

that laboratories performing analyses should be validated in some manner to ensure their competency, although FDA need not be the validator. One comment stated that the public is better and more consistently protected by requiring that certified laboratories conduct the required analyses.

One comment stated that the compliance of bottled water with quality standards is directly related to the competence and reliability of the laboratories that perform the analysis for contaminants. It stated that it is not clear what FDA means by "competent commercial laboratories." It asked, concerning the criteria that would be used to determine whether a laboratory is competent, who would determine whether a laboratory meets these criteria, and how would a bottler be able to determine that a laboratory is able to provide valid test results. The comment stated that the term "competent" is too vague and will not promote uniformity. Another comment stated that the use of uncertified, "competent" laboratories provides little assurance that contaminants, even when present, will be detected.

Comments stated that, because EPA requires that determinations of compliance with its MCL's be based on data generated by a certified drinking water laboratory, it would be consistent with the spirit of the MOU between FDA and EPA for FDA also to require the use of certified laboratories. The comments stated that FDA would not have to expend resources because certification programs are in place and administered by the States, with laboratories bearing the cost. They added that

FDA's adoption of a laboratory certification requirement would be consistent with its stated intent of incorporating EPA drinking water analytical methods for determining compliance with bottled water quality standards.

Comments stated that bottled water laboratory testing certification is a major problem that must be addressed by FDA. They stated that, currently, a number of State regulatory agencies require that bottled water sold in their States be tested in one of their State-certified laboratories, and that this issue causes undue replication expenses for multiple State licensing and hinders free interstate commerce.

One comment stated that water bottlers should be encouraged to perform laboratory tests on site. It stated that transportation to a certified laboratory can require considerable time and can delay results. The comment stated that while it is important for a certified laboratory to serve as a reference, water bottlers would best serve the public by performing analyses on site.

The agency disagrees that it should require the use of certified laboratories to test bottled water. Under § 129.35(a)(3)(iii), analysis of the water samples may be performed for the plant by competent commercial laboratories. Thus, laboratories used to analyze bottled water must be competent whether or not they have been certified competent. A competent laboratory is one that is capable of performing the required analyses and of obtaining valid and accurate results

from its analyses. Any laboratory that has been certified by EPA or a State to test drinking water is deemed to be a competent laboratory. EPA and State-certified laboratories may be used for comparative purposes against other commercial laboratories or a plant's own laboratory. To clarify that the agency believes that EPA and State-certified laboratories are appropriate to perform water analyses to demonstrate compliance with parts 129 and 165, FDA is amending § 129.35(a)(3)(iii) to specifically cite EPA- and State-certified laboratories as examples of competent laboratories. Failure to have been certified will not preclude a laboratory from being considered competent, but the existence of such certification will eliminate any doubt about the laboratory's competency.

FDA agrees with the comment that stated that water bottlers should be encouraged to perform laboratory tests on site. Manufacturers of many types of foods effectively perform their own routine laboratory tests on their products. To the extent possible, bottled water manufacturers should perform routine tests on bottled water. For example, testing for microbiological quality must be conducted at least once a week for source water (§ 129.35(a)(3)), as often as necessary for product water (§ 129.80(a)), and at least once a week for the finished product (§ 129.80(g)(1)). Manufacturers can obtain quick, reliable results using their own laboratories versus the time it would take to send the samples to a commercial laboratory. However, firms must ensure the competency of their labs.

The comments have not convinced the agency that the public health will be better protected by requiring the use of certified laboratories. Regardless of the laboratory used for testing, water containing any substance at a level considered injurious to health is deemed to be adulterated (see section 402(a)(1) of the act and § 165.110(d)). Thus, the agency concludes that the public health is already protected.

The MOU between FDA and EPA delineates jurisdiction over types of drinking water but does not consider the issue of certified laboratories. Although FDA incorporates EPA methods into the quality standard, FDA has yet to be convinced that only EPA-or State-certified laboratories are capable of using EPA methods.

In response to the comment concerning States requiring additional testing in laboratories certified in their own States, the agency points out that regardless of whether it required the use of certified labs, the CGMP regulations are not preemptive and does not preclude States from establishing stricter requirements for bottled water sold in their States.

G. Annual Plant Inspection

IBWA requested that FDA revise the CGMP regulations to include a requirement for annual plant inspections to ensure compliance with the regulations. FDA stated in the January 1993, proposal that without a clear indication of a significant public health problem that could not be corrected by other means, there is no basis for FDA to adopt such a requirement for bottled

water. FDA recognized, however, that IBWA requires third party inspection of its member firms, and FDA encourages such self-regulated programs within industry.

112. A number of comments stated that FDA did not provide sufficient rationale for not imposing annual plant inspection requirements on the growing bottled water industry. Several comments stated that annual inspections would reduce the likelihood that bottlers would be out of compliance for extended periods of time. One comment stated that, irrespective of who performs the inspection, FDA should require inspections at least biannually for bottled water plants. It added that FDA could contract with State regulatory agencies to accomplish these inspections.

Some comments encouraged FDA to consider third party inspections because third party inspections would ensure compliance with the regulations without requiring FDA to increase resource requirements. One comment urged FDA to modify § 129.80(g) to include a requirement for annual inspections by a qualified third party organization because it would address expressed State government concerns. It stated that some State governments require that companies submit a report issued by a recognized organization that inspects bottled water systems for compliance with part 129 (i.e., NSF International or other organization, State, or country with an inspection protocol as stringent as NSF's).

The agency disagrees with the comments and affirms that, in the absence of a significant public health problem, the hazards from bottled water do not warrant this requirement.

The monitoring/inspectional aspect of FDA's program is carried out by its field force. The agency monitors and inspects bottled water products and processing plants as part of its compliance programs for foods. There are roughly 30 compliance programs for foods covering the full range of potential food safety problems, including chemical contaminants, pesticides, filth, and food additives. About one-half of the programs are for imported foods. They provide broad guidance to the field on the agency's inspectional priorities. The agency's work plan further specifies the number of inspections, sample collections, wharf exams, analyses, and other activities in each program by district. The districts have considerable latitude as to the establishments that they inspect and the products that they examine to allow for adequate coverage of local problems and regionalized industry.

Bottled water establishments are covered under the general food safety program. Bottled water plants, along with carbonated beverage bottling plants and warehouses, generally are assigned low priority for inspection. Priorities are based on factors such as the potential for a public health problem and the violation rate of the industry. When compared to products such as low-acid canned foods and products in which Listeria or

Salmonella have a significant potential to develop, bottled water products are a relatively low public health problem.

FDA's experience over the years has supported that ranking (Ref. 24). Studies of bottled water products have generally not found significant problems in these products (id). Consequently, bottled water plants shipping in interstate commerce are inspected about once every 4 years, unless the firm is violative. The frequency of inspection of violative firms is accelerated depending on the number, significance, and recurrence of violations. Furthermore, the districts follow up on consumer and trade complaints and other leads, as appropriate, on potentially violative bottled water products.

FDA also contracts with the States to perform some bottled water plant inspections. The FDA district offices are generally in contact with their State counterparts to exchange information about compliance problems, inspectional coverage, and new food establishments. In addition to FDA inspection, the State and local governments have their own inspection and licensing programs. Therefore, FDA concludes that it need not mandate annual plant inspections for bottled water.

113. One comment suggested that FDA consider establishing specific criteria for the operation of a bottled water plant to ensure that there is compliance with CGMP's for bottled water manufacturing. It stated that it is a lot easier for an inexperienced person to establish a bottling facility for water, capable of producing high volumes of product, than it is to start

up with other food products. The comment held that an effective licensing program is needed far more for this type of product than for other foods and beverages because of a greater risk to the public.

Another comment suggested that FDA establish for its quality standards some type of monitoring timeframes along with deadlines for submission of monitoring results from State-approved drinking water laboratories.

FDA notes that it has established a CGMP regulation in part 129 for the processing and bottling of drinking water. Thus, FDA has established regulations on how to operate a bottled water plant. Bottled water produced in violation of part 129 is adulterated under section 402(a)(4) of the act in that the food has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Part 129 requires monitoring of the source water, product water, and finished product. According to § 129.35(a)(3), samples of source water must be taken and analyzed at a minimum frequency of once each year for chemical contaminants and once every 4 years for radiological contaminants. Additionally, source water obtained from somewhere other than a public water system is to be sampled and analyzed for microbiological contaminants at least once each week. Test and sample methods must be consistent with the minimum requirements set forth in § 165.110(b).

Product water samples must be taken after processing and before bottling, and analyzed as often as is necessary to assure the uniformity and the effectiveness of the processes performed by the plant (§ 129.80(a)).

The compliance procedures for the finished product are set forth in § 129.80(g). A firm must test a representative sample of each product for bacteriological contamination at least once a week. To ensure chemical, physical, and radiological quality, a manufacturer must take and analyze at least annually a representative sample of each product. The finished bottled water must comply with the quality standard in § 165.110(b).

