UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

January 19, 2021

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Dear Mr. Connett:

On November 30, 2020, the U.S. Environmental Protection Agency (EPA or Agency) acknowledged receipt of a submission from you, dated November 4, 2020 (2020 Submission), as counsel to the following organizations and individuals—Food & Water Watch (FWW); Fluoride Action Network (FAN); Moms Against Fluoridation; Audrey Adams, a resident of Renton, Washington (individually and on behalf of her son Kyle Adams); Kristin Lavelle (individually and on behalf of her son Neal Lavelle); and Brenda Staudenmaier (individually and on behalf of her children Ko Staudenmaier and Hayden Staudenmaier).

You characterize the 2020 Submission as a supplement to a petition submitted to EPA on November 22, 2016 (2016 Petition), under section 21 of the Toxic Substances Control Act (TSCA), requesting that EPA reconsider its denial of the 2016 Petition and exercise its authority under section 6(a) of TSCA to prohibit the addition of fluoridation chemicals to drinking water. As you are aware, EPA took final action on the 2016 Petition when it denied the Petition on February 17, 2017. 82 Fed. Reg. 11,878 (Feb. 27, 2017). After EPA denied the 2016 Petition, petitioners brought suit in the Northern District of California to challenge the denial. *See Food and Water Watch v. EPA* (ND Cal. No. 3:17-cv-02162-EMC). On August 10, 2020, after a two-week bench trial, the court held the case in abeyance and directed the plaintiffs to file a *new* petition with the EPA. *Food and Water Watch v. EPA*, 2020 WL 4584194 (ND Cal. Aug. 10, 2020) (order holding proceedings in abeyance).

Under section 21 of TSCA, any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, or 8 or an order under TSCA section 4, 5(e) or 5(f). 15 U.S.C. § 2620(a). The statute requires EPA to grant or deny such a petition within 90 days. *Id.* § 2620(b)(3)-(4). If EPA denies the petition or fails to act within 90 days, the petitioner may "commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition." *Id.* § 2620(b)(4)(A). In such a case, relating to a petition seeking a new rule, the statute provides the petitioner "an opportunity to have *such* petition considered by the court in a de novo proceeding." *Id.* § 2620(b)(4)(B) (emphasis added).

Nothing in section 21, or TSCA more broadly, requires EPA to reopen the record for a section 21 petition and/or reconsider the agency's final action to deny the petition. Absent some provision of law authorizing or requiring reconsideration, EPA's decision whether to reopen the petition and reconsider its final agency action denying the petition, as requested by the petitioners here, is thus committed to EPA's discretion.

EPA declines to exercise its discretion to reopen the administrative record and reconsider the February 17, 2017 petition denial. Instead, EPA is exercising its discretion to allocate its resources to most effectively implement TSCA requirements, including significant new requirements from the 2016 amendments, by prioritizing review of existing chemical substances grounded in risk-based considerations. *See* 15 U.S.C. § 2605(b)(1) (requiring risk-based screening for identifying priorities for risk evaluation); 15 U.S.C. § 2601(c) (directing EPA to administer TSCA in a reasonable and prudent manner). To date EPA has finalized nine of the first ten risk evaluations for chemical substances that the statute requires to be conducted under a new process for chemical prioritization, evaluation, and risk management. 15 U.S.C. § 2605(b)(2)(A). EPA must now begin, and has in many instances already begun, risk management for each condition of use for which EPA made a determination of unreasonable risk, in addition to beginning risk evaluations for the twenty substances prioritized through the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act*, 82 Fed. Reg. 33,753 (July 20, 2017) and for additional risk evaluations requested by manufacturers—of which there are presently three. 15 U.S.C. § 2605(b)(2)(B). Thus, EPA must allocate its resources to meet these new resource-intensive statutory requirements and deadlines.

Additionally, as described in more detail below, the contents of the 2020 Submission do not support diverting significant resources to reopen the 2016 Petition and reconsider the petition denial. Neither the 2016 Petition nor the 2020 Submission satisfies the legal requirements necessary for EPA to initiate a proceeding for a section 6(a) rulemaking because, among other deficiencies, the scientific evidence submitted for evaluating the risk of neurotoxic effects from exposure to fluoride is insufficient for EPA to reach an informed risk determination.

