

Natural Resources Defense Council, Petitioner))))))
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**CITIZEN PETITION TO THE FDA COMMISSIONER
UNDER THE
FEDERAL FOOD, DRUG AND COSMETIC ACT
AND ADMINISTRATIVE PROCEDURE ACT
REQUESTING AMENDMENTS TO FDA RULES,
AND CERTAIN POLICY STATEMENTS**

REGARDING BOTTLED WATER

The Natural Resources Defense Council (NRDC) hereby petitions the Commissioner of the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. §§ 321 et seq., and the Administrative Procedure Act (APA), 5 U.S.C. § 553(e), to amend the FDA's rules respecting bottled water. These rules currently are codified at 21 C.F.R. Parts 129 and 165. NRDC further petitions FDA to issue certain policy statements and/or interpretative rules respecting bottled water. Many of these rule changes are mandated by the new provision of the FFDCA requiring that FDA's bottled water rules be "no less stringent" than EPA tap water Maximum Contaminant Levels (MCLs), and "no less protective of the public health" than EPA treatment techniques. FFDCA § 410, as amended by the Safe Drinking Water Act Amendments of 1996, Pub. L. No. 104-182, 110 Stat. 1641 (August 6, 1996). The detailed grounds for this petition are established in the attached report, technical report, and appendices.

Actions Requested.

NRDC hereby petitions the Commissioner to use her authorities under *inter alia*, FFDCA §§ 201, 401, 402, 403, 403A, 408, 409, 410, 701, 707, 708, and 709, 21 U.S.C. §§ 321, 341, 342, 343, 343-1, 348, 349, 371, 378, 379, 379e, and 42 U.S.C. § 264 *et seq.*, to amend FDA's rules respecting bottled water. Specifically, NRDC requests that FDA amend 21 C.F.R. Part 165, which establishes standards for the quality of bottled water, and 21 C.F.R. Part 129, which establishes standards for the processing and bottling of bottled drinking water, and that the Commissioner issue certain General Statements of Policy as requested below.

1. Public Right to Know About Bottled Water as Now Required for Tap Water.

We petition the FDA to use its authorities cited above under the FFDCa to require that bottled water labels list:

- a. Any contaminants of potential concern^[1] found in the water, and any health goal (Maximum Contaminant Level Goal) or the lowest health advisory for such contaminants (and -- if desired by the bottler -- the standards for those contaminants);
- b. The water's fluoride and sodium content, if any, and applicable EPA health goals or advisories;
- c. A brief statement of the potential health effects of any contaminants found at levels above health advisories or goals;
- d. A brief statement regarding any violations, designated significant by the citing authority, by the bottler of any applicable state or federal bottled water standards or rules over the past year;
- e. The precise source(s) of the water, including a statement as to whether such source is a public water system. If the water is labeled as "spring water," a statement as to whether the water was derived directly from a spring at the surface, or came from a well. This information should be presented in type of equal size to the "spring water" claim. If water is labeled as "glacier" water, or otherwise makes reference to glacial origins, the rules should require that it must be derived directly from melt water from a currently active glacier. Any statement, vignette, photograph, drawing, or other graphic on the label that may suggest to a consumer that the water comes from a particular source or type of source (such as a statement that the water is "mountain water," or a graphic showing mountains), should be required to accurately represent the actual source of the water;
- f. Any treatment used;
- g. Whether the water meets the CDC/EPA criteria for *Cryptosporidium* safety;
- h. The date of bottling;
- i. Reference to the FDA website and addresses or phone numbers for further information;
- j. A recommendation to "refrigerate after opening."

FDA was required by the 1996 Amendments to the Safe Drinking Water Act, § 114(b), Pub. L. No. 104-182, 110 Stat. 1641 (August 6, 1996), to complete a study evaluating the feasibility of such right-to-know labeling for bottled water (a draft study was due 2/6/98, a final was due 2/6/99), though to date FDA has failed to issue a draft of the study. FDA should move forward with rules requiring such disclosure for bottled water. The record before FDA in response to FDA's November 12, 1997 Federal Register notice requesting comment on the issue, 62 Fed. Reg. 60721 (FDA Docket # 97N-0436), documents that such label requirements are imminently feasible and are sufficient to support completion of the study and to propose right-to-know rules.

