Dated: March 6, 2001.

Charles W. Winwood,

Acting Commissioner of Customs.

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 01–7603 Filed 3–27–01; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 129 and 165

[Docket No. 01N–0126]

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its bottled water quality standard regulations by establishing allowable levels for three residual disinfectants (chloramine, chlorine, and chlorine dioxide) and three types of disinfection byproducts (DBP's) (bromate, chlorite, and haloacetic acids (HAA5)). FDA also is revising the existing allowable level for the DBP total trihalomethanes (TTHM). Finally, FDA is revising, for the three residual disinfectants and four types of DBP's only, the monitoring requirement for source water found in the current good manufacturing practice (CGMP) regulations for bottled water. As a consequence of FDA's amending the quality standard for these residual disinfectants and DBP's, bottled water manufacturers are required to monitor their finished bottled water products for these disinfectants and DBP's at least once each year under the CGMP regulations for bottled water. Bottled water manufacturers also are required to monitor for these contaminants at least once each year in their source water, unless the bottlers meet the criteria for source water monitoring exemptions under the CGMP regulations. This direct final rule will ensure that the minimum quality of bottled water, as affected by the previously mentioned disinfectants and DBP's, remains comparable with the quality of public drinking water that meets the Environmental Protection Agency's (EPA's) standards. FDA is issuing a direct final rule for this action because the agency expects that there will be no significant adverse comment on this rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under the agency's usual procedure for notice-and-comment rulemaking to provide a procedural framework to finalize the rule in the event the agency receives significant adverse comment and withdraws this direct final rule. The companion proposed rule and direct final rule are substantively identical.

DATES: This rule is effective January 1, 2002. Submit written comments by June 11, 2001. If FDA receives no significant adverse comments during the specified comment period, the agency will publish a document in the **Federal Register** no later than July 5, 2001, confirming the effective date of the direct final rule. If the agency receives any significant adverse comment during the comment period, FDA intends to withdraw this direct final rule by publication in the **Federal Register** no later than July 5, 2001. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR 51 of certain publications in § 165.110(b)(4)(iii)(I) as of January 1, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–358–3568.

SUPPLEMENTARY INFORMATION:

I. Background

On December 16, 1998, EPA published the Stage 1 Disinfection Byproducts Rule (Stage I DBPR) (63 FR 69390) to address potential public health effects from the presence of disinfectants and DBP's in drinking water. This rulemaking finalized a proposed rule that EPA published in the **Federal Register** on July 29, 1994 (59 FR 38668).

Disinfectants are chemicals, such as chlorine and ozone, that are added to drinking water to control microbial contamination. Both bottlers and public water systems may use disinfectants. Public water systems typically add disinfectants to drinking water at levels sufficient to maintain a disinfectant residual throughout the distribution system (i.e., the system of pipes that takes water from water treatment plants to customers). DBP's are chemicals that result from the unintentional interaction of the disinfectants with inorganic or organic compounds present in the water supply. Examples of DBP's include chloroform (a byproduct of treatment with chlorine) and bromate (a byproduct of ozonation). Both disinfectants and DBP's can have adverse health effects (59 FR 38668 at 38679–38710).

National primary drinking water regulations (NPDWR's) are issued by EPA to protect the public health from the adverse effects of contaminants in drinking water. NPDWR's specify maximum contaminant levels (MCL's) or treatment techniques for drinking water contaminants. In addition, at the same time that it issues NPDWR's, EPA publishes maximum contaminant level goals (MCLG's), which are not regulatory requirements but rather are nonenforceable health goals that are based solely on considerations of protecting the public from adverse health effects of drinking water contamination. In its proposed rule on disinfectants and DBP's (59 FR 38668), EPA also introduced the concept of maximum residual disinfectant levels (MRDL's) and maximum residual disinfectant level goals (MRDLG's). MRDL's and MRDLG's are comparable to MCL's and MCLG's, in that they set contaminant levels and health goals, respectively. EPA used the terms MRDL and MRDLG for disinfectants, rather than using the terms MCL and MCLG, to reflect the fact that disinfectants have beneficial properties (63 FR 69390 at 69398; 59 FR 38668 at 38672, 38679).

In the Stage I DBPR (63 FR 69390), EPA issued NPDWR's consisting of MCL's for the DBP's bromate, chlorite, HAA5, and TTHM. EPA also published MRDL's for the chlorine-based disinfectants chlorine, chloramine, and chlorine dioxide. Finally, EPA published MCLG's and MRDLG's for these contaminants, as well as approved methods of testing for these contaminants.

Under section 410 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349), not later than 180 days before the effective date of an NPDWR issued by EPA for a contaminant under section 1412 of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300g-l),[1] FDA is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems but not in water

[1]FDA considers EPA's compliance date for subpart H public water systems (systems using surface water or ground water under the direct influence of surface water) that serve a population of 10,000 or more to be the effective date for purposes of section 410 of the act. The compliance date was set at December 16, 2001, in the Stage I DBPR (63 FR 69390) and updated in a subsequent rule to January 1, 2002 (65 FR 20303, April 14, 2000).

used for bottled drinking water. The effective date for any such standard of quality regulation is to be the same as the effective date of the NPDWR. In addition, section 410(b)(2) of the act provides that a quality standard regulation issued by FDA shall include monitoring requirements that the agency determines to be appropriate for bottled water. Further, section 410(b)(3) of the act requires a quality standard regulation for a contaminant in bottled water to be no less stringent than EPA's MCL and no less protective of the public health than EPA's treatment technique requirements for the same contaminant.

II. Direct Final Rulemaking

FDA has determined that the subjects of this rulemaking are suitable for a direct final rule. The actions taken should be noncontroversial and the agency does not anticipate receiving any significant adverse comment.

