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by
Jeffrey D. Dintzer, Esq.
and
Brett H. Oberst, Esq.

Gibson Dunn & Crutcher LLP

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Commentary

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Jeffrey D. Dintzer
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Brett H. Oberst

[Editor's Note: Jeffrey D. Dintzer is a partner and Brett H. Oberst is a senior associate in the Environment & Natural Resources Practice Group of Gibson Dunn & Crutcher LLP. They practice in the areas of environmental and toxic tort litigation, including claims related to perchlorate contamination. They can be reached at (213) 229-7860 or jdintzer@gibsondunn.com, and (213) 229-7189 or boberst@gibsondunn.com, respectively. *Replies welcome.]*

Perchlorate is an ingredient used to manufacture fireworks, missiles, rockets, and other pyrotechnic devices. Advances in groundwater testing in 1997 led to the discovery of widespread perchlorate contamination across the country. Since then, federal and state agencies have considered whether and how to regulate the chemical.

The first drinking water standard for perchlorate was enacted in 2006 by Massachusetts. The second was just recently enacted by California in September 2007. Now, the federal government and several other states appear ready to take similar action. If this occurs, it will significantly increase the legal stakes over perchlorate contamination, both because of the direct legal effects of drinking water standards and the indirect effects such standards may have on litigation over perchlorate, including common law tort claims for property damage and personal injury. This article examines these issues, including why intentionally conservative, health-protective regulations should not be misinterpreted as identifying perchlorate levels that likely cause injury.

The State Of Perchlorate Regulation

The U.S. Environmental Protection Agency recently announced it will decide by the end of 2007 whether to set a national health-based drinking water standard for perchlorate. This would be a critical step in EPA's review of perchlorate, which dates back to at least 1998. Perchlorate was included in the first EPA Contaminant Candidate List, which is used to prioritize contaminants for regulation.[1] At that time, EPA identified "significant data gaps" and placed perchlorate "in the categories of needing additional health effects, treatment research, and occurrence information."[2]

After years of research and investigation, the EPA adopted an oral reference dose for perchlorate of 0.007 milligrams per kilogram of body weight based on a review by the National Research Council of the National Academies in February 2005. That reference dose translates to a "Drinking Water Equivalent Level" (DWEL) of 24.5 parts per billion (ppb). In January 2006, EPA issued protective guidance recommending 24.5 ppb as a preliminary cleanup goal for perchlorate.

EPA's recent announcement comes amidst pressure from various sources to set a national drinking water standard for perchlorate. Earlier this year, U.S. Sen. Barbara Boxer (D-CA), Chair of the Senate Committee on Environment and Public Works, introduced two bills (Senate Bills 24 and 150) on this issue. The "Perchlorate Monitoring and Right-to-Know Act

of 2007" and the "Protecting Pregnant Women and Children From Perchlorate Act of 2007" would amend Section 1412(b)(12) of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300g-1[b][12]) and require the EPA administrator to establish a primary drinking water standard for perchlorate by Dec. 31, 2007.

Similar regulatory action has been taken in Massachusetts and California. In July 2006, Massachusetts became the first state to promulgate a drinking water standard for perchlorate. The Massachusetts Department of Environmental Protection enacted a standard of 2 micrograms per liter (µg/L) or parts per billion (ppb), more than 10 times lower than the level EPA found to be safe.[3] In September 2007, the California Department of Public Health adopted a primary drinking water standard of 6 ppb for perchlorate, effective Oct. 18, 2007.

Several other states, including Arizona, Maryland, Nevada, New Mexico, New York, and Texas have established non-enforceable, advisory levels for perchlorate.[4] These states, and perhaps others, may follow the path blazed by Massachusetts and California.

