

FINDING OF NO SIGNIFICANT IMPACT

FOR

The proposed rule to revise the bottled drinking water quality standard in order to modify the allowable level for lead.

The Environmental Impact Section, Center for Food Safety and Applied Nutrition, has determined that this action will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. The evidence supporting this finding is contained in the attached environmental assessment.

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92N-0059

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ENVIRONMENTAL ASSESSMENT FOR

The proposed rule to revise the bottled drinking water quality standard in order to modify the allowable level for lead.

1. DESCRIPTION OF THE PROPOSED ACTION:

The Food and Drug Administration (FDA) is proposing to revise its bottled drinking water quality standard to modify the allowable level for lead. FDA has also determined that it will retain the existing allowable level for copper in bottled drinking water. This action follows a rulemaking¹ by the U.S. Environmental Protection Agency (EPA) promulgating regulations that establish treatment technique requirements for controlling lead and copper contamination of public drinking water. Section 410 of the Federal Food, Drug and Cosmetic Act requires that, whenever EPA prescribes interim or revised national primary drinking water regulations under section 1412 of Title XIV of the Public Health Service Act (The Safe Drinking Water Act), FDA shall consult with EPA and within 180 days after the promulgation of such drinking water regulations "either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the *Federal Register* . . . reasons for not making such amendments." FDA has consulted with EPA and is proposing to establish a maximum allowable level of 0.005 milligrams per liter (mg/L) for lead in bottled drinking water. FDA is amending Title 21, Part 103, Section 103.35 of the *Code of Federal Regulations* to replace the current lead allowable level (0.050 mg/L) with this new allowable level. FDA will retain the existing allowable level for copper in bottled drinking water in 21 *CFR* 103.35. This regulation specifies a maximum allowable level for copper of 1.0 mg/L. FDA believes, in general, that EPA's standards for contaminants in drinking water are appropriate as standards for bottled drinking water when bottled water may be expected to contain the same contaminants. FDA relies on EPA's determinations that EPA's requirements are adequate to protect the public health.

2. ENVIRONMENTAL CONSEQUENCES OF THE PROPOSED ACTION:

FDA's decision to retain the existing allowable level for copper in bottled water has no potential for affecting the quality of the human environment because the allowable level is not changing and, thus, no environmental change will result. The potential environmental impact of changing the allowable level for lead is considered in the remainder of this environmental assessment.

¹U.S. Environmental Protection Agency, "Drinking Water Regulations; Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper; Final Rule," 56 *FR* 26460-26564, June 7, 1991.

a. *Background information:*

(1) Bottled water industry

Information was provided by the International Bottled Water Association (IBWA) on the bottled water industry.^{2&3} IBWA sets the current annual market for bottled water at about two billion gallons. Wells and natural springs are the sources for 75 percent of bottled water and municipal water is the source for the remainder. Wells and natural springs are considered ground water sources.

In the United States, the volume of water produced by public (municipal) water systems is about 100 gallons per person per day.⁴ The two billion gallons of bottled drinking water produced annually is thus about 0.02% of the water produced annually by public water systems.

The top bottled water consuming States are, in rank, California, New York, Texas, Florida, and Illinois with California accounting for 35.6% of the consumption of bottled water.³ The bottled water producers in the United States are regulated and inspected by State health authorities as well as by FDA. Some States (e.g., California, Pennsylvania and Florida) have adopted regulations that are stricter than Federal requirements.⁵

(2) Technologies for removing contaminants from water

In its final rule¹, EPA identified the best available technologies (BAT) for reducing the concentrations of lead in source water. These techniques are ion exchange, reverse osmosis, lime softening, and coagulation/filtration.

²Tyrone Wilson and Geary Campbell, IBWA, 113 North Henry Street, Alexandria, VA 22314, personal communication, December 30, 1991.

³IBWA, *20 Questions about the Bottled Water Industry*.

⁴Parrotta, Mark, Drinking Water Standards Division, Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency, Washington, DC; personal communication, May 31, 1991.

⁵U.S. Environmental Protection Agency, *Bottled Water: Helpful Facts and Information*; EPA 570/9-90-GGG; Office of Water, Washington, DC 20460; September 1990.

(3) Current levels of lead in drinking water

In its final rule,¹ EPA discusses the occurrence of lead in public drinking water. Lead occurs in drinking water from two sources: lead may be present in the source water, or corrosion of plumbing materials in the water distribution system may introduce lead into the water supply. EPA estimates from surveys that water leaving the treatment plant may have lead levels greater than 0.005 mg/L in approximately 600 of the nation's groundwater systems and in about 215 surface water supplied systems. These two data sets together indicate that less than one percent of the public water systems in the United States have water entering the distribution system with lead levels greater than 0.005 mg/L.