FDA is adopting EPA's MCL's for bromate, chlorite, HAA5, and TTHM and EPA's MRDL's for chloramine, chlorine, and chlorine dioxide as allowable levels for these contaminants in the quality standard regulation for bottled water. FDA also is adopting, for these contaminants in bottled water, the analytical methods that EPA approved for monitoring these contaminants in public drinking water. Finally, FDA is adding an exemption to source water testing, under the newly added § 129.35(a)(4)(iii), for the three residual disinfectants and four types of DBP's. Bottled water manufacturers are required to monitor for contaminants at least once each year in their source water unless the bottlers meet the criteria for source water monitoring exemptions under the CGMP regulations. Under the newly added § 129.35(a)(4)(iii), FDA will not require bottled water manufacturers to test under § 129.35(a)(3)(i) their source water for the residual disinfectants and DBP's listed in § 165.110(b)(4)(iii)(H), if their source water is not from a public water system and has not been treated with a chlorine-based disinfectant or ozone. However, bottled water manufacturers whose nonpublic source drinking water has been treated with a chlorine-based disinfectant or ozone must test, consistent with 129.35(a)(3)(i), their source water for the residual disinfectants and the DBP's listed in § 165.110(b)(4)(iii)(H) that are likely to result from such treatment. Under § 129.35(a)(3)(i), bottled water manufacturers who use a public water system are required to test their source water for these residual disinfectants and DBP's at a minimum frequency of once each year, unless they meet the requirements in § 129.35(a)(4)(i).

As a consequence of FDA's amending the quality standard for these residual disinfectants and DBP's in part 165 (21 CFR part 165), bottled water manufacturers are required to monitor their finished water bottled products for these disinfectants and DBP's at least once each year under the CGMP regulations for bottled water in part 129 (21 CFR part 129).

If FDA does not receive significant adverse comment on or before June 11, 2001, the agency will publish a notice in the **Federal Register** no later than July 5, 2001, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective January 1, 2002.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or why it would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. A comment recommending a change to the rule that is in addition to the rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of the rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment. If timely significant adverse comments are received, the agency will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule no later than July 5, 2001.

The companion proposed rule, which is in essence identical to the direct final rule, provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments on the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule and the agency will consider the comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. EPA Standards

The SDWA, as amended in 1996, requires EPA to publish an NPDWR that specifies either an MCL or a treatment technique requirement for contaminants that may ''have an adverse effect on the health of persons,'' are ''known to occur or [have] a substantial likelihood [of occurring] in public water systems with a frequency and at levels of public health concern,'' and for which ''regulation * * * presents a meaningful opportunity for health risk reduction for persons served by public water systems '' (SDWA Section 1412(b)(1)(A)). The SDWA (Section 300g-1(a)(3)) also requires that EPA promulgate MCLG's at the time that it promulgates NPDWR's. MCLG's are nonenforceable health goals that are based solely on considerations of protecting the public from the adverse health effects of contaminants, and not on other considerations, such as potential costs of regulating contaminants and potential technical difficulties of achieving the health goals (59 FR 38668 at 38671). EPA sets MCL's, the enforceable contaminant levels, as close as feasible to the nonenforceable MCLG's.

In its proposed rule on disinfectants and DBP's (59 FR 38668), EPA also introduced the concept of MRDL's and MRDLG's. MRDL's and MRDLG's are comparable to MCL's and MCLG's, in that they set contaminant levels and health goals. EPA used the terms MRDL and MRDLG for disinfectants, rather than using the terms MCL and MCLG, to reflect the fact that disinfectants have beneficial properties and are intentionally added to drinking water to kill disease-causing organisms (63 FR 69390 at 69398; 59 FR 38668 at 38672, 38679).

In the Stage I DBPR (63 FR 69390 at 69396), EPA established an MCL of 0.060 milligram per liter (mg/L) for the total of the five haloacetic acids that make up HAA5 (i.e., mono-, di-, and trichloroacetic acid, and mono- and dibromoacetic acid). EPA also reduced the existing MCL for TTHM from 0.10 mg/L to 0.080 mg/L (63 FR 69390 at 69396). EPA also established MCL's for two inorganic DBP's: 0.010 mg/L for

bromate and 1.0 mg/L for chlorite (63 FR 69390 at 69396). Finally, EPA established MRDL's for three disinfectants: 4.0 mg/L (as Cl_2) for chlorine, 4.0 mg/L (as Cl_2) for chloramine, and 0.8 mg/L (as ClO_2) for chlorine dioxide (63 FR 69390 at 69396).

IV. FDA Standards

A. The Agency's Approach to the Bottled Water Quality Standards Established Under Section 410 of the Act.

Under section 401 of the act (21 U.S.C. 341), the agency may issue a regulation establishing a standard of quality for a food under its common or usual name, when in the judgment of the Secretary of Health and Human Services such action will promote honesty and fair dealing in the interest of consumers. On November 26, 1973 (38 FR 32558), FDA established a quality standard for bottled water that is set forth in § 165.110 (21 CFR 165.110).

Producers of bottled water are responsible for assuring, through appropriate manufacturing techniques and sufficient quality control procedures, that all bottled water products introduced or delivered for introduction into interstate commerce comply with the quality standard (§ 165.110(b)). Bottled water that is of a quality that is below the prescribed standard is required by § 165.110(c) to be labeled with a statement of substandard quality. Moreover, any bottled water containing a substance at a level that causes the food to be adulterated under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) is subject to regulatory action, even if the bottled water bears a label statement of substandard quality.

FDA has traditionally fulfilled its obligation under section 410 of the act to respond to EPA's issuance of NPDWR's by amending the quality standard regulations for bottled water introduced or delivered for introduction into interstate commerce to maintain compatibility with EPA's drinking water regulations. In general, FDA believes that, with few exceptions, EPA standards for contaminants in drinking water are appropriate as allowable levels for contaminants in the quality standard for bottled water when bottled water may be expected to contain the same contaminants.

FDA generally has not duplicated the efforts of EPA in judging the adequacy of MCL's or treatment techniques in NPDWR's for contaminants when determining their applicability to bottled water in order to protect the public health. FDA believes that, in general, it would be redundant for FDA to reevaluate the drinking water standards prescribed by EPA. Further, because bottled water is increasingly used in some households as a replacement for tap water, consumption patterns considered by EPA for tap water can be used as an estimate for the maximum expected consumption of bottled water by some individuals. Therefore, FDA's view is that generally in cases where bottled water is subject to the same contaminants as tap water, FDA should establish standard of quality levels in bottled water at the same levels that EPA establishes as MCL's for such contaminants in tap water.

In its proposed rule on disinfectants and DBP's (59 FR 38668), EPA introduced the term MRDL. As explained in section III of this document, EPA used this term when it first proposed enforceable disinfectant levels (MRDL's) to reflect the fact that disinfectants have beneficial properties. However, disinfectants may have adverse health effects (59 FR 38668 at 38679 to 38694), and they may be expected to be in some source waters used for bottled water. Therefore, FDA is establishing a standard of quality for these disinfectants for bottled water in response to EPA's issuance of NPDWR's for these disinfectants in drinking water.