Plants must retain all records required by part 129 for not less than 2 years, and these documents must be available for official review at reasonable times (§ 129.80(h)). These records must be available for FDA plant inspections. The agency notes that it does not have the resources to review bottled water test results except during FDA plant inspections.

Thus, while FDA has not established a licensing requirement for water bottlers, it has established a regulatory regime to ensure the safety and quality of bottled water products.

H. Recall Procedures

IBWA requested that FDA establish specific recall procedures for bottlers and dealers in the CGMP regulations. In the January 1993 proposal FDA found no basis for this requested revision.

114. A number of comments stated that FDA did not provide sufficient rationale in the proposal for not establishing

specific recall procedures for bottlers and dealers in the growing bottled water industry.

One comment stated that, although there should not be specific recall procedures in the regulations, language that requires that a written recall plan or document be maintained by the bottler should be included in the FDA regulations. It stated that the existence of such a plan would ensure a quick response by a bottler in the event that a recall is necessary.

The agency notes that part 7 (21 CFR part 7), subpart C provides guidelines on policy, procedures, and industry responsibilities for recalls. In § 7.59, FDA advises firms to:

- (1) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall;
- (2) use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots;
- and (3) maintain such product distribution records as are necessary to facilitate locating of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and the expected use of the product.

The agency notes that recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and from products that present risks of injury or gross deception or are otherwise defective. Recall is an alternative to an FDA court

action for removing, distributed products from interstate commerce.

FDA is not aware of any circumstances that establish that there is a unique problem with recalls of bottled water. Therefore, FDA concludes that the guidelines for recall procedures for foods are adequate. If a firm refuses to undertake a recall that is requested by FDA, or where FDA has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing, it may initiate seizure, multiple seizure, or other court action.

V. OTHER MATTERS

A. Ozone

The agency proposed to specify in § 184.1563(d) that the term "bottled water," for purposes of this section, does not include mineral water with TDS greater than 500 ppm. The agency stated that this action is necessary to ensure that FDA's rulemaking on the definition of bottled water in § 165.110 does not inadvertently have the effect of expanding the permitted uses of ozone.

115. Two comments objected to the exclusion of mineral water from ozonation. One of the comments stated that this exclusion conflicts with other FDA proposals to include mineral water as a bottled water. It stated that California has permitted the ozonation of mineral water for many years, and that

ozonation is by far the most common means of germicidal water treatment that California mineral water firms use.

Another comment stated that there is no known reason to preclude ozonation as the antimicrobial agent for mineral water with TDS's greater than 500 ppm, provided that the maximum residual level requirements are met. It stated that the difference between mineral water and bottled water is only how much ozonation is required, at what temperature, and for how long a period of time.

The agency has reconsidered its January 1993, proposal in light of these comments and of its original decision to affirm the use of ozone in bottled water as generally recognized as safe (GRAS). In that decision (47 FR 50209, November 5, 1982), FDA noted its 1968 opinion that ozone used to disinfect potable water is GRAS if it is used in accordance with CGMP and with the recommendations of the U.S. Public Health Service. The only restriction was that the water must be potable. FDA also noted the continuous use of ozone in Europe for disinfecting municipal water for nearly 70 years without any evidence of toxicity. To ensure that the levels of any oxidation products formed are low and safe, the agency included a requirement in the GRAS affirmation regulation that the starting water, before ozonation, meet the microbiological, physical, chemical, and radiological quality standards for bottled water specified in § 103.35(b) through (e). FDA considers this requirement to be a

clarification of what it considered to be CGMP, namely, that ozone would not be used to disinfect polluted water.

A restriction on the use of ozone in mineral water with TDS greater than 500 ppm does not specifically address the goal of the proposal which was to ensure that the level of oxidation products do not exceed the levels anticipated when the GRAS affirmation regulation was issued. The oxidation products of concern from the use of ozone that were considered in establishing the GRAS regulation were those from dissolved organic material, whereas the increased solids content of mineral water consists primarily of minerals (inorganic material). Moreover, the restriction in the GRAS affirmation regulation that the use of ozone in disinfecting water be in accordance with CGMP means that only water that meets the new standard in § 165.110(b), which limits the amount of dissolved organic material that may be present, will be processed with ozone. Therefore, FDA has decided that there is no need to include the restriction limiting the TDS to 500 ppm for mineral water in the GRAS affirmation regulation for ozone.

Of relevance in this regard is the fact that bromate can be formed when ozone is used on waters that contain sufficient levels of bromide (a mineral component). EPA has conducted an evaluation of bromate and classified it as a probable human carcinogen because bromate administered to rodents in their drinking water has been shown to produce several types of tumors in both sexes. EPA has proposed an MCLG for bromate of zero and an MCL of 10 micrograms (μg)/L (59 FR 38668, July 29, 1994). In

the event EPA establishes an MCL for bromate in drinking water, then in accordance with section 410 of the act FDA will propose to establish an allowable level for bromate in bottled water in § 165.110(b). The agency further emphasizes that water that is treated with ozone that results in bromate levels that may be injurious to health is adulterated under section 402(a)(1) of the act.

B. Nutrition Labeling

116. One comment stated that it was concerned with the level of sodium that is allowed under the current regulations, while still allowing the label to claim that the food is "sodium free" or "salt free." It stated that FDA permits the label to claim "sodium free" up to 21.1 ppm in bottled water. The comment noted that bottlers who use ion exchange in their treatment process can actually add sodium to the bottled water. The comment expressed concern about any regulation that permits advertising of "sodium free" when there actually is sodium in the bottled water.

The agency discussed this aspect of its "sodium-free" regulation in the FEDERAL REGISTER of January 6, 1993 (58 FR 2302 at 2321) and stated that it believes that it is appropriate to apply the term "free" to a nutrient when a food contains that nutrient in a dietetically trivial or physiologically inconsequential amount, even though the nutrient is present at a level at or near its reliable limit of quantitation. With modern

analytical methods, the level at which the presence of a nutrient may be quantified is becoming increasingly smaller.

For example, there are almost no foods that can be said to be truly sodium free, yet the level of sodium present in some foods has no impact on the diet. The Daily Recommended Value for sodium is 2,400 mg. Thus, the agency concluded that a food containing less than 5 mg per reference amount customarily consumed (reference amount) could be considered sodium free because 5 mg is a dietarily insignificant fraction of 2,400 mg. The reference amount for bottled water is 240 mL. Therefore, the claim "sodium free" may be used on a bottled water label if the sodium content is less than 5 mg per 240 mL serving (21 ppm). If a "sodium free" claim is made, the bottled water must bear nutrition labeling in accordance with § 101.9.

The agency points out that although the term "salt" is not synonymous with "sodium," salt refers to sodium chloride. Under § 101.61(c)(1), the term "salt free" may be used on the label or in labeling of foods only if the food is "sodium free."

FDA recognizes that some sodium may be added to water during ion exchange treatment. The label of the bottled water product treated in this manner could still qualify to bear the statement "sodium free" if the sodium content of the final product is less than 5 mg per 240 mL serving. However, if the sodium content is 5 mg or greater per 240 mL serving, the bottled water must bear nutrition labeling and could not be labeled as "sodium free."

117. One comment asked that bottled water have a qualified exception from the nutrition labeling regulations except when a claim is made that the water contains a significant level of a nutrient or nutrients. It stated that in that event, nutrition labeling for the nutrient for which the claim is made would be required. The comment stated that, for example, if a bottled water bore a claim of "no sodium" or "no calories," it could be accompanied, on the information panel, by a statement, "not a significant source of _____" with the blank filled in with the items claimed in the statement. Another comment questioned why the declaration "sodium free" would trigger a nutritional panel for information on fat and calories when it is common knowledge that water does not contain these nutrients.

One comment requested that FDA exempt bottled water products other than mineral water from nutrition labeling. It stated that consumers do not expect any nutrition from bottled water, except perhaps for some minerals in mineral water. It suggested that bottled water with less than 250 ppm TDS (i.e., bottled water that is not mineral water) be exempted from nutrition labeling, even if fluoride is added. It stated that label space was a problem.

FDA notes that the requested exemptions and modifications for nutrition labeling fall outside the scope of this rulemaking. However, FDA discussed these issues in the final rule on nutrition labeling of January 6, 1993 (58 FR 2079 at 2149), and stated that:

A recent IOM [Institute of Medicine] report, "Food Labeling: Toward National Uniformity" (Ref. 25), noted that many States have expressed concern about the heightened potential for consumer confusion because of the increased number of bottled water products on the market and the aggressive marketing and advertising claims of superiority made for them. Thus, FDA maintains its position that nutrition information relating to food must be provided for all products, including bottled and mineral water, that contain more than insignificant amounts of any of the nutrients or food components that are required to be listed, or whose label, labeling, or advertising contains a nutrient content claim or any other nutrition information in any context. For products that qualify for the simplified format, if manufacturers voluntarily declare nutrients allowable under § 101.9(c) that are not among the 14 required nutrients (e.g., potassium), the required statement "Not a significant source of _____,"

must be used, with the blank filled in with the name of any of the 14 required nutrients or food components that are not present or are present in insignificant amounts. Moreover, if a product is voluntarily enriched or fortified with added vitamins or minerals, any such nutrients must be declared using the simplified format and followed by the above statement. Thus, a product labeled as "bottled water, minerals added" will have to bear nutrition labeling.

