Appendix H
UNDISPUTED MATERIAL FACTS FROM TRIAL & COURT'S RULING ON DENTAL BENEFITS

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

FURTHER PRETRIAL CONFERENCE ORDER

I. TRIAL DATE AND LENGTH OF TRIAL

A bench trial shall be held beginning on June 8, 2020 at 8:30 AM before Judge Edward M. Chen. In light of the challenges presented by the COVID-19 pandemic, the trial will be conducted via Zoom webinar. The Court notes that the trial will not be livestreamed, but anyone wishing to join the webinar may do so. The Court's license for Zoom webinar will be reserved for 500 people capacity. *See* Docket No. 181. The parties are reminded that recording court proceedings is prohibited. There shall be a total of up to eight trial days, including June 8; the length of trial is subject to further modification by the Court.

Trial days shall last from 8:30 a.m. to 1:30 p.m. The Court may determine that certain full trial days may be necessary as the trial progresses. Thursdays are dark.

Trial dates are set for June 8, 2020, June 9, 2020, June 10, 2020, June 12, 2020, June 15, 2020, June 16, 2020, June 17, 2020, and June 19, 2020.

The Court has worked closely with the parties to determine the most effective and efficient ways for the parties to present their arguments and evidence in this case, given the circumstances. Pursuant to the Clerk's notice posted on April 24, 2020, the Court has permitted the parties to

submit expert declarations in lieu of some direct testimony. *See* Docket No. 177. Each side is limited to a total of 50,000 words for expert declarations (total per side) to be apportioned between experts as each side sees fit. The expert declarations are to be filed by May 20, 2020; any evidentiary objections thereto are due May 27, 2020. Those objections will be resolved at the hearing on June 5, 2020 (along with any unresolved objections to exhibits and discovery excerpts, as discussed below). Each side is limited to 12 hours of testimony in addition to the expert declarations.

As is discussed in greater detail below, with respect to EPA's Second Motion *in Limine*, the Court has decided to bifurcate the trial such that—if it concludes that an unreasonable risk of harm exists—it will permit the EPA to present evidence related to the deferral of rulemaking at a later stage of the proceeding. If necessary, the Court will address whether to bar the introduction of additional evidence (*i.e.* evidence that has not yet been disclosed to Plaintiffs) on the issue of deferral.

II. STIPULATIONS OF FACT

The parties stipulate to the following facts:

1. According to the United States Centers for Disease Control and Prevention (CDC), as of 2014, approximately 200,000,000 people in the United States live in communities that add fluoridation chemicals to the drinking water.
2. Plaintiffs' Citizen Petition sought to prohibit the addition of fluoridation chemicals to water on the grounds that this condition of use presents an unreasonable risk of neurologic harm.
3. Fluoridation chemicals are added to drinking water to prevent tooth decay (*i.e.*, dental caries). In addition to being added to water, fluoride is added to dental products and certain pesticides.
4. In epidemiology, a cross-sectional study is a comparison of the prevalence of a specific health outcome across levels of a specific exposure in study subjects (or vice versa), with the exposure and outcome both measured at a given time, providing a "snapshot" of the association between the exposure and the health

outcome at one time.

5. In epidemiology, a cohort study is a comparison of incidence rates of a specific health outcome between study subjects with various levels of a specific exposure who are observed over time.
6. A person's individual response to fluoride exposure depends on factors such as age, kidney function, body weight, activity level, nutrition, and other factors.
7. Human urine fluoride concentrations (biomonitoring) measures an internal dose.
8. Various factors can affect the concentration of fluoride in a urine sample, such as an individual's metabolism, when a urine sample is collected, and the time since the last void of the individual who provided the sample.
9. Historically, most studies to investigate the impact of fluoride on IQ in humans have used cross-sectional study designs. Most of these cross-sectional studies have been conducted in China, and other countries with elevated levels (>1.5 mg/L) of naturally occurring fluoride in water. By contrast, fluoride is added to water in the United States to reach a concentration of 0.7 mg/L.
10. 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.
11. Risk assessment is the process by which scientific judgments are made concerning the potential for toxicity in humans.
12. The National Research Council (NRC, 1983) has defined risk assessment as including the following components: hazard identification, dose-response assessment, exposure assessment, and risk characterization.
13. The term "risk evaluation" is a specialized term under TSCA.
14. Together, the components of EPA's risk assessment process, coupled with the ultimate risk determination, constitute a "risk evaluation" under TSCA.
15. The final step of a risk evaluation is to weigh a variety of factors to determine

whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment, referred to as the "risk determination" step in the TSCA risk-evaluation process.

