DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. 93N–0085]

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the quality standard for bottled water by establishing or revising allowable levels for 5 inorganic chemicals (IOC's) and 17 synthetic organic chemicals (SOC's), including 3 synthetic volatile organic chemicals (VOC's), 9 pesticide chemicals, and 5 nonpesticide chemicals. However, FDA is staying the effective date for the allowable levels for the 5 IOC's and 4 of the SOC's. FDA also is not changing the existing allowable level for sulfate in the bottled water quality standard. In addition, FDA is deferring final action on the proposed allowable level for the nonpesticide chemical di(2-ethylhexyl)phthalate (DEHP). This final rule will ensure that the minimum quality of bottled water, as affected by at least the 13 chemicals for which allowable levels are adopted and effective, remains comparable with the quality of public drinking water that meets the Environmental Protection Agency (EPA) standards.

DATES: The regulation is effective September 23, 1996. 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 part 51 of certain publications in 21 CFR 165.110(b)(4)(iii), effective September 23, 1996.

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SUPPLEMENTARY INFORMATION:

I. Background

Under section 410 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349), whenever EPA prescribes interim or revised National Primary Drinking Water Regulations (NPDWR's) under section 1412 of the Public Health Service Act (The Safe Drinking Water Act (SDWA) (42 U.S.C. 300f through 300j–9)), FDA is required to consult with EPA and either amend its regulations for bottled drinking water in § 165.110 (21 CFR 165.110) or publish in the Federal Register its reasons for not making such amendments.

In the Federal Register of July 17, 1992 (57 FR 31776) (hereinafter referred to as the July 1992 final rule), EPA published a final rule promulgating NPDWR's consisting of maximum contaminant levels (MCL's) for 18 SOC's and 5 IOC's. Further, in that final rule, EPA deferred establishing an MCL for sulfate in public drinking water.

In accordance with section 410 of the act, FDA published in the Federal Register of August 4, 1993 (58 FR 41612), a proposal to adopt EPA's MCL's for the 18 SOC's and 5 IOC's as allowable levels in the quality standard for bottled water (hereinafter referred to as the August 1993 proposal). In the August 1993 proposal, FDA tentatively concluded that the MCL's that EPA had established based on available toxicological information for the 18 SOC's and 5 IOC's in public drinking water were adequate to protect the public from the adverse health effects of these chemical contaminants in drinking water. Further, FDA tentatively concluded that adopting EPA's MCL's for the 18 SOC's and 5 IOC's as allowable levels in the bottled water quality standard was appropriate to protect the public from the adverse health effects of these chemical contaminants that may be found in bottled water.

FDA did not propose any change in the existing allowable level of 250 milligrams per liter (mg/L) for sulfate in bottled water. FDA had established this level in 1973 (38 FR 32558, November 26, 1973), based on the Public Health Service standard for sulfate in drinking water established on March 6, 1962 (27 FR 2152). Although EPA proposed to establish either 400 or 500 mg/L as the MCL for sulfate in public drinking water (55 FR 30370, July 25, 1990), it deferred action on this MCL in its July 1992 final rule and did not revise the existing secondary maximum contaminant level (SMCL) of 250 mg/L for this chemical (40 CFR 143.3) in public drinking water.

II. Summary of and Response to Comments

A. Summary of Comments

FDA received 11 comments in response to the August 1993 proposal. The comments represented the views of three foreign trade associations and one domestic trade association that represent bottled water manufacturers, two State health departments, a State environmental protection department, a European Communities General Agreement for Tariffs and Trade (EC GATT) Enquiry Point, a bottled water company, a supplier of packaging materials, and a nonprofit private organization. The majority of the comments stated that they generally supported the proposal. Two comments addressed the issue of Federal preemption of State requirements concerning the quality of bottled water and related monitoring requirements. The issue of Federal preemption of State requirements is outside the scope of the proposal and thus will not be discussed here. A number of comments suggested modifications to, or were opposed to, various provisions of the proposal. A summary of the suggested changes, the opposing comments, and the agency's responses follows.

B. Comments Pertaining to Allowable Levels in the Quality Standard for Bottled Water

1. One of the comments addressed the proposed allowable level of 0.006 mg/L for the chemical, DEHP. The comment pointed out that this chemical is prior sanctioned in § 181.27 (21 CFR 181.27) for use as a plasticizer when migrating from food-packaging material into foods with high water content and, as such, is approved for use in contact with food in § 177.1210 (21 CFR 177.1210) *Closures with sealing gaskets for food containers.* The comment also pointed out that DEHP is routinely used as a plasticizer in gaskets used in metal and plastic closures for the packaging of bottled water in accord with this approval, and that such use may result in levels of this chemical migrating into water that exceed the proposed allowable level. Thus, the comment maintained that finalizing the proposed allowable level for DEHP would result in a limit on the level of this chemical in bottled water that conflicts with this chemical's permitted use under the existing food additive regulation for closures with sealing gaskets, and that taking such action would effectively ban the use of this plasticizer. The comment further pointed out that gaskets containing DEHP are permitted for use in packaging food and bottled water under relevant European national regulations, and that these uses comply with the migration limit of 3 mg/kilograms proposed for DEHP established by the Scientific Committee for Food in their Synoptic Document 7.