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Bottled water products containing juice or other flavors are subject to the same nutrition labeling requirements as any other food. If a product meets the criteria for no nutritional significance, and no claims are made, then nutrition labeling is not required. A "sodium free" declaration on bottled water or on any other food label will trigger nutrition labeling, because such a claim promotes the nutritional properties of the product.

As discussed previously under comment 92 of this document, if fluoride is added to bottled water, and the label bears a statement to indicate this addition, other than in the ingredient statement, the label must bear nutrition labeling that complies with the simplified format.

C. Preemption

118. Comments from several States objected to the Federal standards of identity for bottled water preempting any State standards that are not identical to it, as some States have established regulations for bottled water that are more stringent than the FDA standard. One comment stated that it is a fundamental right of a State to make regulations and standards that are at least as stringent as or more stringent than Federal regulations and standards. It contended that FDA's role is more appropriately to establish Federal rules that will protect the public health and prevent fraudulent claims from being made that might mislead consumers of bottled water products. Another State

held that it has made great efforts to ensure that bottled water meets standards at least as stringent as those set forth in EPA's primary drinking water regulations.

A number of comments requested that FDA more clearly explain the scope of the preemption provision, and that it specifically address whether the agency interprets Federal preemption to apply to certain State requirements (i.e., labeling restrictions, laboratory certification, and certain testing requirements).

Comments asserted that many State regulations are costly and do not provide consumers with any more protection than is likely to be provided by those proposed by FDA. One comment stated that FDA should emphasize that a given State should not be allowed to place an undue burden on interstate commerce by requiring that analyses be performed only in laboratories that are certified by that State, or that analyses be performed according to an unduly restrictive frequency unrelated to public health protection. The comment added that regulatory activity by the States in areas such as standards and environmental protection is causing difficulties for those seeking to import goods into the United States.

FDA notes that, under section 403A(a)(1) of the act (21 U.S.C. 343-1(a)(1)), a State may not establish or continue in effect a standard of identity for a food that is the subject of a standard of identity under section 401 of the act if the State standard is not identical to the Federal standard. Section 403A(a)(1) of the act only effects preemption with respect to

matters on which a Federal requirement exists. If there is no Federal requirement to be given preemptive effect, preemption does not occur.

Under § 100.1(c)(4), if the State requirement is identical to the Federal law, there is no issue of preemption. In addition, if the State requirement does the same thing that the Federal law does, even if the words are not exactly the same, then it is effectively the same requirement as the Federal requirement. FDA's view, as embodied in § 100.1(c)(4), is that such a State or local requirement is consistent with the Federal requirement. Therefore, the only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements on matters that are covered by section 403A(a) of the act.

FDA acknowledges that some stringent State laws will be preempted by less restrictive Federal regulations. However, one of the goals of the national uniformity provisions of the 1990 amendments was to give industry some relief from some types of State requirements that interfere with their ability to market products in all 50 States in an efficient and cost-effective manner (Statement of Rep. Madigan, 136 Congressional Record H12954 (October 26, 1990)). Thus, in enacting the 1990 amendments, Congress apparently decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in

these aspects outweigh the loss in consumer protection that may occur as a result.

The agency notes that certain State laws and regulations will not be preempted because FDA's requirements have not been given preemptive effect. Therefore, a State will not be precluded from enforcing its provisions in such circumstances. The agency points out, for example, that FDA has not sought to give preemptive effect to part 129. Therefore, if a State has stricter requirements than those in part 129, the State standard is not preempted by the Federal requirement.

The agency advises that, in those instances where a State requirement is preempted and the State believes that there are significant protections of the public that will be lost as a result, the State may petition the agency to modify the standard in question. FDA intends to give careful consideration to any such petitions that it receives.

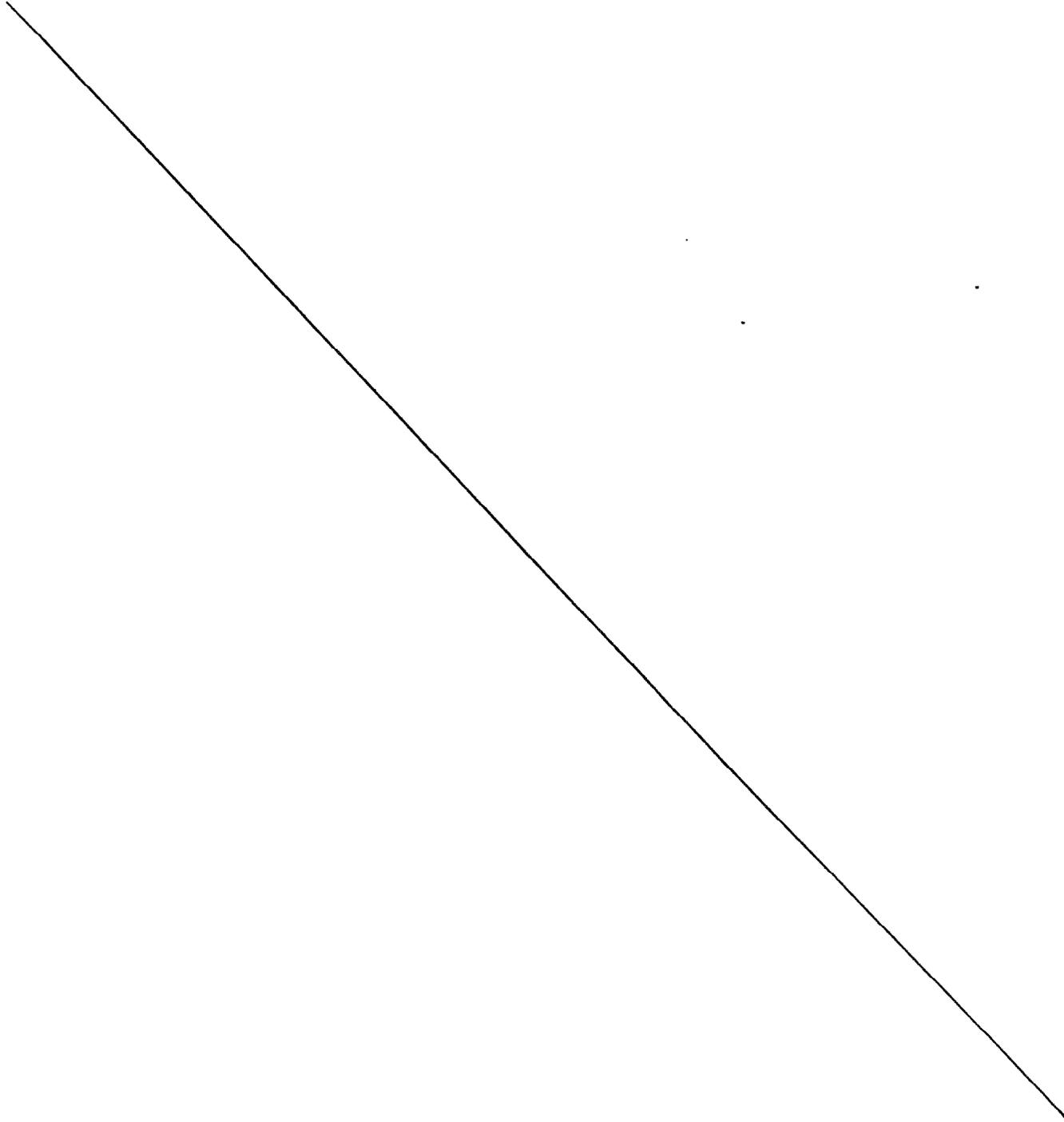
119. Some comments contended that many States have bottlers whose products do not cross State lines, thereby avoiding compliance with FDA regulations. They suggested that the regulation should include all bottlers regardless of intrastate/interstate sales.

One comment from a State contended that by proposing to apply these standards only to interstate manufacturers, FDA establishes an undue logistical burden on regulatory agencies, as they would have to establish two levels of regulation. The comment argued that more consistent regulation is possible by

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applying the same standards to all bottled water firms that desire to sell their products in a particular State.

The agency advises that the act only applies to food that is in, or is intended to be shipped in, interstate commerce. Sections 301 and 304 of the act (21 U.S.C. 331 and 334) specifically describe prohibited acts and liability for seizure



of food that is held for sale in, is in, or has been shipped in interstate commerce. FDA encourages States to apply the Federal standard to both interstate and intrastate commerce to eliminate two levels of regulation and to avoid undue logistical burdens.

