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Fluoride Ruling Charts Path To Bypass EPA Risk Evaluations

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On Sept. 24, in Food and Water Watch Inc. v. U.S. Environmental Protection Agency, Judge Edward Chen of the U.S. District Court for the Northern District of California ordered the EPA to initiate a rulemaking to address the "unreasonable risk of injury" to the health of the public that he found to be posed by drinking water fluoridated to 0.7 milligrams per liter.

Following a multiweek bench trial with competing experts, Judge Chen found that water fluoridation at current levels prevalent in the U.S. creates an unreasonable risk of reduced IQ in children whose mothers drink fluoridated water while pregnant.

This pathbreaking decision demonstrates the power of the 2016 Toxic Substances Control Act amendments in the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

The decision, together with earlier decisions on motions in the same litigation, establishes a road map for how citizen petitioners can bypass the EPA's formal risk evaluation process, by having a court compel the agency to regulate chemical substances under the TSCA.

The EPA's TSCA office had already incorporated the central holding of an earlier decision in the same litigation — that petitioners need only address a single condition of use to have a viable petition — into its standard practice, when it granted a subsequent petition targeting only the use of the rubber additive 6PPD as an anticracking agent in

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tires.

This holding substantially lowered the bar for the TSCA citizen petitions process, particularly for chemicals with many or varied uses, such as fluoride.

Absent an appeal in this litigation, the unreasonable risk analysis procedure established in this litigation will remain, for now, the position of a single district court. Nevertheless, this decision clearly puts the regulation of other chemicals in play that are not currently at the top of the EPA's list.

The Strange History of Fluoridation

The level of water fluoridation primarily considered in the suit is the level currently recommended, but not required, for public water systems by the U.S. Public Health Service, a coalition of federal agencies under the U.S. Department of Health and Human Services, including the National Institutes of Health and the U.S. Food and Drug Administration.

Importantly for public health professionals, absent further action by the EPA or Congress, the decision of whether to fluoridate public water systems rests with state and local authorities as an exercise of their constitutionally reserved residual police power.[1]

However, the outcome of the fluoride litigation calls into question whether the EPA's primary maximum level (4.0 mg/L) and secondary standard (2.0 mg/L) for fluoride in drinking water established under the Safe Drinking Water Act remain appropriate.

The first footnote in the district court's final decision supports the assertion that "[w]ater fluoridation has a long history in the United States and has been a source of political discord" by referencing the 1964 film "Dr. Strangelove."

In the film, released two years after the Public Health Service first recommended fluoridation of water in the U.S., British Royal Air Force base Officer Lionel Mandrake begins to suspect the fraying sanity of his American counterpart Gen. Jack D. Ripper, due to the latter's fixation on water fluoridation as an "international Communist conspiracy to sap and impurify all of our precious bodily fluids."

Opponents of water fluoridation did not have significant success in the courts previously. But the framework for federal involvement in this — and potentially, many similar chemical regulation issues — changed substantially in 2016, when Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

This act provided that if the EPA rejected a citizen petition to regulate an alleged "unreasonable risk" from a chemical under the TSCA, the petitioners could seek a de novo review in federal district court.

With this revision, Congress arguably shifted a reviewing court's focus from whether there was a reasonable basis for a rule, or the lack of a rule, to whether a chemical substance presents an unreasonable risk. Judge Chen's ruling characterizes this standard as less deferential than the standard of review set forth in the Administrative Procedure Act that applies to many agency actions — though his decision does not explore

some potential intricacies of the Lautenberg Act's prescribed standard of review.

Four-Step Analysis of Section 21 Petition Denials

Judge Chen's formula for evaluating whether an EPA denial of a petition was proper is straightforward, and consists of four main steps. Evidence at each step is weighed under a preponderance of the evidence standard, with no deference to any prior finding of the EPA.

The first three steps are drawn from the Natural Resource Council's methodology for risk assessment. The fourth step, in which the court determines whether a risk identified by the first three is unreasonable, is a factor test initially established by the EPA and adopted, but applied differently, by Judge Chen.

First, the court makes a finding concerning the level at which the chemical presents a hazard — the hazard level. Second, the court determines the level at which a segment of the population is exposed to a chemical — the exposure level. The ratio between the hazard level and the exposure level is the actual margin of exposure, or MOE.

Third, the court then determines what a safe or benchmark MOE for the exposure is; this is known as risk characterization. The benchmark MOE is based on standard toxicological practices, and can range from 1 to 3 to 10, or even 100 or higher, based on the uncertainty in the hazard level.

More uncertainty yields a higher benchmark MOE, to guard against that uncertainty. The benchmark MOE determination is a prime example of a determination central to the risk evaluation process for which an agency would ordinarily claim entitlement to deference.