2. Update Bottled Water Quality Standards for Contaminants Potentially Found in Bottled Water.

We petition FDA to update its regulations for certain contaminants regulated under a National Primary Drinking Water Regulation, and for the additional contaminants noted below that are of particular potential concern in bottled water. In light of the legal obligations of FDA, and consumer demand for the purest bottled water possible, these standards should be at least as protective of public health as the strictest standards adopted by other authorities, as noted below. Thus, the standards should be no less protective than the most stringent of the following:

- a. **Total Trihalomethanes.** FDA should amend its rules to issue a standard of 10 ppb for total trihalomethanes (THMs) -- the standard recommended in the International Bottled Water Association and enforceable in California and certain other states for bottled water.
- b. **Other Disinfectants and Disinfection Byproducts.** For other disinfectants and non-THM disinfection byproducts, FDA should adopt standards as stringent as possible for bottled water. Certainly such standards can be no less stringent -- and almost certainly should be more stringent -- than the EPA tap water standards for chloramine (4.0 ppm), chlorine dioxide (0.8 ppm), chlorite (use the 0.8 ppm MRDLG), and bromate (10 ppb), adopted by EPA for public water systems on December 16, 1998. 63 Fed. Reg. 69,390-476. This is mandated by FFDCA § 410. We petition, in addition, that FDA adopt the proposed Stage 2 standard for the total of the five regulated haloacetic acids (HAA 5) of 30 ppb, *see*, 59 Fed. Reg. 38668 (July 29, 1994), rather than the minimum Stage 1 HAA 5 standard of 60 ppb, which is the least stringent standard FDA could adopt under section 410 of the FFDCA. Moreover, we request that FDA adopt a standard for chlorine of 100 ppb, as recommended in the International Bottled Water Association (IBWA) Model Code (which is more stringent than the EPA standard of 4 ppm, the weakest standard FDA could adopt under FFDCA § 410).
- c. **Arsenic.** FDA should amend 21 C.F.R. § 165.110 to establish the most stringent standard for arsenic that is possible for water bottlers to achieve, using best available source waters or best available treatment technology. This should be below five (5) parts per billion (ppb), the California Proposition 65 warning or "safe harbor" level, assuming consumption of two liters per day (see attached list of such levels). We recommend that the standard be set at a level of 2 ppb, which is detectable by current, widely-available EPA-approved atomic absorption (AA) analysis methods, and is readily achievable through use of clean source water, or treatment with appropriate technology such as tight membranes or activated alumina. According to EPA's official Integrated Risk Information System (IRIS) database (see www.epa.gov/iris), 2 ppb inorganic arsenic in drinking water presents a 1×10^{-4} (1 in 10,000) lifetime cancer risk. Moreover, as reviewed in the attached Technical Report, other scientists estimate the cancer risk from this level would be far higher. This cancer risk is at the very high end of what EPA would consider acceptable in drinking water.
- d. **Heterotrophic Plate Count (HPC) Bacteria.** FDA should amend 21 C.F.R. § 165.110(b) to establish the most stringent standard for HPC bacteria that is possible for water bottlers to achieve, using best available source water, treatment technology,

and sanitary processing and bottling methods. In setting the standard, FDA should draw upon several extant HPC standards and guidelines. Certainly, the HPC standard should not allow any bottle to contain more than 500 colony forming units per milliliter (cfu/ml). This is the level at which EPA's regulations at 40 CFR § 141.72 essentially equates the HPC level to a total coliform bacteria positive sample (in the absence of a residual disinfectant), and as discussed in the attached technical report, is the level adopted by certain states as bottled water guidelines. It also should be at least as stringent as the European Union's (EU) standard for bottled water (colony count of 100/ml at 22 degrees C, and 20/ml at 37 degrees C, at point of bottling).^[2] Moreover, the International Bottled Water Association recommends that HPC counts not exceed the limits of <30 colonies/sample in 100% of the samples tested at bottling, and <200 colonies/sample in 90% of the samples tested 5 days after bottling.^[3] Thus, we petition for a standard of: (1) 100 cfu/ml (at 22 degrees C) and 20 cfu/ml (at 37 degrees C) in samples tested at bottling (EU standard, less stringent than IBWA recommendation); (2) 200 cfu/ml in 90% of samples thereafter (5 days or more after bottling; IBWA recommendation) ; and, (3) a single sample maximum standard of 500 cfu/ml at all times after bottling (comparable to multi-state guideline and EPA tap water guideline).

