

February 26, 2026

**Re: Docket #EPA-HQ-OW-2025-3823**

**Review of Science on Fluoride in Drinking Water: Preliminary Assessment Plan and Literature Survey**

To the Environmental Protection Agency:

I write on behalf of my client Fluoride Action Network (“FAN”) regarding EPA’s Preliminary Assessment Plan and Literature Survey (“**Toxicity Assessment**”).

FAN welcomes EPA’s decision to exclude consideration of fluoride’s benefits in the Toxicity Assessment. This marks a much-needed departure from previous risk assessments where EPA’s scientific determination of the risk level was unduly impacted by EPA’s *policy* concerns about water fluoridation. While there is a time and place for EPA and other decision makers to consider benefits as part of future risk *management* decisions, it is critical that risk *assessment* decisions be made independent of these considerations.

In order to ensure that the Toxicity Assessment does not repeat the mistakes of the past, it is particularly critical that EPA adhere to its published procedures on the selection of **uncertainty factors (“UF”)**.<sup>1</sup> In EPA’s previous risk assessments, the undue influence of policy considerations was most apparent in EPA’s selection of arbitrarily small UFs. For example, in 1985, EPA used a UF of just 2.5 despite selecting *crippling* skeletal fluorosis (the most severe form of chronic fluoride exposure) as the critical effect. As EPA later explained, it selected this unusually small UF to ensure “sufficient concentration of fluoride in water to realize its beneficial effects.”<sup>2</sup> More recently, in 2010, EPA published a risk assessment on fluoride in which the Agency established a reference dose of 0.08 mg/kg/day for severe dental fluorosis.<sup>3</sup> This dose (which EPA admitted can cause severe fluorosis in some children) was as high as it was because EPA selected an uncertainty factor of 1 (the equivalent of no uncertainty factor).<sup>4</sup> As FAN discovered during the *Food & Water Watch* litigation, EPA used a UF of 1 in order to avoid any potential conflict with fluoride’s use in caries prevention programs. The following are excerpts from the sworn deposition of EPA’s representative, Dr. Edward Ohanian, in the *Food & Water Watch* case:

*Q. Okay. And because [the “optimal”] level, 0.05 [mg/kg/day], is so close to the reference dose, which is .08 [mg/kg/day], EPA couldn’t apply an uncertainty factor to the reference dose, because it would take you below the level you need for caries prevention, right?*

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<sup>1</sup> EPA (2014). Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation, EPA/100/R-14/002F.

<sup>2</sup> 70 Fed. Reg. 40899, 40903 (July 15, 2005).

<sup>3</sup> EPA (2010). Fluoride: Dose-Response Analysis for Non-cancer Effects, 820-R-10-019.

<sup>4</sup> *Id.* at 105-06.

A. Correct.

Q. I understand EPA's position on that, that it can't apply uncertainty factors because it will interfere with caries prevention programs, correct?

A. Correct.<sup>5</sup>

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Q. So if applying an uncertainty factor, to account for these unexplored susceptibilities, in the Dean study, results in a reference dose below 0.05 milligrams per kilograms per day, EPA is not going to apply those uncertainty factors, correct?

A. Correct.<sup>6</sup>

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Q. You made it clear that EPA can't apply uncertainty factors because they will put the reference dose below the so-called optimal dose for fluoride ingestion, right?

A. Correct.<sup>7</sup>

While FAN recognizes that reduced UFs can be appropriate for *metals* that are *essential* to human health (e.g., iron),<sup>8</sup> fluoride does not fall in this category. Fluoride is neither a metal, nor is it essential. At best, fluoride has therapeutic properties when applied topically to teeth. As Secretary Kennedy has recognized, "fluoride's benefits to teeth come almost entirely from *topical* contact, not ingestion."<sup>9</sup> The notion, therefore, that 0.05 mg/kg/day is an optimal fluoride intake, is a relic of an *outdated* understanding of fluoride's anti-caries properties. It should have no role or influence on the current Toxicity Assessment.

### **The Need for Transparency**

One of the disturbing implications of Dr. Ohanian's testimony is that EPA was not forthright in its 2010 report about why it selected the UF of 1. In the 2010 report, EPA claimed that a database uncertainty factor was unnecessary because the database on fluoride was "complete."<sup>10</sup> At his deposition, however, Dr. Ohanian admitted that, in fact, there *was* sufficient uncertainty on fluoride's neurodevelopmental effects (based on the NRC's 2006 findings) to

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<sup>5</sup> Deposition of Dr. Edward Ohanian, Oct. 15, 2018, p. 205.

<sup>6</sup> *Id.* at 291-92.

<sup>7</sup> *Id.* at 329.

<sup>8</sup> EPA (2007), Framework for Metals Risk Assessment, 120-R-07-001.

