at 100 ppm. The NRDC Report does recognize that on December 16, 1998, EPA reduced the tap water MCL for TTHMs to 80 ppb from 100 ppb; however, this standard is not effective until December 16, 2001 at the earliest, and for small systems not until December 16, 2003 (Fed. Reg. 69389). Therefore, FDA is not yet obligated to make a decision on revising its quality standard for TTHMs.

This leaves four standards with a discrepancy between EPA and FDA. A critical review of the circumstances surrounding these four contaminants shows that the lack of a FDA standard is either a function of FDA's deciding that the contaminant is not relevant to bottled water (as sanctioned by Section 349 (b)(1) of the FFDCA) or, in the case of phthalates, the Agency is in the process of establishing a relevant standard to apply to bottled water. Each of these is briefly discussed:

1. Acrylamide and Epichlorohydrin

EPA regulates acrylamide and epichlorohydrin in tap water because they occur as residual monomers in the polymers used as flocculating agents in the treatment of tap water. EPA did not in fact set MCLs for acrylamide and epichlorohydrin, but instead proposed treatment technique requirements because "standardized analytical methods with adequate limits of detection were not available for analyzing drinking water for these contaminants" (58 Fed. Reg. 382). EPA elected in its January 30, 1991 final rule (56 Fed. Reg. 3526) to establish requirements which limit the residual level of acrylamide and epichlorohydrin in these water treatment chemicals.

FDA affirmatively reviewed EPA's regulation and on December 1, 1994, decided, following public notice and comment, that no MCL for bottled water was needed for acrylamide and epichlorohydrin (59 Fed. Reg. 61529). FDA arrived at this decision because: (1) flocculents may not be used in the manufacture of bottled water unless a food additive regulation or other appropriate authorization exists in accordance with the Food Additive Amendments of 1958; and, (2) using EPA's reasoning, it is not feasible to

establish a MCL given that standardized analytical methods with adequate limits of detection were not available for analyzing drinking water for these contaminants.

2. Asbestos

FDA also decided that a standard for asbestos is not needed for bottled water given that “source waters for bottled water products generally would not contain any significant levels of asbestos” (59 Fed. Reg. 61533). This decision was based on a deliberative review of the available information on the occurrence of asbestos in different water supplies. FDA determined, following a review of EPA’s database, that it was “highly unlikely” that water used for bottling that originated from a source other than a public water system would contain asbestos. Additionally, because asbestos is prohibited from use in the processing, packing or transportation of bottled water, there is no other pathway for asbestos to contaminate the bottled water. Hence, FDA concluded that the available “evidence does not provide a basis for establishing a quality standard for asbestos in bottled water” (59 Fed. Reg. 61533).

3. Phthalates

EPA has established a 6 ppb standard for phthalates. FDA proposed but deferred promulgation of a standard for phthalates in order to harmonize the bottled water standard with other regulations governing phthalates as an indirect food additive (61 Fed. Reg. 13258). It is significant to note that while today there may be no FDA standard for phthalates in bottled water, FDA does regulate, as indirect food additives, the components used in producing articles including phthalate polymers (*e.g.*, 21 CFR 177.1630). IBWA has adopted the EPA standard in its Model Code and supports FDA’s promulgating a standard of the lowest level achievable by the industry and certainly no higher than EPA's current standard.

B. Microbiological Contaminant Limits

The NRDC (p. 42) is alarmed by differences in EPA and FDA's approach to regulating certain important microbiological contaminants, including *E. coli* and *Cryptosporidium*. In an attempt to dramatize the purported shortfalls in the FDA system, the NRDC Report discusses a lengthy list of the problems associated with a number of other bacteria, interestingly, also not regulated by EPA. A closer examination of the regulatory differences the NRDC report emphasizes, once again demonstrates some distinctions that make no material difference to regulatory effectiveness or public health protection.

1. Total Coliform/Fecal Coliform and *E. coli*

Both EPA and FDA have comparable standards for total coliforms. EPA has, on the other hand, established a standard prohibiting any confirmed samples of *E. coli* or fecal coliforms in tap water (40 CFR 141.63). While FDA has not yet promulgated such a prohibition, FDA has proposed the same standard for bottled water (58 Fed. Reg. 52042). IBWA operates with the same strict EPA zero tolerance standard. NRDC's failure to find *E. coli* or fecal coliform anywhere in its survey is testimony to the fact that microbiologic contamination is not a problem in the bottled water industry.

