## <u>Appendix A</u> EXCERPT OF COURT'S AUGUST 10, 2020 ORDER

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	UNITED STATES DISTRICT COURT			
	NORTHERN DISTRICT OF CALIFORNIA			
	FOOD & WATER WATCH,	INC., et al.,	Case No. <u>17-cv-</u>	<u>02162-EMC</u>
	Plaintiffs,			
	v.		ORDER HOLD IN ABEYANCE	ING PROCEEDINGS
	UNITED STATES ENVIRON PROTECTION AGENCY, et			
	Defendants.			

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

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

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

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

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

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

IT IS SO ORDERED.

Dated: August 10, 2020

M. CHEN

EDW AND M. CHEN United States District Judge

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