<sup>9</sup> <https://www.epa.gov/newsreleases/epa-announces-next-step-gold-standard-review-fluoride-inform-protective>

<sup>10</sup> EPA 2010, p. 106.

justify a database uncertainty factor; but, again, EPA did not select one because of fluoride's role in caries prevention. To quote:

*Q. The Academy told you that there is some uncertainty now with respect to fluoride's potential to cause developmental neurotoxicity right?*

*A. Correct.*

*Q. And so, if you didn't have the caries prevention goal, you would apply some database uncertainty factor to account for that potential development[al] neurotoxicity, correct?*

*A. Yes.*<sup>11</sup>

The public deserves to know the level of fluoride exposure that presents a risk to human health. This is critical to ensuring that families and communities are able to make *informed* decisions on if, and how, to use fluoride for caries prevention. Towards this end, FAN implores EPA to follow its established procedures for selecting UFs, and that it do so in a clear and transparent way so that the public can be assured that the RfD is based solely on risk-related principles, and not based on policy concerns related to fluoridation.

### **Additional Considerations Regarding Uncertainty Factors**

#### *Intraspecies Variability*

Based on the existing fluoride database as well as EPA's procedures for selecting UFs, the *intra*-species variability UF will likely be a critical UF in the risk assessment. Per EPA procedure, the default UF of 10 should be used unless there is suitable toxicokinetic and/or toxicodynamic data to justify a deviation.<sup>12</sup> At present, no suitably informative toxicokinetic or toxicodynamic data is available in the fluoride database to justify a departure from the default UF of 10.<sup>13</sup> Accordingly, EPA risk assessment scientist, Dr. Stanley Barone, agreed that the *intra*-species UF for fluoride neurotoxicity should be 10. To quote:

*Q. Did you give any consideration as to what an appropriate benchmark MOE<sup>14</sup> should be for fluoride neurotoxicity?*

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<sup>11</sup> Deposition Transcript of Dr. Ohanian, p. 206.

<sup>12</sup> EPA 2014, p. 12.

<sup>13</sup> The National Research Council has advised that alternatives to default UFs should only be used if they are "clearly superior" to the defaults. *See* NRC (2009). *Science and Decisions: Advancing Risk Assessment*, p. 201.

<sup>14</sup> The benchmark Margin of Exposure ("MOE") is the composite uncertainty factor. The one UF that Dr. Barone was using for his Benchmark MOE of 10 was the UF for intraspecies variability. Dr. Barone recognized, however, that an additional UF might be needed if a LOAEL (as opposed to a BMCL or NOAEL) was used as the point of departure.

A. Yeah, I did. Given the -- given that the critical studies in question are probably epidemiological studies, human studies, **uncertainty factor of 10**, which is appropriate for all life stages, inclusive of all life stages and vulnerabilities at face value would be the benchmark MOE.

Q. Okay. Would that apply whether we used a BMCL, a LOAEL, or a NOAEL?

A. It would apply to all of them. Whether we're using a LOAEL or a NOAEL, that would potentially be another uncertainty factor.<sup>15</sup>

To be clear, the need for an intraspecies UF of 10 could change if EPA is able to follow through on its stated intention to develop a pharmacokinetic (PK) model as part of the Toxicity Assessment. However, pursuant to EPA's standard operating procedure, the development of a PK model would only affect the *toxicokinetic* component of the intra-species UF, and would have no bearing on the *toxicodynamic* component.<sup>16</sup> As such, a default intraspecies UF of 3 for the toxicodynamic component would still need to be applied, even if EPA develops a suitable PK model.

#### *Database Uncertainty*

While FAN believes IQ loss is the most appropriate endpoint to use for the critical effect, if EPA were to select dental fluorosis, it is imperative that EPA apply a database UF to account for fluoride's potential neurodevelopmental effects at low doses. As discussed above, EPA's representative, Dr. Ohanian, agreed that a database UF for fluoride's neurotoxicity was already needed as of 2010 (based on the NRC's findings).<sup>17</sup> The data on fluoride neurotoxicity has become much more robust since that time, including high-quality prospective cohort studies finding associations between fluoride and adverse neurodevelopmental outcomes at so-called "optimal" levels of exposure (e.g., Bashash 2017; Bashash 2018; Green 2019; Till 2020; Malin 2024; Singh 2025). The justification for a database UF to account for fluoride's neurotoxic potential is therefore far greater today than it was in 2010. Applying a database UF to a fluorosis-based RfD would also align with the recent conclusions of Health Canada's expert panel, which noted that: "Given the uncertainty about possible neurocognitive effects at low levels of exposure, the panel recommended the use of an uncertainty factor for database deficiency for deriving the health-based value."<sup>18</sup>

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<sup>15</sup> Deposition Transcript of Dr. Stanley Barone, Oct. 30, 2023, p. 163.

<sup>16</sup> EPA 2014, p. 12.

<sup>17</sup> Deposition Transcript of Dr. Ohanian, p. 206.

<sup>18</sup> <https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/water-quality/expert-panel-meeting-effects-fluoride-drinking-summary.html>

We appreciate EPA's careful consideration of these concerns.

Sincerely,

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