B. Quality Standard for Disinfectants and DBP's

The quality standard for bottled water, as set forth in § 165.110(b)(4)(i)(A), prescribes that bottled water shall not contain TTHM in excess of 0.10 mg/L. It does not, however, prescribe allowable levels for bromate, chlorite, HAA5, chloramine, chlorine, or chlorine dioxide in bottled water.

FDA has evaluated the MRDL's for chloramine, chlorine, and chlorine dioxide, and the MCL's for bromate, chlorite, HAA5, and TTHM that EPA has established for drinking water. Further, FDA has concluded that EPA's MRDL's and MCL's for these contaminants, as standard of quality levels for bottled water, are adequate for the protection of the public health. Certain waters used for bottled drinking water may be expected to contain these contaminants; thus, adopting allowable levels for these contaminants will ensure that the quality of bottled water is comparable to the quality of public drinking water that meets EPA standards.

Therefore, FDA is establishing in a new paragraph (b)(4)(iii)(H) in § 165.110, allowable levels for the following disinfectants and DBP's: chloramine at 4.0 mg/L (as Cl_2), chlorine at 4.0 mg/L (as Cl_2), chlorine dioxide at 0.8 mg/L (as ClO_2), and bromate at 0.010 mg/L, chlorite at 1.0 mg/L, HAA5 at 0.060 mg/L, and TTHM at 0.080 mg/L. FDA is removing the existing entry for TTHM in § 165.110(b)(4)(i)(A).

C. Analytical Methods

In the Stage 1 DBPR that established MCL's for bromate, chlorite, HAA5, and TTHM and MRDL's for chlorine, chloramine, and chlorine dioxide, EPA stipulated that analyses for determining compliance with the MCL's and MRDL's shall be performed by approved analytical methods (63 FR 69390 at 69466). EPA has approved one method for bromate monitoring, two methods for monthly chlorite monitoring, three methods for HAA5 monitoring, three methods for TTHM monitoring, six methods for chloramine monitoring, seven methods for chlorine monitoring, and two methods for chlorine dioxide monitoring. Therefore, in a new paragraph (b)(4)(iii)(I) in § 165.110, FDA is incorporating by reference the 24 analytical methods cited by the EPA (63 FR 69390 at 69417) for determining the levels of these contaminants in bottled water.

D. Monitoring Provisions of CGMP Regulations for Bottled Water

FDA has established CGMP regulations for bottled water in part 129. Under § 129.35(a)(3)(i), source water must be analyzed by the plant as often as necessary, but at least annually for chemical contaminants. Further, to ensure that a plant's production complies with applicable standards, § 129.80(g)(2) requires analysis by the plant, at least annually, of a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The CGMP regulation in § 129.80(a) also requires sampling and analysis, as often as necessary, of product water taken after processing but before bottling, to assure uniformity and effectiveness of the processes performed by the plant.

Disinfectants and DBP's are special types of contaminants in that they result from the deliberate addition of disinfectants to water to control microbial contamination. Because public water systems add disinfectants to water, FDA expects that source water from public water systems will contain disinfectants and DBP's. Therefore, FDA is requiring bottlers who obtain their source water from public water systems to test that water, as specified in § 129.35(a)(3)(i), for the disinfectants

chloramine, chlorine, and chlorine dioxide, and the DBP's bromate, chlorite, HAA5, and TTHM, unless they meet the requirements contained in § 129.35(a)(4)(i). In some cases, bottlers disinfect source water that is not from public water systems (e.g., prior to bulk transportation of that source water to the bottling plant). Such source water would contain residual disinfectants and also may contain DBP's. Therefore, FDA is adding a new paragraph (a)(4)(iii) in § 129.35, stating that firms that do not use a public water system as the source of their water and whose source water has not been treated with a chlorine-based disinfectant or ozone do not have to test their source water for the residual disinfectants and DBP's listed in § 165.110(b)(4)(iii)(H). Firms that do not use a public water system as the source of their water but whose source water has been treated with a chlorine-based disinfectant or ozone must test their source water for the residual disinfectants and the DBP's listed in § 165.110(b)(4)(iii)(H) that are likely to result from such treatment. Treatment of water with ozone is expected to produce the disinfection byproducts (or components of the disinfection byproducts) bromate, HAA5, and TTHM. Treatment of water with chlorine or chloramine is expected to produce the disinfection byproducts (or components of the disinfection byproducts) HAA5 and TTHM.

However, all bottlers, whether or not they obtain their source water from public or nonpublic drinking water sources and whether or not they treat their water with chlorine, chloramine, chlorine dioxide, or ozone, are required to test for the residual disinfectants chloramine, chlorine, and chlorine dioxide and the DBP's bromate, chlorite, HAA5, and TTHM in their finished bottled water products under § 129.80(g)(2) in the CGMP regulations for bottled water. FDA believes that the potential for the presence of disinfectants and DBP's in the finished bottled water product exists. For example, some manufacturers may treat their water with a disinfectant during processing. Further, contamination of the bottled water product with disinfectants may occur during the manufacturing process, for example, if poor manufacturing practices are followed, such as inadequate rinsing of equipment that has undergone sanitizing operations. Section 129.80(d) in the CGMP regulations for bottled water allows for the use of disinfectants (ozone and chlorine-based disinfectants) for sanitizing operations.

Bottled water must comply with the sampling and testing requirements for disinfectants and DBP's under § 129.80(g)(2). In addition, bottled water must comply with the allowable levels for the disinfectants and DBP's in the quality standard for bottled water (§ 165.110 (b)) unless the label bears a statement of substandard quality under § 165.110(c). As stated in § 165.110(d), bottled water is deemed to be adulterated if it contains a substance at a level considered injurious to health under section 402(a)(1) of the act.

V. Environmental Impact

The agency has determined under 21 CFR 25.32(a) and 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

A. Regulatory Impact Analysis

FDA has examined the economic implications of this direct final rule as required by Executive Order 12866. 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, public safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this direct final rule is not a significant regulatory action as defined by Executive Order 12866.

1. The Need for Regulation

In the **Federal Register** of December 16, 1998 (63 FR 69390), EPA published a final rule issuing NPDWR's consisting of MRDL's for the disinfectants chlorine, chloramine, and chlorine dioxide; and MCL's for the DBP's bromate, chlorite, HAA5, and TTHM. Under section 410 of the act, when EPA issues a regulation establishing an MCL for a contaminant in public drinking water, FDA is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health. FDA's standard of quality regulations must also include appropriate monitoring requirements. If FDA does not issue a standard of quality regulation by 180 days before the effective date of EPA's NPDWR's, the NPDWR's become applicable to bottled water.

