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 (EMC)

ORDER REGARDING CLOSING ARGUMENTS

The Court directs the parties to address the following questions during closing arguments:

1. Why is Dr. Grandjean's BMCL of 0.28 mg/L not a legitimate point of departure?

    a. How do Plaintiffs reconcile Dr. Grandjean's BMCL calculation, which incorporates a linear dose-response model, with the NTP Meta-Analysis's conclusion that there is insufficient individualized data at lower fluoride exposure levels to determine the correct curve fit at those levels? *See* Pl's Ex. 68 at 14*). See also* Taher (2024), Tr. Ex. 129.025, 129.021 (identifying similar issue).

2. Is the NTP Monograph's determination that there is moderate confidence regarding an association between fluoride exposure above 1.5 mg/L and IQ expressed in terms of and based upon on fluoride water concentrations, maternal urine concentrations, or both?

3. Even if a BMCL is not used, can the Court use, conservatively, 4 ppm water fluoride as the lowest-observed-adverse-effect-level (LOAEL) (point of departure), *see* Pl's Ex. 68 at 42? Considering:

    a. Dr. Barone admitted he believes fluoride is associated with adverse effects, at higher-dose levels (referring to exposures at 1.5 to 4 ppm). *See* Docket No. 415, February 12, 2024, Trial Tr. at 1372:20-1373:9. Further, Dr. Savitz did not take issue with the NTP conclusion about moderate confidence of an association where the exposure exceeds 1.5 ppm. *See* Docket No. 414, February 9, 2024, Trial Tr. at 1140:10-19.

b. Taher (2024), considering weight of scientific evidence, found "moderate to strong magnitude (strength) of association between fluoride and neurocognitive effects with consistent evidence across studies for impact on childhood IQ at fluoride exposures relevant to current North American drinking water levels." Tr. Ex. 129.021-022. Taher identified 1.5 mg/L as a provisional POD for IQ and ultimately recommended use of 1.56 mg/L as a point of departure for dental fluorosis to account for both harms associated with IQ and dental fluorosis among other end points. *See* Trial Ex. 129.025, 028.

c. The NTP meta-analysis showed that the weight of the studies above 1.5 were in the 2 to 4 ppm range, with few low bias risk studies above 4 ppm. *See* Tr. Ex. 68 at 35-42. And a statistically significant adverse effect was found for exposure below 1.5 mg/L. *See id.*

d. Given all of the above, wouldn't 4 ppm be a highly conservative, and thus defensible point of departure to use?

4. Would it be defensible to identify 1.5 ppm urinary fluoride as the LOAEL, *see* Pl's Ex. 68 at 40-41, and to use this as the point of departure? Taher 2024 agrees that 1.5 ppm is a conservative, provisional point of departure that could be used to assess the health-based-value for water fluoride in North America, Tr. Ex. 129.025.

5. Given that both parties agree neurotoxicity is associated with fluoride at some level of exposure (*See* Docket No. 418, Amended February 13, 2024, Trial Tr. at 1420:24-1421:1; *See* Docket No. 415, February 12, 2024, Trial Tr. at 1372:20-1373:9 (testimony of Dr. Barone)), and that the possibility of neurotoxicity associated at lower levels has not been foreclosed by the studies at those levels (*see* Docket No. 414, February 9, 2024, Trial Tr. at 1165:23-1124:12, (testimony of Dr. Savitz)), what is EPA's basis for refusing to posit a LOAEL at all?

6. Does the NTP dose-response Meta-Analysis Using Mean Effects (Pl's Ex. 68 at 42 (eTable 5)) identify a change per unit of fluoride exposure [independent variable] for a unit change in IQ (as measure by either IQ points or IQ std deviation), and if so, what is that unit? (Compare to NTP's regression slopes analysis identifying change in IQ per 1 mg/L of urinary fluoride, *see* Pl's Ex. 68 at 53).

7. Can risk determination and characterization with respect to condition of use at issue (i.e., water fluoridation at 0.7 mg/L) proceed without source allocation?

a. Can source allocation (e.g. using a PBPK model) be done in the regulatory stage after an unreasonable risk determination has been made? Is there any statutory or regulatory bar to such sequencing (consider use of bifurcation in asbestos regulation)?

8. If a risk is found using an aggregate measure of exposure (e.g., maternal urinary fluoride), can a risk assessment still proceed without a precise source allocation if it is known that drinking water fluoride is the major source or driver of that exposure? *See, e.g.*, Till 2018, Tr. Ex. 108.005 (mean maternal urinary fluoride levels almost two times higher for women living in fluoridated compared to non-fluoridated communities); Tr. Ex. 68 at 77 ("fluoride in water is a major source of exposure [comprising 40% to 70% of total exposure (US EPA 2010)].").

9. Why is it not appropriate to use urinary fluoride levels as an indicator of water fluoridation levels in assessing risk since there is evidence that the relationship is generally linear, at least above 1 ppm concentration and because urinary fluoride level is generally lower than water intake level? Given this, can urinary fluoride be used at least as a rough proxy?

    a. Taher (2024) set forth a formula to convert maternal urinary fluoride to amount of fluoride ingested and, in turn, the fluoride in drinking water. *See* Tr. Ex. 129.025. Even if it is not entirely precise, why can't this conversion ratio be used to determine at least the range of risk as that informs risk assessment?

    b. Thippeswamy (2020) likewise set forth relationship between unit. *See* Tr. Ex. 111.003-004 and Table 3. Why can't this conversion approach be applied?

10. Can severity of the risk be quantified at the risk characterization stage absent source allocation?

IT IS SO ORDERED.

Dated: February 15, 2024

EDWARD M. CHEN
United States District Judge

United States District Court
Northern District of California