

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

FOOD & WATER WATCH, INC., et al.,  
Plaintiffs,  
v.  
UNITED STATES ENVIRONMENTAL  
PROTECTION AGENCY, et al.,  
Defendants.

Case No. [17-cv-02162-EMC](#)

**ORDER HOLDING PROCEEDINGS  
IN ABEYANCE**

As stated on the record at the August 6, 2020 status conference, the Court believes that there are serious questions regarding whether the named Plaintiffs in this case have standing. The evidence presented by Plaintiffs at trial focused overwhelmingly, if not exclusively, on the contention that fluoride poses a risk of *neurodevelopmental* harm. More specifically, the evidence at trial focused on whether fluoride poses a threat of neurotoxic harm during critical developmental periods, such as the gestational and neonatal periods (and specifically to bottle-fed infants). By way of example, all of the studies arising out of the MIREC/ELEMENT birth cohorts pertained to neurodevelopmental findings. *See, e.g.* Declaration of Dr. Howard Hu ¶ 13, Docket No. 198-1 (summarizing the “results of the ELEMENT prospective cohort studies” as “support[ing] the conclusion that fluoride is a *developmental* neurotoxicant” (emphasis added)); Declaration of Dr. Bruce Lanphear ¶ 12, Docket No. 198-2 (“Our study of *prenatal fluoride* and IQ in the MIREC cohort (Green 2019) further enhances the quality of data related to the neurotoxicity of fluoride.” (emphasis added)). Likewise, Dr. Philippe Grandjean summarized his opinion, in part, by saying: “The weight of epidemiological evidence leaves no reasonable doubt that *developmental* neurotoxicity is a serious human health risk associated with elevated fluoride

1 exposure.” Declaration of Dr. Philippe Grandjean ¶ 20, Docket No. 198-3. In addition, his  
 2 benchmark analysis—which was based on MIREC/ELEMENT data—investigated the level of  
 3 fluoridated that would “protect against developmental neurotoxicity.” *Id.* ¶ 20. Dr. Kathleen  
 4 Thiessen also focused her risk analysis on the “prenatal period.” Declaration of Dr. Kathleen  
 5 Thiessen ¶ 118, Docket No. 202-1.

6 None of the standing Plaintiffs in this case claim to be subject to that risk of harm; there  
 7 are no allegations that the named Plaintiffs are pregnant, planning to become pregnant, or caring  
 8 for infants. Instead, they contend that fluoride exposure causes them—as adults—headaches,  
 9 increased pain sensitivity, and an increased risk of Alzheimer’s disease or dementia. However,  
 10 Plaintiffs have failed to demonstrate any link between the evidence presented at trial—which,  
 11 again, pertained to neurotoxic harm to fetuses and infants—and the harms of which they  
 12 personally complain.

13 Even assuming that statutory standing under TSCA extends to the fullest extent allowed by  
 14 the constitution (*cf. Bennett v. Spear*, 520 U.S. 154, 165–66 (1997) (finding that “standing was  
 15 expanded to the full extent permitted under Article III” where the statutory language clearly  
 16 “permit[s] enforcement by every [person]”)), the Supreme Court has explained “that the  
 17 irreducible constitutional minimum of [Article III] standing contains three elements.” *Lujan v.*  
 18 *Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Those three elements are:

19 First, the plaintiff must have suffered an “injury in fact”—an  
 20 invasion of a legally protected interest which is (a) concrete and  
 21 particularized and (b) “actual or imminent, not conjectural or  
 22 hypothetical.” Second, there must be a causal connection between  
 23 the injury and the conduct complained of—the injury has to be  
 24 “fairly traceable to the challenged action of the defendant, and not  
 the result of the independent action of some third party not before  
 the court.” Third, it must be “likely,” as opposed to merely  
 “speculative,” that the injury will be “redressed by a favorable  
 decision.”

25 *Id.* at 560–61 (internal citations, some quotation marks, and brackets omitted).

26 At trial, Plaintiffs were required to prove the elements of standing by a preponderance of  
 27 evidence. *Id.* at 561 (“The party invoking federal jurisdiction bears the burden of establishing [the  
 28 three] elements. Since they are not mere pleading requirements but rather an indispensable part of

the plaintiff's case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation. . . . at the final stage, those facts (if controverted) must be 'supported adequately by the evidence adduced at trial.'"); *see also Salmon Spawning & Recovery All. v. U.S. Customs & Border Prot.*, 550 F.3d 1121, 1132 (Fed. Cir. 2008) ("What is required to establish standing depends on the stage of the proceeding."). Mere survival beyond the motion to dismiss and summary judgment stages does not obviate their burden of proof at trial.

In light of the fact that Plaintiffs have not shown any relationship between the evidence presented on neurodevelopmental harm to fetuses/infants and the harms alleged by the named Plaintiffs, it is doubtful they have carried their burden of demonstrating that they would likely be redressed by a favorable ruling from the Court. Even if the Court were to find an unreasonable risk of harm to fetuses and/or infants from water fluoridation, one possible outcome of the rulemaking under Section 6 might be limited to the establishment of warnings to expectant mothers and parents of bottle-fed infants about fluoridated drinking water. That result would do nothing to ameliorate the harms allegedly experienced by the standing Plaintiffs.