In the following analysis, FDA finds that issuing standard of quality regulations and monitoring requirements for these residual disinfectants and DBP's under FDA bottled water CGMP regulations has the highest net benefits. FDA's testing requirements are less costly than the testing requirements under our assumptions of how EPA NPDWR's would apply to bottled water, with the same health benefits, and the health benefits of testing for these contaminants outweigh the cost.

2. Cost of the Regulation

If FDA does not establish a regulation for quality standards for these residual disinfectants and DBP's, bottled water producers would be subject to NPDWR testing and monitoring requirements for these contaminants. Therefore, we consider this possibility the baseline for the purposes of this analysis. Also, we assume that the regulatory options we consider will have no organoleptic effect on the final bottled water product, and thus no impact on sales due to product quality, so the cost of the regulation will be limited to the direct cost of testing, record keeping, and possible disinfection technology investment.

Bottled water producers market their products based on meeting government safety testing requirements. However, any change in sales resulting from successful marketing either transfers revenue from one producer to another with no net loss to society, or causes increased sales of bottled water, which would mitigate the cost of this regulatory effort.

FDA considers three options for this analysis:

(1) FDA does not establish residual disinfectant and DBP quality standard regulations or make a finding that they are not necessary to protect the public health because these contaminants are not used in water used for bottled drinking water. Bottled water producers would be subject to the requirements set forth in the NPDWR's for these contaminants.

(2) FDA establishes residual disinfectant and DBP quality standard regulations. For these contaminants, bottled water producers would be subject to allowable levels in 21 CFR § 165.110 and CGMP monitoring

requirements in part 129, as modified in this direct final rule.

(3) Bottled water producers are not subject to either FDA quality standard regulations or EPA NPDWR's for these residual disinfectants and DBP's.

Regarding option 3, because it is not the case that these contaminants are contained in water used in public drinking water systems, but not in water used for bottled water, section 410(b)(1) of the Federal Food, Drug, and Cosmetic Act does not permit this option. The act specifies two alternatives: ''promulgate a standard of quality regulation under this subsection,'' or find that ''such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems * * * but not in water used for bottled drinking water.''

However, the Office of Management and Budget (OMB) cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that may prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. Our analysis finds that option 3 does not have the highest net benefits, therefore, even if option 3 were permissible, the statute does not preclude the option with the highest net benefits.

a. *Testing costs*. Option 3 is the least cost option. If producers are not subject to any disinfectant residual and DBP regulations, bottled water firms incur no additional costs. Firms already test for TTHM under the CGMP regulations, so the new lower bound of the TTHM test should cause only a small increase in cost per plant. However, the TTHM frequency differences still affect the choice between options 1 and 2, so we include TTHM testing in the analysis.

We assume the following testing frequency and requirements under option 1. This option considers the cost if bottled water facilities were subject to EPA NPDWR's by interpreting how such requirements may apply to bottled water facilities. EPA bases testing frequencies for public water systems on the size of the population served by the treatment plant. Since bottled water plants do not fall into the size and type categories established in the 1998 Stage 1 DBPR regulations, for the purposes of this analysis, we assume that all bottled water facilities would be regulated as if they were a small ground water treatment system. This is the smallest category identified in the 1998 Stage 1 DBPR analysis.

EPA regulations also provide two testing process exemptions. If a public water system does not use ozone for oxidation or disinfection, then EPA does not require a bromate test; and if a public water system does not use chlorine dioxide for oxidation or disinfection, then EPA requires neither a chlorine dioxide nor a chlorite test. All plants have to test for HAA5, TTHM, chlorine, and chloramine regardless of disinfection method. For this analysis, the bottled water industry would be subject to the following monitoring:

i. TTHM and HAA5: One test per plant per year, decreasing to one test per 3 years in the event of 1 or 2 years of very low levels of both TTHM and HAA5.

ii. Chlorite: A three-sample set per month only for plants using chlorine dioxide as a disinfectant. Reduced to a three-sample set per quarter if low levels of chlorites found in routine monitoring in a 1-year period.

iii. Bromate: One test per month only for plants using ozone for oxidation or disinfection. Reduced to one test per quarter if average water bromide is low, based on 1-year average of monthly samples.

iv. Chlorine and Chloramine: One test per plant per month. Monitoring may not be reduced.

v. Chlorine Dioxide: One test per day, at the distribution system entrance, only for plants using chlorine dioxide as a disinfectant. Monitoring may not be reduced.

Because few bottled water facilities use chlorine dioxide for disinfection, we assume that they all will qualify for the chlorite testing exemption. For the HAA5 and TTHM frequency requirements, we assume that one-third of the plants will qualify for the frequency reductions after 1 year, one-third will qualify for the reductions after 2 years, and one-third will continue to have to test once yearly. Finally, we assume that no bottled water facility will qualify for the bromate testing exemption, but that half of the plants will qualify for lower frequency testing under option 1.

For option 2, under 21 CFR § 129.35(a)(3), bottled water producers are required to test their source water for contaminants at least once per year unless exempted from such testing under § 129.35(a)(4). For example, bottled water facilities that use a public water source already subject to EPA regulations may substitute public water system testing results for source water testing. We assume that no facilities that use a public water source will need to test their source water for residual disinfectants and DBP's. Bottled water manufacturers that do not use a public water system as the source of their water and whose source water has not been treated with a chlorine-based disinfectant or ozone do not have to test their source water for these disinfectants and the DBP's likely to result from such treatment. Manufacturers that do not use a public water system as the source of their water but whose source water has been treated with a chlorine-based disinfectant or ozone must test their source water for the residual disinfectants and the DBP's likely to result from such treatment. For example, some source water may be disinfected if it is transported across large distances prior to entering the bottled water plant. We assume in this analysis (explained below) that 75 percent of bottled water producers use nonpublic sources. Of these, we assume that one-third of bottled water producers using nonpublic water will need to test their source water. All bottled water producers are required to test their final bottled water product for contaminants at least once per year under § 129.80(g)(2).