FDA was not aware of the potential conflict between the proposed allowable level for DEHP and the existing prior sanction for this substance in § 181.27 at the time it published the proposal. The agency needs additional time to evaluate this matter and to determine an

appropriate course of action with respect to the proposed allowable level for DEHP. Therefore, FDA is deferring final action on the proposed allowable level for DEHP at this time.

2. Several comments asked FDA to clarify the status of bottled water products labeled as mineral water with respect to compliance with the existing allowable level of 250 mg/L for sulfate in bottled water. The comments stated that, in the Federal Register of January 5, 1993 (58 FR 393), FDA proposed to exempt bottled mineral water from complying with the allowable levels for certain substances, such as sulfate, that may be present at high levels in some mineral waters because the allowable levels in question have been established for aesthetic reasons and not for public health protection.

FDA did not fully address this issue in the August 1993 proposal. These comments are correct in noting that in January of 1993, FDA proposed to subject bottled mineral water to the bottled water quality standard but to exempt mineral water from complying with certain allowable levels, including that for sulfate, that were established for aesthetic reasons and not for public health protection. The January 1993 proposal was still pending when the August 1993 proposal was published. Bottled mineral water was not yet subject to the bottled water quality standard. Therefore, in addressing the allowable level for sulfate in the August 1993 proposal, FDA did not provide in the codified material that bottled mineral water would be exempt from the quality standard for sulfate.

In the Federal Register of November 13, 1995 (60 FR 57076) (hereinafter referred to as the November 1995 final rule), FDA published a final rule based on the January 1993 proposal that, among other things, established a standard of identity for bottled water (21 CFR part 165), which includes a definition for mineral water and which subjects mineral water to the quality standard regulations for bottled water. Bottled mineral water must also comply with the current good manufacturing practice (CGMP) regulations for bottled water in part 129 (21 CFR part 129). Thus, under the newly established regulations, bottled waters that meet the definition for ''mineral water'' in § 165.110(a)(2)(iii) must comply with the bottled water quality standard (i.e., the allowable levels for physical, chemical, microbiological, and radiological contaminants) in § 165.110(b).

However, FDA recognizes that mineral water with a high mineral content may not meet the allowable levels in the quality standard for certain physical and chemical attributes (i.e., color, odor, total dissolved solids (TDS), chloride, iron, manganese, sulfate, and zinc) that are based on EPA's SMCL's and, as such, are intended only to ensure the aesthetic quality of the water, i.e., SMCL's are not established for public health reasons. Consequently, in the November 1995 final rule (60 FR 57076 at 57125), FDA included provisions that exempt bottled mineral waters that meet the definition for ''mineral water'' in § 165.110(a)(2)(iii) from complying with the allowable levels for color, odor, TDS, chloride, iron, manganese, sulfate, and zinc. Therefore, bottled mineral waters do not have to comply with the allowable level of 250 mg/L for sulfate. FDA reflected this fact in the November 1995 final rule (60 FR 57076 at 57125) by including a footnote to the entry for sulfate in the listing of allowable levels under § 165.110(b)(4)(I)(A). Therefore, no action in response to this comment is necessary in this final rule.

3. One comment from an EC GATT Enquiry Point questioned whether European mineral waters that meet EC Council Directive 80/777/EEC of July 15, 1980, which established standards relating to the exploitation and marketing of natural mineral waters for member countries of the EC, but that contain levels of chemical contaminants that exceed FDA's proposed allowable levels, particularly those allowable levels that are based on EPA's SMCL's, can be marketed in the United States. The comment stated that European mineral waters should be exempt from complying with allowable levels that are based on aesthetic factors to prevent any unnecessary trade barriers.

The same comment also stated that, with regard to drinking waters, the proposed standards for barium, chloride, copper, fluoride, nitrate, trihalomethanes, TDS, and zinc are stricter than those established in EC Council Directive 80/778/EEC of July 15, 1980, relating to the quality of water intended for human consumption (other than natural mineral waters and medicinal waters). Moreover, the comment stated that EC Council Directive 80/778/EEC does not contain any limit for beryllium, thallium, dichloromethane, 1,2,4-trichlorobenzene, 1,1,2-trichloroethane, dioxin, DEHP, di(2-ethylhexyl)adipate (DEHA), and hexachlorocyclopentadiene. Consequently, the comment questioned whether European bottled waters that comply with EC Council Directive 80/778/EEC will be accepted on the U.S. market, or whether the allowable levels for chemical contaminants addressed in this final rule might create technical barriers to trade.

With regard to the U.S. standards for barium, chloride, copper, fluoride, nitrate, trihalomethanes, TDS, and zinc, FDA notes that the allowable levels for these chemical contaminants were established in previous rulemakings and thus are outside the scope of this rulemaking.

Further, FDA disagrees with the comment's assertion that trade barriers might be created because European bottled water products meeting EC Council Directives 80/777/EEC and 80/778/EEC may not meet the allowable levels for certain chemical contaminants in the quality standard for bottled water for the following two reasons:

First, as stated above, FDA recognizes that the levels of these physical and chemical contaminants in bottled mineral waters with high mineral content may exceed the allowable levels.