The Direct Effects Of Drinking Water Standards For Perchlorate

Under the Safe Drinking Water Act, an enforceable primary drinking water standard, also referred to as a "Maximum Contaminant Level" (MCL), is the maximum permissible level of a contaminant in water that may be delivered to any user of a public water system.[5]

MCLs are also used to establish cleanup levels required under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Perchlorate is not specifically listed as a "hazardous substance" for purposes of CERCLA or corresponding state cleanup laws, such as the California Hazardous Substances Account Act (HSAA).[6] Nevertheless, in 2003, a federal district court in California found that CERCLA applied because perchlorate is ignitable and therefore a "characteristic" hazardous waste.[7]

The National Contingency Plan (NCP) provides that remedial goals under CERCLA must be developed by considering "legally applicable or relevant and appropriate requirement[s], standard[s], criteria or limitations[s]" (ARARs).[8] For groundwater designated as drinking water, MCLs are used as the cleanup standard if found to be relevant and appropriate.[9]

Under these laws, single-digit MCLs for perchlorate would significantly increase the number of sites requiring cleanup. In May 2005, the U.S. Government Accountability Office reported perchlorate had been found by federal and state agencies at almost 400 sites across 35 states, the District of Columbia, and two commonwealths of the United States.[10] Perchlorate was found in 153 public drinking water systems, but only 14 of those had perchlorate concentration levels above EPA preliminary cleanup goal of 24.5 ppb.[11] There will be a significant increase in the number of sites requiring cleanup if EPA and other states follow the lead of Massachusetts and California and adopt a single-digit MCL for perchlorate.

The Indirect Legal Effects Of Perchlorate Regulation

The enactment of low MCLs for perchlorate will trigger much more than an increase in the number of mandatory cleanups under federal and state law. CERCLA lawsuits for cost recovery and contribution will follow given the significant remediation costs. In 2004, U.S. Sen. Diane Feinstein (D-CA) explained, "The costs to clean up perchlorate contamination are astronomical, reaching early $1 million in capital costs per drinking well and $500,000 in annual operating costs."[12] More recent estimates for total remediation costs vary from hundreds of millions to over a billion dollars if low MCLs are enacted.

The effect of a low MCL on litigation over perchlorate is unlikely to end with the mandatory cleanup costs. Even without a national MCL, there are already many toxic tort and property damage lawsuits over perchlorate contamination, particularly in California where historic aerospace and firework manufacturing operations led to perchlorate groundwater contamination. Sites with perchlorate contamination levels that are above a federal or state MCL are more likely to be the subject of litigation, even if they are not immediately subject to mandatory cleanup.

Property Damage Tort Claims

Courts consider MCLs in evaluating whether contamination gives rise to common law property damage claims such as negligence, nuisance, and trespass. In City of Moses Lake v. United States, a federal dis-

trict court found such claims accrued only when the contaminant level exceeded the MCL.[13] The court reasoned, "[I]f and when one of the wells exceeds the MCL for [the chemical at issue], Moses Lake will have a cause of action because clearly then a health risk will exist."[14] Applying this reasoning, it will be more difficult for defendants to obtain dismissals or summary judgment in cases in which contamination levels are greater than an MCL because courts may presuppose such levels constitute a health risk. The lower the MCL, the more properties will be in this category.

There is less clarity as to how courts will respond to contamination levels that are below an MCL. Some courts have found claims based on such facts fail as a matter of law, either because of a lack of standing or a failure to prove an injury. In Brooks v. E.I. DuPont De Nemours & Co. Inc., a federal district court found the defendant was entitled to judgment as a matter of law because the plaintiff-property owners did not show that past or present contamination violated the state MCL.[15] Relying on the same reasoning, in Adams v. A.J. Ballard Jr. Tire & Oil Co., a state superior court found that "unless each Plaintiff can establish the existence of concentrations . . . sufficient to violate the state groundwater quality standards, they do not have standing to pursue their claims at trial and their claims must be dismissed."[16]