Table 1 of this document contains the required annual testing frequencies for source and final product water for the four types of DBP's and three disinfectants under options 1 and 2. For this table, we split option 2 into 2a and 2b, referring to whether or not the facility uses a public water source. This table is for ''year 1'' testing; under our assumptions no firm has yet qualified for less frequent testing requirements under option 1. We assume that facilities will perform separate tests for free chlorine and combined chlorine (which detects chloramine) and that all facilities use ozone for oxidation or disinfection. Under option 2a, all facilities must perform at least one final product test annually, and 25 percent (one-third of the 75 percent of the facilities using a nonpublic water source) of facilities must perform an annual source water test, for an average of 1.25 tests per facility.

TABLE 1.—ANNUAL AVERAGE PLANT TESTING FREQUENCY[1]

Test	Option 1 NPDWR's Apply	Option 2a CGMP Regulations Apply (Nonpublic Source Water)	Option 2b CGMP Regulations Apply (Public Source Water)
Bromate	12	1.25	1
Chlorite	0	1.25	1
TTHM	1	1.25	1
HAA5	1	1.25	1
Chorine	12	1.25	1
Chloramine	12	1.25	1
Chlorine Dioxide	0	1.25	1

The cost estimates in table 2 of this document include labor, and are the same testing costs EPA used for the 1998 Stage 1 DBPR impact analysis (Ref. 1). FDA also collected other testing cost estimates (Ref. 2); the EPA testing costs generally are in the high end of the range of the estimates we collected. FDA considers EPA's cost estimates reliable for this analysis. FDA believes it likely that a bottled water plant would be able to test for these substances at a cost close to this range. However, we do not define ''likely'' in any statistical sense. We examine the sensitivity of our final results to sample testing cost estimates.

TABLE 2.—ESTIMATED COST PER TEST

Test	Cost (Dollars)
Bromate	100
Chlorite	125
TTHM	100
HAA5	200
Chlorine	20
Chloramine	20
Chlorine Dioxide	20

Table 3 of this document presents annual testing costs. Both option 2a and 2b cost estimates are considerably lower than option 1 (year 1) estimates for a typical bottled water plant, due to the less frequent required testing for bromate, chlorine, and chloramine.

TABLE 3.—ANNUAL PLANT TESTING COSTS (DOLLARS)

Test	Option 1 NPDWR's Apply	Option 2a CGMP Regulations Apply (Nonpublic Source Water)	Option 2b CGMP Regulations Apply (Public Source Water)
Bromate	1,200	125	100
Chlorite	0	156.25	125
TTHM	100	125	100
HAA5	200	250	200
Chlorine	240	25	20
Chloramine	240	25	20
Chlorine Dioxide	0	25	20
Total	1,980	731.25	585

Table 4 of this document applies these totals and assumptions to the structure of the bottled water industry. We also recombine options 2a and 2b in table 4. Approximately 1,550 plants produce bottled water (63 FR 25764, May 11, 1998). According to another database search conducted for this analysis, the industry contains only 914 plants that would be subject to these rules, but the current count may not include bottled water services to business. Because of this uncertainty, we estimate totals for both 914 and 1,550 plants. This affects neither the relative ranking of options nor the sensitivity analysis.

About 25 percent of bottled water products sold are produced by facilities that use public source water. Based on this, FDA assumes that 25 percent of bottled water plants use public source water, and that 75 percent use nonpublic sources (mostly ground water.) For ease of computation, table 4 of this document also assumes an equal distribution of the once per 3-year cost across later years, so one-third of the TTHM and HAA5 cost is incurred in any one year for plants meeting the less frequent testing requirements under option 1.

TABLE 4.—TOTAL COST TO INDUSTRY (IN DOLLARS, ASSUMING 1,550 PLANTS)

Year	2002	2003	2004	2005
Option 2 (a and b)	1,076,766	1,076,766	1,076,766	1,076,766
Option 1	3,069,000	2,268,167	2,164,833	2,164,833

Assuming a 7 percent discount rate and no relative testing cost increases, the present (year 2001) value costs of the testing regimes are $18,787,984 (914 plants) to $31,861,461 (1,550 plants) under option 1 and $9,070,634 (914 plants) to $15,382,366 (1,550 plants) under option 2.

FDA ran a rough sensitivity analysis to determine how the range of testing costs, exemptions, and frequency assumptions affected the relative cost of options 1 and 2. This is a break-even analysis, which identifies how much the costs or assumptions would have to change in order to alter our conclusions.

(1) Testing costs; the major components of the higher option 1 cost are bromate, chlorine, and chloramine testing requirements. Even if bromate testing cost dropped to zero, option 1 cost would still be higher than option 2. If chorine and chloramine testing costs dropped to zero, and the cost of testing a water sample for bromate dropped from $100 to $52 (or if only 52 percent of bottled water plants have to test for bromate), the cost of options 1 and 2 would be roughly the same. This is in the range of the lowest bromate testing cost estimates collected by FDA (Ref. 2). TTHM and HAA5 testing costs do not have a significant impact on the relative cost of the options.

(2) Frequency and requirement exemptions; even if all bottled water plants qualified for less frequent bromate, TTHM, and HAA5 testing, option 1 costs would still be higher than option 2 costs.

(3) Discount rate; since option 2 costs, under the original assumptions, were lower for every year, the option ranking is not affected by the choice of the discount rate.

FDA concludes that under the most likely assumptions and in a wide range around those assumptions, testing costs under option 1 exceed those under option 2.

b. *Recordkeeping costs*. Bottled water producers already must follow FDA CGMP requirements for other contaminants, so option two recordkeeping requirements may be lower in cost than option 1. Firms have sufficient experience with recordkeeping, so we believe that any cost differences are minimal.

c. *Residual disinfectants and DBP control costs*. The 1998 Stage I DBPR impact analysis estimated costs for public water systems to come into compliance if a test found unacceptable residual disinfectant or DBP levels. However, bottled water producers differ from public water suppliers in two ways. First, we assume one-fourth of bottled water producers use source water already subject to EPA regulations. For the purposes of this analysis, we assume they will not have to adopt any costly technology to come into compliance. Second, almost all producers who do not use public water systems for their source water use ground water. In the 1998 Stage I DBPR analysis, EPA estimated that only 12 percent of small ground water facilities will have to adopt new disinfection technology in order to avoid excessive residual disinfectants or DBP's. FDA considers this a high estimate of the number of bottled water plants that may need to adopt new technology, because these plants do not use as many different types of disinfectants. Therefore, at most only 9 percent (0.75 x 0.12) of bottled water plants may have to adopt new technology. FDA cannot discriminate between the EPA and FDA testing regimes under options 1 and 2 in terms of the degree to which they will require new disinfection technology in bottled water plants. Once again, no standards will guarantee that producers will not have to invest in new compliance technology, so option 3 would have the lowest cost.