16. EPA does not require that human exposure levels exceed a known adverse effect level to make an unreasonable risk determination under TSCA. For example, if human exposure levels exceed a known no-adverse effect level divided by combined uncertainty factors, EPA may make an unreasonable risk determination under TSCA.

17. In the ideal world, all risk assessments would be based on a very strong knowledge base (*i.e.*, reliable and complete data on the nature and extent of contamination, fate and transport processes, the magnitude and frequency of human and ecological exposure, and the inherent toxicity of all of the chemicals). However, in real life, information is usually limited on one or more of these key data needed for risk assessment calculations. This means that risk assessors often have to make estimates and use judgment when performing risk calculations, and consequently all risk estimates are uncertain to some degree. For this reason, a key part of all good risk assessments is a fair and open presentation of the uncertainties in the calculations and a characterization of how reliable (or how unreliable) the resulting risk estimates really are.

18. EPA's *Guidelines for Neurotoxicity Risk Assessment* were designed in 1998 to guide EPA's evaluation of substances that are suspected to cause neurotoxicity, in line with substantive standards established in the statutes administered by the Agency.

19. EPA's *Guidelines for Neurotoxicity Risk Assessment* preceded the 2016 TSCA amendments.

20. The current non-enforceable health goal for fluoride under the Safe Drinking Water Act ("SDWA"), or Maximum Contaminant Level Goal (MCLG), of 4.0 mg/L was promulgated in 1985 to protect against a condition known as crippling skeletal

fluorosis (*i.e.*, "stage III skeletal fluorosis"). Crippling fluorosis is the final, and most severe, stage of skeletal fluorosis.

21. Based on its 2006 review, the National Research Council (NRC) of the National Academies of Science (NAS) recommended that the MCLG of 4 mg/L be lowered to prevent children from developing severe dental fluorosis and reduce the lifetime accumulation of fluoride into bone that the majority of the committee concluded is likely to put individuals at increased risk of bone fracture and possibly skeletal fluorosis.

22. Based on the NRC's recommendation, in 2010, EPA's Office of Water completed a dose-response analysis using available data between 2000 and 2010 to calculate a reference dose ("RfD")—an estimate of the fluoride dose protective against severe dental fluorosis, stage II skeletal fluorosis, and increased risk of bone fractures—of 0.08 milligrams per kilograms per day (mg/kg/day), a measure of daily intake by body weight.

23. In addition to the tooth and bone effects, the NRC also evaluated neurotoxicity as an effect of fluoride exposure, among other health effects. The NRC concluded that the available data were inadequate to demonstrate a risk for neurotoxicity at 4.0 mg/L and made recommendations for additional research. Since that time, additional research has been conducted and the scientific database for studies that have examined neurotoxicity as an effect of fluoride exposure has grown.

24. In determining whether adding fluoridation chemicals to drinking water presents an unreasonable risk of neurotoxic effects under TSCA, EPA's Office of Pollution Prevention and Toxics would not rely on the 2010 RfD, but would instead apply a weight of the scientific evidence approach for identifying and characterizing the best available science from the most up-to-date scientific database of studies that have examined neurotoxicity as an effect of fluoride exposure.

25. In conducting TSCA risk evaluations, EPA generally uses the Margin-of Exposure (MOE) approach to characterize the risk as a step in the risk assessment process.

Using this approach, an MOE is calculated by comparing (dividing) the point-of departure directly to the expected exposure level. The MOE is then compared to a benchmark MOE, which is the product of all relevant uncertainty factors.

26. EPA considers the MOE, relative to the benchmark MOE, in addition to other factors, in determining whether risks are unreasonable under TSCA.

27. The National Research Council has stated that "the inference that results from animal experiments are applicable to humans is fundamental to toxicologic research."

28. EPA agrees that effects observed in animals are relevant to humans unless human data counterindicate.

29. The developing brain is distinguished by the absence of a blood-brain barrier. The development of this barrier is a gradual process, beginning in utero and complete at approximately 6 months of age.

