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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
AT SAN FRANCISCO

FOOD & WATER WATCH, et al., Plaintiffs, vs. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al. Defendants.	Civ. No. 17-CV-02162-EMC **PLAINTIFFS' OPPOSITION TO THE ENVIRONMENTAL PROTECTION AGENCY'S MOTION TO DISMISS** DATE: November 30, 2017 TIME: 1:30 pm Courtroom: No. 5, 17th Floor

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I. INTRODUCTION

In its motion to dismiss, the Environmental Protection Agency ("EPA") contends that Plaintiffs did not provide sufficient information in their Citizen Petition to permit the Agency, or this Court, to conduct a risk evaluation under the standards of the recently amended Toxic Substances Control Act ("TSCA"). Specifically, EPA contends that Plaintiffs' Petition was legally deficient because it (1) did not identify the specific "chemical substance," or "category" of chemical substances at issue, and (2) did not identify all "conditions of use" of fluoridation chemicals.

As set forth herein, EPA's contentions do not withstand scrutiny. First, assuming *arguendo* that EPA does not know the chemicals used to fluoridate drinking water in the United States, Plaintiffs specifically identified these chemicals by name in their Petition, as well as in the supporting documentation attached to the Petition. Second, a Citizen Petition need only identify a "category" of chemical substances, and EPA itself has long treated, and has specifically characterized, fluoridation chemicals as a "category" of chemicals due to their similarity of chemical structure and use. Finally, EPA's contention that citizen petitioners must identify all conditions of use is not only at odds with the plain meaning and legislative intent of TSCA, but EPA's own recent interpretation of the Act. At bottom, EPA's untenable statutory interpretation, which has never been subject to notice and comment rulemaking, is little more than a litigating position which warrants no deference from this Court.

II. FACTUAL BACKGROUND

On November 22, 2016, Plaintiffs filed a Citizen Petition ("Petition") requesting that EPA exercise its authority under the Toxic Substances Control Act to prohibit the purposeful addition of fluoridation chemicals to U.S. water supplies. (Complaint ¶ 24.) The three fluoridation chemicals used in the United States are fluorosilicic acid (*aka* HFSA), sodium silicofluoride (*aka* sodium fluorosilicate), and sodium fluoride. The EPA acknowledged that these are the three fluoridation chemicals in an August

12, 2013 denial of a previous Citizens Petition.[1]

The majority of western nations have already rejected or ended the practice of adding fluoridation chemicals to water, but the practice remains widespread in the United States. (Petition at 1, attached as Exhibit 1 to the Declaration of Norman Rave). In recent years, a large number of human, animal, and cellular studies have linked fluoride exposure to adverse neurotoxic effects, including reduced IQ, impaired memory, and behavioral disturbances. (Complaint ¶¶ 12-16, 50-79.) These neurotoxic risks are the grounds upon which Plaintiffs sought Agency action through their Citizen Petition. According to the Petition:

> [A]pplication of the Agency's own *Guidelines for Neurotoxicity Risk Assessment* to the existing database on fluoride shows that (1) neurotoxicity is a hazard of fluoride exposure, and (2) the reference dose that would reasonably protect against this hazard is incompatible with the doses now ingested by millions of Americans in fluoridated areas.

In support of their Petition, Plaintiffs attached over 2,400 pages of documentation, including 196 studies published since 2006 that have investigated fluoride's impact on cognition, behavior, and the brain. (Petition at 4.) The vast majority of these studies found adverse effects from fluoride exposure. (*Ibid*.)

EPA is vested with authority to regulate the addition of fluoridation chemicals to drinking water under both TSCA[2] and the Safe Drinking Water Act ("SDWA"). 42 U.S.C. § 300f. In carrying out its duties under SDWA, EPA regulates all fluoride chemicals in water, whether naturally occurring or artificially added, as "fluoride."[3] Under this longstanding regulatory approach, EPA's risk assessments on fluoride have made no distinction between naturally occurring or artificially added fluoride chemicals,

[1] 78 Fed. Reg. at 48846 ("[T]he Centers for Disease Control and Prevention (CDC) conducted a study of the relationship between the additives used for fluoridation (i.e., *HFSA, sodium silicofluoride, and sodium fluoride*) and blood lead concentrations . . . ." (emphasis added)).

[2] *See* Memorandum of Understanding Between The Environmental Protection Agency and The Food and Drug Administration (June 12 & 22, 1979), *available at* https://www.fda.gov/ (agreeing that EPA has authority to "regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA").