Plaintiffs' standing is also problematic because the evidence of the harm alleged by the named Plaintiffs was practically non-existent at trial. For example, the sum total of Plaintiffs' scientific evidence regarding headaches and fluoride was: (1) one citation to a book (Waldbott 1978) in the 2006 NRC Report, which purportedly summarized a study (Waldbott 1958) in which one participant mentioned suffering headaches; (2) one appearance of the word "headaches" in the 2006 NRC Report, referring to one of several symptoms reported in a study (Petraborg 1977) of the "gastrointestinal effects" of fluoride in humans; and (3) evidence (in the form of the Roholm 1937 study) that three percent of people who are occupationally exposed to extremely high levels of fluoride experienced headaches; and (4) evidence (from the Sharma 2009 study) that people living in areas of endemic fluoride exposure may experience headaches, while people living in areas with water-fluoride levels comparable to the levels found in the United States do not. The Court has doubts as to whether this meager evidence establishes—by a preponderance of the evidence—that fluoride exposure poses a credible threat of harm to the named Plaintiffs.

1 In addition to standing issues, there is good reason for the Court to pause these  
 2 proceedings. As the Court discussed with the parties, the evidence contained in Plaintiff's  
 3 underlying petition to the EPA (from 2016) is also very different from the evidence that was  
 4 presented to the Court at trial. In particular, the studies arising out of the MIREC/ELEMENT  
 5 birth cohorts were all published after the EPA had denied Plaintiff's petition and this lawsuit had  
 6 already been filed. Importantly, even EPA acknowledges that these studies are the highest quality,  
 7 most reliable studies to date on the subject. *See, e.g.*, Stipulated Fact #10, Docket No. 197  
 8 ("Prospective cohort studies have been conducted in Mexico City (ELEMENT cohort), where  
 9 fluoride is added to salt, and Canada (MIREC cohort), where fluoride is added to water. These  
 10 studies are the most methodologically reliable human studies to date on the impact of fluoride on  
 11 neurodevelopment."); Deposition of Dr. Joyce Donohoe at 243, 257, Docket No. 237 (agreeing  
 12 that epidemiological studies emerging from the ELEMENT cohort were "very well-conducted"  
 13 and agreeing that Dr. Lanphear is an "important lead person" who has done "very important and  
 14 reliable research"); Transcript of June 15, 2020 Proceedings (Dr. Chang Direct Testimony) at 806,  
 15 Docket No. 243 (describing the "Mexico City and Canadian cohort studies" as "higher quality  
 16 than the other studies that are available at present"); *id.* at 885–86 (Dr. Chang Testimony on  
 17 Cross-Examination) (identifying the Bashash, Green, and Till studies as "the most rigorous from a  
 18 methodological standpoint").

19 Moreover, although there is some uncertainty as to the date of its final publication, release  
 20 of the NTP's systematic review (or at least its proposed findings as may be presented to the  
 21 National Academy of Science for further comment) is imminent, and its findings are likely to add  
 22 substantially to the body of scientific analysis relevant to the precise questions before this court.  
 23 In addition, although the Court also acknowledges that scientific research is never "finished,"  
 24 there may be other developments that are also impending and which would shed important light on  
 25 the issues contested in this case (*e.g.*, pooling of the MIREC/ELEMENT data, publication of the  
 26 Spanish birth cohort studies study, etc.).


27 For the foregoing reasons, and as explained at the hearing, the Court will hold this case in  
 28 abeyance and directs Plaintiffs to file a new petition with EPA. Doing so will enable Plaintiffs to

1 address the serious standing issues raised above. A second petition will also afford EPA an  
 2 opportunity to consider the significant scientific developments that have occurred since the  
 3 original petition was filed. Its own staff members have stated that the new studies may be a reason  
 4 to “do[] an update to the fluoride assessment.” *See* Deposition of Dr. Joyce Donohoe at 257–58,  
 5 Docket No. 237 (“I think [the Till study is] a reason for doing not just the United States. I think  
 6 it’s a reason for doing an update to the fluoride assessment.”). Clearly, the MIREC/ELEMENT  
 7 studies warrant serious consideration by EPA.

8 As set at the hearing, the Court ordered the parties to report back on November 5, 2020.  
 9 The Court will hold the trial record open, and await Plaintiffs’ prosecution of a new petition with  
 10 EPA. The Court urges Plaintiffs to include in the new petition as much underlying data and as  
 11 many calculations as possible (including those of Dr. Grandjean) and to include as much of the  
 12 information as might be found in a systematic review as practicable. The Court likewise urges the  
 13 EPA to give such a petition due consideration on the merits in light of the substantial scientific  
 14 evidence proffered at trial. The EPA is urged *not* to deny the petition simply because a complete  
 15 set of raw data from the studies cited in the petition is not provided or available. Should the EPA  
 16 deny the new petition, the Court will permit amendment of the complaint herein and consider  
 17 permitting supplementation of the record in this case to account for, *e.g.*, new evidence contained  
 18 in the new petition or new studies published since the trial in this case.

19  
 20 **IT IS SO ORDERED.**

21  
 22 Dated: August 10, 2020

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 25 EDWARD M. CHEN  
 26 United States District Judge  
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