VI. CONCLUSIONS

After review and consideration of the comments received in response to the January 1993 proposal, FDA concludes that it should amend part 129 and establish part 165 as set forth in the proposal but with the specific modifications to the proposed regulation discussed in this document. For the purposes of this final rule, certain changes, in addition to those discussed in this document, were made for editorial purposes, clarity, and consistency only. These changes do not modify any matter of substance.

VII. ENVIRONMENTAL IMPACT

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (58 FR 393, January 5, 1993). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VIII. ANALYSIS OF IMPACTS

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when

regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is "economically significant" if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million or adversely affect in a material way a sector of the economy, competition, or jobs. A regulation is considered "significant" under Executive Order 12866 if it raises novel legal or policy issues.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In compliance with the Regulatory Flexibility Act, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

In the economic assessment to the proposal in this rulemaking (58 FR 393), FDA considered the costs and benefits of taking this action. FDA estimated compliance costs to be between \$18 million and \$21 million and benefits to be approximately \$35 million plus the value of any increase in interstate commerce that might occur because of the elimination of conflicting State regulations. Thus, benefits were estimated to exceed costs by

from \$14 million to \$17 million, plus the value of any increase in interstate commerce in bottled water.

The comments to the proposal discussed three issues relevant to the economic assessment. The first issue involves the ability of the product definitions adopted in this final rule to communicate information about bottled water products to consumers. The second issue involves the cost of label changes. The third issue involves the economic consequences of the definitions and labeling requirements adopted in this final rule for particular bottled water manufacturers.

A. Ability of Definitions to Communicate Information to Consumers

Some comments suggested or provided data indicating that some of the definitions for particular types of bottled water adopted in this final rule may not correspond to some consumers' current ideas about the essential features of various types of bottled water. The implication of these comments is that the definitions adopted in this final rule will generate confusion over the characteristics of these products.

Although FDA acknowledges that some of the definitions may not correspond to some consumers' current ideas about the essential features of some types of bottled water, this phenomenon does not necessarily imply that confusion over these products will be increased by this final rule. In States in which these products are not currently defined, the terms currently used to refer to various bottled water products may also not correspond to some consumers' current ideas about the

essential features of those types of bottled water. Similarly, in States in which these products are already defined, the State definitions may also not correspond to some consumers' current ideas about the essential features of those types of bottled water.

Other comments suggested that alternative definitions could be adopted that would be more consistent with most consumers' current ideas about the essential features of various types of bottled water than the definitions adopted in this final rule. These comments imply confusion will be greater under the definitions adopted in this final rule than under the alternative definitions. Similarly, some comments suggested definitions already adopted by particular States are more consistent with consumers' current ideas about the essential features of various types of bottled water than the definitions adopted in this final rule. These comments imply confusion will be increased if existing state definitions are superseded by the definitions adopted in this final rule.

For example, a number of comments suggested that most consumers believe "spring water" must be extracted from the natural orifice of a spring and not from a bore hole. This final rule defines "spring water" to include water extracted from both the natural orifice of a spring and from a bore hole tapping the underground formation feeding the spring. The comments imply the definition of "spring water" adopted in this final rule will generate greater confusion over the characteristics of this

product than would a definition specifying that "spring water" be extracted from the natural orifice of a spring. As discussed in the preamble to this document, FDA believes that these comments are in error, and that most consumers do not believe "spring water" must be extracted from the natural orifice of a spring.

Another comment discussed the results of a survey in which the majority of respondents thought "artesian well water" flowed to the surface due to natural pressure. In contrast, the geological definition of an artesian well does not imply water from this type of well flows to the surface due to natural pressure. The definition of "artesian well water" adopted in this final rule is consistent with the geological definition of an artesian well and does not require that this type of water flow to the surface due to natural pressure. The comment suggested the definition adopted in this final rule will create more confusion over the characteristics of this product than would a definition specifying that "artesian well water" flows to the surface due to natural pressure.

FDA acknowledges that many consumers may be unaware of the geological definition of an "artesian well," and that, in the short run, the definition of "artesian well water" adopted in this final rule may lead some consumers to be confused over the characteristics of this product. However, in the long run, this confusion will be less than the confusion that would be generated if FDA failed to adopt a definition for this term or adopted a definition that failed to correspond to the accepted geological

definition of an artesian well. Adopting a standardized definition for this term will increase the ability of interested consumers to interpret this term. Adopting a standardized definition consistent with accepted geological terminology will increase the ability of interested consumers to attain information on this type of water.

Comments also discussed a number of other elements of the definitions adopted in this final rule. These comments are addressed in the preamble to this document. These comments do not provide sufficient information to establish that alternative definitions would be more consistent with most consumers' current ideas about the essential features of various types of bottled water than the definitions adopted in this final rule.

B. The Cost of Label Changes

Comments provided a wide range of estimates of the cost of relabeling bottled water products to conform to the proposed definitions and labeling requirements. One comment suggested label changes will cost \$2,000 per product, per location, not including the cost of the actual label. Another comment suggested the cost of each label plate change alone will be \$200. Another comment suggested it will cost a single firm "hundreds of thousands of dollars" to change their labels.

In the economic assessment of the proposal in this rulemaking, FDA used an average relabeling cost of \$45,000 per label change. This cost estimate was based on information previously provided by a bottled water manufacturer. Although

the comments suggest the cost of relabeling may be highly variable across firms, and that the cost of relabeling may be lower than \$45,000 per label for many firms, the comments do not provide sufficient information to determine an appropriate adjustment in the average cost of relabeling.

Some comments implied that changes in advertising would also be required to accommodate the product definitions established under this final rule. In the economic assessment to the proposal in this rulemaking, FDA did not consider these costs because FDA believed the proposed definitions were sufficiently broad that no firm legally selling a given type of bottled water would be unable to do so because of the proposed regulation.

One comment suggested 44 brands of bottled water currently marketed as mineral water in the United States would no longer be able to be marketed as mineral water under this final rule. However, the only brands listed in this comment were Mountain Valley, Volvic, and Poland Spring. Based on the information available to the agency, this comment is in error. It appears that no mineral water is actually being marketed under these brand names.

Another comment suggested most of the mineral water sold in the world, including the U.S. market, is produced in Europe, and that these products currently exhibit a wide range of total dissolved solids (TDS) levels, from under 100 mg/L to over 1,000 mg/L. The implication of this comment is that some mineral water produced in Europe with less than 250 ppm TDS is currently being

marketed as mineral water in the United States and would no longer be able to be marketed as mineral water under this final rule. However, this comment did not identify any European brands that would actually be affected in this manner, and FDA is not aware of any such brands.

FDA, therefore, has no information that this final rule will require extensive modification of existing advertising.

C. Economic Consequences of Definitions and Other Labeling Requirements on Particular Bottled Water Manufacturers

A number of comments suggested that the definitions and the labeling requirements in this final rule will have a negative impact on the sales of some bottled water products and thus a negative impact on some bottled water manufacturers.

Two comments suggested that some water currently sold as mineral water would no longer be able to be sold as mineral water under this final rule, and that this would have a negative impact on the sales of those products. This issue is different from the advertising cost issue, which is the context in which these same comments were discussed in the preceding section. However, FDA's response to these comments is the same in this context as in the context of advertising costs. FDA is not aware of any brand of mineral water that will no longer be able to be marketed as mineral water under this final rule.

Another comment noted the definition of "bottled water" does not allow for the addition of ingredients such as minerals for flavor, sodium fluoride, flavors which comprise less than one percent by weight, and carbon dioxide. According to this

comment, many products currently sold simply as "bottled water" contain these ingredients, and that by causing these products to be labeled differently, this final rule will generate a tremendous adverse economic impact on the firms producing these products. FDA believes this comment is in error because it is currently illegal to sell water containing these ingredients as simply "bottled water," and FDA is not aware of any products that are labeled in this manner.

Another comment suggested that if drinking water is not recognized by FDA as a specific type of bottled water, severe economic repercussions would occur for companies that currently sell bottled drinking water. This final rule does not define "drinking water" as a specific type of bottled water, although it does allow for the use of the term "drinking water" as a synonym for "bottled water." However, this comment provided no information to support the claim that consumers believe drinking water is a specific type of bottled water. In addition, nearly all bottled water sold in the United States meets the conditions suggested in this comment as being peculiar to drinking water. Therefore, FDA does not believe the sales of drinking water will be significantly affected by this final rule.

Another comment suggested that the additional labeling requirements for bottled water marketed for use in infant formula will cause a negative impact on the sales of these products and will effectively destroy this product line. However, the comment provided no information to support this claim. Therefore, there

is no basis for FDA to take any action in reliance on this comment.

D. Conclusions

The economic assessment to the proposal in this rulemaking (58 FR 393) estimated net benefits of \$14 million to \$17 million plus the value of any increase in interstate commerce that might occur because of the elimination of conflicting State regulations.