[3] *See, e.g.*, 82 Fed. Reg. at 3531-33; 51 Fed. Reg. 11396. *See also* EPA "Questions and Answers About Fluoride" (January 2011), *available at*: http://www.epa.gov .

or between fluorosilic acid, sodium silicofluoride, and sodium fluoride.[4] Consistent with this longstanding regulatory approach that EPA has taken with fluoride, Plaintiffs' Petition treated fluoridation chemicals as a category[5] of chemical substances. In addition, however, the Petition did specifically identify both fluorosilicic acid and sodium silicofluoride as fluoridation chemicals. (Petition at 28.) Moreover, several of the studies that Plaintiffs attached to their Petition specifically identified each of the three fluoridation chemicals. For example, the first sentence of one of the attached studies declares: "Over 91% of US fluoridated water is treated with either sodium silicofluoride (Na2SIF6) or fluorosilicic acid (H2SiF6)—henceforth, the silicofluorides or SiFs. Less than 10% is treated with simple sodium fluoride (NaF)." (Declaration of Michael Connett "Connett Decl.", Exhibit 1.)

On February 17, 2017, EPA denied the Petition. Plaintiffs thereupon timely challenged this denial by filing the instant action on April 18, 2017. On September 25, 2017, EPA moved to dismiss the action for several of the same reasons asserted in its denial of the Petition, namely: (1) Plaintiffs purportedly failed to specifically identify the "chemical substances" or "category" of chemical substances at issue, and (2) Plaintiffs failed to identify all "conditions of use" of fluoridation chemicals. Plaintiffs now respond.

III. STATUTORY AND REGULATORY FRAMEWORK

A. TSCA Background

The Toxic Substances Control Act ("TSCA" or "Act"), 15 U.S.C. §2601 et seq., was enacted in 1976 to create a national program for assessing and managing the risks of chemicals to human health and the environment. Among the law's goals are (1) that "adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment" and (2)

[4] *See, e.g.*, 82 Fed. Reg. at 3531-33 (summarizing EPA's recent review of the Agency's drinking water standards for fluoride); 51 Fed. Reg. 11396 (promulgating EPA's safe drinking water standards for fluoride).

[5] In its denial of the Petition, EPA specifically refers to "fluoridation chemicals" as "a *category* of chemical substances." 82 Fed. Reg. at 11882 (emphasis added).

"adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment."[6] To achieve these goals, Section 6[7] of the Act authorizes the EPA to ban or restrict the manufacture, processing, use and disposal of chemicals determined to present an unreasonable risk. 15 U.S.C. § 2605.

B. Citizens' Petitions Under Section 21

Since its inception, TSCA has contained a petition process by which citizens can seek to compel action by EPA under different provisions of the law. 15 U.S.C. § 2620 ("Section 21"). As enacted in 1976, Section 21 authorizes citizens to petition for issuance of a rule under Section 6(a), which includes the restriction or ban on particular uses of chemicals. *Id.* § 2620(b)(4)(B). If EPA denies the petition or fails to act within 90 days, Section 21 empowers the petitioner to file a civil action in federal district court to "compel the [EPA] Administrator to initiate a rulemaking proceeding as requested in the petition." 15 U.S.C. §2620(b)(4)(A). Under Section 21, "the petitioner shall be provided an opportunity to have such petition considered by the court in a *de novo* proceeding." 15 U.S.C. §2620(b)(4)(B).

The DC Circuit has recognized "TSCA's unusually powerful citizen-petition procedures." *Trumpeter Swan Society v EPA*, 774 F.3d 1037, 1939 (DC Cir. 2014). Their presence in the law reflects Congress's intent to provide citizens with an independent role in setting EPA's rulemaking agenda where a court determines, in a *de novo* proceeding, that the Agency has failed to act on a chemical determined to present an unreasonable risk of injury. While EPA may view Section 21 petitions as inconvenient or disruptive, Congress made the judgment that the public's ability to spotlight serious chemical threats that EPA has overlooked as an "important mechanism" for effectuating the Act's purpose in the face of EPA foot-dragging or inaction.[8] As noted by the D.C. Circuit Court of Appeals, Section 21 deputizes the public to "ensure that bureaucratic lethargy does not prevent the appropriate administration of [TSCA's]

[6] 15 U.S.C. § 2601(b)(2).
[7] Section 6 is codified at 15 U.S.C. § 2605.
[8] H. Rep. No. 94-1341 (94th Cong. 2d Sess., July 14, 1976) at 57.

vital authority." *Environmental Defense Fund v. Reilly*, 909 F.2d 1497, 1499 (D.C. Cir. 1990). This safeguard is now more important than ever, given Congress' dissatisfaction with the pace of EPA rulemaking under TSCA, a subject to which we now turn.

C. Frank R. Lautenberg Chemical Safety Act for the 21st Century ("LCSA")

In the decades since TSCA was first enacted, there has been growing concern about the effectiveness of the Act in addressing chemical risks. Much of this concern centered on the lack of meaningful progress in EPA's use of its rulemaking authority under Section 6 to impose controls on unsafe chemicals. Ultimately, disappointment in the weaknesses of the Agency's administration of the law resulted in a bi-partisan effort to overhaul and strengthen its key provisions, culminating in enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("LCSA"), which took effect on June 11, 2016. LCSA modifies several portions of TSCA but at its heart is a set of improvements to the chemical regulatory authorities in Section 6 designed to accelerate assessment of chemical risks and enactment of rules to protect against these risks.