30. Fluoride passes through the placenta and gets into the fetal brain.

31. Whether harm would actually occur depends on the dose and nature of exposure.

See Docket No. 150 ("Joint Pretrial Conference Statement"). Furthermore, at the hearing on May 8, 2020, the Court urged the parties to agree to further stipulations, if possible, and the parties indicated that they will endeavor to do so.

III. MOTIONS *IN LIMINE*

A. Plaintiffs' Motion *in Limine*

1. First Motion *in Limine* to Exclude Evidence of Fluoridation Chemicals' Alleged Benefits (or Lack Thereof) (Docket No. 144)

Section 21 specifies that determinations of "unreasonable risk of injury to health" must be made "without consideration of costs or other nonrisk factors." 15 U.S.C. § 2620(b)(4)(B)(ii). The statute does not define "costs" or "nonrisk factors," and the parties disagree as to whether this applies to the health benefits of fluoridation. Plaintiffs wish to exclude evidence of benefits, while EPA seeks to introduce it. For the reasons outlined below, the Court **GRANTS** Plaintiffs' First Motion *in Limine*; the introduction of evidence intended to demonstrate the benefits of fluoride

will not be permitted.

a. Statutory Language, Structure, and Purpose

Plaintiffs contend that "the plain language, structure, purpose, and legislative history of TSCA support the interpretation that benefits are a 'nonrisk' factor that cannot be considered as part of an unreasonable risk determination." Plaintiffs' First Motion *in Limine* ("First Motion *in Limine* to Exclude Evidence of Fluoridation Chemicals' Alleged Benefits (or Lack Thereof)") (hereinafter PMIL 1), Docket No. 144. They believe that benefits should "only be considered during EPA's rulemaking proceeding," which follows risk evaluation. *Id.* The plain language, structure, purpose, and legislative history of TSCA are each addressed in turn; the Court then turns to EPA's promulgated regulation on risk evaluations, as well as the parties' discussion of the *Framework for Metals Risk Assessment*.

Beginning with the plain language of TSCA, the statute—as noted above—states that the relevant inquiry is whether "the chemical substance or mixture . . . presents an unreasonable risk of injury to health or the environment, *without consideration of costs or other nonrisk factors*." 15 U.S.C. § 2620(b)(4)(B)(ii) (emphasis added). Plaintiffs contend that "an ordinary plain meaning interpretation is that 'nonrisk' is anything that is not a risk" and that "[b]enefits come within this umbrella." PMIL 1 at 2. For its part, EPA argues that "any plain reading of '*unreasonable* risk of injury to *health*' would entail some *weighing* of *health* benefits." PMIL 1 Opp. at 5–6. The Agency contends that "without a counterbalancing consideration" of benefits "any risk would be unreasonable." *Id.* While EPA's phrase "*unreasonable* risk" could imply some amount of weighing of costs and benefits, that is not the only reasonable interpretation. Unreasonable could be a relative measure of risk, *e.g.*, something more than *de minimis*. Moreover, even if the term could imply weighing various factors, it does not dictate *what may be considered* in that weighing process. A weighing process does not inherently require consideration of benefits. TSCA's broad preclusion of "nonrisk factor" literally encompasses benefits; benefit after all is a nonrisk factor.

EPA advances the argument that health-related benefits are properly considered "risk factors, not nonrisk factors" and are therefore properly considered during risk evaluation. PMIL 1 Opp. at 3. Specifically, EPA asserts:

> For chemical substances that provide a health benefit, the absence of those chemical substances may be characterized as a risk to human health. And the presence of those chemicals can be characterized as a risk reduction. In other words, when a chemical has direct biological health benefits, that health benefit can be a risk factor—in effect, the reducing or cancelling out a health risk/hazard—instead of a nonrisk factor (*e.g.*, economic benefits) that can only be considered in risk management.

Id. Because it is "undisputed that fluoride reduces dental caries to some degree," EPA contends that the health benefits of water fluoridation are properly considered as part of a TSCA risk evaluation. *Id.*[1] One might label this position an "inverse benefits" argument: barring the substance creates a health risk. The trouble with EPA's contention is that in asserting the existence of the inverse risk, it presumes the absence of the fluoridation if an unreasonable risk is found. However, the rulemaking process does not require that a substance which poses an unreasonable risk be banned outright. It merely triggers a rulemaking process, in which the costs and benefits of the substance are considered in determining how to manage that risk. As a result of that rulemaking, the EPA may choose from a wide range of management tools other than an outright ban, including less expansive restrictions or warning label requirements. That the inverse risk cannot be determined at the "unreasonable risk" juncture (because the ultimate rule will not be determined until the subsequent rulemaking process is completed) undermines EPA's inverse risk construct.