The previous economic assessment did not consider the potential effect of the definitions and labeling requirements on the level of consumer confusion over bottled water products. Accounting for this effect will probably increase estimated net benefits. However, FDA has insufficient information to estimate this increase in net benefits.

In addition, the definitions and labeling requirements adopted in this final rule may result in a decrease in the sales of some products and an increase in the sales of other products. However, FDA has insufficient information to determine the size or significance of these effects.

Therefore, FDA estimates that the benefits of this final rule will exceed the costs by \$14 million to \$17 million, plus the value of any increase in interstate commerce which might occur because of the elimination of conflicting State regulations and the value of any reduction in consumer confusion over these products.

IX. EFFECTIVE DATE

FDA proposed that any final rule that was issued based upon the proposal would become effective 180 days following issuance of the final rule.

120. One comment asked FDA to consider the cost and phase-in considerations for bottled water companies whose main business involves 3-, 5-, or 6-gallon reusable polycarbonate silk-screened bottles. The comment stated that these bottles, which are generally recycled when no longer fit for use, cost approximately \$4 to \$5 each and have a normal life span of 5 to 7 years, although they can last 10 years or longer. It stated that a company with about \$6 million in sales has an inventory of about 200,000 bottles or a bottle investment of \$800,000 to \$1,000,000. The comment maintained that any change in labeling requirements has major potential expense implications for bottlers using 3-, 5-, or 6-gallon polycarbonate silk screened bottles. It held that any relabeling of these bottles with adhesive labels can be costly and presents potential problems in the washing process. It asked that consideration be given to extended phase-in periods for reusable bottles where a change in labels is required because of the new regulations.

Under section 403(g) of the act, a food is deemed to be misbranded if it purports to be, or is represented as, a food for which a definition and standard of identity has been prescribed by regulation unless it conforms to such definition and standard, and its label bears the name of the food specified in the

definition and standard. Thus, all bottled water labels must bear appropriate labeling in conformance with an effective standard of identity.

FDA recognizes that some bottled water labels will have to be modified to comply with the standard of identity for bottled water, even though the definitions are based on current meanings of terms. The agency has provided for additional nomenclature (e.g., "drinking water") in this final rule, and as a result, many label changes that the comment may have anticipated will not be required.

However, FDA realizes that it may be a hardship for some firms to make required label changes on reusable polycarbonate silk-screened bottles because these bottles are used for years before replacement, and replacement of an entire stock would be burdensome by the effective date of this final rule. Therefore, the agency is allowing an alternative means of compliance whereby the labeling information required by the standard of identity that is otherwise required on reusable polycarbonate silk-screened bottles may be placed on the customer invoice or bill of lading that is provided with each delivery. This alternative means of compliance is provided in lieu of having the labeling information required by the standard of identity permanently affixed to an existing bottle as otherwise required by section 201(k) of the act. This alternative means of compliance only applies to information on the polycarbonate silk-screened bottles and does not apply to information on the bottle cap.

The special labeling provision is provided for currently existing containers. As a firm replaces the polycarbonate silk-screened bottles presently in use with new ones, the required information must be permanently affixed to the new bottles. To fulfill the intent of the act, all labeling on the invoice or bill of lading must be in compliance with FDA requirements. The agency notes that this alternative means of compliance is consistent with that established for nutrition labeling under § 101.9(g)(9).

X. REFERENCES

The following information has been placed on display in the Dockets Management Branch (address above), and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

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25. Committee on State Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, "Food Labeling: Toward National Uniformity," National Academy Press, Washington DC, 1992.

List of Subjects

21 CFR Part 103

Beverages, Bottled water, Food grades and standards.

21 CFR Part 129

Beverages, Bottled water, Food packaging, Reporting and recordkeeping requirements.

21 CFR Part 165

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter I is amended as follows:

PART 103--QUALITY STANDARDS FOR FOODS
WITH NO IDENTITY STANDARDS

1. The authority citation for 21 CFR part 103 continues to read as follows:

AUTHORITY: Secs. 201, 401, 403, 409, 410, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 349, 371, 379e).

Subpart B-- [Reserved]

2. Subpart B, consisting of § 103.35 Bottled water, is removed and reserved.

PART 129--PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

3. The authority citation for 21 CFR part 129 continues to read as follows:

AUTHORITY: Secs. 402, 409, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 348, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

4. Section 129.35 is amended by revising paragraphs (a)(3)(ii) and (a)(3)(iii) and by adding new paragraph (a)(4) to read as follows:

§ 129.35 Sanitary facilities.

* * * * *

(a) * * *

(3) * * *

(ii) Test and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum requirements set forth in § 165.110(b) of this chapter.

(iii) Analysis of the sample may be performed for the plant by competent commercial laboratories (e.g., Environmental Protection Agency- (EPA) and State-certified laboratories).

* * * * *

(4) Source water testing exemptions. (i) Firms that use a public water system for source water may substitute public water system testing results, or certificates showing full compliance with all provisions of EPA National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants (40 CFR parts 141 and 143), for the testing requirements of § 129.35(a)(3).

(ii) Firms that do not use a public water system as the source of their water may reduce the frequency of their testing of that source, as well as the number of chemical contaminants for which they test the source water, if they can document that such reduction is consistent with a State-issued waiver under EPA regulations (40 CFR parts 141 and 143).

(iii) The finished bottled water must comply with bottled water quality standards (21 CFR 165.110(b)) and section 402(a)(1) of the act dealing with adulterated foods.

* * * * *

5. Section 129.80 is amended by revising the introductory text of paragraph (g) to read as follows:

§ 129.80 Processes and controls.

* * * * *

(g) Compliance procedures. A quality standard for bottled drinking water is established in § 165.110(b) of this chapter. To assure that the plant's production of bottled drinking water complies with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction, the plant will analyze product samples as follows:

* * * * *

6. New part 165 is added to read as follows:

PART 165--BEVERAGES

Subpart A--General Provisions

Sec.

165.3 Definitions.

Subpart B--Requirements for Specific Standardized Beverages

165.110 Bottled water.

AUTHORITY: Secs. 201, 401, 403, 403A, 409, 410, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 343A, 348, 349, 371, 379e).

Subpart A--General Provisions

§ 165.3 Definitions.

(a) A lot is:

(1) For purposes of determining quality factors related to manufacture, processing, or packing, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible and usually designated by a common container code or marking, or in the

absence of any common container code or marking, a day's production.

(2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.

(b) A sample consists of 10 subsamples (consumer units), one taken from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific standard in this part.

(c) An analytical unit is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.

Subpart B--Requirements for Specific Standardized Beverages
§ 165.110 Bottled water.

(a) Identity--(1) Description. Bottled water is water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Fluoride may be optionally added within the limitations established in § 165.110(b)(4)(ii). Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). It does not include those food ingredients that are declared in ingredient labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "sparkling water," and "tonic water." The

processing and bottling of bottled water shall comply with applicable regulations in part 129 of this chapter.

(2) Nomenclature. The name of the food is "bottled water," "drinking water," or alternatively one or more of the following terms as appropriate:

(i) The name of water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer is "artesian water" or "artesian well water." Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to appropriate regulatory officials that the water level stands at some height above the top of the aquifer.

(ii) The name of water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure is "ground water." Ground water must not be under the direct influence of surface water as defined in 40 CFR 141.2.

(iii) The name of water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source, may be "mineral water." Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, due account being taken of the

cycles of natural fluctuations. No minerals may be added to this water.

(iv) The name of water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition of "purified water" in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 551(a) and 1 CFR part 51. (Copies may be obtained from the United States Pharmacopial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC), may be "purified water" or "demineralized water." Alternatively, the water may be called "deionized water" if the water has been processed by deionization, "distilled water" if it is produced by distillation, "reverse osmosis water" if the water has been processed by reverse osmosis, and "_____ drinking water" with the blank being filled in with one of the defined terms describing the water in this paragraph (e.g., "purified drinking water" or "deionized drinking water").

(v) The name of water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at emergence from the source may be "sparkling bottled water."

(vi) The name of water derived from an underground formation from which water flows naturally to the surface of the

earth may be "spring water." Spring water shall be collected only at the spring or through a bore hole tapping the underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified. Spring water collected with the use of an external force shall be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the bore hole and the natural spring, and shall have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring's natural orifice. Plants shall demonstrate, on request, to appropriate regulatory officials, using a hydrogeologically valid method, that an appropriate hydraulic connection exists between the natural orifice of the spring and the bore hole.

(vii) The name of water that meets the requirements under "Sterility Tests" <71> in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR 51. (Copies may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC, or at the Office of the Federal Register,

800 North Capitol St. NW., suite 700, Washington, DC), may be "sterile water." Alternatively, the water may be called "sterilized water."

(viii) The name of water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer may be "well water."

(3) Other label statements. (i) If the TDS content of mineral water is below 500 ppm, or if it is greater than 1,500 ppm, the statement "low mineral content" or the statement "high mineral content", respectively, shall appear on the principal display panel following the statement of identity in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch. If the TDS of mineral water is between 500 and 1,500 ppm, no additional statement need appear.