D. Risk Evaluations Under Section 6(b) of the Amended Act

LCSA amended Section 6, in part, by imposing new requirements on the EPA for prioritizing chemicals and conducting risk evaluations. The prioritization requirements are set out in Section 6(b), which directs EPA to establish a "risk-based screening process" for designating chemicals as "high priority" or "low priority."[9] 15 U.S.C. § 2605(b)(1). Chemicals must be designated "high-priority" under Section 6(b) if EPA concludes that "they may present an unreasonable risk to health or the environment because of potential hazard and a potential route of exposure under the conditions of use." *Id.* § 2605(b)(1)(B)(i). Once designated, a high-priority chemical must be subject to a risk evaluation. *Id.* § 2605(b)(3)(A). Under certain circumstances, EPA must also conduct risk evaluations on chemicals

[9] This process must be in place within a year of enactment. EPA promulgated final rules establishing the prioritization process on July 20, 2017. 82 Fed. Reg. 33753.

nominated by industry. *Id.* § 2605(b)(4)(C)(ii) & (E).[10]

As stated in Section 6(b), a risk evaluation must:

> determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

Id. § 2605(b)(4)(A). In a change from the old law, EPA must directly address risks to vulnerable populations and determine if they are unreasonable, even if EPA concludes that risks to the general population are not unreasonable.[11] *Ibid*. It can also no longer weigh cost and other non-risk factors in determining whether a risk is unreasonable. *Ibid.*

The risk evaluation process must start with publication of a scope document within six months under Section 6(b); this document must describe "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." *Id.* § 2605(b)(4)(D). The required contents of these risk evaluations themselves are extensive. *See id.* § 2605(b)(4)(F). As such, Congress gave EPA three years to complete the risk evaluations, with an extension of up to six months. *Id.* § 2605(b)(4)(G).

If EPA determines that a chemical substance presents an unreasonable risk, Section 6(c) obligates the Agency to conduct rulemaking to address the risk under Section 6(a). *Id.* § 2605(c)(1). To facilitate rulemaking, Congress deleted a directive in the original law that EPA adopt the "least burdensome requirements" (a provision that had proven difficult to implement in practice) and directed the Agency to

[10] In addition to these two mechanisms for triggering risk evaluations, EPA is obligated to initiate risk evaluations on 10 chemicals selected from the so-called EPA "Workplan" list within 180 of the enactment of LCSA under Section 6(b)(2)(A).

[11] Like the original statute, the amended Act does not define the term "unreasonable risk." Based on the legislative history of TSCA and use of analogous terms in other statutes, courts construed this term to require a balancing of benefits and costs. *Corrosion Proof Fittings v. EPA* 947 F.2d 1201 (5th Cir. 1991). However, with the express exclusion of cost and other economic factors in the new law, the "reasonableness" of a risk for purposes of a risk evaluation will now be based entirely on health considerations.

impose restrictions "to the extent necessary so that the chemical substance no longer presents [the unreasonable] risk." *Id.* § 2605(a). Otherwise, Congress largely retained Section 6(a) in its original form.

E. EPA's July 2017 Risk Evaluation Rule

In Section 6(b), Congress directed EPA to establish, by rule, a process to conduct risk evaluations under the new law. *Id.* § 2605(b)(4)(B). EPA proposed this rule on January 19, 2017[12] and finalized it on July 20, 2017.[13] Several changes in the rules occurred between the proposed rule in January and final rule in July that bear on the issues in this case. For example, the proposed rule adopted the interpretation that risk evaluations must address *all* of the "conditions of use" of the chemical being evaluated.[14] In the face of opposition from industry, the final rule backed away from this approach.[15] EPA's motion claims that EPA retained the goal of addressing all conditions of use, save for those that are "*de minimis* or otherwise insignificant" (Mem. at 9:24) but the final rule reserved far broader discretion for EPA to pick and choose which conditions of use will be assessed:

> In defining conditions of use, many commenters raised concern about EPA's interpretation that "the conditions of use" must include "all conditions of use." Concerns were raised in this regard was [sic] specifically about the ability of EPA to meet the statutory risk evaluation deadlines if all intended, known and reasonably foreseen activities must be considered conditions of use, and that attempting to identify every activity relating to the chemical substance was unnecessary and impractical. . . . Given the strength and variety of the concerns presented in the comments, EPA has reevaluated its proposal. . . . EPA's final approach is informed in part by the legislative history of the amended TSCA, which explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical, in order to ensure that the Agency's focus is on the conditions of use that raise the greatest potential for risk. . . . Consequently, *EPA may, on a case-by- case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern*, and consequently merit an unreasonable risk determination.[16]

[12] 82 Fed. Reg. 7562.
[13] 82 Fed. Reg. 33726.
[14] 82 Fed. Reg. at 7565.
[15] 82 Fed. Reg. at 33728-29.
[16] 82 Fed. Reg. at 33728-29. Plaintiffs do not necessarily agree with EPA's interpretation, which was strongly opposed by many public health and environmental groups in EPA's rulemaking. These groups are seeking judicial review of EPA's risk evaluation rule for failing to consider all conditions of use.