Turning to the structure of the statute, Plaintiffs focus on two points. First, they contend that "[t]he only places in the statute where the word 'benefit(s)' appears are sections that govern the rulemaking phase." PMIL 1 at 2. In discussing rulemaking, the statute explicitly mentions benefits on three occasions: (1) "In proposing and promulgating a rule . . . the Administrator shall consider and publish a statement based on reasonably available information with respect to . . . the

[1] EPA contends that benefits could properly be considered during the risk characterization process, which could permit evaluation of "the dose-response relationship for both the health benefit and any adverse impacts." *See* Defendants' Trial Brief, Docket No. 154. Alternatively, benefits could be considered during the "risk determination" part of the risk-evaluation process. PMIL 1 Opp. at 3. Risk determination is the final step in the risk evaluation process, during which the EPA "may weigh a variety of factors in determining unreasonable risk." Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726 (July 20, 2017) (codified at 40 C.F.R. pt. 702).

benefits of the chemical substance or mixture for various uses[,] and [2] the reasonably ascertainable economic consequences of the rule, including consideration of . . . the costs and **benefits** of the proposed and final regulatory action," and (3) "The Administrator may, as part of a rule promulgated . . . grant an exemption from a requirement . . . for a specific condition of use of a chemical substance or mixture, if the Administrator finds that . . . the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial **benefit** to health, the environment, or public safety." 15 U.S.C. § 2605(c) and (g) (emphases added). In contrast to the explicit identification of benefits in Sections 6(c) and 6(g), the *absence* of any mention of benefits in Section 6(b) (which outlines the risk evaluation procedures that EPA is to follow) proves benefits should not be considered as part of risk evaluation procedures under Section 21. PMIL 1 at 2. Section 6(b) identifies a number of other factors that must be considered by the EPA (*e.g.* "available information on hazards and exposures for the conditions of use of the chemical substance" and "information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator") but does not mention "benefits"; that section also prohibits EPA from "consider[ing] costs or other nonrisk factors," as in Section 21. 15 U.S.C. § 2605(b)(4)(F). Thus, when Congress wanted the EPA to consider benefits, it so stated. It did not do so in Section 6(b) or Section 21. *See Bates v. United States*, 522 U.S. 23, 29–30 (1997) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)) (internal quotation marks and modification omitted) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."); *see also Pit River Tribe v. Bureau of Land Mgmt.*, 939 F.3d 962, 971 (9th Cir. 2019) (quoting *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002)) (same text).

Turning to statutory purpose, Plaintiffs point to the distinction in TSCA between a determination that an unreasonable risk exists and any decision about how to manage such a risk as mentioned above. The bifurcated structure of TSCA strongly suggests that any consideration of benefits is properly deferred to the risk management (*i.e.* rulemaking) stage. As plaintiffs argue:

The requirement that the *determination* of risk precede the

> *management* of the risk serves several purposes, including (1) eliminating the redundancy of performing two separate risk-benefit analyses, and (2) making a clear delineation between the (strictly science-based) determination of *whether there is a risk* and the (policy-influenced) decision of *if and how to manage the risk.* These purposes would be frustrated by requiring risk-benefit analyses in both phases.

PMIL 1 at 3. This construct is perfectly sensible: if the Court determines that an unreasonable risk exists, then the Agency is directed to go through the rulemaking process and at that point takes benefits into account in tailoring a management plan accordingly. This approach also coheres with the statutory text and (as is discussed next) with the legislative history of TSCA.

Finally, Plaintiffs argue that their position is supported by legislative history. *See* PMIL 1 at 3. Specifically, they look to comments submitted by Senate Democratic negotiators intended to clarify "the intent of the negotiators on elements of the final bill text." 162 Cong. Rec. S3517 (daily ed. June 7, 2016) (statement of S. Democratic negotiators). At the hearing, the parties directed the Court's attention to the following portion of those comments:

> TSCA as in effect before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 2lst Century Act authorized EPA to regulate chemical substances if it determined that the chemical substance "presents or will present an unreasonable risk of injury to health or the environment." In its decision in *Corrosion Proof Fittings vs EPA*, the U.S. Court of Appeals, 5th Circuit overturned EPA's proposed ban on asbestos, in part because it believed that
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> > In evaluating what is 'unreasonable,' the EPA is required to consider the costs of any proposed actions and to 'carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action.' 15 U.S.C. § 2601(c).
> >
> > As the District of Columbia Circuit stated when evaluating similar language governing the Federal Hazardous Substances Act, '[t]he requirement that the risk be 'unreasonable' necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers.' *Forester v. CPSC*, 559 F.2d 774 789 (D.C.Cir. 1977). We have quoted this language approvingly when evaluating other statutes using similar language. *See, e.g., Aqua Slide, 569 F.2d at*

839.