Other courts have been unwilling to adopt a "bright-line rule" based on the MCL. In In re: Methyl Tertiary Butyl Ether (MTBE) Products Liability Litigation, the federal district court rejected the defendants' arguments that "only contamination in excess of the MCL can constitute an injury."[17] The court found, "[W]hile courts have looked to applicable MCLs to determine whether an injury has occurred, they have not held that an injury cannot have occurred."[18] The court continued:

> W]hile the MCL may serve as a convenient guidepost in determining that a particular level of contamination has likely caused an injury, the MCL does not define *whether* an injury has occurred. Although linking injury to the MCL would provide a bright-line rule, it would do little else to promote standing principles. . . . While it may eventually be determined that some levels of contamination below the applicable MCLs do not injure plaintiffs' protected interests, plaintiffs have presented sufficient evidence for purposes of standing to show that they may have been injured-not as a theoretical matter, but rather as a question that is appropriate for judicial resolution.[19]

The court further declined to grant summary judgment in favor of defendants, leaving open the possibility plaintiffs could prove injuries caused by the below-MCL contamination (*e.g.*, increased monitoring, testing, and treatment costs incurred because of the contamination).[20]

Personal Injury / Toxic Tort Claims

Another issue is whether MCLs are relevant to proving personal injury claims. The number of potential claims is staggering. According to the May 2005 GAO Perchlorate Report, an EPA official has estimated about 10 million people may have been exposed to perchlorate through their drinking water.[21] As noted earlier, the majority of those exposures are below the current EPA protective guidance level of 24.5 ppb. If EPA adopts a single-digit MCL, then the great majority of those persons will be able to claim exposures above the regulatory limit. But would that mean they were exposed to a level capable of causing injury?

Plaintiffs will argue the answer is certainly yes. They will contend that, by law, MCLs are based on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices," and "data collected by accepted methods or best available methods . . . "[22] Moreover, they will argue the MCL is determined by government officials and scientists who have no stake in the litigation, unlike the hired experts testifying for the defense. Why should the court and jury not accept the views of EPA?

The answer is when EPA sets an MCL, it is not answering the question of how much exposure to a chemical will likely cause injury to that plaintiff, which is the issue in the toxic tort case. Rather, MCLs are intended to "represent the level of water quality that EPA believes is acceptable for over 200 million Americans to consume every day from public drinking water supplies."[23] Making sure all of those consumers are safe, including sensitive groups, requires setting the MCL at a level so low that exposures above

it are not expected to be harmful to most, if not all, individuals.

This difference between a level that is safe versus one that may cause injury is well-recognized. The Federal Judicial Center's Reference Manual on Scientific Evidence notes that "generalizations . . . from regulatory positions" are "[p]articularly problematic" in toxic tort cases.[24] This is because "the impetus for the development of risk assessment has been the regulatory process, which has different goals." "Because of their use of appropriately prudent assumptions in areas of uncertainty and their use of default assumptions when there are limited data, risk assessments intentionally encompass the upper range of possible risks.[25]

Given this worst case scenario approach, regulatory levels are not treated as competent evidence of causation in a toxic tort case. In the landmark case, In re: Agent Orange Product Liability Litigation, Judge Weinstein observed:

> The distinction between avoidance of risk through regulation and compensation for injuries after the fact is a fundamental one. In the former, risk assessments may lead to control of a toxic substance even though the probability of harm to any individual is small and the studies necessary to assess the risk are incomplete; society as a whole is willing to pay the price as a matter of policy. In the latter, a far higher probability (greater than 50 percent) is required since the law believes it unfair to require an individual to pay for another's tragedy unless it is shown that it is more likely than not that he caused it.[26]

The Fifth Circuit offered similar reasoning in Allen v. Pennsylvania Engineering:

> Regulatory and advisory bodies such as [the International Agency for Research on Cancer], OSHA and EPA utilize a 'weight of the evidence' method to assess the carcinogenicity of various substances in human beings and suggest or make prophylactic rules governing human exposure. This methodology results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances. The agencies' threshold of proof is reasonably lower than that appropriate in tort law, which 'traditionally makes more particularized inquiries into cause and effect' and requires a plaintiff to prove 'that it is more likely than not that another individual has caused him or her harm.'[27]