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EPA's final rule reversed the Agency's position in another critical area—the extent of its obligation to consider all conditions of use in conducting risk evaluations requested by industry. In the proposed rule, EPA required the manufacturers submitting the request to include all information necessary to conduct a risk evaluation on all conditions of use. However, "the final rule allows manufacturers to submit requests for risk evaluation on *only the conditions of use of the chemical substances that are of interest to the manufacturer*."[17] EPA may then limit the risk evaluation to these conditions of use or add other conditions of use in its discretion.[18] Finally, the rule makes explicit that EPA will make separate unreasonable risk determinations for *each* condition of use it evaluates, that these determinations may be finalized before the entire risk evaluation is completed and that an unreasonable risk finding for a *particular* condition of use triggers rulemaking under Section 6(a) to restrict *that use*.[19]

F. The Impact of the LCSA Amendments on Citizen Petitions

Not surprisingly, Congress retained Section 21 under the new Act. It received virtually no attention in the legislative process. The final legislation preserves the bulk of the original language but makes a number of small changes, including new language to confirm that the determination of unreasonable risk must consider "potentially exposed or susceptible subpopulations" and cannot consider "cost or other nonrisk factors." 15 U.S.C. § 2620(b)(4)(B)(ii). A related change is the addition of the

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Indeed, there are distinct reasons why EPA should consider all conditions of use in conducting its risk evaluations (so as not to overlook an unsafe use) that do not apply in the context of Citizen Petitions (where petitioners are specifically directing EPA's attention to unsafe uses.) The point here, however, is that EPA's motion contradicts the Agency's own position, as set forth in its rule. Since this mischaracterization is the basis for EPA's argument that Section 21 petitions must address all conditions of use, EPA should receive no deference from this Court, as discussed *supra* at pages 20-22.

[17] 82 Fed. Reg. at 33736 (emphasis added).

[18] *Ibid.*

[19] 82 Fed. Reg. at 33744

phrase "under the conditions of use."[20] *Ibid.* There is no indication in LCSA or its legislative history that any of these changes were intended to weaken the petition process or burden citizen petitioners with new requirements. Indeed, the Senate Report states that "[n]o substantive or policy change is intended by these amendments [to Section 21]."[21]

IV. ARGUMENT

A. PLAINTIFFS DEFINED THE CHEMICAL SUBSTANCE TARGETED BY THEIR PETITION WITH SUFFICIENT SPECIFICITY TO SATISFY SECTION 21

EPA's claim that Plaintiffs' petition failed to adequately identify the chemical substance on which it requested action is meritless.

First, contrary to EPA's claim, Plaintiffs *did* identify the specific fluoridation chemicals at issue in their Petition. The Petition states that action against artificial fluoridation chemicals is "justified by laboratory and epidemiological research linking artificial fluoridation chemicals *(i.e., fluorosilicic acid and sodium fluorosilicate)* with pipe corrosion and elevated blood lead levels." Petition at 28 (emphasis added). In support of this point, Plaintiffs cited and attached four studies, each of which identify the three chemicals used to fluoridate water. (*Id.*) One of these studies identified the three fluoridation chemicals in the first sentence, along with the relative percentage of the fluoridation chemical market they represent. (Connett Decl., Exhibit 1, at 1091.) EPA's claim, therefore, that Plaintiffs did not provide the Agency with sufficient information to determine the identity of the chemical substances is simply incorrect.

Second, even if Plaintiffs had not specifically identified the fluoridation chemicals by name, EPA has conceded by its own words and actions that fluoridation chemicals qualify as a "category" of chemical substances. In its moving papers, EPA recognizes that TSCA authorizes the Agency to regulate

[20] "Conditions of use" is defined in 15 U.S.C. § 2602(4) as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."