3. Benefits of the Regulation

In this case, FDA assumes that both option 1 and option 2 adequately protect the health of the public. FDA cannot discriminate between options 1 and 2 in terms of their ability to guarantee the absence of residual disinfectants and DBP's in bottled water. Option 3 is the lowest cost, but in the 1998 Stage 1 DBPR analysis, EPA concluded that testing for these substances in water destined for human consumption has net positive benefits (63 FR 69390, December 16, 1998). Water used by bottled water producers, from both public and nonpublic sources, may need some manner of disinfection, so we believe the economic argument from the Stage 1 DBPR analysis applies equally well to bottled water. We do not estimate the number of illnesses avoided under these different testing options.

4. Net Benefits

Option 2 has lower testing costs and may have lower record-keeping costs than option 1, and protects the health of the public at least as well as option 1. Option 2 also has higher net benefits than option 3, since the Stage 1 DBPR conclusion that testing for these substances has net positive benefits applies equally well to bottled water. Therefore, option 2, where FDA issues standard of quality regulations for these residual disinfectants and DBP's under part 165 and where the monitoring requirements in part 129 apply, has the highest net benefits.

B. Small Entity Analysis

Under Section 603(a) of the Regulatory Flexibility Act (RFA), for any proposed rule for which the agency is required by section 553 of the Administrative Procedure Act or any other law to publish a general notice of proposed rulemaking, the agency is required to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency has published, in the companion proposed rule published elsewhere in this **Federal Register**, an initial regulatory flexibility analysis. Because the companion proposed rule is a proposed rule for which a general notice of proposed rulemaking is required, and therefore, is subject to the Regulatory Flexibility Act, the agency will consider any comments it receives on the initial regulatory flexibility analysis in the companion proposed rule when deciding whether to withdraw this direct final rule.

FDA has examined the economic implications of this direct final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this rule would have a significant economic impact on a substantial number of small entities.

This rule would have an impact on small entities, but that impact would not be large. In addition, option 2 in the

impact analysis is more flexible and has a smaller testing frequency burden than the NPDWR requirements for drinking water under option 1, therefore lowering the impact of this rule on small businesses while still protecting the public health. FDA also believes that adopting residual disinfectant and DBP standards yields net positive benefits regardless of the size of the bottled water facility, so option 2 in the impact analysis is more appropriate than option 3 for small businesses.

FDA also believes that the flexibility allowed in source testing requirements under option 2 in the impact analysis is the maximum amount of flexibility possible in this regulation. FDA is not establishing exemptions for final product testing since there is a need to test for these disinfectant residuals and DBP's: bottled water producers use these disinfectants, residual disinfectants and DBP's may be present in both public and nonpublic source water, and disinfectants may be used for equipment or other sanitation in any bottled water plant under CGMP regulations.

According to the latest database search across the bottled water industry mentioned above, approximately 72 percent of firms qualify as small by Small Business Administration (SBA) standards. Assuming the same exemptions and frequency requirements, the yearly average cost per plant for both small and large entities is between $585 (public source) and $731 (nonpublic source) for firms under the FDA requirements in option 2 in the impact analysis, and between $1,397 (year 3) and $1,980 (year 1) for the NPDWR requirements in option 1. We assume that almost all small entities in the bottled water industry are single plant firms. Although FDA does consider the option 2 higher cost of $731 per plant per year a significant impact for small firms, this number represents 0.13 percent of the $580,000 annual revenue of the median small bottled water firm.

C. Unfunded Mandate

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4), requiring cost-benefit and other analyses, in section 1531 (a) defines a significant rule as ''a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any 1 year.'' FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VII. Paperwork Reduction Act

FDA tentatively concludes that this final rule contains no collections of information. Therefore, clearance by the OMB under the Paperwork Reduction Act of 1995 is not required.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

IX. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this direct final rule on or before June 11, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

X. Effective Date

The agency intends to make the direct final rule effective January 1, 2002. The agency will publish a confirmation notice for the direct final rule in the **Federal Register** no later than 180 days before the effective date. The agency is providing 180 days before the effective date to permit affected firms adequate time to take appropriate steps to bring their product into compliance with the standard imposed by the new rule.

XI. References

1. U.S. EPA, Regulatory Impact Analysis of Final Disinfectant/Disinfection By-Products Regulations, Washington, DC, app. E, pp. E–4 and E–5, EPA 815–B–98–002, PB 99–111304, 1998.

2. Memorandum from Dominic Mancini to the record, March 13, 2001.

List of Subjects

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.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 129 and 165 are amended as follows:

PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

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

Authority: 21 U.S.C. 342, 348, 371, 374; 42 U.S.C. 264.

2. Section 129.35 is amended by redesignating paragraph (a)(4)(iii) as paragraph (a)(4)(iv) and by adding new paragraph (a)(4)(iii) to read as follows:

§ 129.35 Sanitary facilities.

* * * * *

(a) * * *

(4) * * *

(iii) Firms that do not use a public water system as the source of their water and whose source water has not been treated with a chlorine-based disinfectant or ozone do not have to test their source water for the residual disinfectants and DBP's listed in § 165.110(b)(4)(iii)(H) of this chapter. Firms that do not use a public water system as the source of their water but whose source water has been treated with a chlorine-based disinfectant or ozone must test their source water for the residual disinfectants and the DBP's listed in § 165.110(b)(4)(iii)(H) that are likely to result from such treatment.

* * * * *

PART 165—BEVERAGES

1. The authority citation for 21 CFR part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343-l, 348, 349, 371, 379e.

2. Section 165.110 is amended by revising paragraph (b)(1)(ii); by adding paragraphs (b)(1)(iii), (b)(4)(iii)(H), and (b)(4)(iii)(I); and in the table in paragraph (b)(4)(i)(A) by removing the entry for ''Organics: Total Trihalomethanes'' to read as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(1) * * *

(ii) *Total trihalomethanes* (TTHM) means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane, dibromochloromethane,

bromodichloromethane, and tribromomethane), rounded to three significant figures.

(iii) *Haloacetic acids* (five) (HAA5) means the sum of the concentrations in milligrams per liter of the haloacetic acid compounds (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid), rounded to two significant figures after addition.