2. *Giardia* and *Cryptosporidium*

EPA requires public water systems using surface water to disinfect and filter to remove microbiologic contaminants such as *Giardia* unless they can document and get a waiver that their water quality is high and their source water is protected from contamination (40 CFR 141.72). Since 1996, under EPA's Information Collection Rule (61 Fed. Reg. 24354), big city systems that use surface water generally must also test for parasites such as *Giardia* and *Cryptosporidium*. As previously discussed, instead of imposing a monitoring requirement to determine whether treatment is needed, the IBWA Model Code automatically requires treatment by ozonation, filtration or equivalent techniques for *Giardia lamblia* and *Cryptosporidium* and any other pathogens whenever unprotected surface waters are used.

3. Heterotrophic Plate Count

The NRDC Report advocates that the FDA adopt EPA's treatment technique for Heterotrophic Plate Count (HPC) bacteria in the regulation of bottled water (54 Fed. Reg. 27527, 27544). The NRDC Report asserts that this is necessary for three reasons: (1) as a result of the 1996 Amendments to the SDWA, FDA is required to adopt standards no less stringent than those EPA adopts unless the contaminant does not occur in drinking water; (2) HPC bacteria have been linked to gastrointestinal illnesses; and, (3) high HPC levels can interfere with testing for coliform bacteria by masking their presence.

NRDC's discussion on HPC overstates the health implications in order to fabricate a problem. The concise response to the HPC issues raised by the NRDC Report is that HPC is not a health concern. HPC is universally recognized as a naturally occurring flora in drinking water as well as many foods. According to Dr. Stephen Edberg of the Yale University School of Medicine and Clinical Microbiology Laboratory, there has never been an association of any particular HPC concentration with health risk.² The only basis for a health risk cited in the NRDC Report is a study of gastrointestinal illness linked to reverse-osmosis-treated tap water (p. TR-19). Dr. Edberg has reviewed this and other studies by the same researcher and except for one isolated case, there is no association between HPC levels and gastroenteritis. Moreover, two EPA-sponsored studies found no association at all between HPC concentrations and gastroenteritis.

In advocating FDA's adoption of EPA's approach to HPC, the NRDC Report obscures the objective of EPA's requirement for HPC which is to measure the effectiveness of public water supply disinfection to ensure adequate control of microbiologic pathogens, and not HPC itself. EPA's regulations require that a "residual disinfectant concentration in the distribution system...cannot be undetectable in more than 5 percent of the samples each month for any two consecutive" (40 CFR 141.72(a)(4)(i)). HPC monitoring offers a means to determine whether adequate disinfectant is present. If the HPC bacteria

² "Assessing Health Risk in Drinking Water from Naturally Occurring Microbes," *Environmental Health*, January/February, 1996, p.19.

concentration in the water measures 500 colony-forming units/ml (cfu/ml) or less, adequate disinfectant residual is deemed present.

However, contrary to the NRDC Report, when HPC levels exceed 500 cfu/ml, the water sample is not considered to be contaminated; rather, where there is evidence that high levels of HPC may have interfered with coliform detection, the system must retest for coliform until it gets a valid result (54 Fed. Reg. 27544). The Preamble advises and the regulations provide for a test which is less vulnerable to HPC interference (54 Fed. Reg. 27544, 27556).

In its 1993 rulemaking, FDA reviewed the need to regulate HPC and explicitly addressed and decided against setting a HPC limit for bottled water:

FDA still believes that, when bottled waters are free of microorganisms that are of public health significance (i.e., indicated by the absence of coliforms) and are bottled under sanitary conditions in compliance with the CGMP regulations (Part 129), the presence of heterotrophic bacteria that are part of the natural flora in those bottled water normally will not pose a health risk because these organisms do not colonize the digestive tract of humans.³

4. Monitoring Frequency for Contaminants

FDA regulations specify the frequency that bottled water suppliers must monitor for contaminants: weekly for microbiologics; annually for chemicals; and, every four years for radiological contaminants (21 CFR 129). The IBWA Model Code, builds on the FDA regulatory structure and requires a minimum of daily analysis for total coliform and other microbials for testing “for each type of bottled water produced by the plant.”