(ii) When bottled water comes from a community water system, as defined in 40 CFR 141.2, except when it has been treated to meet the definitions in paragraphs (a)(2)(iv) and (a)(2)(vii) of this section and is labeled as such, the label shall state "from a community water system" or, alternatively, "from a municipal source" as appropriate, on the principal display panel or panels. This statement shall immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, other than statements required by paragraph (c) of this section, in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch.

(iii) When the label or labeling of a bottled water product states or implies (e.g., through label statements or vignettes with references to infants) that the bottled water is for use in feeding infants, and the product is not commercially sterile under § 113.3(e)(3)(i) of this chapter, the product's label shall bear conspicuously and on the principal display panel the statement "Not sterile. Use as directed by physician or by labeling directions for use of infant formula."

(4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) Quality. The standard of quality for bottled water, including water for use as an ingredient in beverages (except those described in the labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "sparkling water," and "tonic water"), is as follows:

(1) Definitions. (i) Trihalomethane (THM) means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

(ii) Total trihalomethane (TTHM) means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane, dibromochloromethane, bromodichloromethane and tribromomethane), rounded to two significant figures.

(2) Microbiological quality. Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), American Public Health Association, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (copies may be obtained from the American Public Health Association, 1015 15th St. NW., Washington, DC 20005, or a copy may be examined at the Office of the FEDERAL REGISTER, 800 North Capitol St. NW., suite 700, Washington, DC, or at the Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC), meet the following standards of microbiological quality:

(i) Multiple-tube fermentation method. Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or

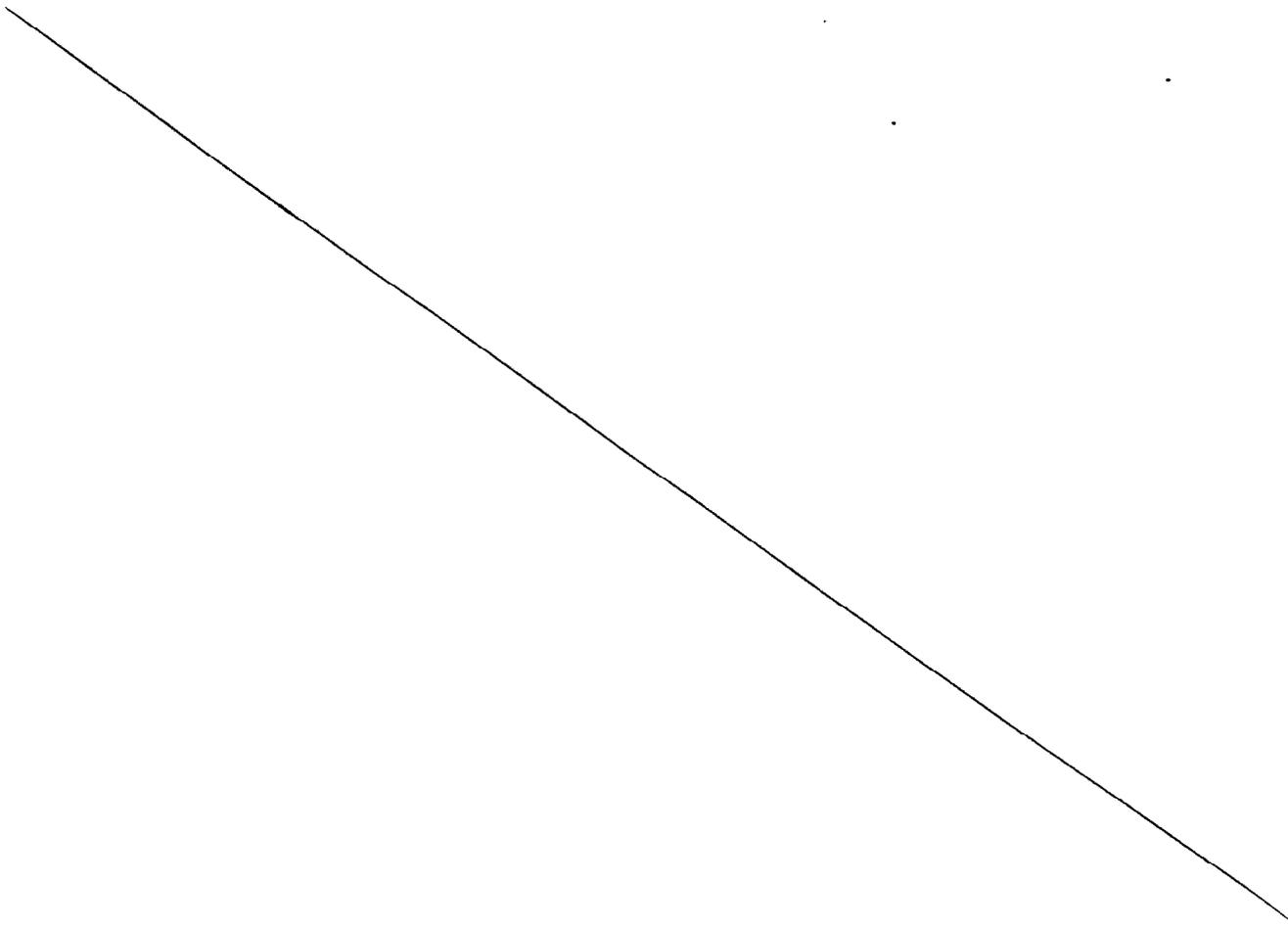
(ii) Membrane filter method. Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.

(3) Physical quality. Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), which is incorporated by reference (the availability of this incorporation by reference is given in

paragraph (b) (2) of this section), meet the following standards of physical quality:

- i) The turbidity shall not exceed 5 units.
- ii) The color shall not exceed 15 units.
- iii) The odor shall not exceed threshold odor No. 3.

(4) Chemical quality. (i) (A) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b) (4) (i) (B) of this section, meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:



SUBSTANCE	CONCENTRATION IN MILLIGRAMS PER LITER
Arsenic.....	0.05
Chloride.....	250.0
Iron.....	0.3
Manganese.....	0.05
Phenols.....	0.001
Sulfate.....	250.0
Total dissolved solids.....	500.0
Zinc.....	5.0
Organics:	
Endrin (1,2,3,4,10,10-hexachloro-6,7-epoxy- 1,4,4a,5,6,7,8,8a-octa-hydro-1,4-endo, endo-5,8-dimethane naphthalene).....	0.0002
Total Trihalomethanes.....	0.10

Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(B) Analyses conducted to determine compliance with paragraph (b)(4)(i)(A) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), or "Methods for Chemical Analysis of Water and Wastes," Environmental Monitoring and Support Laboratory (EMSL), EPA-600/4-79-020, March 1983, U.S. Environmental Protection Agency (EPA), both of which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(C) Analyses for organic substances shall be determined by the appropriate methods set forth below. The methods in paragraphs (b)(4)(i)(C)(1) and (C)(2) of this section are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and are described in "Standard Methods for Examination of Water and Wastewater," 15th Ed. (1980). Copies may be obtained from the American Public Health Association, 1015 Fifteenth St. NW., Washington DC 20005, and examined at the Office of the Federal Register 800 North Capitol St. NW., suite 700, Washington DC, or the Center for Food Safety and Applied Nutrition, 200 C St. NW., Washington DC. The methods in paragraphs (b)(4)(i)(C)(3) and (C)(4) are cross-referenced in 40 CFR part 141, subpart C, Appendix C.

(1) "Methods for Organochlorine Pesticides in Industrial Effluents;"

(2) "Methods for Chlorinated Phenoxy Acid Herbicides in Industrial Effluents," November 28, 1973;

(3) "Part I: The Analysis of Trihalomethanes in Finished Waters by the Purge and Trap Method;" which is cross-referenced in 40 CFR part 141, Subpart C, Appendix C;

(4) "Part II: The Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction," Method 501.2 which is cross-referenced in 40 CFR part 141, Subpart C Appendix C;