[21] S. Rept. 114-67 (114th Cong. 1st Sess., June 18, 2015) at 28-29. It is clear from the text of the Senate bill that the amendments described in the report are to Section 21 of TSCA, not Section 20 as the report erroneously states.

categories of chemical substances where the chemicals have a "similarity in molecular structure, similarity in use, or any other basis suitable for purposes of TSCA." Mem. at 2 n.2 (citing 15 U.S.C. § 2625(c)(1). A citizen petition thus provides sufficient specificity for Agency action where the petition identifies a category of chemical substances. Here, there is a clear and logical basis for treating fluoridation chemicals as a category because they are all inorganic fluoride compounds that are added to water for the same purpose (to prevent tooth decay). EPA itself has a long published track record of regulating all fluoridation chemicals as simply "fluoride."[22] For the EPA to now claim, therefore, that it lacks sufficient information to determine whether fluoridation chemicals are sufficiently similar to qualify as a category stretches credulity past the breaking point. In fact, EPA actually used the words "category of chemical substances" to describe fluoridation chemicals *in its dismissal of Plaintiffs' Petition*. To quote:

> Rather than comprehensively addressing the conditions of use that apply to a particular chemical substance, the petition requests EPA to take action on a single condition of use (water fluoridation) that cuts across a *category of chemical substances* (fluoridation chemicals).[23]

EPA's argument, therefore, that the Petition failed to identify a "category" of chemical substances does not withstand scrutiny.

Finally, in light of EPA's longstanding treatment of fluoridation chemicals as a category, and in light of EPA's prior knowledge of the three chemicals used to fluoridate water,[24] the Agency's argument that this case should be dismissed for purported imperfections in the way Plaintiffs identified the fluoridation chemicals elevates form over substance to an intolerable degree. As a practical matter, the only effect of granting the motion on this ground is that Plaintiffs will have to re-file an amended petition which specifically identifies the 3 chemicals, wait to have it denied, and then re-file a complaint. Not

[22] *See, e.g.*, 82 Fed. Reg. at 3531-33; 51 Fed. Reg. 11396.
[23] 82 Fed. Reg. at 11881-82 (emphasis added).
[24] As noted earlier, EPA identified the three chemicals used to fluoridate drinking water in a previous dismissal of a Citizen Petition. *See* 78 Fed. Reg. at 48846.

only would this waste valuable judicial and administrative resources, it would fly in the face of congressional intent—Congress sought to encourage public participation, not stymie it.

B. SECTION 21 OF TSCA DOES NOT REQUIRE A PETITIONER TO CONDUCT A RISK EVALUATION ON ALL USES OF A CHEMICAL, BUT SIMPLY TO DEMONSTRATE THAT A PARTICULAR USE PRESENTS AN UNREASONABLE RISK

Next, EPA argues that Plaintiffs have failed to state a claim for relief under Section 21 because their petition for rulemaking only addressed the risks presented by a single condition of use of fluoridation chemicals—their addition to drinking water—and did not assess the risks of all other uses. As the Agency states, Plaintiffs' "petition provides no information about the uses of fluoridation chemicals other than as a drinking water additive, and makes no attempt to evaluate the risks from such other uses, or demonstrate that such uses are insignificant or otherwise unnecessary to the completion of a risk evaluation." (Mem. at 13:14-17). In essence, EPA demands that Section 21 petitioners must undertake the laborious and unnecessary exercise of conducting a risk evaluation on the full suite of chemical uses to qualify for relief—even though their petition demonstrates that a single use presents an unreasonable risk of injury warranting regulation under Section 6. This reading of Section 21 places additional burdens on petitioners that are not imposed by the plain language of the Act and presumes a false equivalence between the tasks that EPA must undertake under Section 6(b) and the showing that citizens must make to compel agency action on unsafe chemicals under Section 21. The roadblocks that EPA's interpretation would create would effectively make it impossible for petitioners to obtain relief under Section 21, negating the independent citizens' remedy that Congress sought to provide.

1. The Plain Language of Section 21 Fails to Support EPA's Interpretation

As EPA outlines in its motion, and as discussed above, the recent amendments to TSCA create a new framework by which the Agency must evaluate and address chemical risks. A key step under this framework, prescribed under Section 6(b), is the performance of a risk evaluation to determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the

conditions of use."[25] 15 U.S.C. § 2605(b)(4)(A). Where EPA makes such a determination, it must then initiate a rulemaking under Section 6(a) to impose "one or more" requirements on the manufacture, processing, use or disposal of the substance "to the extent necessary so that the chemical substance no longer presents such risk."[26] *Id.* § 2605(a).

EPA argues that "the statutory scheme would be substantially undermined if Section 21 petitions were not required to present a scientific basis for action that is reasonably comparable, in its quality and scope to a risk evaluation by EPA under TSCA Section 6(b)." (Mem. at 10:6-9.) But this is not what Section 21 says. In relevant part, Section 21 provides that the district court reviewing denial of a petition for rulemaking under Section 6(a) "shall order the Administrator to initiate the action requested by the petitioner" if the "petitioner demonstrates to the satisfaction of the court" that "the chemical substance to be subject to such rule presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or vulnerable population, under the conditions of use." 15 U.S.C. § 2620(b)(4)(B)(i). Nowhere does this provision state that the petitioner must conduct a risk evaluation that satisfies the requirements applicable to EPA reviews conducted pursuant to Section 6(b). Section 21 makes no reference to the term "risk evaluation" or even any reference to Section 6(b) at all. *See id.* In fact, Congress amended Section 21 so that requests for rulemaking under Section 6 now specifically refer to Section 6(a), rather than Section 6 generally. *Id.* § 2620(b)(4)(ii).