Thus, in the November 1995 final rule, FDA has provided that bottled mineral waters are exempt from complying with the allowable levels for color, odor, TDS, chloride, iron, manganese, sulfate, and zinc that are all based upon EPA's SMCL's. Therefore, European bottled mineral waters that meet the definition for ''mineral water'' in § 165.110(a)(2)(iii) do not have to comply with the allowable levels for these contaminants in the quality standard for bottled water. There is, consequently, no basis for the concern expressed by the comment.

Second, with respect to other chemical contaminants (i.e., beryllium, thallium, dichloromethane, 1,2,4-trichlorobenzene, 1,1,2-trichloroethane, hexachlorocyclopentadiene, dioxin, DEHP, and DEHA) addressed in this final rule and for which no limits are established in the EC Council Directive 80/778/EEC, the comment did not provide any evidence of any European bottled waters that would not meet the allowable levels for these chemical contaminants. In addition, except for the chemical DEHP, FDA is not aware of any evidence that would indicate that European bottled waters would not meet the allowable levels for the chemical contaminants addressed in this final rule.

Moreover, if a bottled water product (domestic or imported) exceeds an allowable level for a particular contaminant, under the labeling provisions of § 165.110(c), the bottler can still market that product, provided that the labeling bears a statement of substandard quality (e.g., if it exceeds the allowable level for thallium, the

labeling shall state either ''Contains Excessive Thallium'' or ''Contains Excessive Chemical Substances'' if the bottled water is not mineral water under § 165.110(c)(3)). Therefore, should a European or an American bottled water product exceed the allowable levels for certain contaminants, it still can be marketed in the United States if its labeling bears the prescribed statement for those contaminants.

Consequently, because FDA does not expect that European bottled waters will exceed the allowable levels for the chemical contaminants addressed in this final rule, and because bottled water that exceeds the allowable level for a contaminant can still be sold in the United States if it bears the prescribed label statement, FDA rejects the comment's suggestion that this final rule will create technical trade barriers.

However, FDA reminds water bottlers (domestic and foreign) that any bottled water containing a substance at a level considered injurious to health is adulterated under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) and is subject to regulatory action, regardless of whether or not the bottled water bears a label statement of substandard quality prescribed in § 165.110(c). In this regard, FDA notes that the GATT Agreement on Sanitary and Phytosanitary (SPS) measures, resulting from the Uruguay Round of Multilateral Trade Negotiations, permits countries to give food safety requirements priority over trade when those requirements are based on valid scientific information.

4. One comment from a trade association representing bottled water manufacturers opposed FDA's proposal to adopt EPA's MCL for endrin as the allowable level in bottled water because EPA's level for endrin in public drinking water is higher than the existing allowable level for this contaminant in the bottled water quality standard. The comment argued that bottlers can and have met, without exception, the existing allowable level for endrin in bottled water, and thus, FDA should keep the more stringent allowable level for endrin in bottled water. The comment further argued that while it does not disagree with FDA's acknowledgment of EPA's risk assessment for contaminants, FDA should not weaken the bottled water quality standard merely because EPA has established less stringent level for public water utilities based on their technical limitations.

FDA rejects the comment's call to retain the existing allowable level for endrin in the bottled water quality standard that is lower than the EPA's MCL for endrin in public drinking water. In the past, in similar circumstances where FDA had proposed to establish allowable levels for contaminants in bottled water based upon EPA's MCL's that were less stringent than existing allowable levels, FDA has concluded (see e.g. 59 FR 61529 at 61531, December 1, 1994) that its general policy of adopting EPA's MCL's for chemical contaminants as allowable levels in bottled water (where bottled water may be expected to contain the contaminants at issue (58 FR 41612 at 41613, August 4, 1993)) is appropriate because it will protect the public health, maintain consistent standards for identical contaminants in bottled water and public drinking water, prevent duplication of efforts between FDA and EPA in evaluating the effects of contaminants in drinking water, and not foster public perception that bottled water is required to be of better quality than tap water. This continues to be the agency's position. Therefore, for these reasons, FDA is adopting EPA's MCL's for endrin as the allowable level in the quality standard for bottled water.

In conclusion, the majority of the comments to the August 1993 proposal supported the proposed allowable levels for the 5 IOC's and 18 SOC's in the quality standard for bottled water. Further, the agency has addressed the comments that suggested modifications to or were opposed to various allowable levels in the proposal. With the exception of the comment pertaining to the proposed allowable level for DEHP (see comment 1 of this document), none of the comments have persuaded FDA that it should not adopt the allowable levels as proposed for the remaining chemical contaminants. The agency, therefore, is adopting the allowable levels for 22 of the 23 chemical contaminants (excluding DEHP) in the quality standard for bottled water as proposed (58 FR 41612).

C. Comments Related to Monitoring for Chemical Contaminants Under the Bottled Water CGMP Regulations

5. One comment from a nonprofit private organization stated that laboratory equipment (e.g., inductively coupled plasma-mass spectroscopy (ICP–MS)) for determining a number of trace elements such as antimony, beryllium, and nickel) addressed in this rulemaking is not available to a large number of laboratories because of the cost of such equipment. Further, the comment maintained that a limited number of laboratories exist that are qualified to perform many of the methods that FDA is proposing to adopt for measuring these chemical contaminants in bottled water. Consequently, the comment asserted that a large number of bottlers could be in violation of monitoring requirements for these contaminants because laboratories qualified to perform the analytical methods to determine these chemical contaminants may not be readily available.

