## Case Study
## Judicial Review of EPA's Promugulation of Rules
## Implementing the Safe Water Drinking Act

Chlorine Chemistry Council v. EPA, 206 F.3d 1286 (D.C.Cir., March 31, 2000)

The Safe Water Drinking Act (SWDA) directs EPA to set standards for the regulation of drinking water contaminants. For each contaminant, EPA sets a "maximum contaminant level goal" (MCLG), which is defined as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The MCLG is somewhat ambitious: after setting it, EPA is to promulgate an enforceable standard, known as a maximum contaminant level (MCL). The MCL is to take practical considerations into account, while remaining as close to the MCLG as is feasible.

In July 1994, EPA issued a proposed rule on disinfectants in water which included a zero MCLG for chloroform. This was based on the Agency's finding of an absence of data to suggest a threshold level below which there would be no carcinogenic effects. In 1996, Congress amended the SWDA, enshrining a timetable previously set by EPA for rules relating to disinfectants associated with water treatment. Faced with a new deadline of November 1998, EPA prepared for the necessary rulemaking by forming a Scientific Advisory Group (SAG) to collect, share and analyze new data. Among the findings of the SAG was that chloroform was "unlikely to be carcinogenic below a certain dose range." EPA agreed, and subsequently proposed a MCLG of 300 parts per billion (ppb), a level that built in both a 1000-fold margin of error relative to the studies being used and some non-cancer effects such a liver toxicity.

But in promulgating its final rule in December 1998, EPA retained the existing zero standard which was based on the previously held assumption that there was no safe threshold. The Agency stuck with its 1994 zero level despite explicitly stating that it now believed that the underlying science for a nonlinear approach was well founded. EPA justified its action on a variety of grounds, including an alleged need to consult the report of its Scientific Advisory Board (SAB) – which would not be available until after the statutory deadline for the rulemaking had expired – before departing from a long-held policy.

The Chlorine Chemistry Council, a trade association comprised of chlorine and chlorine product manufacturers, petitioned for review, arguing that EPA violated its statutory mandate to use the "best available" evidence as required when implementing SWDA. In promulgating a zero MCLG, the Chlorine Council argued, EPA overrode the best available scientific evidence which suggested chloroform is a threshold carcinogen.

EPA challenged Petitioner's theory, arguing first that setting a non-zero MCLG would be a precedent setting step, representing a major change in the regulatory decisions regarding chloroform.

Second, EPA argued that it could not complete the deliberations of the SAB before the 1998 deadline. Third, EPA argued that because the final MCL was unaffected, the MCLG of zero had no actual effect. Last, the Agency contended that its 1998 statements did not represent "ultimate conclusions, and thus in adopting a zero MCLG it did not in fact reject what it considered to be the "best available evidence." The Agency contended that the zero MCLG merely represented an "interim risk management decision" pending the outcome of the final SAB report.

The U.S. Court of Appeals for the District of Columbia agreed with the Petitioners. While the Court agreed that adopting a nonzero MCLG would be a significant departure from previous practice, it concluded that the change would occur solely as a result of applying the relevant rules: first, a statutory mandate to set MCLGs at the "no known or anticipated adverse effects" level; and second, EPA's Carcinogenic Risk Assessment Guidelines which requires the Agency to reject the default assumption (in this case a zero standard) when adequate data shows it is no longer the most reasonable working judgement. That the outcome was novel, or even politically charged concluded the Court, was of no significance relative to the Agency's statutory obligation.

As for the timing of the rulemaking, the Court rejected the notion that the Agency could act against its own scientific findings, however desirable it might be to consult the SAB or revise its conclusion in the future. The Court maintained that the statute requires the Agency to take into account the best evidence available at the time, regardless of a possibility that it might be contradicted in the future; this, the Court said, is a possibility that will always be present.

The Court dismissed the contention that the zero standard had no effect, citing examples of actual Agency practice that belie the inconsequentiality of the MCLG (i.e., setting a cleanup standard at a level below an MCL). The Court described cases where the Agency used the MCL to set cleanup standards under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), but went on to say that even if the zero standard had no actual effect, it still would not justify EPA's disregard of its own scientific findings.

Finally, the Court characterized EPA's contention that its 1998 statements were not "ultimate conclusions" as semantic somersaults. Regardless of whether the statements were ultimate or interim is irrelevant to whether it represented the "best available evidence." The word "available" would be senseless if construed to mean "expected to be available at some future date," said the Court. EPA, concluded the Court, cannot avoid Congress' requirement to take actions based on the best science available at the time by dubbing its action interim.

Finding that the Agency's November 1998 rule adopting a zero MCLG for chloroform arbitrary and capricious, and in excess of statutory authority, the Court vacated the rule.

**Discussion Questions**:

- Why did EPA contend that its action was justified so as to "avoid a major change in the substance of regulatory decisions related to chloroform"? To what extent does precedent matter in the realm of administrative rulemakings?

- What might account for the Agency's decision to stick with the zero level MCLG when promulgating the 1998 rule, despite concluding that chloroform was "unlikely to be a carcinogen below a certain dose range"?

- EPA contended that because the SAB report would not be available before the statutory deadline for the rulemaking, it was justified in retaining the zero standard. Is this a reasonable position? In writing SWDA, did Congress truly intend for the Agency to promulgate rules before it had complete scientific information?