The precondition for rulemaking under Section 6(a) is that the "manufacture, processing, distribution in commerce, *use* or disposal . . . or any combination of such activities" presents an unreasonable risk. *Id.* § 2605(a) (emphasis added). The rule must then restrict these specific activities

[25] EPA's obligation to conduct a risk evaluation can be triggered by the Agency's designation of a chemical as a "high priority" substance under Section 6(b)(1)(B) or an industry request for a risk evaluation that meets the criteria in Section 6(b)(4)(E). *See* 15 U.S.C. § 2605.

[26] EPA has not yet undertaken a rulemaking under Section 6(a) following a risk evaluation. But any such rulemaking would necessarily seek to eliminate the unreasonable risk by restricting the particular use or uses determined in the evaluation to create or contribute to that risk.

"to the extent necessary so that the chemical substance no longer presents" the unreasonable risk. *Id.* If EPA is authorized to restrict a chemical under Section 6(a) where one or more particular conditions of use present an unreasonable risk, there is no reason to require petitioners to meet a higher standard when seeking a Section 6(a) rulemaking under Section 21.

To be sure, in a change from the original version of the Act, a Section 21 petition must demonstrate an unreasonable risk "under the conditions of use" of the substance. *Id.* § 2620(b)(4)(B)(ii). But the logical reading of this language is that the petitioner can meet the criteria for rulemaking by showing that the chemical presents an unreasonable risk under the *particular* condition or conditions of use highlighted by the petition; if such showing is made, there is no need to evaluate all other conditions of use. Importantly, nothing in this process would absolve the chemical of risk for other conditions of use for which evaluation was triggered by other sections of TSCA or by future Section 21 petitions.

2. EPA's Risk Evaluation Rule and Initial Actions under Section 6(a) Demonstrate That a Finding of Unreasonable Risk for a Single Condition of Use Is Sufficient to Trigger Rulemaking to Restrict the Use

Insofar as EPA is now arguing that only an unreasonable risk determination for the chemical *as a whole* is sufficient to trigger rulemaking under Section 6(a), its position is contrary to the approach EPA itself has taken in its July 20 rule establishing chemical risk evaluation procedures under the amended Act.[27] Section 702.47 of the July 20 rule provides that:

> As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment *under each condition of use* within the scope of the risk evaluation.[28]

(emphasis added). Section 702.41(a)(9) specifies that EPA can make a determination of unreasonable risk for a specific condition or subset of conditions of use before it completes the full risk evaluation:

> EPA may complete its evaluation of the chemical substance *under specific conditions of use* or categories of conditions of use at any point following the issuance of the final scope document, and issue its determination as to whether the chemical substance under those

[27] 82 Fed. Reg. at 33752.
[28] 82 Fed. Reg. at 33740 (emphasis added).

> conditions of use *does or does not present an unreasonable risk to health or the environment under those conditions of use.*[29]

(emphasis added). And, under Section 702.49(c), where EPA makes a determination of unreasonable risk for a single condition of use, it is obligated to conduct rulemaking to restrict that use under Section 6(a):

> Upon determination by the EPA that a chemical substance *under one or more of the conditions of use* within the scope of the risk evaluation presents an unreasonable risk of injury to health or the environment as described in § 702.47, *the Agency will initiate action* as required pursuant to 15 U.S.C. § 2605(a).[30]

In the preamble to its rule, EPA explained that this approach "explicitly allowed for the expedited evaluation *for a particular condition of use* to, if necessary, move more rapidly to risk management under TSCA Section 6(a)" and would apply in "a situation in which a single use presented an unreasonable risk of injury for the population as a whole or for a susceptible subpopulation (e.g., one use results in risks that EPA would determine unreasonable regardless of the risk posed by other uses)."[31]

Consistent with its risk evaluation rule, EPA has in fact used its rulemaking authority under Section 6(a) of the new law to restrict specific uses of three chemicals that it has determined present unreasonable risks of injury.[32] These proposed rules ban tricholoethylene TCE for use in aerosol and vapor degreasing and dry cleaning spot removal[33] and phase out methylene chloride (MC) and N-methylpyrrolidone (NMP) for use in paint and coating removal.[34] EPA has proceeded with these