FDA disagrees with this comment. In its July 1992 final rule (57 FR 31776 at 31798), that established NPDWR's for the chemical contaminants addressed in this final rule, EPA stated that selection of analytical methods for compliance monitoring of the chemical contaminants was based on the following factors: (1) Reliability (i.e., precision/accuracy) of the analytical results; (2) specificity in the presence of interferences; (3) availability of enough equipment and trained personnel to implement a national monitoring program (i.e., laboratory availability); (4) rapidity of analysis to permit routine use; and (5) cost of analysis to water supply systems.

Further, EPA stated in its July 1992 final rule (57 FR 31776 at 31799) that, although the ICP–MS technique for determining inorganic chemical contaminants (i.e., elements such as antimony, beryllium, and nickel) is not used widely, it expects that routine use of this equipment for determining trace elements in water samples will soon become the norm comparable to current routine laboratory use of gas chromatography/mass spectrometry (GC/MS) techniques for water analysis. In addition, EPA stated that, although the cost of the equipment is high, the capability of ICP–MS technique (i.e., high sensitivity, short analysis times, and multiple metal analytical capability) makes it a cost effective investment because of lower operational costs when compared to trace element determination with such techniques as conventional atomic absorption spectrophotometry. EPA concluded that the ICP–MS technique is technologically and economically feasible for routine compliance monitoring of water samples and adopted the technique for determining trace elements in water samples. Finally, EPA stated that the ICP–MS technique is one of many being approved for determining trace elements in water samples, and laboratories without ICP–MS technique capability may use other conventional methods.

Based on the factors discussed above (i.e., reliability, specificity, availability, rapidity) that EPA considered in adopting analytical methods for determining the levels in public drinking water of the 24 chemical contaminants that are the subject of this rulemaking, FDA concludes that

laboratories are readily available that are competent in performing the applicable analytical methods for the 22 chemical contaminants for which it is establishing allowable levels. FDA therefore rejects the comment's suggestion that a large number of bottlers could be in violation of the monitoring requirements for a number of the contaminants because laboratories qualified to perform the required analytical methods are not readily available.

6. Comments from a trade association representing bottled water manufacturers and from a nonprofit private organization maintained that, for nine of the chemical contaminants addressed in the proposal, namely the IOC's antimony, beryllium, cyanide, nickel, and thallium and the SOC's diquat, endothall, glyphosate, and dioxin, finalization of the proposed allowable levels would, under the CGMP requirements for bottled water (part 129), require additional analytical testing to be performed by water bottlers for monitoring purposes. Bottlers would have to test for these contaminants at least annually using methods other than those that are being used to analyze bottled water for compliance with the quality standard. The comment from the bottled water trade association stated that this additional testing would impose an additional cost of over one million dollars annually on bottlers. To ease the economic burden that would result from these testing requirements, the comments recommended that the agency adopt monitoring requirements for bottled water that are similar to EPA's monitoring requirements, which would allow bottlers to obtain waivers permitting them to monitor finished bottled water products for chemical contaminants less frequently than once per year if they can establish that a contaminant is not likely to be present in the source water for bottling or in the finished bottled water products.

However, comments from two State public health departments contended that water bottlers should continue to be required to test their products at least annually for chemical contaminants. One of these comments argued that the current minimum annual testing is essential, and that cost should not be a consideration, even for small bottling companies.

FDA recognizes that the number of chemical contaminants that bottlers must monitor under the bottled water CGMP regulations has increased substantially in recent years. FDA also recognizes that the increased monitoring requirements pose additional costs to water bottlers. Further, data submitted by one commenter that was obtained from a nonprofit private organization that offers testing services for the bottled water industry suggest that bottled water frequently would not be expected to contain detectable levels of the types of nonnaturally occurring contaminants regulated under the bottled water quality standard (i.e., pesticides and SOC's), and that the instances where such chemicals are detected are relatively few in number. Moreover, the levels of such contaminants, when found, are well below the allowable levels. The data also suggest that naturally occurring contaminants, e.g., IOC's, are frequently not found in bottled water, and that when they are found in bottled water, they do not exceed the allowable levels and, in fact, are usually found at levels well below the allowable levels.

For example, a 1990 analytical test summary showed that among a set of 97 bottled water products analyzed for 6 pesticide chemicals (endrin, lindane, methoxychlor, toxaphene, 2,4-D, and 2,4,5-TP), none tested positive for any of these 6 pesticide chemicals, i.e., no pesticide chemical was detected in 582 (i.e., 6×97) analyses. The analytical test summary also showed that among another set of 21 bottled water products analyzed for 11 different pesticide chemicals (simazine, atrazine, alachlor, heptachlor, chlordane, oxamyl, carbofuran, dalapon, pentachlorophenol, dinoseb, and picloram), none tested positive for any of these 11 pesticide chemicals, i.e., no pesticide chemical was detected in the 231 (i.e., 11×21) analyses. Further, in 1993, among 150 bottled water samples analyzed for the above 17 pesticide chemicals for which EPA has established MCL's, none showed the presence of any of these 17 pesticide chemicals, i.e., no pesticide chemical was detected in the 2,550 (i.e., 17×150) analyses.

