By Carolyn Raffensperger

How Much Chloroform Is Good for You?

A regulatory system built around establishing "safe" levels for a myriad of questionable substances found in our air, water, soil, and food is mind boggingly cumbersome and expensive. And it makes for bad science and bad law. Let me walk you through one example — and there are many more — of how our current system can muster all its resources to protect the public and still fail badly.

The example concerns the D.C. Circuit's March 31 decision in *Chlorine Chemistry Council and Chemical Manufacturers Association v. EPA, Natural Resources Council, et al.* But it really begins 20 years ago, when EPA decided, sensibly enough, that when it didn't have adequate data to establish "safe" levels for a substance that is carcinogenic at some level, it would assume that the substance is carcinogenic at *any* level. Thus, for two decades "zero tolerance" has been the default standard for carcinogens.

This is no longer true, at least for chloroform, one of four by-products of drinking water chlorination. In 1994, EPA issued a proposed rule on disinfection by-products in drinking water. As part of its rule, the agency established both an enforceable standard for chloroform and a goal, the Maximum Contaminant Level Goal, or MCLG. The MCLG, if approved, would determine the safe level for chloroform in drinking water.

As the rulemaking progressed, EPA published a Notice of Data Availability, based on the findings of a panel of experts that concluded that chloroform is indeed a likely carcinogen, but only above a certain level. The agency concluded, in other words, that there was enough information about chloroform to establish a safe threshold. The gist of the argument favoring a threshold was that chloroform can damage cells, but it apparently does not affect DNA. Organisms are more likely to tolerate low levels of cell damage than damage to their genes; thus, low levels of this carcinogen could be deemed safe.

While this might be a plausible argument, the data supporting it were equivocal, according to the very reports used by EPA. A World Health Organization review indicated that, in fact, half the bacteria and cell line assays showed DNA damage. Adult rodent tumor assays were fraught with ambiguities and indicated both cell damage and gene damage. As a result, scientists argued throughout the rulemaking that the available data were not adequate to set a safe threshold, and that the default standard should prevail: zero tolerance.

Nevertheless, in its Notice of Data Availability, the EPA had set the chloroform MCLG at 600 parts per billion. A little later, the agency lowered the goal to 300 ppb because chloroform has several known effects besides cancer, notably liver toxicity. And in the final rule, promulgated in 1998, EPA set the goal at zero. Apparently the agency had second thoughts and agreed with those who argued that there was too much uncertainty to set a safe level.

The two industry groups brought suit challenging this rule and, in effect, the agency's regulatory default assumption. EPA moved for a voluntary remand to give it time to consider a new report on chloroform from its Science Advisory Board, which had not been available when the rule was promulgated. The D.C. Circuit denied the motion and granted standing to the petitioners on the flimsy grounds that they had suffered injury in fact, since they might incur liability. That is, under a zero level, they might actually have to clean up contaminated sites to ensure clean drinking water under a zero level. Then the court found that the agency had violated the Safe Drinking Water Act by establishing an MCLG at zero.

This ruling is surprising in light of the major uncertainties in this case — some of them acknowledged by the court. For instance, the court noted that EPA was in the process of reevaluating its technical assumptions, one of which had to do with exposure paths. The agency had assumed that drinking water accounted for 80 percent of total exposure but wanted to revise that figure to 20 percent. There are other sources of exposure, such as inhalation from vaporized contaminants during showers or while cooking.

The court took it upon itself to interpret this finding scientifically. It found that the change might move the level down and put it in the range of 70 and 300 ppb — but definitely not zero. What the numbers actually demonstrate, of course, is the inherent uncertainty of numerical standards in the face of changing assumptions.

A second uncertainty acknowledged by the court is that how chloroform actually causes cancer has not been established. Until this is determined, conservative assumptions and goals are in order to provide an adequate margin of safety.

A third uncertainty concerns the fact that chloroform never shows up alone in chlorinated drinking water. It is accompanied by the three other chemicals — a class called trihalomethanes — produced during chlorination. The rodent bioassays used in this standard were done with chloroform alone, rendering the test meaningless in the real world.

And one factor that neither the court nor the agency considered is the effect on children, although the SDWA requires taking children's special vulnerability into account.

There were so many uncertainties in the science concerning the carcinogenicity of chloroform that EPA was more than justified in using its default standard. Ignoring uncertainties makes for bad science and bad law. You may have heard the old maxim that "law is what judges do." As this ruling shows, law — not science — is what they should stick to.

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