> The Frank R Lautenberg Chemical Safety for the 21st Century Act clearly rejects that approach to determining what "unreasonable risk of injury to health or the environment" means, by adding text that directs EPA to determine whether such risks exist "without consideration of costs or other nonrisk factors" and, if they do, to promulgate a rule that ensures "that the chemical substance no longer presents such risk." In this manner, Congress has ensured that when EPA evaluates a chemical to determine whether it poses an unreasonable risk to health or the environment and regulates the chemical if it does, the Agency may not apply the sort of "balancing test" described above.

162 Cong. Rec. S3516 (daily ed. June 7, 2016) (statement of S. Democratic negotiators). This statement strongly suggests an intention to move away from a free ranging "balancing test."

In their briefing, Plaintiffs also highlight the portion of the negotiators' statement that "addressed a question that arose regarding how EPA is to carry out its responsibilities under Section 6(c)(2)" (which governs rulemaking). *Id.* at 3–4. Section 6(c)(2) lays out four factors that the Administrator must consider and address in a published statement when proposing and promulgating a rule under TSCA. *See* 15 U.S.C. § 2605(c)(2)(A). The pertinent portion of the negotiators' statement notes:

> Senate Democratic negotiators clarify that sections 6(c)(2)(A)(i) ["the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture"] and (ii) ["the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture"] do not require EPA to conduct a second risk evaluation-like analysis to identify the specified information, but rather, can satisfy these requirements on the basis of the conclusions regarding the chemical's health and environmental effects and exposures in the risk evaluation itself.

162 Cong. Rec. S3517 (daily ed. June 7, 2016) (statement of S. Democratic negotiators). As Plaintiffs note, the Senate report "makes no mention" of EPA relying on risk evaluation findings for evidence related to 6(c)(2)(A)(iii) and (iv), which pertain to the "the benefits of the chemical substance" and the "economic consequences of the rule, including . . . the costs and benefits of the proposed and final regulatory action." *See* PMIL 1 at 4. Here, too, the omission of the benefits-related factors suggests that the Senate had an "understanding that the issue of benefits w[ould]

not be raised during the risk evaluation" process. *Id.*

Taking all of this together, the plain text of the statute, the structure of the statute, and its legislative history all indicate that consideration of benefits at the risk evaluation stage is inappropriate.

b. Agency Interpretation

Plaintiffs contend that EPA's own regulation relating to risk evaluation also supports the exclusion of benefits evidence at the risk evaluation stage. As required by Section 6(b)(4) of TSCA, EPA promulgated a rule "that establishes a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors." Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726 (July 20, 2017) (codified at 40 C.F.R. pt. 702) (hereinafter "Final Rule"). The Final Rule included factors that EPA would consider in conducting risk evaluations, but it does not explicitly mention benefits. In relevant part, the Rule states:

> To make a risk determination, EPA may weigh a variety of factors in determining unreasonable risk. The Administrator will consider relevant factors including, but not limited to: The effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard, the irreversibility of hazard), and uncertainties.

Id. Here, too, the factors to be considered explicitly include the (risk-related) factors noted in Section 6(c)(2)(A)(i) and (ii) of the statute but do *not* mention the benefit-related factors in Section 6(c)(2)(A)(iii) and (iv). While the Court acknowledges that the Rule does put a great deal of emphasis on flexibility, *see id.* ("the Agency did not think it was appropriate to define 'unreasonable risk' because each risk evaluation will be unique"; "This is not intended as an exhaustive list, but merely identifies some of the considerations that are likely to be among the most commonly used."; "To make a risk determination, EPA may weigh a variety of factors in determining unreasonable risk."), that general orientation toward customization does not overcome

the fact that the rule enumerated certain factors obviously considered to be important in conducting risk evaluations and, in doing so, did not mention benefits.[2]