In addition, the commenter submitted another 1990 analytical summary showing that among 97 bottled water products tested for 32 contaminants (18 IOC's, 11 nonpesticide SOC's, and 3 physical/quality attributes) for which FDA has established allowable levels in the bottled water quality standard, none contained any of these contaminants above the allowable levels. Nonpesticide SOC's were detected in 70 instances among the 1,067 (i.e., 11×97) analyses, but in no case did the level detected exceed 20 percent of the allowable level. Further, when testing was done for other types of contaminants (IOC's) and physical/quality attributes (e.g., odor, turbidity), such contaminants were not detected in 76 percent (i.e., 1,554 of 2,037) of the analyses, and in no case did a contaminant exceed the allowable level. Contaminants exceeding 50 percent of the allowable level were detected in only 12 instances among 2,037 analyses, and in all but 1 of these instances, the contaminants or physical/quality attributes that were detected (e.g., color, odor, TDS, iron, manganese) were those for which FDA has established allowable levels based on EPA's SMCL's to address the aesthetic effects, but not the health effects, of the contaminants. Contaminants exceeding 20 percent of the allowable level were detected in 100 instances among the 2,037 analyses, and in all but 6 of these instances, the contaminants or physical/quality attributes detected were those for which FDA has established allowable levels based on EPA's SMCL's.

In view of these facts, the commenter's suggestion that FDA adopt monitoring requirements for bottled water that are similar to EPA's monitoring requirements (i.e., that would allow bottlers to monitor finished bottled water products for chemical contaminants less frequently than once per year if they can establish that a contaminant is not likely to be present in the source water for bottling or in the finished bottled water products) merits consideration by the agency. However, any revision of the monitoring requirements for chemical contaminants in bottled water would require a careful consideration of all the relevant facts and an opportunity for input from all concerned parties. It would also require an amendment of the bottled water CGMP regulations. As such, it is beyond the scope of this rulemaking. This rulemaking only addresses the allowable levels for certain chemical contaminants in the quality standard for bottled water.

FDA intends to initiate rulemaking to address the issue of the circumstances in which reduced frequency of monitoring for chemical contaminants in bottled water products is appropriate. This rulemaking will consider the issues raised in the comments from the State health department summarized above. However, the agency's ability to undertake this rulemaking expeditiously will depend on the availability of agency resources and other competing priorities, particularly those of a significant public health concern.

As discussed above, FDA is adopting the allowable levels for 22 of 23 chemical contaminants (excluding DEHP) in the quality standard for bottled water as proposed (58 FR 41612). However, given the cost of testing for the nine chemical

contaminants in question (antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and dioxin), and the fact that the comments have submitted data showing that it is unlikely that IOC's, SOC's, and pesticide contaminants will be found in bottled water at levels that would pose a quality or safety concern, FDA finds that it is in the public interest and in the interest of justice to stay the effective date of the allowable levels for these nine comtaminants, in accordance with 21 CFR 10.35(e). FDA is staying the effect of these allowable levels until it has completed a rulemaking to address the issue of reduced frequency monitoring for chemical contaminants in bottled water. As a result of this action, bottlers are not required to monitor source waters and finished bottled water products annually for these nine chemical contaminants at this time.

FDA, however, reminds water bottlers that they are responsible for ensuring that all bottled water products introduced or delivered for introduction into interstate commerce are safe, wholesome, and appropriately labeled. Moreover, any bottled water containing any substance (including any of the nine chemical contaminants for which the allowable levels are being stayed) at a level that may be injurious to health under section 402 of the act is adulterated and will be subject to regulatory action. Consequently, FDA advises water bottlers to ensure through appropriate manufacturing techniques and sufficient quality control procedures that their bottled water products are safe with respect to levels of these nine chemical contaminants.

III. Conclusion

The agency is adopting the provisions concerning allowable levels for 22 of the 23 chemical contaminants (excluding DEHP) in the quality standard for bottled water as proposed (58 FR 41612). However, FDA is staying the effective date of the allowable levels for nine of these chemical contaminants (five IOC's and four SOC's) for the reasons explained in the response to comment 6 of this document. Further, as explained in response to comment 1 of this document, FDA is deferring final action on the proposed allowable level for the nonpesticide chemical DEHP.

The majority of the comments to the August 1993 proposal supported the provisions concerning allowable levels that FDA is adopting in this final rule. Further, after carefully considering the comments that the agency received that suggested modifications to, or that were opposed to, various provisions of the proposal, the agency has determined that no changes in the final rule other than those discussed in the response to comment 6 of this document concerning staying of the effective date for 9 of the 23 contaminants and in response to comment 1 of this document concerning deferring final action on DEHP are warranted.

In the November 1995 final rule that established a standard of identity for bottled water, FDA moved the standard of quality for bottled water from § 103.35 (21 CFR 103.35) to § 165.110. Therefore, the provisions that are being added to the quality standard in this final rule are being codified under § 165.110 and not under § 103.35 (as was proposed), which has been superseded.