(ii) (A) Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

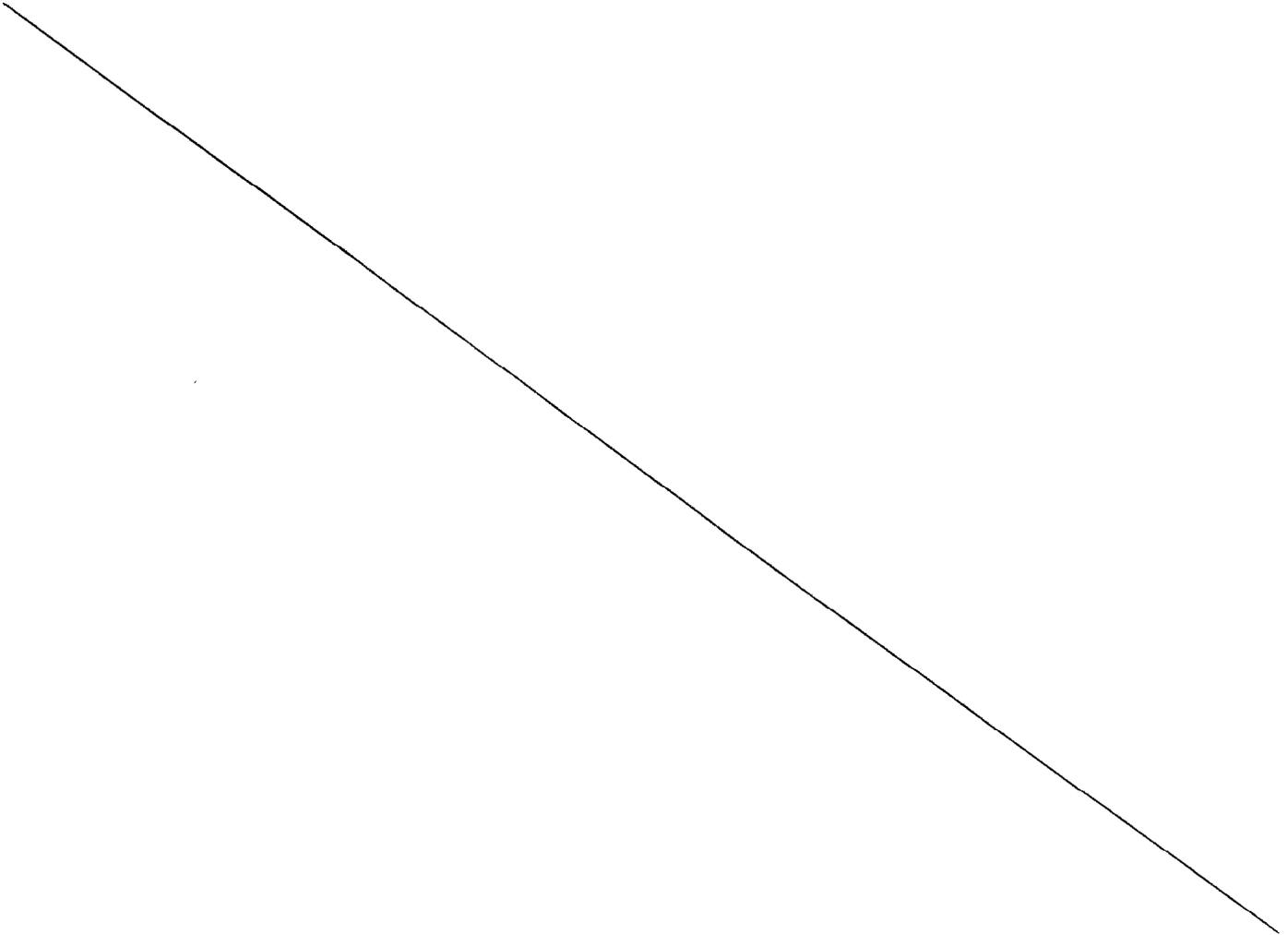


TABLE 1

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below.....	2.4
53.8-58.3.....	2.2
58.4-63.8.....	2.0
63.9-70.6.....	1.8
70.7-79.2.....	1.6
79.3-90.5.....	1.4

(B) Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

(C) Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 2

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below.....	1.7
53.8-58.3.....	1.5
58.4-63.8.....	1.3
63.9-70.6.....	1.2
70.7-79.2.....	1.0
79.3-90.5.....	0.8

(D) Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

(iii) Having consulted with EPA as required by section 410 of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has determined that bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraphs (b)(4)(iii)(E) through (b)(4)(iii)(F), and (b)(4)(iii)(G) of this section, shall not contain the following chemical contaminants in excess of the concentrations specified in paragraphs (b)(4)(iii)(A) through (b)(4)(iii)(D) of this section.

(A) The allowable levels for inorganic substances are as follows:

Contaminant	Concentration milligrams per liter (or as specified)
Barium.....	2
Cadmium.....	0.005
Chromium.....	0.1
Copper.....	1.0
Lead.....	0.005
Mercury.....	0.002
Nitrate.....	10 (as nitrogen)
Nitrite.....	1 (as nitrogen)

Total Nitrate and Ni-	
trite.....	10 (as nitrogen)
Selenium.....	0.05

(B) The allowable levels for volatile organic chemicals (VOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Benzene (71-43-2).....	0.005
Carbon tetrachloride (56-23-5)....	0.005
<u>o</u> -Dichlorobenzene (95-50-1).....	0.6
<u>p</u> -Dichlorobenzene (106-46-7).....	0.075
1,2-Dichloroethane (107-06-2)....	0.005
1,1-Dichloroethylene (75-35-4)....	0.007
<u>cis</u> -1,2-Dichloroethylene (156-59- 2).....	0.07
<u>trans</u> -1,2-Dichloroethylene (156- 60-5).....	0.1
1,2-Dichloropropane (78-87-5)....	0.005
Ethylbenzene (100-41-4).....	0.7
Monochlorobenzene (108-90-7).....	0.1
Styrene (100-42-5).....	0.1
Tetrachloroethylene (127-18-4)....	0.005
Toluene (108-88-3).....	1

1,1,1-Trichloroethane (71-55-6)...	0.20
Trichloroethylene (79-01-6).....	0.005
Vinyl chloride (75-01-4).....	0.002
Xylenes (1330-20-7).....	10

(C) The allowable levels for pesticides and other synthetic organic chemicals (SOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Alachlor (15972-60-8).....	0.002
Atrazine (1912-24-9).....	0.003
Carbofuran (1563-66-2).....	0.04
Chlordane (57-74-9).....	0.002
1,2-Dibromo-3-chloropropane (96-12-8).....	0.0002
2,4-D (94-75-7).....	0.07
Ethylene dibromide (106-93-4).....	0.00005
Heptachlor (76-44-8).....	0.0004
Heptachlor epoxide (1024-57-3).....	0.0002
Lindane (58-89-9).....	0.0002
Methoxychlor (72-43-5).....	0.04
Pentachlorophenol (87-86-5).....	0.001
PCB's (as decachlorobiphenyl) (1336-36-3)..	0.0005
Toxaphene (8001-35-2).....	0.003
2,4,5-TP (Silvex) (93-72-1).....	0.05

(D) The allowable levels for certain chemicals for which EPA has established secondary maximum contaminant levels in its drinking water regulations (40 CFR part 143) are as follows:

Contaminant	Concentration in milligrams per liter
Aluminum	0.2
Silver	0.1

(E) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(A) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(E)(1) through (b)(4)(iii)(E)(13) of this section and described, unless otherwise noted, in "Methods for Chemical Analysis of Water and Wastes," U.S. EPA, Environmental Monitoring and Support Laboratory (EPA-600/4-79-020), March 1983, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Office of Plant and Dairy Foods and Beverages (HFS-305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office

of the FEDERAL REGISTER, 800 North Capitol St. NW., suite 700, Washington, DC.

(1) [Reserved]

(2) Barium shall be measured using the following methods:

(i) Method 208.2--"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 208.1--"Atomic Absorption; direct aspiration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(A) of this section.

(iii) Method 200.7--"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Office of Plant and Dairy Foods and Beverages (HFS-305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW.,

Washington, DC, or at the Office of the FEDERAL REGISTER, 800 North Capitol St. NW., suite 700, Washington, DC.

(3) [Reserved]

(4) Cadmium shall be measured using the following methods:

(i) Method 213.2--"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(ii) Method 200.7--"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(2)(iii) of this section.

(5) Chromium shall be measured using the following methods:

(i) Method 218.2--"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(ii) Method 200.7--"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic

Emission Spectrometry," Rev. 3.3, April 1991. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(iii) of this section.

(6) Copper shall be measured as total recoverable metal without filtration using the following methods:

(i) Method 220.2--Atomic Absorption; furnace technique, in "Methods for Chemical Analysis of Water and Wastes," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 220.1--Atomic Absorption; direct aspiration, in "Methods for Chemical Analysis of Water and Wastes," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(iii) Method 200.7--"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, (EPA/600/4-91/010), June 1991, which is

incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Office of Plant and Dairy Foods and Beverages (HFS-305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or at the Office of the FEDERAL REGISTER, 800 North Capitol St. NW., suite 700, Washington, DC.

(iv) Method 200.8--"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(7)(iii) of this section.

(v) Method 200.9--"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Revision 1.2, April 1991. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation

by reference is given in paragraph (b) (4) (iii) (E) (2) (iii) of this section.

(7) [Reserved]

(8) Lead shall be measured as total recoverable metal without filtration using the following methods:

(i) Method 239.2--Atomic Absorption; furnace technique, in "Methods for Chemical Analysis of Water and Wastes," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b) (4) (iii) (E) (2) (iii) of this section.