- e. **Parasites, Pathogens, *Enterococci*, *Pseudomonas aeruginosa*, Sporulated Sulfite-Reducing Anaerobes.** We petition FDA to ban all parasites, pathogens, *Enterococci*, *Pseudomonas aeruginosa*, and sporulated sulphite-reducing anaerobes from bottled water. The EU bans all of these in bottled natural mineral water, and prohibits *Pseudomonas aeruginosa* and *Enterococci* (0/250 ml) in all bottled water. Furthermore, the EU bans any other "microorganisms and parasites...which in numbers or concentrations constitute a potential danger to human health."^[4]
- f. **Total Coliform and *E. Coli*.** FDA should immediately finalize its proposal of over five years ago to prohibit all coliform bacteria, including total coliform bacteria, fecal coliform bacteria, and *E. coli*, in all bottled water, 58 Fed. Reg. 52042 (October 6, 1993). The EU has banned *E. coli* in all bottled water.^[5]
- g. **Di(2-Ethylhexyl)Phthalate (DEHP, or Phthalate).** FDA should establish a standard for DEHP that is the lowest level achievable by the bottled water industry, certainly no greater than 6 ppb (the EPA tap water standard), as required by FFDCA § 410. Monitoring for DEHP -- and for its chemical cousin Di(2-Ethylhexyl)adipate (DEHA) -- should be required after substantial storage (2 years) at room temperature in the bottle, because they both can leach from plastic bottles into the water over time.
- h. **Pesticides and Chemical Contaminants.** FDA should establish standards for other chemicals including:
 - (i) **Individual and Total Pesticides Standards.** FDA should adopt a standard of 0.1 ppb for any single pesticide (except where current FDA or California Proposition 65 level is more stringent), and a "total pesticides" standard of 0.5 ppb. These are the European Union's tap water and bottled water standards.^[6]
 - (ii) **Individual Synthetic Organic Chemicals.** FDA should establish strict standards for individual synthetic organic chemicals found in bottled water that the EU regulates more stringently than does FDA (such as vinyl chloride), or that are listed by the State of California as developmental or reproductive toxins or carcinogens

(e.g. bromodichloromethane and dibromochloromethane). These standards should be no less stringent than the EU standards, or California's Proposition 65 "safe harbor" levels (22 California Code of Regulations §12705, attached), whichever is lower. Our recommended levels, based on these EU or California limits, are included in the attached tables and regulatory language.

(iii) ***Total Non-THM Volatile Organic Compound Standard for Source Water.*** FDA should adopt a standard for total volatile organic compounds (other than THMs) in source water that is at least as stringent as the California bottled water rules. That is, FDA should require that "if a volatile organic compound is confirmed to be in the source water it shall be treated using granular activated carbon treatment or an equivalent treatment operated in accordance with good manufacturing practice as provided in [21 CFR §129.80] until the time that the concentration of the volatile organic compound does not exceed either one part per billion or" an FDA standard (including the new standards we are petitioning FDA to adopt), whichever is stricter.^[7] The attached Technical Report discusses this California source water standard in greater detail.

(iv) ***Other Chemicals.*** FDA should adopt as a bottled water standard the strictest of the EU standards^[8] or the IBWA Model Code for certain other chemical contaminants which may be found in bottled water, and for which such limits stricter than FDA standards have been adopted. These standards are included in the attachments to this petition and in the attached proposed regulatory language.

3. Establish Monitoring, Reporting, Treatment Technique, Source Protection, and Operator Certification Rules as Stringent as Those Applicable to City Tap Water.

Under its authorities and mandates under the FFDCA and other law cited above, FDA should establish treatment and monitoring requirements for bottled water no less stringent than EPA's rules for tap water in major cities in 40 CFR Part 141. These should include treatment technique requirements for microbiological contaminants (including filtration and disinfection or strict source protection requirements), and rules for monitoring unregulated contaminants. In addition, they should require operator certification, lab certification, and certain other measures to assure safety. FDA should adopt, or incorporate by reference, EPA's rules and guidance with respect to the critical requirements noted below, or should adopt rules of its own that are as stringent as EPA tap water rules. Among the key areas needing reform for bottled water are:

- a. **Surface Water Treatment and Source Water Protection Rules.** EPA's surface water treatment rule at 40 CFR part 141, subparts H and P (as recently amended by EPA in its December 1998 adoption of the interim enhanced surface water treatment rule, see 63 Fed. Reg. 69477-69521 (December 16, 1998)) must be applied to bottlers who use surface water or groundwater under the influence of surface water. In addition, FDA should adopt the IBWA Model Code requirement that bottlers using source water that is not protected from *Cryptosporidium* should be treated to remove or inactivate this parasite.
- b. **Meaningful Criteria for "Approved Source" of Bottled Water.** FDA should amend 21 CFR parts 129 and 165 to establish clearly defined and meaningful criteria

and protections for an "approved source" of bottled water. These criteria should include specific requirements for VOC levels (see discussion of California VOC standards above), and source protection (such as a full source water assessment and protection program, including setbacks and potential pollution source identification and elimination). FDA should also require annual state reevaluation of compliance with these new "approved source" rules, including review of potential contamination problems. In crafting these rules, FDA should rely upon EPA's Source Water Protection Guidance for groundwater and surface water-supplied public water systems, as implemented at the state level by state primacy programs (guidance and overview available at www.epa.gov/ogwdw), and upon the IBWA Model Code source protection provisions.