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[29] 82 Fed. Reg. at 33751 (emphases added).
[30] 82 Fed. Reg. at 33753 (emphases added).
[31] 82 Fed. Reg. at 33740 (emphasis added).
[32] Because the risk assessments for these chemicals were conducted before enactment of the new law, in Section 26(l)(4) of amended TSCA, Congress authorized EPA to proceed with Section 6(a) rulemaking without conducting a risk evaluation in accordance with Section 6(b). At the same time, however, it instructed EPA to comply with "other applicable requirements of Section 6" as amended. Thus, these rulemakings confirm that findings of unreasonable risk for particular uses are a sufficient basis for imposing restrictions under Section 6(a) without evaluating all other uses of the chemicals involved.
[33] 81 Fed. Reg. 91592 (December 16, 2016) (banning TCE use for aerosol degreasing and as a spot remover in dry cleaning); 82 Federal Register 7432 (January 19, 2017) (banning TCE use in vapor degreasing).
[34] 82 Fed. Reg. 7464 (January 19, 2017) (banning and restricting MC and NMP use in paint and coating removal products).

proposed rules even though evaluations of the remaining conditions of use of the three chemicals have just begun.[35]

In sum, contrary to its position in this case, EPA recognizes that its rulemaking obligation under Section 6(a) may be triggered by a determination that a single condition of use presents an unreasonable risk, irrespective of how it ultimately evaluates other conditions of use. Nothing in Section 21 suggests that petitioners who seek to compel EPA to conduct a rulemaking based on an equivalent showing of unreasonable risk for a particular use must meet a higher standard.

3. The Scant Legislative History for the Amended Version of Section 21 of TSCA Demonstrates that the Insertion of the Phrase "Conditions of Use" Was Not Intended to Impose a Higher Bar on Petitioners

EPA's motion describes the addition of the phrase "conditions of use" to Section 21(b) in the 2016 amendments to the Act as an "important" substantive change that significantly altered the requirements for citizens' petitions. (Mem. at 5:8-10.) But the only legislative history from the TSCA amendments addressing Section 21 downplays the Section 21 revisions. According to the Senate report on the new law:

> Section 19 of S. 697 amends Section 20 of TSCA to make changes necessary to conform the citizens' petition process to the requirements of the Act. *No substantive or policy change is intended by these amendments*.[36]

Under the old law, Section 21 provided that, to obtain relief in a judicial action, petitioners were required to demonstrate to the court that, "there is a reasonable basis to conclude that the issuance of such a rule [under Section 6(a)] . . . is necessary to protect health and the environment against an unreasonable risk." 15 U.S.C. § 2620(b)(4)(B)(ii). This showing could obviously be made by demonstrating that a particular use of a chemical presents an unreasonable risk.

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[35] The three chemicals are among the group of 10 substances that EPA selected for its initial risk evaluations under Section 6(b). 81 Fed. Reg. 91927 (December 16, 2016). EPA is still in the stage of developing scoping documents, the first step in risk evaluation under the law. 82 Fed. Reg. 31,592 (July 7, 2017).

[36] S. Rept. 114-67 (114th Cong. 1st Sess., June 18, 2015) at 28-29 (emphasis added).

Despite this, EPA now argues that the rewording of Section 21 in the amended law was intended to dramatically raise the bar that citizen petitioners would have to meet in order to justify a court order requiring rulemaking under Section 6(a). This would clearly constitute a "substantive or policy change" in Section 21—exactly what the Senate report expressly did not intend. Given the Senate report's description of the Section 21 revisions as "conforming," it is much more likely that Congress added the phrase "conditions of use" to Section 21 merely for purposes of consistency with other reworded TSCA provisions.[37] The other changes Congress made in Section 21 clearly have this narrow purpose.[38]

4. EPA Grossly Overstates the Adverse Impacts on the TSCA Program of Allowing a Section 21 Remedy Based on a Showing of Unreasonable Risk for a Single Condition of Use

EPA's motion paints a dire picture of the consequences for the Agency of a successful citizens' petition based on a showing of unreasonable risk for a particular chemical use. However, this litany of concerns reflects a tortured reading of the statute seemingly designed to make EPA's path as difficult as possible, combined with a failure to recognize why Congress empowered citizens to petition for rulemaking and gave district courts broad jurisdiction to impose remedies in worthy cases.

For example, EPA warns that, "[i]f the statute were interpreted to allow petitioners to force a Section 6(a) rulemaking based on analysis of a single condition of use, it would require EPA to conduct a 'catch up' risk evaluation addressing the conditions of use not addressed by the petition." (Mem. at 11:11-14.) The Agency does not explain where this "requirement" comes from. Clearly, Section 21,

[37] For example, one logical purpose of defining the term "conditions of use" in Section 3(4) and then including the term in the various substantive provisions of the law would be to set boundaries on the chemical-related activities that EPA is empowered to address. In the context of Section 6(b), this would mean that EPA risk evaluations could only examine activities that constitute conditions of use as defined in Section 3(4). Correspondingly, the showing of unreasonable risk required in Section 21 petitions would likewise need to be for activities that comprise conditions of use and could not be based on other activities. This would achieve consistency between the provisions without requiring a Section 21 petitioner to evaluate the risks of *all* conditions of use, a requirement that is nowhere included in the statutory text and would indeed represent a "substantive or policy change."