(ii) Method 200.8--"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Revision 4.4, April 1991. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b) (4) (iii) (E) (7) (iii) of this section.

(iii) Method 200.9--"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The availability of this incorporation by reference is given in paragraph (b) (4) (iii) (E) (2 iii) of this section.

(9) Mercury shall be measured using the following methods:

(i) Method 245.1--"Manual cold vapor technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 245.2--"Automated cold vapor technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b) (4) (iii) (E) of this section.

(10) [Reserved]

(11) Nitrate and/or nitrite shall be measured using the following methods:

(i) Method 353.3--"Spectrophotometric cadmium reduction," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 353.2--"Colorimetric, automated, cadmium reduction," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(iii) Method 300.0--"The Determination of Inorganic Anions in Water by Ion chromatography," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, Port Royal Rd., Springfield, VA 22161, or may be examined at the Office of Plant and Dairy Foods and Beverages (HFS-305), Center for Food Safety and Applied

Nutrition, Food and Drug Administration, 200 C St. SW.,
Washington, DC.

(iv) Method 353.1--"Colorimetric, automated, hydrazine reduction," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(12) Selenium shall be measured using the following methods:

(i) Method 270.2--"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 270.3--"Atomic Absorption; gaseous hydride," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(13) [Reserved]

(F) Analyses to determine compliance with the requirements of paragraphs (b)(4)(iii)(B) and (b)(4)(iii)(C) of this section shall be conducted in accordance with an applicable method or applicable revisions to the methods listed in paragraphs (b)(4)(iii)(F)(1) through (b)(4)(iii)(F)(20) of this section and described, unless otherwise noted, in "Methods for the Determination of Organic Compounds in Drinking Water," Office of Research and Development, Environmental Monitoring Systems

Laboratory EPA/600/4-88/039, December 1988, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Office of Plant and Dairy Foods and Beverages (HFS-305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the FEDERAL REGISTER, 800 North Capitol St. NW., suite 700, Washington, DC.

(1) Method 502.1--"Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography," Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(2) Method 502.2--"Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series," Rev. 2.0, 1989 (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(3) Method 503.1--"Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography," Rev. 2.0, 1989 (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(4) Method 524.1--"Measurement of Purgeable Organic Compounds in Water by Packed Column Gas Chromatography/Mass

Spectrometry," Rev. 3.0, 1989 (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(5) Method 524.2--"Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry," Rev. 3.0, 1989 (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(6) Method 504--"1,2-Dibromoethane (EDB) and 1,2-Dibromo-3-Chloropropane (DBCP) in Water by Microextraction and Gas Chromatography," Rev. 2.0, 1989 (applicable to dibromochloropropane (DBCP) and ethylene dibromide (EDB)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(7) Method 505--"Analysis of Organohalide Pesticides and Commercial Polychlorinated Biphenyl (PCB) Products in Water by Micro-Extraction and Gas Chromatography," Rev. 2.0, 1989 (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene and as a screen for polychlorinated biphenyl's (PCB's)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(8) [Reserved]

(9) Method 507--"Determination of Nitrogen- and Phosphorus-Containing Pesticides in Water by Gas Chromatography with a Nitrogen-Phosphorus Detector," Rev. 2.0, 1989 (applicable to

alachlor and atrazine), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(10) Method 508--"Determination of Chlorinated Pesticides in Water by Gas Chromatography with an Electron Capture Detector," Rev. 3.0, 1989 (applicable to chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, and as a screen for PCB's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(11) Method 508A--"Screening for Polychlorinated Biphenyls by Perchlorination and Gas Chromatography," Rev. 1.0, 1989 (used to quantitate PCB's as decachlorobiphenyl if detected in methods 505 or 508) in paragraph (b)(4)(iii)(F)(7) or (b)(4)(iii)(F)(9) of this section, respectively), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(12) Method 515.1--"Determination of Chlorinated Acids in Water by Gas Chromatography with an Electron Capture Detector," Rev. 5.0, May 1991 (applicable to 2,4-D, 2,4,5-TP (Silvex) and pentachlorophenol), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(13) Method 525.1--"Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry," Rev. 2.2, May 1991 (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, and

pentachlorophenol), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(14) Method 531.1--"Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Water by Direct Aqueous Injection HPLC with Post Column Derivatization," Rev. 3.0, 1989 (applicable to carbofuran , which is incorporated by reference in accordance with 5 U.S.C. 552(a), and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(F) of this section.

(15) [Reserved]

(G) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(D) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(G)(1) and (b)(4)(iii)(G)(2) of this section and described, unless otherwise noted, in "Methods of Chemical Analysis of Water and Wastes," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(1) Aluminum shall be measured using the following methods:

(i) Method 202.1--"Atomic Absorption; direct aspiration technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(ii) Method 202.2--"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C.

552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(iii) Method 200.7--"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, The revision is contained in "Methods for the Determination of Metals in Environmental Samples," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of the incorporation by reference is given in paragraph (b)(4)(iii)(E)(2)(iii) of this section.

(iv) Method 200.8--"Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, The revision is contained in "Methods for the Determination of Metals in Environmental Samples," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(iii) of this section.

(v) Method 200.9--"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption, Spectrometry," Rev. 1.2, April 1991, The revision is contained in "Methods for the Determination of Metals in Environmental Samples," June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The

availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(7)(iii) of this section.

(2) Silver shall be measured using the following methods:

(i) Method 272.1--"Atomic Absorption, direct aspiration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 272.2--"Atomic Absorption, furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(iii) Method 200.7--"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, The revision is contained in "Methods for the Determination of Metals in Environmental Samples," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(iii) of this section.

(iv) Method 200.8--"Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, The revision is contained in "Methods for the Determination of Metals in Environmental Samples," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this

incorporation by reference is given in paragraph (b) (4) (iii) (E) (1) (iii) of this section.

(v) Method 200.9--"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption, Spectrometry," Rev. 1.2, April 1991, in "Methods for the Determination of Metals in Environmental Samples," which is incorporated by reference in accordance with 5. U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b) (4) (iii) (E) (1) (iii) of this section.

(3) and (4) [Reserved]

(5) Radiological quality. (i) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b) (5) (ii) of this section, meet standards of radiological quality as follows:

(A) The bottled water shall not contain a combined radium-226 and radium-228 activity in excess of 5 picocuries per liter of water.

(B) The bottled water shall not contain a gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water.

(C) The bottled water shall not contain beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or

more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year.

(ii) Analyses conducted to determine compliance with paragraph (b)(5)(i) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), and "Interim Radiochemical Methodology for Drinking Water," U.S. EPA, EMSL, EPA-600/4-75-008 (Revised), March 1976, both of which are incorporated by reference. The availability of these incorporations by reference is given in paragraph (b)(2) of this section.

(c) Label statements. When the microbiological, physical, chemical, or radiological quality of bottled water is below that prescribed by paragraphs (b)(2) through (b)(5), of this section, the label shall bear the statement of substandard quality specified in § 130.14(a) of this chapter except that, as appropriate, instead of or in addition to the statement specified in § 130.14(a) the following statement(s) shall be used:

(1) "Contains Excessive Bacteria" if the bottled water fails to meet the requirements of paragraph (b)(2) of this section.

(2) "Excessively Turbid", "Abnormal Color", and/or "Abnormal Odor" if the bottled water fails to meet the requirements of paragraph (b)(3)(i), (ii), or (iii), respectively, of this section.

(3) "Contains Excessive _____," with the blank filled in with the name of the chemical for which a maximum contaminant level in paragraph (b)(4) of this section is exceeded (e.g., "Contains Excessive Arsenic," "Contains Excessive Trihalomethanes") except that "Contains Excessive Chemical Substances" may be used if the bottled water is not mineral water.

(4) "Excessively Radioactive" if the bottled water fails to meet the requirements of paragraph (b)(5) of this section.

(d) Adulteration. Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) of this section.

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED
AS GENERALLY RECOGNIZED AS SAFE

7. The authority citation for 21 CFR part 184 continues to read as follows:

AUTHORITY: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

8. Section 184.1563 is amended by revising paragraph (c) to read as follows:

§ 184.1563 Ozone.

* * * * *

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Category of food	Maximum treatment level in food	Functional use
Bottled water that prior to ozonation meets the microbiological, physical, chemical, and radiological quality standards of § 165.110(b)(2) through (b)(5) of this chapter.	Not to exceed current good manufacturing practice. Current good manufacturing practice results in a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water.	Antimicrobial agent, § 170.3 (o)(2) of this chapter.

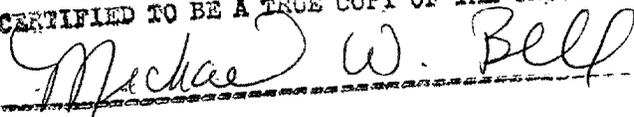
Dated:

November 3, 1995

November 3, 1995



William K. Hubbard
Acting Deputy Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

 Michael W. Bell