Typically, a bottled water plant whose daily production volume is 250,000 gallons, conducts 30 total coliform tests per day.

³ On the same day it issued the final rule declining to regulate HPC, the FDA proposed GMP regulations requiring bottled water to be monitored for pathogenic organisms and that bottled water be processed, bottled and held and transported under sanitary conditions to ensure product safety (38 Fed. Reg. 32563); Final GMP rule, 40 Fed. Reg. 11566.

According to the NRDC Report, the monitoring frequency for bottled water is deficient because bottled water is monitored less frequently than tap water. For example, the Executive Summary of the report states that a “bottled water plant must test for coliform bacteria just once a week; big-city tap water must be tested 100 or more times a month” (NRDC report, Executive Summary, p. vi).

The comparison that NRDC constructs of the total coliform monitoring requirements between a bottler and “big-city tap water” does not adequately reflect the true difference in sampling frequency. In fact, as shown below, on a per gallon basis, bottled water is analyzed for microbiologic contamination hundreds of times more frequently than tap water.

EPA regulations at 40 CFR 141.21 specify the number of total coliform samples that a public water system is required to conduct on a monthly basis (see Table below which summarizes the EPA total coliform requirements based on system size).

Population Served from	to	Minimum Number of Tests
25	1000	1
1001	2500	2
2501	3300	3
3301	4100	4
4101	4900	5
4901	5800	6
5801	6700	7
6701	7600	8
7601	8500	9
8501	12900	10
12901	17200	15
17201	21500	20
21501	25000	25
25001	33000	30
33001	41000	40
41001	50000	50
50001	59000	60

Population Served from	to	Minimum Number of Tests
59001	70000	70
70001	83000	80
83001	96000	90
96001	130000	100
130001	220000	120
220001	320000	150
320001	450000	180
450001	600000	210
600001	780000	240
780001	970000	270
970001	1230000	300
1230001	1520000	330
1520001	1850000	360
1850001	2270000	390
2270001	3020000	420
3020001	3960000	450
3960001	>	480

As can be readily seen, the number of required coliform samples is directly proportional to the population served by the water system. For example, large systems serving a

population greater than 3,960,001 are required to conduct 480 samples per month while small systems serving between 3,301 and 4,100 are required to take 4 samples per month.

An evaluation of these requirements on a facility basis shows that a bottled water plant samples more frequently than most public water systems. For example, in the State of Maryland, the majority of public water systems (3226 out of 3238) serve fewer than 33,000 persons. Depending upon the actual population served, these systems would be required to analyze between 1 and 30 samples per month in contrast with a typical 250,000 gallon bottled water plant which conducts 30 samples per day.

But the true difference in sampling frequency can only be fully appreciated when one compares the number of monitoring samples on a delivered water basis. This is necessary given that public water systems distribute significantly more water per day than a bottle water plant since tap water is used for such things as clothes and dish washing, bathing, on lawns, and many other uses.

Based on the table above, a public water system serving 100,000 people is required to conduct 100 coliform tests per month. Such a system is typically serving in excess of 16 million gallons of water per day.⁴ Therefore, only one analysis for total coliform is conducted for every four million gallons of tap water produced. Since, as already noted a typical 250,000 bottle water plant conducts 30 total coliform samples per month, on a delivered water basis the bottled water plant is analyzing over 500 times more frequently than the public water system.

To further demonstrate the disparity in sampling frequency, the above assumptions were applied to the different size systems within the State of Maryland to calculate a population weighted average sampling frequency using the data provided in EPA's Envirofacts database. The following Table summarizes the number of different size systems, an estimate of the population served by each system size and the required

⁴ For purposes of this calculation, it is assumed that a typical public water system produces 160 gallons of water per capita per day which is a conservative estimate based on EPA's recently released Community Water System Survey

number of total coliform samples required per month. This is then extended to estimate the number of gallons delivered for every sample of total coliform required on a population weighted basis.

