

Appendix 2

US Federal Court Ruling

US Federal Court Ruling made by Judge Chen attachment.

	UNITED STATES OF AMERICA
Background	Food and Water Watch v the US EPA
UNSAFE	p. 2: the Court finds that fluoridation of water at 0.7 milligrams per liter (“mg/L”) – the level presently considered “optimal” in the United States – poses an unreasonable risk of reduced IQ in children. "In all, there is substantial and scientifically credible evidence establishing that fluoride poses a risk to human health; it is associated with a reduction in the IQ of children and is hazardous at dosages that are far too close to fluoride levels in the drinking water of the United States...Reduced IQ poses serious harm. Studies have linked IQ decrements of even one or two points to, e.g., reduced educational attainment, employment status, productivity, and earned wages." p. 3: There is little dispute in this suit as to whether fluoride poses a hazard to human health. Indeed, EPA’s own expert agrees that fluoride is hazardous at some level of exposure. And ample evidence establishes that a mother’s exposure to fluoride during pregnancy is associated with IQ decrements in her offspring.
EXPOSURE	p. 5: The pooled benchmark dose analysis concluded that a 1-point drop in IQ of a child is to be expected for each 0.28 mg/L of fluoride in a pregnant mother’s urine. This is highly concerning, because maternal urinary fluoride levels for pregnant mothers in the United States range from 0.8 mg/L at the median and 1.89 mg/L depending upon the degree of exposure. Not only is there an insufficient margin between the hazard level and these exposure levels, for many, the exposure levels exceed the hazard level of 0.28 mg/L. p. 5: Even if the toxicologically determined hazard level of 0.28 mg/L were deemed insufficiently substantiated, evidence in the record still establishes with little doubt that fluoridated drinking water presents a risk of injury to health. p. 6: “The EPA’s default margin of error requires a factor of 10 between the hazard level and exposure level due to variability in human sensitivities...Here, an even greater margin (100x) is owed because the methodology (which yields the 4 mg/L hazard level) uses the lowest observed adverse effect level (“LOAEL”); this methodology adds an additional level of uncertainty (and hence the application of a 100x rather than 10x margin). But even if only the default 10x margin is required, the safe level of fluoride exposure would be

	0.4 mg/L (4 mg/L (hazard level) divided by 10). The “optimal” water fluoridation level in the United States of 0.7 mg/L is nearly double that safe level of 0.4 mg/L for pregnant women and their offspring.”
RISK	p. 77: The scientific literature in the record provides a high level of certainty that a hazard is present; fluoride is associated with reduced IQ. There are uncertainties presented by the underlying data regarding the appropriate point of departure and exposure level to utilize in this risk evaluation. But those uncertainties do not undermine the finding of an unreasonable risk; in every scenario utilizing any of the various possible points of departures, exposure levels and metrics, a risk is present in view of the applicable uncertainty factors that apply.
CERTAINTY	p. 78: There is significant <i>certainty</i> in the data set regarding the association between fluoride and reduced IQ. Namely, there is a robust body of evidence finding a statistically significant adverse association between fluoride and IQ. A large majority of the 72 epidemiological studies assessed by the NTP Monograph observed this relationship including all but one of the 19 high-quality studies, see ¶¶ 34-36, and literature published after the NTP Monograph cutoff date observed the same relationship, see ¶ 37 – and countervailing evidence, for various reasons described previously, are of little impact on this repeated, and consistently observed association between fluoride and reduced IQ, see ¶ 39. Moreover, complete consistency amongst studies is not expected. See Dkt. No. 414, Feb. 9, 20240, Trial Tr. at 1172:23-1173:6 (Savitz). Notably, notwithstanding inherent difficulties in observing this association at lower exposure levels, studies assessing such levels still observed a statistically significant relationship between fluoride and reduced IQ. See ¶¶ 42-44. Again, to put the breadth of evidence supporting this finding in perspective, the EPA has identified a LOAEL based upon far less in other contexts. For instance, in the EPA’s risk evaluation of Methylene, conducted pursuant to Amended TSCA, the EPA used a LOAEL for developmental neurotoxicity, derived from the analysis of one study conducted upon mouse pups (Fredriksson et al., 1992). See Methylene Risk Evaluation at 262. Compare this with 6 (water fluoride) and 9 (urinary fluoride), high-quality, epidemiological studies of human populations underling the 4 mg/L LOAEL underlying the POD here. Dkt. No. 431-2, Trial Ex. 68 at 39, 41 (eTable 4). The scientific literature in the record provides a high level of certainty that a hazard is present; fluoride is associated with reduced IQ. The qualitative evidence is superior.
VULNERABLE POPULATION	p. 76: The size of the affected population is vast. Approximately 200 million Americans have fluoride intentionally added to their drinking water at a concentration of 0.7 mg/L. See Dkt. No. 421 at 206-07 (undisputed). Other Americans are indirectly exposed to fluoridated water through consumption of commercial beverages and food manufactured with fluoridated water.
SUSCEPTIBLE POPULATION	p. 76: Approximately two million pregnant women, and over 300,000 exclusively formula- fed babies are exposed to fluoridated water. The number of pregnant women and formula-fed babies alone who are exposed to water fluoridation each year exceeds entire populations exposed to conditions of use for which EPA has found unreasonable risk; the EPA has found risks unreasonable where the population impacted was less than 500 has found unreasonable risk; the EPA

	has found risks unreasonable where the population impacted was less than 500 people.
RULING	p. 79: Plaintiffs have proven, by a preponderance of the evidence, that water fluoridation at the level of 0.7 mg/L – the prescribed optimal level of fluoridation in the United States – presents an “unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation under the conditions of use.” The Court thus orders the Administrator to initiate rulemaking pursuant to Subsection 6(a) of TSCA. See id. §§ 2605(a), 2620(a)
DIRECTION	The ruling did not specify exactly what measures must be adopted by the EPA, but under the Toxic Substances Control Act (TSCA), once the court rules that a chemical poses an unreasonable risk, the EPA is obligated by law to restrict or eliminate the risk. Judge Chen described a range of options for regulating fluoridation, including banning it, but he warned, “One thing the EPA cannot do, however, in the face of this Court’s finding, is to ignore that risk.”
IMPORTANCE OF THE NTP	The US Federal Court leant heavily on the finalisation of the NTP review hence why the ruling came soon after the publishing of the NTP report. The NTP concluded: “with moderate confidence, that higher estimated fluoride exposures (e.g., as in approximations of exposure such as drinking water fluoride concentrations that exceed the World Health Organization Guidelines for Drinking-water Quality of 1.5 mg/L of fluoride) are consistently associated with lower IQ in children.”].