With respect analytical methods for the determination of chemical contaminants, FDA is making the following changes in 165.110(b)(4)(iii).

In § 165.110(b)(4)(iii)(E)(*1*)(*iv*), FDA cites the updated version of proposed Method D–3697–87 (i.e., Method D–3697–92), and in § 165.110(b)(4)(iii)(E)(*7*)(*iv*), FDA cites the updated version of proposed Method D–2036–89A (i.e., Method D–2036–91).

These methods are contained in the manual entitled ''Annual Book of ASTM Standards,'' vols. 11.01 and 11.02, 1995, American Society for Testing and Materials (ASTM), 100 Barr Harbor Dr., West Conshoocken, PA 19428, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The source for the manual containing the two methods is the American Society for Testing and Materials. FDA is adopting the updated versions of the two methods because the proposed older versions (i.e., Method D–3697–87 and Method D–2036–89A) are contained in the 1991 edition of the manual entitled ''Annual Book of ASTM Standards,'' vols. 11.01 and 11.02, which the publisher has discontinued printing, and therefore, is no longer commercially available.

Further, FDA is deleting proposed § 103.35(d)(3)(v)(H)(5) that contains the analytical method, 4500–CN–F which is one of five methods that FDA proposed to adopt for determining cyanide in bottled water. FDA proposed to adopt Method 4500–CN–F that is contained in ''Standard Methods for the Examination of Water and Wastewater,'' 17th ed. (1989), published by the American Public Health Association, Washington, DC. However, the publisher has discontinued printing the 1989 edition of the Standard Methods for the Examination of Water and Wastewater. Consequently, the 1989 version of Method 4500–CN–F is no longer commercially available. Therefore, because the 1989 version of Method 4500–CN–F is no longer commercially available, and because FDA is incorporating by reference four other methods (three EPA methods and one ASTM method) for determining cyanide in bottled water, FDA is not adopting Method 4500–CN–F.

Finally, FDA is consolidating and relisting in alphabetical order all of the appropriate analytical methods that the agency either previously incorporated by reference or is incorporating by reference in this final rule in recodified § 165.110(b)(4)(iii)(E), (b)(4)(iii)(F), and (b)(4)(iii)(G).

Therefore, upon the effective date of this rule, September 23, 1996, any bottled water that contains any of the 13 chemical contaminants for which the allowable levels are effective at a level that exceeds the applicable allowable levels will be misbranded under section 403(h)(1) of the act (21 U.S.C. 343(h)(1)) unless it bears a statement of substandard quality as provided by § 165.110(c)(3).

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (58 FR 41612, August 4, 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.

V. Analysis of Economic Impacts

FDA has examined the impacts of this final rule which amends the quality standard for bottled water by establishing or revising allowable levels for 5 IOC's and 17 SOC's (excluding DEHP) as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–654). 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).

The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the agency certifies that the final rule will

not have a significant impact on a substantial number of small businesses.

A. Costs

In the August 1993 proposal, FDA presented an analysis of the economic impact of the proposed requirements under the previous Executive Order 12291. In that analysis, the agency stated that the benefits of the proposed rule are expected to be zero because none of the 23 chemicals found in currently marketed bottled water are expected to be above the levels of the proposed standard. FDA also stated that the costs of this regulation will only be for testing of these chemicals according to the CGMP regulations for bottled water. A single test can be used to simultaneously analyze a number of chemicals and can cost up to $3,000 per sample. To the extent that the tests currently being performed can be used to test for any of the 23 chemicals, there would be no additional costs imposed by this rule.

As mentioned above, in response to that analysis the agency received two comments, one from a trade association representing bottled water manufacturers and one from a nonprofit private organization. One of the comments stated that, under the proposal, 14 contaminants may be analyzed using methods that can simultaneously test for a number of currently regulated chemicals, and that no additional testing cost would be required. However, the other nine of these chemicals would require additional testing, which would increase costs for each bottled water product by $1,290 per sample, and by another $1,290 for each nonmunicipal source. In the United States there are 1,000 to 1,100 bottled water products that under the proposed requirements would require additional testing (Ref. 1). The incremental annual costs to bottlers would then range between $1.29 to $1.419 million for additional testing of the finished bottled water products (i.e., $1,290×1,000 to 1,100 bottled water products). The number of nonmunicipal sources affected is not known, but assuming that, on average, 50 percent of the total bottled water products are from nonmunicipal sources, the cost of the additional testing would be $1,290 × 500 nonmunicipal sources or $645,000 annually. The total annual costs of additional testing would be approximately $2 million.

According to a trade association comment, approximately 140 of their member bottlers are considered small or have sales that are below $1 million. These 140 small bottlers represent approximately half of the small bottlers in the country (Ref. 1). On average, each small bottler produces two products. Thus the incremental annual cost to small bottlers is estimated as 280 bottlers × 2 products × $1,290, which would be equal to $722,400. The total future discounted costs (6 percent) to small businesses would be $12 million.