A. Section 21 petitions should include a well-supported risk assessment fit for informing EPA's risk determination under TSCA.

TSCA section 6(a) requires that a finding of unreasonable risk be made in accordance with the risk evaluation process provided for in subsection (b)(4)(A). In most cases, prior to the issuance of a TSCA section 6(a) rule, EPA will conduct a risk evaluation. The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation identified as relevant by the Administrator. As part of this process, EPA must evaluate both hazard and exposure, exclude consideration of costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA to use the best available science, and ensure decisions are based on the weight-of-scientific-evidence. 15 U.S.C. § 2605(b)(4)(F); 15 U.S.C. § 2625(h). This is a resource-intensive process that requires expertise in a number of different scientific fields.

With the exception of the first 10 TSCA risk evaluations, EPA-conducted risk evaluations can be initiated in only one of two ways—upon EPA's designation of a chemical substance as a high-priority substance, or in response to a request for risk evaluation by a manufacturer of the chemical substance. 15 U.S.C. §§ 2605(b)(3)(A); (b)(4)(C). The purposes of the prioritization process are (1) to ensure that the Agency's priorities for risk evaluation and risk management are grounded in risk-based considerations and (2) to provide the public and interested stakeholders with an opportunity to provide relevant information. 82 FR at 33,754. If a petitioner could circumvent the prioritization process and unilaterally compel a TSCA risk evaluation through section 21, the purpose and intent of these statutory provisions would surely be frustrated.

In limited circumstances, EPA may proceed with section 6(a) risk management rulemaking without an EPA-conducted risk evaluation. However, TSCA prescribes the circumstances under which such rulemaking may occur.[1] Section 21 requires that petitions for a section 6(a) rulemaking "set forth the facts which it is claimed establish that it is necessary to issue" such a rule. 15 U.S.C. § 2620(b)(1). Section 26(h)-(i) require the Administrator to make decisions under section 6 using the best available science and based on the weight of the scientific evidence. 15 U.S.C. §§ 2625(h)-(i). Thus, a risk evaluation containing scientific evidence and analysis that will support a risk determination consistent with the scientific standards required by section 26 is necessary for supporting a section 21 petition requesting the initiation of proceeding for a section 6(a) rulemaking. See 82 Fed. Reg. at 11,879.

As required by statute, EPA has developed a guidance document to assist petitioners in developing and submitting draft risk evaluations. Petitioners should look to and utilize the *Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act*, 82 FR 33765 (June 22, 2017). This guidance document is available on EPA's website here: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/guidance-assist-interested-persons-developing-and. The guidance document describes the "quality of the information submitted and the process to be followed in developing draft risk evaluations," in part, so that petitioners may better understand how to submit information in support of the scientific standards applicable to the Administrator's decision-making under Section 6.

B. The evidence submitted by petitioners for evaluating the risk of neurotoxic effects from exposure to fluoride is insufficient for reaching an informed risk determination.

After careful consideration, EPA denied the 2016 Petition on February 17, 2017, primarily because the petition did not support the request with a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride through the purposeful addition of fluoridation chemicals to drinking water or otherwise from fluoride exposure in the U.S. In denying the petition, EPA concluded, in part, that the scientific data

[1] *See, e.g.*, TSCA section 26(l)(4) (enabling EPA to issue proposed and final section 6(a) rules for certain chemical substances with risk assessments predating 2016 TSCA amendments, provided such rules are "consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of [section 6]").

relied on in the petition were unsuitable for evaluating levels of fluoride associated with neurotoxic effects, for deriving dose-response relationships necessary for risk assessment, or for considering the countervailing beneficial health impacts. 82 Fed. Reg. at 11,879.

Petitioners' claim—that fluoride exposure causes an unreasonable risk of neurodevelopmental harm—is currently subject to review in pending litigation, *Food and Water Watch v. EPA* (N.D. Cal., No. 17-cv-02162). EPA has spent considerable resources analyzing the evidence in that litigation and defending the Agency's position. After three years of litigation, the matter culminated in a two-week trial between June 8 and June 17, 2020. Your 2020 Submission to EPA and request for reconsideration consists almost entirely of the record presented and pending before the district court, with a few exceptions that are described below. EPA's position concerning the evidence presented at trial has not changed.

