

at zero for known or probable human carcinogens.

EPA response: EPA believes setting MCLGs for known or probable human carcinogens at zero is consistent with the statutory directive to set MCLGs at the level at which no known or anticipated adverse effects on the health of persons occur and which provide for an adequate margin of safety. The U.S. Court of Appeals for the D.C. Circuit has upheld this approach in *NRDC v. Thomas*, 824 F.2d 1211 (D.C. Cir. 1987). As discussed previously, the Agency continues to believe that MCLGs of zero are consistent with the statutory directive.

7. Comments on Monitoring and Reporting Requirements

Thirteen commenters discussed monitoring and reporting requirements for the regulated contaminants. Several commenters felt that each State should establish its own public notification and monitoring requirements and maintain all responsibility for issuing variances. One commenter noted that the States strongly support maximum State discretion in establishing monitoring requirements, particularly for synthetic organic chemicals.

A number of commenters discussed the three-tiered monitoring scheme which varies monitoring requirements based upon the occurrence and health effects of the specific contaminants. Most commenters expressed support for this monitoring approach and the resulting flexibility. Two commenters were concerned that the guidelines for each tier will not have enough flexibility resulting in small systems undertaking costly monitoring programs which are not affordable.

EPA response: The SDWA mandates that EPA establish MCLGs/MCLs, public notification, monitoring and variance requirements (among others) while States may implement and enforce these requirements. The monitoring requirements for this regulation propose a phased-in sampling requirement based on system size and reduced monitoring frequency for small systems. This approach would reduce the small system economic burden of monitoring. Furthermore, today's proposed rule allows the State flexibility in requiring initial monitoring for pesticides and PCBs based upon a vulnerability assessment. The proposed repeat monitoring frequency for these contaminants is also dependent upon the system's vulnerability and whether pesticides or PCBs are detected in initial sampling results.

8. Comments on Financial Considerations

Six individuals or organizations discussed financial considerations in developing regulations. Several commenters stated that national drinking water standards (including the monitoring requirements) should be flexible and cost-effective.

EPA response: Under the SDWA, MCLs are applicable nationwide and apply to all systems, except where a public water supply obtains a variance or exemption under the Act. EPA does take costs into consideration in developing NPDWRs and the Agency agrees that cost effectiveness considerations should be taken into account. In terms of compliance monitoring, EPA agrees that the monitoring requirements should be tailored to local conditions and is proposing monitoring requirements which allow States to determine which systems must monitor based on a vulnerability assessment.

F. Proposed MCLGs for Inorganic Chemicals

1. Asbestos. EPA proposed an MCLG of 7.1 million fibers/liter for asbestos fibers exceeding 10 μ m in length in November 1985. That proposal was based upon evidence of occurrence of benign polyps in male rats following oral administration of intermediate (>10 μ m range chrysotile asbestos. EPA also requested comment on the option of not proposing a primary regulation for asbestos due to the inconclusive nature of the health data. EPA has reexamined both options and has decided to repropose an MCLG of 7 million long fibers/liter (rounded off from 7.1 million) since sufficient health and occurrence data exist to justify a national regulation and the 1986 SDWA Amendments require the Agency to regulate this contaminant.

EPA has classified asbestos as a Group A, known human carcinogen, based upon human and animal evidence that inhaled asbestos is associated with lung tumors. However, EPA has not proposed an MCLG for asbestos based upon this classification, since the evidence for the association between ingested asbestos and cancer is limited (see discussion at 50 FR 46961). Instead, EPA has proposed an asbestos MCLG considering the chemical for drinking water purposes as if it were in Group C, based on the limited evidence of carcinogenic effects via ingestion.

EPA has considered whether inhalation exposure to indoor airborne asbestos from the water could present a health concern. EPA examined this issue

and based upon available data has concluded that the risk of this route of exposure is not significant. This is supported by a recent study from the New York State Department of Health (1986) (Investigation of Indoor Airborne Asbestos, Woodstock, New York, 1986). This is considered to be a worst case example since the drinking water was very corrosive resulting in severe degradation of the water system's asbestos-cement (A/C) pipe. Levels of asbestos were measured in excess of 300 million fibers per liter. Levels of asbestos in air were found not to be significantly different than background levels. Also, the levels in drinking water from corrosion of A/C pipe will be controlled in some systems by the corrosion control treatment technique regulation for lead and copper currently being developed by EPA.