Scale of Tap Water Plant	Number of Plants	Population Served	Population Served (median)	Population Served (estimated total)	Percentage of Estimated Total Population	Coliform Samples Required per Month
Very Small	2959	25-500	263	778,217	12.5%	1
Small	221	501-3,300	1901	420,121	6.7%	2
Medium	30	3,301-10,000	6651	199,530	3.2%	7
Large	24	10,001-100,000	55001	1,320,024	21.1%	60
Very Large	4	>100,000	881,150*	3,524,600*	56.5%	270
Total	3238			6,242,492	100.0%	

* For very large plants, the average value and actual population total is used.

Scale of Tap Water Plant	Production Volume (gallons/day)	Coliform Samples Required (number/month)	Gallons/Sample	Percentage of Total Population in Service	Weighted Average*
Very Small	42,080	1	1,262,400	12.5%	157,376
Small	304,160	2	4,562,400	6.7%	307,050
Medium	1,064,160	7	4,560,686	3.2%	145,774
Large	8,800,160	60	4,400,080	21.1%	930,432
Very Large	140,984,000	270	15,664,889	56.5%	8,844,620
Total				100.0%	10,385,252

* Weighted average is the Gallons/Sample time the percentage of total population in service

Based on these assumptions, only one analysis for total coliform is required to be conducted by public water systems in the state of Maryland for every 10 million gallons of water.

The dramatic discrepancy in microbiologic sampling frequency between bottled water and tap water is not intended to raise concern about the microbiologic safety of tap water; but merely to show the comprehensive nature of the contaminant analyses conducted for bottled water and to correct the mistaken premise that bottled water is analyzed much less frequently than tap water. It should be noted that this type of comparison could be conducted for essentially any contaminant and would reveal a similar conclusion, *i.e.*, that on a delivered water basis, bottled water is being sampled much more frequently than

(CWSS) (see www.epa.gov/OGWDW/cwssvr.html.)

water provided by a public water system.

C. Testing after Storage

The NRDC Report expresses concern that FDA has no requirement for testing water after it has been bottled and stored. The concern arises that HPC bacteria, *Pseudomonas aeruginosa* and other microbes that may be present at very low or non-detectable levels immediately after bottling can then bloom and grow in the stored product. Particular concerns are raised for the immune suppressed population and for vulnerable older and younger persons. In addition to advocating limits for HPC, the NRDC Report recommends that for *Pseudomonas aeruginosa*, which is banned by the European Union for bottled water and is recommended for control by the World Health Organization Codex Alimentarius and Health Canada, FDA adopt microbiologic standards for bottled water at least as strict as the EU and mandate labels that relate the date and source of bottling, how the water was treated, and whether it meets EPA-CDC guidelines.

The FDA considered post bottling contamination in its mid-1990's bottled water rulemaking. The Preamble to the Final Rule (60 Fed. Reg. 57108) offers FDA's rationale that if the water is bottled properly by conforming to FDA's microbiological standards for weekly testing, there are no grounds for further concern about microbiologic contamination in stored water. FDA acknowledges that "some bacteria can grow in bottled water, and that bottled water, unless treated in some manner, is not sterile." However, the FDA finds that while innocuous bacteria may be present in the bottled product and may enter it upon exposure to open air, bottled water is "not a good source of nutrients for most microorganisms." NRDC's own testing using standard indicators found no pathogenic bacteria in the bottled water analyzed.

D. Radioactive Substances

EPA, FDA, and IBWA's Model Code contain essentially identical standards and requirements for radionuclides. Specifically, the MCL for radium-226 and radium-228

(combined) is 5 pico curies/liter (pCi/l) and for gross alpha particle activity (including radium-226 but excluding radon and uranium) is 15 pCi/l. For beta and photon emitters, the MCL is based on a concentration limit that results in no more than an average annual total exposure to 4 millirems/year.