In addition, as mentioned above (see response to comment 6 of this document, *supra*), 1990 and 1993 data from a nonprofit private organization that offers testing services for the bottled water industry suggest that bottled water frequently may not be expected to contain detectable levels of the types of nonnaturally occurring contaminants regulated under the bottled water quality standard (e.g., pesticides and SOC's), and that the instances where such chemicals may be detected are relatively few in number. The data also show that the levels of such contaminants, when found, are well below the allowable levels. FDA has also received data that suggest that some types of contaminants, e.g., IOC's, are frequently not found in bottled water and, when found in bottled water, do not exceed the allowable levels and are usually found at levels well below the allowable levels. For these reasons, the comment suggested that FDA provide waivers similar to those provided by EPA that would allow less frequent monitoring of contaminants not likely to be found in bottled water. Although this suggestion warrants consideration by the agency, any revision of the monitoring requirements for chemical contaminants in bottled water would require amending the bottled water CGMP regulations. An amendment of CGMP regulations is beyond the scope of this rulemaking.

As mentioned earlier, FDA intends to initiate rulemaking to address the issue of reduced frequency monitoring for chemicals that are unlikely to be present in bottled water. However, the agency's ability to undertake such rulemaking expeditiously will depend on the availability of agency resources and other competing priorities, particularly for those that pose significant public health concerns. Therefore, as explained above, FDA decided to finalize the allowable levels for the nine contaminants that cannot be analyzed with currently used methods but to stay the effective date for these allowable levels until it undertakes a rulemaking on reduced frequency monitoring for chemical contaminants in bottled water. Thus, while stayed, this rule results in no additional testing costs for these nine contaminants.

To assess the minimum expected cost of this rule if the monitoring frequency requirements in the CGMP are reduced, FDA assumes that any revision of the CGMP would require at least initial testing for the nine contaminants for which the allowable levels are being stayed. The cost for this initial testing for 1,000 to 1,100 bottled water products and 500 nonmunicipal sources would be approximately $2 million as stated above. This is the minimum expected cost since additional testing (at less frequent intervals) still would be required after the initial testing. No reformulation costs are expected because none of the 23 contaminants are found in bottled water above the levels of the proposed standard.

B. Benefits

In the Economic Impact Analysis of the proposed rule FDA determined that, because none of the 23 contaminants are expected to be found in bottled water above the levels of the standards, benefits of the proposed rule were expected to be zero. However, this rule ensures that, should current conditions change, such as new sources of water or new manufacturing practices, the level of these contaminants will remain low. Although the health benefits of this regulation are expected to be small, regulation similar to that for municipal water may improve consumer perceptions of the risk associated with bottled water, particularly relative to municipal water.

VI. Reference

The following reference has been place on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20875, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum of telephone conversation to Tyrone Wilson of the International Bottled Water Association (IBWA), from Christinia Ford, (FDA), September 7, 1995.

List of Subjects in 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 part 165 is amended as follows:

PART 165—BEVERAGES

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

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).

2. Section 165.110 is amended in the table in paragraph (b)(4)(i)(A) by removing the entries for ''Sulfate'' and ''Endrin * * *'', by alphabetically adding new entries in the tables in paragraphs (b)(4)(iii)(A), (b)(4)(iii)(B), (b)(4)(iii)(C), and (b)(4)(iii)(D), and by revising paragraphs (b)(4)(iii)(E), (b)(4)(iii)(F), and (b)(4)(iii)(G) to read as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(4) * * *

(iii) * * *

(A) * * *

Contaminant	Concentration in milligrams per liter (or as specified)
Antimony [1]	.006
* * * * * * *	*
Beryllium [1]	0.004
* * * * * * *	*
Cyanide [1]	0.2
* * * * * * *	*
Nickel [1]	0.1
* * * * * * *	*
Thallium [1]	0.002
* * * * * * *	*

[1] Stayed until further notice. See § 165.110(b)(4)(iii) (G)(*3*)(*iv*).

(B) * * *

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
* * * * * * *	*
Dichloromethane (75–09–2)	0.005
* * * * * * *	*
1,2,4–Trichlorobenzene (120–82–1)	0.07
* * * * * * *	*
1,1,2–Trichloroethane (79–00–5)	0.005
* * * * * * *	*

(C) * * *

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
* * * * * * *	*
Benzo(a)pyrene (50–32–8)	0.0002
* * * * * * *	*
Dalapon (75–99–0)	0.2
* * * * * * *	*
* * * * * * *	*
Di(2-ethylhexyl)adipate (103–23–1)	0.4
Dinoseb (88–85–7)	0.007
Diquat (85–00–7)[1]	0.02
Endothall (145–73–3) [1]	0.1
Endrin (72–20–8)	0.002
* * * * * * *	*
Glyphosate (1071–53–6) [1]	0.7
* * * * * * *	*
Hexachlorobenzene (118–74–4)	0.001
Hexachlorocyclopentadiene (77–47–4)	0.05

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
* * * * * * *	
Oxamyl (23135–22–0)	0.2
* * * * * * *	
Picloram (1918–02–1)	0.5
Simazine (122–34–9)	0.004
2,3,7,8-TCDD (Dioxin) (1746–01–6) [1]	3×10^{-8}
* * * * * * *	

[1] Stayed until further notice. See § 165.110(b)(4)(iii) (G)(*3*)(*iv*).