On January 29, 1986, EPA proposed a rule under Section 6 of the Toxic Substances Control Act (TSCA) to ban the manufacture of certain asbestos products, including A/C pipe, and to phase out others. The TSCA proposal does not impact the use of currently installed A/C pipe. EPA recommends that water suppliers adopt corrosion control strategies to minimize corrosion of A/C piping material.

Public comments: A total of 23 individuals or organizations commented on the MCLG proposal for asbestos. A number of commenters stated that it was not appropriate to set an MCLG for asbestos since there are inadequate data to establish that ingestion of asbestos fibers presents a health risk. Three commenters felt that since epidemiological studies have not shown a correlation between asbestos in drinking water and cancer and the only evidence of carcinogenicity of asbestos by ingestion is from the National Toxicology Program (NTP) bioassay, an MCLG should not be established.

Several commenters stated that it is not appropriate to set an MCLG for asbestos since there are inadequate occurrence data. They stated that the NTP bioassay indicated that only asbestos fibers longer than 10 μ m appear to be of health significance in drinking water and there are no data that indicate that fibers longer than 10 μ m occur in drinking water.

Additional commenters felt that an MCLG should not be established for asbestos, since analytical methods to measure low levels of asbestos are not available. One commenter agreed that it was appropriate to set an MCLG for asbestos but expressed concern over the expense involved in monitoring for asbestos. Another commenter felt that

See next page also

imprecise analytical results can only justify an MCLG of one significant figure. One commenter stated that the EPA did not consider the interactive effects observed in the NTP bioassay.

EPA response: EPA recognizes that the evidence of the health effects of ingested asbestos is limited. There was an increased incidence of benign polyps in male rats following ingestion of intermediate (>10 μ m in length) range chrysotile asbestos. However, EPA believes that there is a sufficient basis to justify regulating asbestos for the reasons outlined in the November 13, 1985, notice. Furthermore, the 1986 SDWA Amendments direct EPA to regulate asbestos.

EPA believes that sufficient occurrence data exist to warrant an MCLG for asbestos, since asbestos entering water supplies from asbestos/cement pipe is common where corrosive water is being used. While EPA agrees that the great majority of the asbestos fibers found in ground and surface waters are less than 10 μ m in length, available data indicate that a small percentage of fibers are greater than 10 μ m in length.

Under the SDWA, the availability of analytical methods is not a prerequisite to the establishment of an MCLG for a contaminant. Rather, that availability impacts on whether EPA promulgates an MCL or treatment technique as the enforceable standard (see sections IV and VI for a discussion of analytical methods and monitoring requirements for asbestos proposed in this notice).

EPA is proposing that only vulnerable systems monitor for asbestos, based upon a vulnerability determination by the State. This should significantly reduce the costs of monitoring.

EPA agrees that this MCLG should only be one significant figure and is reproposing an MCLG of 7 million fibers/liter for asbestos fibers exceeding 10 μ m in length.

Regarding the comment on interactive effects, the NTP bioassay, which studied rats exposed to 1,2-dimethyl-hydrazine dihydrochloride (DMH) and DMH with intermediate range chrysotile asbestos did not appear to significantly affect the carcinogenic potential of DMH, neither increasing or decreasing biologically important neoplasms.

2. **Barium.** EPA proposed an MCLG of 1.5 mg/l for barium in the November 1985 proposal on the basis of a study showing that chronic exposure to barium resulted in hypertension in rats (Perry, H.M.; Kopp, S.J.; Erlanger, M.W.; Perry, E.F. 1983. "Cardiovascular Effects of Chronic Barium Ingestion." In: Hemphill, D.D., ed., *Trace Substances in Environmental Health—XVII*.