E. Unregulated Contaminants

NRDC asserts that chemical-contaminant-testing requirements for bottled water are weaker than EPA standards for tap water because municipal water, but not bottled water, must be tested for sixteen unregulated contaminants. EPA requires suppliers of tap water to analyze these contaminants once/quarter and report results on sixteen unregulated organic chemicals. These sixteen substances have no EPA health-based water standards and they are not subject to any enforceable MCLs or treatment requirements. Moreover, FDA has recently reminded the bottled water industry that, “any bottled water containing any substance...at a level that may be injurious to health under section 402 of the Act is adulterated and subject to regulatory action (59 Fed. Reg. 13258, 13262). Also, under the IBWA Model Code, bottled water manufacturers annually monitor for these 16 unregulated contaminants plus an additional twenty⁵ that are not required of municipal tap water suppliers. Thus, the industry has chosen a much stricter set of requirements for monitoring unregulated contaminants in bottled water than the EPA has for tap water suppliers (Appendix A p. 23 Model Code).

F. Reporting and Record Retention

The NRDC Report points out that tap water suppliers must report test results and violations to EPA or to state authorities approved by EPA. Serious violations must be reported within 48 hours to the state which then reports to EPA.

The FDA does not explicitly require reporting; however, as previously discussed, the FDA labeling, enforcement and recall system for foods ensures that appropriate

⁵ The additional 20 contained in the IBWA Model Regulation are those substances which monitoring may be required at the discretion of the State as described in 40 CFR Subpart E § 141.40(j).

information is conveyed to the consumer or the label and that products that pose a serious health risk are promptly removed from the market.

With regard to record-keeping, EPA regulations require public water systems to retain bacterial testing results for 5 years and chemical test results for 10 years. On the other hand, FDA requires that records be retained for two years which NRDC contends is inadequate.

The FDA has affirmatively determined that to support its food compliance responsibilities, retaining records for two years is adequate; although, some states impose further record retention requirements. Nonetheless, IBWA's Model Code Rule 4(e) stipulates that all records of sampling and analysis "shall be maintained on file at the plant for not less than five years and shall be available for official review upon request of the [state or department]."

IV. NRDC's Product Contamination Survey Shows Bottled Water Is Remarkably Safe

In a further effort to document alleged weaknesses in the bottled water system of quality, in late 1997 and early 1998, NRDC undertook a product survey and analysis in which more than 1,200 bottles of 103 different brands were tested for contamination. While NRDC attempts to portray its survey results as documenting contamination, in fact the results show that none of the bottled waters tested contained contaminants in concentrations that would be considered unsafe. The NRDC Report concedes that "[m]ost waters contained no detectable bacteria, and the levels of synthetic organic chemicals and inorganic chemicals of concern for which were tested were either below detection limits or well below all applicable standards" (p. 26).

Throughout all of the samples tested by NRDC, federal FDA or EPA limits were allegedly exceeded only four times, twice for total coliforms and twice for fluorides. Upon closer inspection, the NRDC Report admits that the coliform results were not

reproducible. Additionally, the fluoride values must be judged as insignificant from a public health perspective because they apply to a very narrow circumstance of weather and geography. Moreover, the results found would have been considered in compliance with the higher fluoride drinking water standard established by EPA. The more serious presence of *E. coli* or fecal coliform was not reported in a single sample. To create the impression of a greater number and more serious incidents of contamination, the NRDC Report compares its survey results to state, European Union (EU), and other unenforceable guidelines.

NRDC uses various techniques to inflate the percentage of bottled water that they claim to be contaminated. As already noted, NRDC focused its analytical program on 103 brands of water; the actual analysis was performed on many different bottles from the same brand. All of the reported statistics are presented by brands and not by bottles such that, if 10 samples from the same brand were tested and only one out of 10 bottles was found to be “contaminated,” NRDC’s statistics would have reported that the entire brand or 100% was considered contaminated.

Several specific contaminants highlighted in the NRDC Report are discussed in greater detail below to put these contaminants into their proper public health context. These include coliform, fluorides, nitrate, and arsenic.

A. Coliforms

The NRDC reported that two of the 103 brands of bottled water tested for coliform bacteria violated the federal bottled water standards, leading to a 2% coliform violation rate. However, upon closer examination of the data, it becomes apparent that these results were never confirmed nor repeated in later tests conducted by state-certified labs. NRDC’s analysis reported that two brands exceeded the FDA limit of less than 1 coliform/100ml. In both cases, however, coliform was detected only in initial tests, when a single bottle of each brand was tested using EPA’s membrane-filtration method.