The California Court of Appeal recently reached a similar conclusion in In re: Groundwater Cases.[28] At issue was whether regulated water companies could be held liable for serving water containing chemicals in excess of regulatory levels. The court held these claims failed for several reasons, including that regulatory levels are not set at a number above which injury is expected to occur. The court explained:

> MCLs are developed for the purpose of protecting the public from possible health risks associated with *long-term* exposure to contaminants. . . . Because the MCL for carcinogenic chemicals is set based on an assumption that an individual drinks two liters of water per day from a contaminated source over a 70-year lifetime, the theoretical cancer risk will very often overstate the *actual* risk, since it is unlikely that most people will drink two liters of water daily from the same contaminated source for 70 years. Thus, where levels of contamination are below an MCL or [Action Level] or *temporarily exceed these levels,* no health hazard is reasonably expected to occur.[29]

These concerns particularly apply to the regulation of perchlorate. The current EPA position on perchlorate — and likely any future MCL — is based on the review conducted by the National Research Council of the National Academies, "Health Implications of Perchlorate Ingestion" (NRC, 2005). That review explains the conservative and health-protective approach underlying EPA's position on perchlorate.

The NRC found, "Perchlorate can affect thyroid function because it is an ion that competitively inhibits the transport of iodide into the thyroid . . . "[30] This is "the only effect that has been consistently documented in humans exposed to perchlorate."[31] "To cause declines in thyroid hormone production that would have adverse health effects, iodide uptake would most likely

have to be reduced *by at least 75 percent for months or longer*."[32]

Thus, the NRC calculated "the perchlorate dose required to cause hypothyroidism in adults would probably be more than 0.40 mg/kg per day, assuming a 70-kg body weight."[33] This is more than 570 times higher than the reference dose of 0.0007 mg/kg per day recommended by NRC and adopted by EPA. The reason for the significantly lower reference dose is that there are sensitive populations that *might* be affected by lower doses of perchlorate, including pregnant women, infants, children, and people with low iodide intake.[34]

To protect those potentially sensitive populations, the NRC recommended "that inhibition of iodide uptake by the thyroid in humans, which is the key biochemical event *and not an adverse effect*, should be used as the basis of the risk assessment."[35] "Using a nonadverse effect that is upstream of the adverse effects is a conservative, health-protective approach to the perchlorate risk assessment."[36]

To achieve this goal, the NRC reviewed the available research and identified a "no-observed-effect level (NOEL) for inhibition of iodide uptake by the thyroid at 0.007 mg/kg per day."[37] Then, to be even safer, it recommended adding a "total uncertainty factor of 10" (meaning a level one tenth of the NOEL) "to protect the most sensitive population — the fetuses of pregnant women who might have hypothyroidism or iodide deficiency."[38] This is how the NRC arrived at the reference dose of 0.0007 mg/kg per day, which was adopted by EPA.[39]

This review of the science and policy underlying EPA's reference dose is revealing. Any MCL based on that value will be intentionally lower than the amount of perchlorate necessary to cause *any* effect, even among the most sensitive populations.

This is certainly a conservative approach to protecting public health and should not be confused with an approach that identifies an exposure level that likely causes injury, especially among non-sensitive persons. That is the critical difference between the goals of regulators and proving causation in a tort case. While this distinction will likely be lost in the upcoming public debate over perchlorate regulation, it is one that courts will undoubtedly face in the lawsuits that follow.