If the actual MOE is greater than the benchmark MOE, there is a risk — and thus there is a fourth question for the court to answer: whether that risk is unreasonable. The term "unreasonable risk" comes from the TSCA, but it is not defined therein.

The court largely adopted a multipronged factor test discussed by the EPA's expert and used by the agency in prior risk assessments. In this way, the court could be said to have deferred to the EPA's methodology, if not its original conclusions. But the factors in this test provide ample room for interpretation.

Under the fourth and final step in the judicial analysis — risk determination — the factors to evaluate to determine if a risk is unreasonable, as found by Judge Chen, are:

- The severity of the hazard;
- The duration, magnitude or frequency of the exposure, and the size of the affected population; and
- The characteristics of the exposed population, including the susceptibility of subpopulations.

Judge Chen found that these three factors weighed in favor of an unreasonable risk determination for fluoride in drinking water.

Two additional factors that were not extensively discussed in the opinion relate to the overall level of confidence in the data underlying the rest of the risk assessment. Ultimately, the court determined both these factors to be neutral, and found unreasonable risk based on the first three alone.

The EPA contended, unsuccessfully, that uncertainty in the science justified a finding that the fourth and fifth factors, related to uncertainty, weighed against finding that the risk was unreasonable. This demonstrates the potency of the prescribed de novo district court review under the Lautenberg Act.

The Future of Fluoride in Drinking Water and Beyond

The EPA is now compelled to begin a rulemaking process to mitigate the unreasonable risk identified by the court. The potential outcome ranges from a simple warning — which might, for example, warn individuals who are or may become pregnant that consuming fluoridated water during pregnancy has the potential to lower child IQ — to a total ban on drinking water fluoridation.[2]

A warning would, at the very least, address the fictional Gen. Ripper's contention that a "foreign substance is [being] introduced into our precious bodily fluids without the knowledge of the individual." The plaintiffs in the litigation have stated that a warning would be "a positive step," but have nonetheless already called for an outright ban following the decision.

The EPA is being directed by the court to regulate fluoride in drinking water under the TSCA, rather than the Safe Drinking Water Act. Under Section 9 of the TSCA, the EPA can conduct interagency and intra-agency coordination during the risk management phase.

TSCA Section 9(a)(2) includes a public interest analysis, and requires the EPA to consider a comparison of the estimated costs and efficiencies of the action to be taken under the TSCA against action taken under other EPA-administered laws. Here, as it pertains to addressing risks to the environment, "other EPA-administered laws" would be the SDWA.

The EPA may choose which environmental law is best suited to address the risk based upon consideration of "all relevant aspects of the risk described above and a comparison of the estimated costs and efficiencies," with an action to be taken under another law to protect against such risk. While the agency is required to coordinate the TSCA with other laws it administers, the decision to use the TSCA to regulate is discretionary.

The Food and Water Watch litigation shows the potency of the Lautenberg Act changes to the citizen petition process under the TSCA. To be sure, a petition and a district court challenge of a denial may not be a fast track to getting a chemical regulated. The fluoride litigation took about seven years.

But the litigation certainly shows how a district court challenge can provide an effective end run around the EPA's ability to choose its own agenda and outcomes, which is a substantial portion of the agency's authority under Section 6 of TSCA.

When the Section 21 mechanism is successfully used to challenge a petition denial, the EPA is left with only the authority to determine how to mitigate an unreasonable risk that has already been confirmed and defined for the agency by a court.

This case also demonstrates the dual-track process that allows the federal judiciary to perform the risk evaluation task ordinarily assigned to the EPA when the agency denies a petition.

The process of evaluating fluoride, and whether a risk is unreasonable, would likely have provided substantial room for deference to the agency if this had been an APA suit, even after the overturning of Chevron deference this past summer, insofar as the undefined statutory term "unreasonable" is being construed.

In view of the outcome of this litigation, the EPA may be more hesitant to deny Section 21 petitions, so that it can retain more control over the process. At the same time, a proliferation of these lawsuits could disrupt the agency's carefully crafted agenda of risk evaluations well into the future.

For example, those advocating for restrictions on per- and polyfluoroalkyl substances may soon decide to file a Section 21 petition for a Section 6(a) restriction on these chemicals. Other chemicals on the EPA's 2014 work plan not currently scheduled for risk evaluation are also potential candidates for this approach.

[1] E.g., Beck v. City Council of Beverly Hills , 30 Cal. App. 3d 112 (Ct. App. 1973) (rejecting an attempt by the citizens of Beverly Hills to enjoin city water fluoridation).

[2] See 15 U.S.C. 2605(a)(1) through (7) (listing the options available to the EPA after an unreasonable risk finding).