A second set of tests, performed on aliquots of 10 new bottles of the same two brands and using the same test method, did not detect the presence of any coliform bacteria. These tests were conducted by a California-certified independent commercial lab. A third set of tests, conducted by yet another state-certified independent commercial lab, also showed no evidence of the presence of coliform bacteria in an additional 10 bottles of each brand.

Finally, over twenty samples were retested using the Colilert method, in order to analyze the samples solely for coliform bacteria, without interference from the presence of HPC bacteria. The NRDC determined that this retesting was necessary after initial tests for total coliform bacteria, using the EPA multiple-tube fermentation with Most Probable Number, were rendered invalid. Again, no coliform bacteria were detected in this fourth set of tests.

Therefore, while the NRDC insists on reporting that two of the 103 brands of bottled water tested positive for coliform bacteria, this was true only of the first preliminary screening, and was not supported by at least three rounds of tests that followed, all conducted by state-certified, independent commercial labs.

B. Fluoride

Fluoride, the ionic form of fluorine, is a natural component of the biosphere and the 13th most abundant element in the earth's crust. It is found in a wide range of concentrations in virtually all inanimate and living things. In non-industrial settings, fluoride enters the body principally by ingestion. Intake is lowest in rural areas in which there are no fluoride-rich waters or soils, and no exposure to industrial, agricultural, dental, or medical sources. The largest source of human exposure to fluoride is from drinking fluoridated municipal tap water. Consumption of high-fluoride foods such as tea and some fishes may also contribute to daily exposure.

As the NRDC Report notes, the issue of fluoridation of water has not been without controversy or allegations of adverse health effects ranging from heart problems to

cancer. Several expert groups, including the World Health Organization (WHO)⁶ have reviewed and assessed the health information on fluoride. A WHO expert working group concluded that the optimal levels for fluoride in drinking water to help prevent dental decay was 0.7-1.2 mg/l (depending on climatic conditions). The U.S. Surgeon General noted that fluoride at a concentration of approximately 1 mg/l in drinking water has been shown to reduce the prevalence of dental caries by more than 50 percent.⁷ The Dutch Expert Committee for Occupational Standards (DECOS) also reviewed the health effects of fluoride and concluded that there is no evidence of an increased risk of cancer due to fluoridation of community water supplies.⁸ In 1982, International Agency for Research on Cancer (IARC) reached a similar conclusion.⁹

Given the ubiquitous nature of fluoride in the environment, it is not surprising that fluoride is naturally present in some of the bottled waters tested by NRDC. Of all the non-fluoridated bottled waters tested by NRDC, only one was reported to exceed FDA's warm weather standards by an average of 0.15 ppm (well within the limits of analytical variation). For the fluoridated bottled waters, fluoride was present in two composite samples at a level of 0.13 – 0.5 ppm above the FDA warm weather standard and was not detected in a third sample of the same water. For non-warm weather areas, not a single bottled water was in excess of FDA standards. This is in stark contrast to 11 municipal water systems providing drinking water to over 75,000 persons which were in violation of the EPA's fluoride standard, as documented by NRDC.¹⁰ It is significant to note that the EPA fluoride standard for municipal drinking water is 4 ppm and has no provision whatsoever for a reduction in warm weather areas and that all of the bottled water analyzed contained fluoride levels less than the EPA MCL.

⁶ World Health Organization (WHO) Working Group. Environmental Health Criteria. 36, 1984.

⁷ The Surgeon General's Report on Nutrition and Health. (1988). DHHS, Public Health Service Publication N0. 88-50210, U.S. Government Printing Office, Washington, DC.

⁸ DECOS, Health based recommended occupational exposure limits for fluorine, hydrogen fluoride and inorganic fluorine compounds. Directorate General of Labour, the Netherlands, RA 1/89, 1989.

⁹ International Agency for Research on Cancer (IARC). 1982. IARC Monograph 27, pp. 237-303.

¹⁰ NRDC, "Just Add Water: Violations of Federal Health Standards in Tap Water 1994-1995." NRDC, Washington, DC.