Causation is relevant to hazard assessment (including hazard identification). As EPA's *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* ("Risk Evaluation Rule") expressly states: "[a] hazard assessment identifies the types of adverse health or environmental effects or hazards that can be *caused* by exposure to the chemical substance in question, and to characterize the quality and weight of the scientific evidence supporting this identification." 82 Fed. Reg. 33,726, 33,741 (July 20, 2017) (emphasis added). Hazard identification is further defined as "the process of determining whether exposure to a chemical stressor can *cause* an increase in the incidence of specific adverse health or environmental effects." *Id.* at 33,741-42 (emphasis added). The foundation for these statements provided in the Risk Evaluation Rule are multiple EPA hazard assessment guidance documents and National Academies of Science ("NAS") reports.[2] While the evidence for fluoride may be sufficient to indicate a *potential* developmental neurotoxic hazard at some level, a great deal of scientific judgment, based on experience with neurotoxicity data and with the principles of study design and statistical analysis, is required to adequately evaluate the database on neurotoxicity to determine whether the database is sufficient to establish and determine at what level a hazard will be manifest based on the total available data.

When focusing on findings from studies with exposures in ranges typically found in community drinking water programs in United States (0.7 mg/L), the evidence of effects on cognitive neurodevelopment is inconsistent and unclear, and, therefore, insufficient to reach and support a hazard conclusion. EPA believes that it is premature and inappropriate to rely upon either the MIREC or ELEMENT cohort studies as key studies for quantitative analysis such as benchmark-dose modeling.

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[2] *See Guidelines for Developmental Toxicity Risk Assessment*, 56 FR 63798 (December 5, 1991); *Guidelines for Neurotoxicity Risk Assessment*, 63 FR 26926 (May 14, 1998); National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (1983); National Research Council, *Science and Judgment in Risk Assessment* (1994); National Research Council, *Science and Decisions: Advancing Risk Assessment* (2009).

For these reasons, the evidence in your recent submission that is duplicative of what was presented at trial does not justify reopening the 2016 Petition and reconsidering the petition denial.

You also attached to your recent submission and request for reconsideration three new documents that were not part of the trial record—(1) the National Toxicology Program's (NTP) *draft* Monograph entitled: *Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects*; (2) an unpublished pooled benchmark dose analysis; and (3) an op-ed authored by Drs. Bruce Lanphear, Christine Till, and Linda Birnbaum.

First, NTP conducts literature-based evaluations to determine whether exposure to environmental substances may be associated with adverse health effects. These evaluations result in hazard conclusions or characterize the extent of the evidence and are published in the NTP Monograph series. NTP Monographs serve as an environmental health resource to provide information that can be used to make informed decisions about whether exposure to a substance may be of concern for human health.

NTP conducted a systematic review to evaluate the evidence that exposure to fluoride is associated with neurodevelopmental or cognitive effects. NTP's review was initiated in response to a nomination from the Fluoride Action Network, a petitioner in this matter. NTP's final conclusions are still pending. To ensure the integrity of its report, NTP asked the NAS to review the monograph. As a result of that request, NAS convened a committee, which focused its efforts on evaluating whether NTP's draft conclusions are supported by the scientific evidence.

In September 2019, the NAS committee published a report concluding that NTP failed to provide adequate scientific evidence for its draft conclusions and expressed "substantive concerns" with how NTP evaluated the evidence. The committee's report stated that NTP would need to conduct and present more analysis before it could reach and support a conclusion about fluoride's effect on neurodevelopment. The NAS committee report also identifies other concerns about the NTP monograph. For example, the committee noted that the studies that NTP included in its systematic review "did not undergo rigorous statistical review" and called this a "flaw" because some of these research papers contained errors or other issues that "compromised their internal validity." The committee also wrote that NTP classified some studies with a low risk of bias even though "the measure of the neurodevelopmental and cognitive outcome was seriously flawed."