- c. **Record Retention.** As recommended by the General Accounting Office and other experts for many years, FDA should require bottlers to retain records longer than the current, inadequate two-year period. For microbial test results, FDA should require retention for 5 years, and for chemical tests, retention for 10 years, as EPA now requires for tap water suppliers.
- d. **Certified Labs.** As recommended by GAO, FDA should require that labs used for bottled water analysis must be certified by EPA or by a state operating an EPA-approved lab certification program (or by FDA if the Commissioner chooses to establish a certification program), for the contaminants for which the lab is testing. EPA currently requires this for all tap water suppliers.
- e. **Monitoring Frequency.** FDA rules should direct that water must be tested daily at the plant for total coliforms (and for *E. coli* and fecal coliforms if total coliforms are found), and HPC bacteria. These tests should be required both at the time of bottling, and after 5 days storage -- see recommendations for HPC standards above. In addition, the water should be tested weekly by a certified lab for all other regulated microbes noted above (i.e. *Pseudomonas aeruginosa*, Enterococci, sporulated sulphite-reducing anaerobes). Monitoring also should be done at least quarterly for all regulated chemicals (during bottling). Further quarterly monitoring should be required of bottles after two years of extended storage for chemicals that leach from bottles (e.g. DEHP and DEHA), and for microbial contaminants for which post-bottling growth is possible (e.g. HPC, coliform, and *Pseudomonas aeruginosa*).
- f. **Unregulated Contaminant Monitoring.** FDA should require unregulated contaminant monitoring for bottlers at least as stringent and frequent as those applicable to tap water systems under EPA rules at 40 CFR §§ 141.40-141.41.
- g. ***Cryptosporidium* and Other ICR Contaminant Monitoring.** FDA should track EPA's Information Collection Rule for large tap water systems by requiring testing for *Cryptosporidium*, *Giardia*, and viruses by bottlers using surface water or groundwater under the influence of surface water.
- h. **Reporting of Test Results.** FDA's rules should require quarterly reporting of test results to states and FDA. Reporting should be required within 24 hours to state and FDA officials if there is an acute violation, or within 7 days for other violations of standards.
- i. **Prohibiting All Sales of Water Contaminated at Levels Above FDA Standards.** FDA should simply prohibit sales of any bottled water containing

contaminants or produced in violation of FDA standards, and should repeal the provisions of its rules providing that such waters can be sold if labeled as "containing excessive" contaminants.

- j. **Applying FDA's standards to all intrastate bottled water sales.** FDA should issue a clear rule indicating that all bottled water, including water bottled and sold in one state, is covered by FDA rules. While we are cognizant of the perceived limitations on FDA's authority, it should be noted that all bottled water sales in the U.S. have a clear nexus to interstate commerce. The bottles, packaging, bottling equipment, and materials are shipped interstate, the water itself, even if bottled and sold in one state, can directly affect interstate commerce (e.g. competitively, and if contaminated, illnesses can affect people from out of state who consume the water). If FDA determines that additional legislative authority is necessary to carry out this recommendation, FDA should request such authority from Congress.
- k. **Training and Certification.** FDA should require that water bottlers be trained and certified, just as tap water supply operators must be. States or certified third parties using EPA or FDA-approved curricula for drinking water or bottled water operators could carry out such certification and training. If FDA determines that additional legislative authority is necessary to carry out this recommendation, FDA should request such authority from Congress.
- l. **State Bottled Water Program Review & Approval.** If FDA plans to continue to rely upon states to implement and enforce the bottled water program, FDA should establish criteria for state program adequacy and should require state bottled water programs to be reviewed and approved by FDA in order to obtain federal funding. FDA should oversee their effectiveness after approval. If FDA determines that additional legislative authority is necessary to carry out this recommendation, FDA should request such authority from Congress.
- m. **Mandatory Recall Authority.** FDA should promulgate a rule under its authorities provided in the FFDCA establishing its clear mandatory recall authority for FDA. If FDA determines that additional legislative authority is necessary to carry out this recommendation, FDA should request such authority from Congress.
- n. **Committing to Annual Inspections.** FDA should promulgate a rule or statement of policy committing to conducting annual inspections (or FDA-funded, overseen, and reviewed annual state inspections) of all bottling facilities and of their water sources. If FDA finds that additional resources are needed to honor such a commitment, FDA should reprogram or request such resources.
- o. **Maintaining an Inventory of Water Bottlers.** FDA should maintain a public and up-to-date inventory and register all water bottlers.
- p. **Covering All Bottled Water Under FDA Standards.** FDA should amend its rules at 21 CFR parts 129 and 165 to cover all water sold in a bottle that is likely to be ingested by people. Thus, "purified," "disinfected," "seltzer," etc. water should be covered under the FDA bottled water standards, unless the water is sweetened or juices (other than trace flavorings) are added. California and many other states' laws cover such waters. In light of consumer expectations that these seltzer and other waters are protected by bottled water standards, there is no reason why FDA standards should not cover these waters.