(4) * * *

(iii) * * *

(H) The allowable levels for residual disinfectants and disinfection byproducts are as follows:

Substance	Concentration in milligrams per liter
Disinfection byproducts	
Bromate	0.010
Chlorite	1.0
Haloacetic acids (five) (HAA5)	0.060
Total Trihalomethanes (TTHM)	0.080
Residual disinfectants	
Chloramine	4.0 (as Cl_2)
Chlorine	4.0 (as Cl_2)
Chlorine dioxide	0.8 (as ClO_2)

(I) Analysis to determine compliance with the requirements of paragraph (b)(4)(iii)(H) of this section shall be conducted in accordance with an applicable method listed in paragraphs (b)(4)(iii)(I)(*1*) through (b)(4)(iii)(I)(*7*) of this section and described in ''Method 300.1, Determination of Inorganic Anions in Drinking Water by Ion Chromatography,'' Rev. 1.0, U.S. EPA, 1997, EPA/600/R–98/118; ''Methods for the Determination of Inorganic Substances in Environmental Samples,'' U.S. EPA, August 1993, EPA/600/R–93/100; ''Methods for the Determination of Organic Compounds in Drinking Water-Supplement II,'' U.S. EPA, August 1992, EPA/600/R–92/129; ''Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,'' U.S. EPA, August 1995, EPA/600/R–95/131; ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., American Public Health Association, 1995; and ''Annual Book of ASTM Standards,'' vol. 11.01, American Society for Testing and Materials, 1996, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the following publications are available from the National Technical Information Service (NTIS): EPA/600/R–95/131 (NTIS number PB95–261616), EPA/600/R–92/129 (NTIS number PB92–207703), EPA/600/R–93/100 (NTIS number PB94–121811), and EPA/600/R–98/118 (NTIS number PB98–169196). NTIS can be contacted at NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, 1–800–553–6847 or 703–605–6000, www.ntis.gov. Copies of the publication EPA/600/R–98/118 are also available from the Chemical Exposure Research Branch, Microbiological and Chemical Exposure Assessment Research Division, National Exposure Research Laboratory, U.S. EPA, Cincinnati, OH 45268, 513–569–7757, (FAX) 513–569–7757. Copies of ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., are available from the American Public Health Association, 1015 15th Street, NW., Washington, DC 20005. All of the publications cited in paragraph (b)(4)(iii)(I) of this section 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's Library, 200 C St. SW., Washington, DC 20204. Copies of ''Annual Book of ASTM Standards,'' 1996, vol. 11.01, are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohoken, PA 19428, or may be examined at the Office of the Federal Register. Copies of the methods incorporated by reference in paragraph (b)(4)(iii)(I) of this section may also be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington DC 20204.

(*1*) Bromate shall be measured using the following method: Method 300.1—''Determination of Inorganic Anions in Drinking Water by Ion Chromatography,'' Rev. 1.0, U.S. EPA, 1997, EPA/600/R–98/118, 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)(I) of this section.

(*2*) Chlorite shall be measured using the following methods:

(*i*) Method 300.0—''Determination of Inorganic Anions by Ion Chromatography,'' Rev. 2.1. The revision is contained in the manual entitled ''Methods for the Determination of Inorganic Substances in Environmental Samples,'' U.S. EPA, August 1993, EPA/600/R–93/100, 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)(I) of this section.

(*ii*) Method 300.1—''Determination of Inorganic Anions in Drinking Water by Ion Chromatography,'' Rev. 1.0, U.S. EPA, 1997, EPA/600/R–98/118, 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)(I) of this section.

(*3*) HAA5 shall be measured using the following methods:

(*i*) Method 552.1—''Determination of Haloacetic Acids and Dalapon in Drinking Water by Ion Exchange Liquid-Solid Extraction and Gas Chromatography with Electron Capture Detection,'' Rev. 1.0. The revision is contained in the manual entitled ''Methods for the Determination of Organic Compounds in Drinking Water-Supplement II,'' U.S. EPA, August 1992, EPA/600/R–92/129, 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)(I) of this section.

(*ii*) Method 552.2—''Determination of Haloacetic Acids and Dalapon in Drinking Water by Liquid-Liquid Extraction, Derivatization and Gas Chromatography with Electron Capture Detection,'' Rev. 1.0. The revision is contained in the manual entitled ''Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,'' U.S. EPA, August 1993, EPA/600/R–95/131, 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)(I) of this section.

(*iii*) Method 6251 B—''Disinfection By-Products: Haloacetic Acids and Trichlorophenol,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*4*) TTHM shall be measured using the following methods:

(*i*) 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. 2.1. The revision is contained in the manual entitled ''Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,'' U.S. EPA, August 1993, EPA/600/R–95/131, 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)(I) of this section.

(*ii*) Method 524.2—''Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry,'' Rev. 1.0. The revision is contained in the manual entitled ''Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,'' U.S. EPA, August 1993, EPA/600/R–95/131, 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)(I) of this section.

(*iii*) Method 551.1—''Determination of Chlorination Disinfection Byproducts, Chlorinated Solvents, and Halogenated Pesticides/Herbicides in Drinking Water by Liquid-Liquid Extraction and Gas Chromatography with Electron-Capture Detection,'' Rev. 1.0. The revision is contained in the manual entitled ''Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,'' U.S. EPA, August 1993, EPA/600/R–95/131, 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)(I) of this section.

(*5*) Compliance with the chloramine standard can be determined by measuring combined or total chlorine. The following methods shall be used to measure chloramine:

(*i*) ASTM Method D1253-86—'' Standard Test Method for Residual Chlorine in Water,'' which is contained in the book entitled ''Annual Book of ASTM Standards,'' 1996, vol. 11.01, 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)(I) of this section.

(*ii*) Method 4500-Cl D—''Amperometric Titration Method,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*iii*) Method 4500-Cl F—''DPD Ferrous Titrimetric Method,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*iv*) Method 4500-Cl G—''DPD Colorimetric Method,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*v*) Method 4500-Cl E—''Low-Level Amperometric Titration Method,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*vi*) Method 4500-Cl I—''Iodometric Electrode Technique,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*6*) Compliance with the chlorine standard can be determined by measuring free or total chlorine. The following methods shall be used to measure chlorine:

(*i*) ASTM Method D1253-86—''Standard Test Method for Residual Chlorine in Water,'' which is contained in the book entitled ''Annual Book of ASTM Standards,'' 1996, vol. 11.01, 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)(I) of this section.