(D) * * *

Contaminant	Concentration in milligrams per liter
* * * * * * *	
Sulfate [1]	250.0

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

(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 (EMSL), Cincinnati, OH 45258 (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 (NTIS), U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C Street SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(*1*) Antimony shall be measured using the following methods:

(*i*) Method 204.2—''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 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. 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 Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C Street SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(*iii*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method D–3697–92—''Standard Test Method for Antimony in Water,'' contained in the Annual Book of ASTM Standards, vols. 11.01 and 11.02, 1995, American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, 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 American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C Street SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(*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)(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, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

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

(*i*) Method 210.2—''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, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iii*) Method 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*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, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

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

(*1*) 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.

(*2*) 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, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) 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,'' 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,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these 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, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(*ii*) of this section.

(*v*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

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

(*i*) Method 335.1—''Titrimetric; Spectrophotometric'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 335.2—''Titrimetric; Spectrophotometric'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*iii*) Method 335.3—''Colorimetric, Automated UV,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(iv) Method D–2036–91—''Standard Test Methods for Cyanides in Water,'' contained in the Annual Book of ASTM Standards, vols. 11.01 and 11.02, 1995, American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, 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 American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C Street SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

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

(*i*) Method 239.2—''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 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iii*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) 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 these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*10*) Nickel shall be measured using the following methods:

(*i*) Method 249.1—''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 249.2—''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 these 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, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*v*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

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

(*i*) Method 300.0—''The Determination of Inorganic Anions in Water by Ion Chromatography—Method 300.0,'' EPA, EMSL (EPA–600/4–84–017), March 1984, 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 NTIS, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C Street SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(*ii*) Method 353.1—''Colorimetric, automated, hydrazine reduction,'' for nitrate only, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*iii*) Method 353.2—''Colorimetric, automated, cadmium reduction,'' for both nitrate and nitrite, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*iv*) Method 353.3—''Spectrophotometric, cadmium reduction,'' for both nitrate and nitrite, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*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*) Thallium shall be measured using the following methods:

(*i*) Method 279.2—''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 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iii*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(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, EMSL, EPA/600/4–88/039, December 1988, or in ''Methods for the Determination of Organic Compounds in Drinking Water, Supplement 1,'' Office of Research and Development, EMSL, EPA/600/4–90/020, July 1990, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of these publications are available from NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 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 Microextraction and Gas Chromatography,'' Rev. 2.0, 1989, (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, endrin, hexachlorobenzene, hexachlorocyclopentadiene, simazine, 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

(*8*) Method 506—''Determination of Phthalate and Adipate Esters in Drinking Water by Liquid-Liquid Extraction or Liquid-Solid Extraction and Gas Chromatography with Photoionization Detection,'' applicable to di(2-ethylhexyl) adipate which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*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, atrazine, and simazine), 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, endrin, hexachlorobenzene, 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, 1991, (applicable to 2,4–D, 2,4,5–TP (Silvex), pentachlorophenol, dalapon, dinoseb, and picloram), 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, pentachlorophenol, benzo(a)pyrene, di(2-ethylhexyl) adipate, endrin, hexachlorobenzene, hexachlorocyclopentadiene, and simazine), 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 and oxamyl (vydate)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*15*) Method 547—''Determination of Glyphosate in Drinking Water by Direct-Aqueous-Injection HPLC, Post-Column Derivatization, and Fluorescence Detection,'' (applicable to glyphosate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*16*) Method 548—''Determination of Endothall in Drinking Water by Aqueous Derivatization, Liquid-Solid Extraction, and Gas Chromatography with Electron-Capture Detection,'' (applicable to endothall), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*17*) Method 549—''Determination of Diquat and Paraquat in Drinking Water by Liquid-Solid Extraction and HPLC with Ultraviolet Detection,'' (applicable to diquat), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*18*) Method 550—''Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Liquid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection,'' (applicable to benzo(a)pyrene and other polynuclear aromatic hydrocarbons), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*19*) Method 550.1—''Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Solid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection,'' (applicable to benzo(a)pyrene and other polynuclear aromatic hydrocarbons), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(F) of this section.

(*20*) Method 1613—''Tetra- through Octa- Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS,'' Rev. A, 1990, EPA, Office of Water Regulations and Standards, Industrial Technology Division, (applicable to 2,3,7,8–TCDD (Dioxin)), 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 USEPA–OST, Sample Control Center, P.O. Box 1407, Alexandria, VA 22313, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 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.

(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*) through (b)(4)(iii)(G)(*3*) 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, or

(*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).

(*iii*) Method 200.7—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*v*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

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

(*i*) Method 272.1—''Atomic Absorption; direct aspiration technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, 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 Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. 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. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*v*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. 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. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

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

(*i*) Method 300.0—''The Determination of Inorganic Anions in Water by Ion Chromatography—Method 300.0,'' EPA, EMSL (EPA–600/4–84–017), March 1984, 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)(*11*)(*i*) of this section.

(*ii*) Method 375.1—''Colorimetric, Automated, Chloranilate,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*iii*) Method 375.3—''Gravimetric,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*iv*) Method 375.4—''Turbidimetric,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1

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

[Note: the allowable levels in § 165.110 for the chemicals antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and dioxin are stayed until further notice.]

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Dated: March 18, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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