Proceedings of University of Missouri's 17th Annual Conference on Trace Substances in Environmental Health. Columbia, MO: University of Missouri Press). The 1985 notice also described the results of an epidemiology study which found that male and female adults consuming drinking water containing high levels of barium (7.3 mg/l) for more than ten years did not manifest significant differences in mean systolic/diastolic blood pressures (Brenniman, G.R., Kojola, W.H., Levy, P.S., Carnow, B.W., Namekata, T. 1981. "High Barium Levels in Public Drinking Water and Its Association with Elevated Blood Pressure." *Arch. Environ. Health*. 36(1):28-32; and see also Brenniman, G.R., Levy, P.S. 1984. "Epidemiological Study of Barium in Illinois Drinking Water Supplies.") While the Agency proposed an MCLG of 1.5 mg/l, EPA also solicited comment on whether the MCLG for barium should be based upon a chronic suggested no-adverse-response level (SNARL) of 4.7 mg/l derived by the National Academy of Science (NAS) (Drinking Water and Health, 1982, Vol. IV). EPA noted some concerns about the Perry and Brenniman studies as well as the SNARL derived by the NAS. Because of these questions, EPA believed that further study was appropriate and the Agency instituted a human study subsequent to the 1985 notice that examined the effect of barium in drinking water on blood pressure (Wones *et al.*, 1987, "Lack of Effect of Drinking Water Barium on Cardiovascular Risk Factors," University of Cincinnati College of Medicine, Cincinnati, OH, manuscript in preparation). After reevaluating the available data in light of the human study, EPA is reproposing an MCLG of 5 mg/l for barium.

In the Wones study, eleven healthy men were enrolled in a 10-week dose-response protocol in which diet was controlled, other aspects of lifestyle known to affect cardiac risk factors were controlled, and the barium content of the drinking water (1.5 l/day) was varied from 0 (first 2 weeks) to 5 mg/l (next 4 weeks) to 10 mg/l (last 4 weeks). Multiple blood and urine samples, morning and evening blood pressures, and 48-hour electrocardiographic monitoring were performed at each dose of barium. There were no changes in morning or evening systolic or diastolic blood pressures, plasma cholesterol or lipoprotein or apolipoprotein levels, serum potassium or total calcium or glucose levels, or urine metanephrine levels. There were no arrhythmias related to barium exposure detected on electrocardiographic monitoring. In summary, drinking water barium at

levels of 5 and 10 mg/l did not appear to affect any of the cardiovascular risk factors studied in this project.

In light of the Wones *et al.* study, EPA believes that it is not appropriate to rely on the Perry *et al.* study in deriving the MCLG for barium. As the Agency noted in the preamble to the 1985 proposal, the rats in the study were exposed to minimal levels of trace metals, including calcium, and the lack of calcium may have contributed to the hypertensinogenic effects observed. Because the weight of the available human data (Wones *et al.*, 1987; Brenniman *et al.*, 1981; Brenniman and Levy, 1984) appear to contradict the results found in the Perry *et al.* rat study and thereby substantiate the Agency's concerns about that study, EPA is not relying on Perry *et al.* to derive the reproposed MCLG.

The Wones *et al.* study failed to detect adverse effects at 10 mg/l. EPA has applied an uncertainty factor of 2 to derive an MCLG of 5 mg/l. EPA applied an uncertainty factor of 2 rather than a factor of 10 which would normally be applied with a human study with a NOAEL due to the fact that the study is corroborated by the results of other studies (i.e., the Brenniman *et al.*, 1981 study). EPA has not factored RSC into this number since the basis is a human study in which contribution from food and air is already taken into account. The reproposed MCLG is supported by the results of Brenniman *et al.*, which failed to find adverse effects at slightly higher levels of 7.3 mg/l. Furthermore, the reproposed MCLG is also consistent with the 4.7 mg/l value recommended by the NAS. EPA stated in the preamble to the 1985 proposal that 4.7 mg/l did not appear to be adequately protective of children. EPA now believes this is not the case since hypertension is an effect which is seen after many years of exposure and thus adults would be the population at risk for this effect.

EPA requests public comment on the approach used to set the MCLG for barium.

Public Comments: A total of 14 individuals or organizations submitted comments in response to the barium proposal.

One commenter raised two points regarding the health effects of barium: (1) barium may have beneficial effects on teeth and bone, and (2) EPA has incorrectly assumed that barium acts with no toxic threshold. One commenter argued that barium should not be classified as a heavy metal since the solubility of barium is adequate to allow excretion from the body and prevent cumulative toxicity.