EPA¹ notes that lead in drinking water results primarily from corrosion of materials located throughout the distribution system and in publicly- and privately-owned structures connected to the distribution system. Although EPA notes that available data are not sufficient to determine the national distribution of lead levels in drinking water at the tap, an estimate is presented based on a study prepared in 1981. For this study 782 samples of water were obtained in 58 cities in 47 States. The average lead level was 0.013 mg/L, with 90 percent of the values below 0.033 mg/L. The treatment techniques required by EPA regulations¹ are expected to reduce the levels of lead in tap water.

All public water systems are required by EPA regulations¹ to have their water monitored for lead. If lead is detected in municipal water systems at a level exceeding the specified action level, specified programs that will reduce lead levels must be followed by those systems. In EPA's regulations,¹ the final lead action level is exceeded if the level of lead in more than 10 percent of the targeted tap samples is greater than 0.015 mg/L. Thus, water from municipal sources used by bottling companies may contain lead at a level greater than 0.005 mg/L.

A 1987 survey⁶ of 60 different bottled water products sold in Massachusetts included analyses for lead. The products tested originated in the States of Massachusetts, Maine, New Hampshire, Arkansas, Connecticut, California, New Jersey, Pennsylvania, Vermont, New York, and Georgia and the countries of France, Sweden, Canada, Germany, Switzerland, and Italy. The limit of detection for lead was 0.002 mg/L. Lead was found in amounts above the limit of detection in 13 of the bottled water samples. The median amount of lead found was 0.004 mg/L. Three of the 60 samples were found to have levels of lead above 0.005 mg/L. The maximum level found was 0.100 mg/L.

⁶Massachusetts Department of Public Health, Division of Food and Drugs, *Survey of Bottled Water Sold in Massachusetts*, Jamaica Plain, MA 02130, December 1987.

Allen et al.⁷ conducted a study of 37 brands of bottled water in which they analyzed for many inorganic chemicals including lead. The countries of origin of these products were Germany, Switzerland, France, United States, Italy, United Kingdom, Yugoslavia, Poland, Spain, and Austria. The limit of detection for lead was 0.001 mg/L. Lead was found in amounts above the limit of detection in 11 of the bottled water samples, with a median amount of lead found of 0.0034 mg/L. Five of the 37 samples were found to contain lead at levels above 0.005 mg/L. The maximum level found was 0.0108 mg/L.

Information from IBWA² indicates that water from sources other than municipal systems, i.e., privately-owned, protected sources, do not contain lead because lead is primarily introduced into water from the distribution system. This statement agrees with information in EPA's final rule.¹

b. *Environmental consequences:*

(1) Removal of lead from source water

Implementation of the proposed bottled drinking water regulation for lead has potential for increased emissions into the environment as a result of the removal of lead from water. These increases would occur if the water used by bottled water companies for their products were to contain lead in excess of the allowable level. The occurrence data presented in the preceding section, 2.a.(3), indicates that lead has been detected in bottled drinking water at levels above FDA's proposed allowable level and that municipal water may contain lead at a level above FDA's proposed allowable level.

Information available to FDA^{2&3} indicates that bottling companies who use water from a municipal water system and who find that the water is contaminated are likely to treat the water to bring it into compliance. If bottled water companies treat their water to remove lead, they are likely to choose to use one of the best available technologies selected by EPA according to information from IBWA². Information from IBWA² further indicates that, when the source of bottled water is not a municipal water system, i.e., it is privately owned, this water is unlikely to be contaminated with problem levels of lead. Furthermore, information from IBWA² indicates that, if a privately owned source of water were found to contain lead, the bottling company would be more likely to change sources than to treat.

⁷Allen, H.E., M.A. Halley-Henderson, and C.N. Hass, "Chemical Composition of Bottled Water," *Archives of Environmental Health*, 44, 102-116, March/April 1989.

The following information pertaining to the removal technologies is paraphrased from EPA's 1989 proposed rule⁸ for National Primary Drinking Water Regulations for 30 synthetic organic chemicals and 8 inorganic chemicals.

The removal technologies ion exchange and reverse osmosis generate waste products in the form of brines. Brines can be disposed of by discharge to wastewater treatment plants or by direct discharge to receiving waters. However, permits are needed to discharge brines to surface waters, and EPA has alerted public water systems using these technologies to contact the wastewater treatment plant before discharging brines to a sanitary sewer and to contact their NPDES authority before discharging directly to surface waters. EPA lists some alternatives for disposing of brines: evaporation pond dewatering followed by land disposal and chemical precipitation followed by nonmechanical dewatering (lagoons or drying beds) and land disposal.

The removal technologies coagulation/filtration and lime softening generate waste products in the form of sludges. Sludges can be disposed to wastewater treatment plants. EPA has alerted public water systems using these technologies to contact the wastewater treatment plants before discharging to the sanitary sewer. EPA lists some alternatives for disposing of sludges: nonmechanical dewatering (lagoons or drying beds) followed by land disposal and direct land application for lime softening wastes.

EPA concludes that regulatory constraints will influence the selection of waste by-product disposal alternatives, e.g., industrial pretreatment requirements for sanitary sewer discharges, Resources Conservation and Recovery Act requirements for hazardous waste disposal, and effluent limitations for discharge of some contaminants into local receiving waters.