(*ii*) Method 4500-Cl D—''Amperometric Titration Method,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*iii*) Method 4500-Cl F—''DPD Ferrous Titrimetric Method,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*iv*) Method 4500-Cl G—''DPD Colorimetric Method,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*v*) Method 4500-Cl E—''Low-Level Amperometric Titration Method,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*vi*) Method 4500-Cl I—''Iodometric Electrode Technique,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*vii*) Method 4500-Cl H—''Syringaldazine (FACTS) Method,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*7*) Chlorine dioxide shall be measured using the following methods:

(*i*) Method 4500-ClO_2 D—''DPD Method,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

(*ii*) Method 4500-ClO_2E—''Amperometric Method II,'' which is contained in the book entitled ''Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., 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)(I) of this section.

* * * * *

Dated: March 20, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–7561 Filed 3–23–01; 3:50 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 989

Environmental Impact Analysis Process (EIAP); Correction

AGENCY: Department of the Air Force, DoD.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final rule that was published in the **Federal Register** of Thursday, July 15, 1999 (64 FR 38127). The rule related to the Air Force process for compliance with the National Environmental Policy Act (NEPA) and Executive Order (E.O.) 12114, Environmental Effects Abroad of Major Federal Actions.

EFFECTIVE DATE: March 26, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Jack Bush (HQ USAF/ILEB), 1260 Air Force Pentagon, Washington, DC 20330–1260, (703) 604–0553.

SUPPLEMENTARY INFORMATION:

Background

The final rule that is the subject of these corrections integrated environmental analysis and aligned environmental document approval levels with the Air Force decision-making process. It also expanded Air Force environmental participants and responsibilities of the Environmental Planning Function (EPF) and the proponent of an action.

Need for Correction

As published, the final rule contains minor errors that need to be corrected.

List of Subjects in 32 CFR Part 989

Environmental protection, Environmental impact statements.

Accordingly, 32 CFR Part 989 is corrected by making the following amendments:

PART 989—ENVIRONMENTAL IMPACT ANALYSIS PROCESS (EIAP)

1. The authority citation for Part 989 continues to read as follows:

Authority: 10 U.S.C. 8013.

§ 989.1 [Corrected]

2. In § 989.1, paragraph (a), in the last sentence, correct ''989.32 and 989.33'' to read ''989.37 and 989.38.''

3. In § 989.1, paragraph (b), in the second to last sentence, correct ''Department of Defense Regulation 5000.2–R, Mandatory Procedures for Major Defense Acquisition Programs and Major Automated Information Systems'' to read ''Department of Defense Regulation 5000.2–R, Mandatory Procedures for Major Defense Acquisition Programs and Major Automated Information System Acquisition Programs.''

§ 989.3 [Corrected]

4. In § 989.3, paragraph (a)(4)(i), correct ''Air Force Instruction (AFI) 35–205, Air Force Security and Policy Review'' to read ''Air Force Instruction (AFI) 35–101, Public Affairs Policies and Procedures.''

5. In § 989.3, paragraph (a)(4)(iii), correct ''AFI 35–202, Environmental Community Involvement'' to read ''AFI 35–101.''

6. In § 989.3, paragraph (c)(2)(iv), correct ''USAF/ILEVP'' to read ''USAF/ILEB.''

7. In § 989.3, paragraph (d)(7), second sentence, correct ''USAF/ILEV'' to read ''USAF/ILEB.''

8. In § 989.3, paragraph (h)(7), correct ''AFI 35–202'' to read ''AFI 35–101.''

§ 989.5 [Corrected]

9. In § 989.5, paragraph (d), correct ''USAF/ILEV'' to read ''USAF/ILEB.''

§ 989.12 [Corrected]

10. In § 989.12, remove the last sentence.

§ 989.13 [Corrected]

11. In § 989.13, paragraph (c), correct ''USAF/ILEV'' to read ''USAF/ILEB.''

§ 989.14 [Corrected]

12. In § 989.14, paragraph (g), remove the first sentence. In the second sentence correct ''through'' to read ''to,'' remove ''to HQ USAF/ILEVP,'' and correct ''is'' to read ''could be.''

13. In § 989.14, paragraph (h), correct ''HQ USAF/ILEVP'' to read ''HQ USAF/ILEB.''

14. In § 989.14, paragraph (i), correct ''HQ USAF/ILEVP'' to read ''HQ USAF/ILEB.''

15. In § 989.14, paragraph (j), correct ''HQ USAF/ILEVP'' to read ''HQ USAF/ILEB.''

§ 989.17 [Corrected]

16. In § 989.17, correct ''HQ USAF/ILEV'' to read ''HQ USAF/ILEB.''

§ 989.18 [Corrected]

17. In § 989.18, paragraph (a), third to last sentence, correct ''AF/ILEV'' to read ''HQ USAF/ILEB.''

§ 989.19 [Corrected]

18. In § 989.19, paragraph (a), last sentence, correct ''USAF/ILEV'' to read ''HQ USAF/ILEB.''

19. In § 989.19, paragraph (b), correct ''HQ USAF/ILEV'' to read ''HQ USAF/ILEB'' in the three places it appears.

20. In § 989.19, paragraph (c)(2), in the first and last sentences, correct ''Attachment 3'' to read, ''Appendix C to this part.'' In the fourth sentence, correct ''HQ USAF/ILEV'' to read ''HQ USAF/ILEB.'' In the last sentence, correct ''HQ USAF/ILEVP'' to read ''HQ USAF/ILEB.''

§ 989.20 [Corrected]

21. In § 989.20, first and second sentences, correct ''HQ USAF/ILEV'' to read ''HQ USAF/ILEB.''

§ 989.21 [Corrected]

22. In § 989.21, paragraph (a), first sentence, correct ''HQ USAF/ILEV'' to read ''HQ USAF/ILEB.''

23. In § 989.21, paragraph (b), in the first sentence, correct ''989.23'' to read ''989.24.''

§ 989.22 [Corrected]

24. In § 989.22 (a), add a new second sentence after the first sentence to read as follows:

§ 989.22 Mitigation.

(a) * * * If using Best Management Practices (BMPs), identify the specific BMPs being used and include those BMPs in the mitigation plan. * * *

* * * * *

25. In § 989.22, paragraph (b), second to last sentence, correct ''HQ USAF/ILEV'' to read ''HQ USAF/ILEB.''

26. In § 989.22, paragraph (d), last sentence, correct ''HQ USAF/ILEV'' to read ''HQ USAF/ILEB.''