- q. **Routine FDA Spot Check Monitoring of Bottled Water and Publication of Results.** FDA should conduct routine monitoring of bottled water quality for waters sold across the country, as has been done in Canada for many years, and release the results, including brand names, to the public in published reports and on its website.

4. Other Requests.

- **FDA Website and Public Information Enhancements.** FDA should upgrade its website and establish a phone-accessible information system on bottled water. The website and a FDA hotline should provide a user-friendly array of information on bottled water brands, including all of the basic information noted in the right-to-know section above, for each bottler. This bottled water information should mirror and expand upon the EPA hotline and website that gives specific information on individual tap water systems and drinking water generally. The FDA hotline and website should make available the results of all government, industry, or other bottled water testing by certified labs for all brands. It also should include information on all inspections and recalls, and any other relevant consumer information on particular brands of bottled water.
- **A "Penny Per Bottle" Fee to Assure Bottled Water Safety.** FDA should seek to establish a fee for bottlers of one cent per bottle of bottled water produced, to be placed in a trust fund for use by FDA to pay for a stringent bottled water regulatory program. The proceeds from the fee should fund improved FDA implementation, random testing, a public website, state and federal inspections, and funding and oversight of state programs and bottlers. If FDA determines that additional legislative authority is necessary to carry out this recommendation, FDA should request such authority from Congress.

Conclusion

Therefore, the undersigned hereby petitions the Commissioner for such rules and actions as noted above, in order to assure that consumers are protected against potential adverse health effects in bottled water, and are provided accurate and reliable information in making decisions about whether to purchase bottled water.

Respectfully Submitted,

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Notes

1. The contaminants for which disclosure should be required are any contaminants: (a) regulated in bottled water by FDA; (b) which FDA determines may present a health hazard; (c) for which EPA has issued a National Primary or Secondary Drinking Water Regulation; (d) for which the State of bottling or sale has established limits or warning levels; (e) that are unregulated contaminants for which monitoring is required of public water systems; (f) which EPA has placed on the SDWA Contaminant Candidate List; or, (g) for which EPA has established a health advisory.

2. European Community Council Directive on the Quality of Water Intended for Human Consumption, 98/83/EC, November 3, 1998, Annex I.

3. IBWA, IBWA Plant Technical Manual, at 28-29 (Revised, 1995).

4. European Community Council Directive on the Quality of Water Intended for Human Consumption, 98/83/EC, November 3, 1998, Article 4(1)(a) and Annex I; European Community Council Directive on Exploitation and Marketing of Natural Mineral Waters, 80/777/EEC, Article 5 (as amended by Council Directives 80/1276/EEC of 22 December 1980, 85/7/EEC of 19 December 1984, and by Directive 96/70/EC of the European Parliament and of the Council of 28 October 1996).

5. *Ibid.*

6. European Community Council Directive on the Quality of Water Intended for Human Consumption, 98/83/EC, November 3, 1998, Annex I, Part B. Pesticides are defined by the EU as "organic insecticides, organic herbicides, organic fungicides, organic nematocides, organic aricides, organic algicides, organic rodenticides, organic slimicides, related products (inter alia, growth regulators), and their metabolites, degradation and reaction products."

7. Cal. Health & Safety Code § 111150(c).

8. European Community Council Directive on the Quality of Water Intended for Human Consumption, 98/83/EC, November 3, 1998, Annex I, Part B.