Since the amount of bottled drinking water is a small fraction of the amount of water produced by public water systems, any treatment of the water used by any bottled water plants would result in environmental effects that will be considerably less than the effects of treating water produced by public systems. In addition, regulations constrain the disposal of waste products from treatment techniques, as indicated above.

(2) Changing source water

If a bottled drinking water company found that its source water contained lead in excess of the allowable level, the company could decide to change sources. This change could result in increased transportation needs which could increase energy use and/or increase air emissions. It is not known how many bottled water companies may change sources because of FDA's regulation and thereby cause an increase in energy use and air emissions from the increased transportation. The bottled water companies using

⁸U.S. Environmental Protection Agency, "National Primary and Secondary Drinking Water Regulations; Proposed Rule," 54 FR 22062-22160, May 22, 1989.

municipal sources are likely to treat their source water rather than to change sources to bring the water into compliance.^{2&3} The low frequency of occurrence of lead in bottled water (see Section 2.a.(3) above) and the information from IBWA² on non-occurrence of lead in privately-owned source water indicates that lead is unlikely to occur above the proposed levels for bottling companies that use privately owned water sources. Therefore, it is likely that few, if any, of the bottled water companies will change sources.

(3) Recalled bottled drinking water

If FDA detects lead in a representative sample of bottled water and initiates a recall of the batch of bottled water the sample represents, and if it becomes necessary for that batch of bottled water to be disposed of, there is potential for emissions to the environment from this disposal. However, FDA's regulations implementing the National Environmental Policy Act require the consideration of the potential environmental impact of the disposition of articles following a recall, see 21 *CFR* Sections 25.22(a)(3) and 25.24(a)(4). Therefore, before the disposal of recalled bottled water, FDA would consider whether this disposal will adversely affect the environment.

3. MITIGATION MEASURES:

Since no adverse environmental effects are expected to be associated with the proposed action, no measures need to be taken to avoid or mitigate such effects.

4. DESCRIPTION OF REGULATORY ALTERNATIVES TO THE PROPOSED ACTION AND THE EXPECTED ENVIRONMENTAL CONSEQUENCES:

Section 410 of the Federal Food, Drug and Cosmetic Act requires FDA either to promulgate bottled drinking water regulations or to publish reasons for not doing so after EPA has promulgated national drinking water regulations. Hence, an alternative to this proposed action is not to change the allowable level for lead and give reasons. The nature and magnitude of human health effects, if any, due to existing levels of lead in bottled drinking water are not fully known. However, if the allowable level is not changed, there is potential for environmental impact in the form of adverse human health effects from exposure to lead at levels that are higher than the proposed allowable level. Available information shows that currently known levels of lead in bottled drinking water are generally lower than FDA's proposed allowable level; there is no reason to suspect that the levels of lead would increase in the absence of an FDA action. Consequently, the magnitude of the impact, if any, would be expected to be small.

Another regulatory alternative is to set an allowable level that is either higher or lower than the proposed 0.005 mg/L. The analysis of the factors applying to an allowable level set at 0.005 mg/L would also apply to an allowable level set at a level higher than

0.005 mg/L, leading to the conclusion that there would be little, if any, expected environmental impact from this alternative. If FDA sets an allowable level that is lower than 0.005 mg/L, there would be increased potential for environmental impact from this alternative, because an allowable level lower than 0.005 mg/L would increase the possibility that bottled water companies would need to treat or change their source water. To fully assess the environmental impact of a lower allowable level it would be necessary to know the proposed lower level and this is not known now. However, even with an allowable level lower than 0.005 mg/L in place, any environmental effects resulting from treatment to remove lead from the source water would be considerably less than the effects of treating water in public systems, because the amount of bottled drinking water is a small fraction of the amount of water produced by public water systems. These effects were evaluated by EPA, see Section 2.b.(1) above. The potential environmental impact that might result from the need to change source water if an allowable level lower than 0.005 mg/L were to be implemented cannot be fully evaluated because of the lack of information about the likelihood of bottled water companies changing sources as well as about the numerical value of a possible lower allowable level. However, the information on the low occurrence of lead in bottled drinking water presented in Section 2.a.(3) indicates it is unlikely that setting an allowable level lower than 0.005 mg/L would precipitate the need for changing privately-owned source water. When the source water is municipal drinking water, bottled water companies are not likely to change sources; rather than change, they treat the water to remove contaminants^{2&3}.

5. COMPARATIVE ANALYSIS OF PROPOSED ACTION AND ALTERNATIVES:

There is little, if any, environmental impact expected from either the proposed action or the alternatives, because the amounts of lead currently present in bottled water sources and products are low. The proposed action is preferred to the alternatives because FDA has evaluated EPA's regulations for lead in public water supplies and has determined that 0.005 mg/L is appropriate as an allowable level for lead in bottled drinking water and to protect the public health.

6. LIST OF PREPARERS:

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