In spite of this, the NRDC Report unnecessarily and without cause raises a health concern for young children, if they “consume significant amounts of highly fluoride-rich bottled water.”

C. Nitrate

Nitrate is a naturally occurring form of nitrogen found in soil, foods, and water. Nitrate is also naturally produced in the human body. In moderate amounts, nitrate is a harmless constituent of food and water.

Nitrate can be converted to nitrite by bacteria in the stomach and intestines. Nitrite is absorbed in the blood and oxygen-carrying hemoglobin is converted to methemoglobin, which can no longer carry oxygen. Infants, between the ages of two weeks and six months, are more susceptible to nitrate because they typically have more bacteria in their gastrointestinal system than adults and they cannot change methemoglobin back to hemoglobin. In excessive quantities, nitrate in infants can cause serious illness (blue-baby syndrome – methemoglobinemia) and in severe cases, if untreated, death. Studies have demonstrated that “blue-baby syndrome” is very rare at nitrate concentrations in water below 50 mg/l.

Most nitrate and nitrite human exposure is from the diet. The highest nitrate concentrations are found in celery, spinach, lettuce, beets, radishes, melon, turnip greens and rhubarb. For most of the population, 97% of daily nitrate intake comes from food and only 3% from drinking water. Furthermore, natural production of nitrate within the human body accounts for almost half of total daily exposure.

The NRDC Report states that to be safe “babies probably should not be fed with *mineral*¹¹ water containing elevated nitrate levels” and “according to some, nitrate may

¹¹ This is NRDC’s first (apparently purposeful) use of the term “mineral water” as it relates to an alleged adverse health effect. The use of this term by NRDC is in relation to bottled water labeled as “mineral water” (see page TR-37 of the NRDC Report). Not a single “mineral water” tested by NRDC had nitrate levels higher than 5.6 ppm and the highest nitrate level measured in bottled water (not labeled as mineral water) was 2.8 ppm. These values are well below FDA, EPA and IBWA Model Code.

be linked to cancer in adults...thyroid problems, hypertension, and certain birth defects.” IBWA and its members agree that infants should not consume any water (bottled or tap) containing elevated nitrate (>10 ppm) levels.

What is disturbing about the NRDC Report’s recommendation is that it is contained within a discussion of elevated nitrate levels in bottled water. NRDC provides no definition of what they consider to be “elevated.” By NRDC’s own account, not a single bottled water (or a *single* mineral water) tested contained nitrate levels anywhere near current standards; no sample had a nitrate level higher than about 5 ppm and the state surveys cited in the NRDC Report found a single instance where a bottled water was 1.1 ppm in excess of the current standard. This should be compared with an earlier NRDC study which found that between 1994 and 1995 over 471,000 people drank water from 588 municipal water suppliers that violated the EPA nitrate standard.¹² EPA, FDA, and the scientific community would not construe any of the values obtained by NRDC on bottled water as “elevated.”

Furthermore, the NRDC Report’s assertion that <10 ppm “leaves no margin of safety for infants and probably actually allows some susceptible infants to become ill at this level” is inflammatory and without merit. In establishing the MCL for nitrate, EPA (1990) concluded that there is no convincing evidence that nitrate (or nitrite) is associated with any adverse health effect other than methemoglobinemia.

Nevertheless, the NRDC Report unjustifiably raises public fears concerning potential adverse health effects in children (brain damage, death) and adults (cancer, birth defects) from consuming bottled water containing “elevated” levels of nitrate.

D. Arsenic

Arsenic is the 20th most abundant element in the earth’s crust. As such, it occurs naturally in soil, foods, water, and the human body. According to the EPA, the average

¹² NRDC Report “Just Add Water: Violations of Federal Health Standards in Tap Water 1994-1995.”