NTP revised its draft monograph and, in September 2020, asked the NAS to review the revised version. The same NAS committee that performed the review of the original monograph will determine whether the changes made by NTP sufficiently address the committee's concerns about the original draft. The NAS committee's review is ongoing and no report has been issued at this time. Because the pending NAS peer review report and final NTP monograph will provide significant information for informing whether exposure to fluoride under the condition of use may be of concern for human health, the draft NTP monograph attached to your recent submission does not justify reconsideration at this time.

Second, you also attached to your recent submission an unpublished paper titled: *A Benchmark Dose Analysis for Maternal Pregnancy Urine-Fluoride and IQ in Children*. The paper purports to use data from the Early Life Exposures in Mexico to Environmental Toxicants (ELEMENT) cohort in Mexico and the Maternal-Infant Research on Environmental Chemicals (MIREC) cohort in Canada for benchmark dose modeling. The paper's authors are listed as Philippe Grandjean, Howard Hu, Christine Till, Rivka Green, Morteza Bashash, David Flora, Martha Maria Tellez-Rojo, Peter Song, Bruce Lanphear, and Esben Budtz-Jørgensen. Drs. Philippe Grandjean, Howard Hu, and Bruce Lanphear noted their conflicts of interest as each having served as expert witnesses on behalf of the petitioners at trial.

The paper is a preliminary report of work that has neither been published nor certified by peer review. It was self-published on the website medRχiv, which specifically directs that the posted studies "should not be relied on to guide clinical practice or health-related behavior and should not be reported in news media as established information." EPA generally does not rely on analyses that have not undergone peer review in supporting a conclusion regarding the dose-response relationship of a chemical substance.

More importantly, however, because the trial record and proposed supplemental data are currently insufficient to reach and support a hazard conclusion, it is premature to conduct a quantitative analysis such as benchmark dose modeling. That would require EPA to assume an effect on human developmental neurotoxicity from exposure to fluoride prior to the completion of a critical assessment of the evidence of hazard. This is especially true where the draft NTP conclusions note that the effects on cognitive neurodevelopment are unclear and inconsistent at concentrations below 1.5 mg/L. Therefore, the preliminary benchmark dose analysis attached to your recent submission does not provide any new evidence that would justify reconsideration at this time.[3]

Third, the op-ed in Environmental Health News authored by Drs. Bruce Lanphear, Christine Till, and Linda Birnbaum offers the policy opinions of its three authors. It is not a scientific or peer-reviewed publication of data or analyses and accordingly does not provide references or citations supporting any of the statements therein. Therefore, the op-ed does not provide any new scientific data that would justify reconsideration at this time.

In sum, the materials you attached to your request do not provide sufficient scientific or administrative justification to reopen and reconsider the November 2016 petition.

C. Given anticipated new analyses and competing TSCA priorities, reconsideration is not warranted at this time.

EPA is aware that new information regarding the exposure and health effects of exposure to fluoride continues to develop. Researchers continue to study the potential health effects associated with exposure to fluoride in drinking water. For example, EPA is aware of research from the Spanish INMA cohort showing positive (*e.g.*, beneficial) associations between fluoride

[3] Additionally, where a chemical substance has beneficial health effects, such as fluoride, consideration of those effects should be included as part of the risk evaluation and risk determination.

levels during pregnancy and neuropsychological development at 4 years of age. This research contradicts the findings of the MIREC and ELEMENT studies in that detrimental effects of fluoride in neurodevelopment were not supported by the data.

While the science on this issue develops and, particularly, without the final NTP monograph, reconsidering the petition denial at this time would not be a prudent use of EPA's resources. Reconsideration would divert significant resources from ongoing risk evaluations and rulemakings the Agency is already undertaking, as well as other high priority work within the Office of Pollution Prevention and Toxics.

For all the reasons set forth above, EPA declines to exercise its discretionary authority to reopen the administrative record and reconsider the February 17, 2017 petition denial.

If you have any questions regarding your submission, please feel free to contact Susanna Blair of my staff at Blair.Susanna@epa.gov or 202-564-4371.

Sincerely,

YVETTE COLLAZO REYES
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Yvette T. Collazo
Director
Office of Pollution Prevention and Toxics