Endnotes

1. Announcement of the Drinking Water Contaminant Candidate List, 63 Fed. Reg. 10274 (1998).
2. *Id.* at 10282.
3. Mass. Regs. Code tit. 310, § 22.06 (2007).
4. *See* http://www.epa.gov/safewater/contaminants/index.html (State Perchlorate Advisory Levels and Other Resources).
5. 42 U.S.C. § 300f(3) (2007); Protection of Environment, 40 C.F.R. § 141.2 (2007). *See also* Cal. Health & Safety Code § 116275(f) (2007) ("[MCL] means the maximum permissible level of a contaminant in water.").
6. Cal. Health & Safety Code § 25300 *et seq.* (2007).
7. Castaic Lake Water Agency v. Whittaker, 272 F. Supp. 2d 1053, 1059-61 (C.D. Cal. 2003).
8. 42 U.S.C. § 9621 (2007); Protection of Environment, 40 C.F.R. § 300.430(e)(2)(i)(A) (2007).
9. Protection of Environment, 40 C.F.R. § 300.430(e)(2)(i)(B)-(C) (2007).
10. GAO Report — Perchlorate: A System to Track Sampling and Cleanup Results is Needed — Report to the Chairman, Subcommittee on Environment and Hazardous Materials, Committee on Energy and Commerce, House of Representatives — May 2005 (GAO Perchlorate Report).
11. *Id.* at 3.
12. *See* http://feinstein.senate.gov/04Releases/r-dod-perch.htm.
13. 430 F. Supp. 2d 1164, 1184 (E.D. Wash. 2006).
14. *Id.*
15. 944 F. Supp. 448, 449-50 (E.D.N.C. 1996).
16. No. 01-Civ-1271, 2006 WL 1875965 (N.C. Super. June 30, 2006).

17. 458 F. Supp. 2d 149, 154 (S.D.N.Y. 2006).

18. *Id.* at 158.

19. *Id.* (footnotes omitted).

20. *Id.* at 158-59 (citing, among others, German v. Federal Home Loan Mortgage Corp., 885 F. Supp. 537, 558-59 (S.D.N.Y. 1995) (denying summary judgment where contamination was below MCL because whether injury occurred remained in dispute); Bentley v. Honeywell International Inc., 223 F.R.D. 471, 478 n.11 (S.D. Ohio 2004) ("Regardless of whether the municipal water supply has been deemed safe by the Ohio EPA and/or determined to be below the federal and state established [MCL], the [plaintiffs] still may have suffered diminution in their property values . . . ").

21. GAO Perchlorate Report at 14.

22. 42 U.S.C. § 300g-1(b)(3)(A)(i)-(ii) (2007).

23. National Oil and Hazardous Substances Pollution Contingency Plan, 55 Fed. Reg. 8666, 8750 (Mar. 8, 1990).

24. Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology, in Reference Manual on Scientific Evidence, at 423 (Federal Judicial Center, 2d ed. 2000).

25. *Id.* at 413 (footnote omitted).

26. In re: Agent Orange Product Liability Litigation, 597 F. Supp. 740, 781 (E.D.N.Y. 1984).

27. 102 F.3d 194, 198 (5th Cir. 1996) (quoting Wright v. Willamette Industries Inc., 91 F.3d 1105, 1107 [8th Cir. 1996]).

28. Cal.Rptr.3d, 2007 WL 2405687 (Cal.App. 1 Dist.).

29. *Id.* at *15 (italics in original, citations and internal quotation marks omitted).

30. *Id.* at 6.

31. *Id.* at 13.

32. *Id.* at 8 (emphasis added).

33. *Id.*

34. *Id.*

35. *Id.* at 14 (emphasis added).

36. *Id.* at 15.

37. *Id.* at 15.

38. *Id.* at 15-16.

39. *Id.* at 17. ■

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1018 West Ninth Avenue, 3rd Floor, King of Prussia Pa 19406, USA
Telephone: (610) 768-7800 1-800-MEALEYS (1-800-632-5397)
Fax: (610) 962-4991
Email: mealeyinfo@lexisnexis.com Web site: http://www.lexisnexis.com/mealeys
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