The parties also address whether the *Framework for Metals Risk Assessment* (authored by the Office of the Science Advisor) ("*Framework*") compels consideration of the benefits associated with water fluoridation. In relevant part, Section 6 of TSCA states:

> In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

15 U.S.C. § 2605(b)(2)(E). Although the *Framework* directs that the essentiality of a metal to health be considered, the statute specifically makes the *Framework* relevant to risk evaluations of "metals and metal compounds," and fluoride is neither a metal nor a metal compound. The *Framework* is therefore irrelevant unless reference to the *Framework* was intended to convey a broader mode of analysis applicable to non-metals.

The Court concludes it does not. "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Bates*, 522 U.S. at 29–30 (quoting *Russell*, 464 U.S. at 23) (internal quotation marks and modification omitted); *see also Pit River Tribe*, 939 F.3d at 971 (quoting *Barnhart*, 534 U.S. at 452). Thus, had Congress intended to apply the *Framework* to other portions of TSCA, it knew how to do so; instead, the fact that it did not mention the *Framework* in any other provisions suggests that it intended the *Framework* to apply narrowly, and prescriptively only to metals.

Moreover, even if the *Framework* mode of analysis were applied to non-metals like fluoride, the *Framework* only examines whether a substance is essential for—rather than merely

[2] Notably, the EPA's own website includes a page entitled *How EPA Evaluates the Safety of Existing Chemicals*, which states: "TSCA prohibits EPA from considering non-risk factors (e.g., costs/benefits) during risk evaluation." *How EPA Evaluates the Safety of Existing Chemicals*, U.S. ENVTL. PROT. AGENCY, https://www.epa.gov/ assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals (last visited May 11, 2020).

beneficial to—human health. As Plaintiffs contend, under the *Framework*, "only 'essentiality' can be considered in risk assessment, not mere benefit." PMIL 1 at 5. The *Framework for Metals Risk Assessment* distinguishes between metals that are essential and those which are merely beneficial: "Metals that are currently deemed nutritionally essential for humans are Co, Cr III, Cu, Fe, Mg, Mn, Mo, Se and Zn (Table 4-1). Some metals (e.g., B, Ni, Si, V, and perhaps As), while not essential to human health, may have some beneficial effects at low levels of exposure (NAS/IOM, 2003)," but those non-essential benefits are not considered under the Framework. *Framework for Metals Risk Assessment* at 4-16; *see also* Table 6-3. The *Framework* does not employ a general cost/benefit analysis.[3]

c. Conclusion

Accordingly, the Court **GRANTS** Plaintiffs' First Motion *in Limine*. However, the Court notes that it will still permit EPA to challenge Plaintiffs' experts on the topic of benefits, to the extent those experts wrote extensively about benefits in their expert reports for the limited purpose of challenging the credibility of these expert reports. However, since this is a collateral matter, any such inquiry will be limited.

2. Second Motion *in Limine* to Exclude Any Evidence in Support of a Deferral of Rulemaking Under 15 U.S.C. § 2620(b)(4)(B)(ii) (Docket No. 145)

In the event that the Court finds that fluoridation chemicals pose an unreasonable risk of injury to health, the Court must "order the Administrator to initiate the action requested by the petitioner." 15 U.S.C. § 2620(b)(4)(B). However, Section 21 of TSCA contains a provision that affords the Court some leeway in ordering that action. Specifically, Section 21 enables to the Court to "permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes" if it finds "[1] that the extent of the risk to health or the

[3] The EPA concedes that fluoride is not an essential substance. In his deposition, Edward Ohanian (EPA's 30(b)(6) representative) was asked: "I understand you believe there's a benefit to ingesting fluoride, but EPA recognizes that fluoride is not an essential nutrient, correct?" To which he answered: "That's right." *See* Exhibit 3 (Deposition of Edward Ohanian) to Plaintiff's First Motion *in Limine*, Docket No. 144. EPA's assertion that "fluoride is essential to the prevention of dental caries" does not establish that fluoride is "an essential nutrient" in the way that term is used in the *Framework*.

the Court **OVERRULES** EPA's objection.

This order disposes of Docket Nos. 139, 140, 141, 142, 143, 144, 145, and 150-1.

IT IS SO ORDERED.

Dated: May 19, 2020

EDWARD M. CHEN
United States District Judge