U.S. arsenic levels are 5,000 ppb in soil, 20 to 140 ppb in food, 2 ppb in water, and 0.02 to 0.10 ug/m³ in air. As a result of all these “natural” exposures, the average American is exposed to approximately 50 ug/day of arsenic. Once absorbed into the body, most arsenic is metabolized and excreted quite quickly, with a half-life of 2-4 days. Because arsenic can be metabolized within the body into less toxic forms, many scientists believe that there exists an exposure level below which no adverse health effects would occur. There is also evidence that at least in animals, arsenic may be an essential trace element. Based on the evidence in animals, the potential human nutritional requirements have been calculated to be 12 - 25 ug/day.¹³

Since 1980, the health risks associated with arsenic in drinking water have undergone extensive review, not only by the EPA, but by panels of experts around the world. In each of these reviews, it was found that knowledge of arsenic’s adverse health effects largely comes from studies of foreign populations exposed to very high levels of arsenic - - substantially higher than those found in the U.S. This fact, combined with the nutritional and environmental differences between foreign populations and the U.S. populace, makes it difficult to extrapolate the results of these overseas studies to the U.S. Consequently, a significant amount of uncertainty exists regarding arsenic’s potential health risks at the low exposure levels commonly found in the U.S.

As a basis for its arsenic position, the NRDC Report presents a rather biased summary of the health concerns regarding arsenic in drinking water. While the summary initially notes that the information on health effects was “based on ...studies of people ...who ...drank water containing levels of arsenic in excess of EPA’s current standard of 50 ppb,” this qualifier is often lost in subsequent discussions. The tone of the NRDC Report is that these adverse effects will most assuredly occur at the current MCL.

The National Academy of Sciences’ National Research Council (NRC) recently

¹³ Uthus, E.O. Estimation of Safe and Adequate Daily Intake for Arsenic, Risk Assessment of Essential Elements, Intl. Life Science Inst. Press, Washington, DC (1994).

completed a review of arsenic's potential health risks in the United States.¹⁴ As part of its review, the NRC committee evaluated the existing database on arsenic's health effects and then detailed the uncertainties that still exist regarding each of the specific health effects. For some of the health issues raised in the NRDC Report, the NAS report had the following to say:

Cancer

With minor exception, the epidemiological evidence for cancer comes from places where exposed populations were exposed to arsenic concentrations in drinking water of at least several hundred micrograms per liter. Few data address the degree of cancer risk at lower concentrations of ingested arsenic.

In studies that have observed a positive relationship between arsenic ingestion and cancer, the doses of ingested arsenic were of a sufficient magnitude to cause cutaneous signs of arsenicism. At the present time, epidemiological data are insufficient to demonstrate an observed risk of cancer in populations exposed to ingested arsenic at doses too low to result in overt nonmalignant cutaneous effects.

Birth defects; spontaneous abortions and other reproductive problems

Developmental and reproductive effects resulting from chronic ingestion of inorganic arsenic have not been demonstrated in humans...there is little evidence to suggest teratogenicity by oral or inhalation routes. Although some studies show an association between arsenic exposure and adverse pregnancy outcomes, they are inadequate to draw firm conclusions. No effects on fertility were observed in a multigeneration study in mice...

Vascular disease; diabetes mellitus; hypertension and ischemic heart disease

The study subjects were drawn from populations with overt cutaneous signs of arsenic intoxication; information is lacking on the magnitude of the potential risk associated with exposure to low concentrations of arsenic.

¹⁴ National Research Council Arsenic in Drinking Water, National Academy Press, Washington, DC (1999).

Skin Lesions

With regard to the NRC's observation that when human cancers are associated with arsenic, skin lesions are also seen, the report states that:

It should be noted that the limited U.S. epidemiology studies that have been done on arsenic in drinking water have never found increased incidences of the characteristic arsenic related skin lesions.

Despite the uncertainties in the arsenic health effects database, the NRC recommended that EPA seriously consider lowering the arsenic standard for drinking water. EPA is currently planning to propose a revised arsenic standard in 2000 and issue a final standard in 2001. If EPA lowers the tap water standard, FDA will likely also lower the bottled water standard. The IBWA is similarly evaluating the NRC report.

V. Conclusion

The NRDC Report is an extensive initiative to find fault with the bottled water sold in the United States. A dispassionate review of the report reveals that NRDC failed to accomplish this objective. Instead, the FDA regulatory system that governs bottled water is functioning and provides full public health protection. When combined with the "Model Code" of the International Bottled Water Association there is an even more robust system to ensure that the consumer receives a safe and healthy product. This view is confirmed by laboratory contaminant analysis including the extensive analytical program conducted by NRDC.