[38] Reflecting Section 6's amended standard, Section 21 now provides that an unreasonable risk includes risks to "susceptible subpopulation[s]" and that the determination of unreasonable risk is to be made "without consideration of cost or other nonrisk factors." 15 U.S.C. § 2620(b)(4)(B)(i)(II).

which does not mention risk evaluations or refer to Section 6(b), would not force the Agency down this path. Nor would Section 6(b) itself, which compels EPA to conduct a risk evaluation only in response to a high-priority designation under Section 6(b)(1)(B) or an industry request in accordance with Section 6(b)(4)(C)(ii).[39] Thus, EPA's only obligation in response to a successful petition under Section 21 would be to initiate a Section 6(a) rulemaking targeted at the condition of use demonstrated by the petition to present an unreasonable risk.[40] Of course, if EPA made the judgment that all other conditions of use of the chemical should be examined in the interest of public health or the environment, it could opt to initiate the prioritization process under Section 6(b)(1), which could then trigger a risk evaluation. But this course would be purely discretionary—it would not be compelled by either Section 6(b) or Section 21.

EPA also warns that the "carefully tailored" risk evaluation and chemical management process in the new law is based on Congress's "recognition of the limitations of EPA's capacity and resources" and therefore Congress could not have "intended to empower petitioners to promote chemicals of particular concern to them over other chemicals . . . based on risks arising from one condition of use."[41] (Mem. at 12:13-15.) If accepted, this argument would nullify Congress' express inclusion of a judicially enforceable mechanism that citizens can invoke to compel EPA to conduct rulemakings to restrict unsafe

[39] Even where EPA is compelled by an industry request to conduct a risk evaluation, the Agency's position is that it need not examine all conditions of use. In a change from its proposal, Section 702.37(e)(3) of its risk evaluation rule provides that EPA may limit industry-requested evaluations to the specific conditions of use proposed by the manufacturer and exclude all other conditions of use. 82 Fed. Reg. at 33749-50. If EPA considers itself free to focus on a narrow set of uses when an evaluation is requested by industry, it is disingenuous for it to argue before this Court that it would be compelled to evaluate all conditions of use in response to a successful Section 21 petition.

[40] EPA's contrary argument is based on the fallacious assumption that it could only meet a Section 21-imposed obligation to conduct a rulemaking under Section 6(a) by evaluating and making unreasonable risk determination for all other conditions of use. But as discussed above, EPA itself recognizes that a Section 6(a) rulemaking is triggered by an unreasonable risk finding for a single condition of use and is in fact conducting use-specific rulemakings for three chemicals.

[41] EPA seems to think that an unreasonable risk presented by a single condition of use is inherently insignificant and therefore insufficient to warrant the expenditure of Agency resources on rulemaking. But this is illogical. Depending on the circumstances, a single use can present a greater threat to health or the environment than multiple uses that have a less harmful impact. Use of fluoride in drinking water, for example, potentially raises serious public health concerns given the tens of millions of Americans who are exposed to fluoride through the drinking water supply.

chemicals. Obviously, Congress believed that the priorities set by EPA are not sacrosanct and there may be occasions where the Agency, deliberately or otherwise, fails to act on serious chemical risks that should be addressed. Indeed, Congress considered the Citizens Petition remedy an "important mechanism" for effectuating the Act's purpose,[42] and deliberately kept the remedy in the Act despite criticism from some legislators that it might "erode" EPA's capacity to make judgments in "discretionary areas."[43] Thus, the inclusion of Section 21 in TSCA necessarily and unambiguously reflects Congress' intent to provide the public with an independent ability to compel EPA to initiate rulemaking on unsafe chemicals, even if the Agency may need to adjust its priorities in response. Congress left no room to infer anything to the contrary.

Furthermore, Section 21 provides a built-in mechanism to take into account EPA's resources in fashioning a remedy where the court agrees that the petitioner has demonstrated an unreasonable risk of injury. In such cases, the court must order the Agency to initiate rulemaking but may adjust the rulemaking schedule "if the court finds that the extent of the risk to health or the environment is less than the extent of risks to health or the environment with respect to which the [Agency] is taking action under this Act and there are insufficient resources available to the [Agency] to take the action requested by the petitioner." 15 U.S.C. § 2620(b)(4)(B). In short, while assuring that the Agency conducts rulemaking, the court may set a timetable which accommodates other EPA priorities and available resources. Given the flexibility that Section 21 provides the Court in fashioning a remedy, there is no merit to EPA's demand that, in order to protect the Agency's workload, courts must take the extreme step of denying access to petitioners who fail to evaluate all conditions of use.

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[42] H. Rep. No. 94-1341 (94th Cong. 2d Sess., July 14, 1976) at 57.

[43] Legislative History of the Toxic Substances Control Act (1976), at 253 (quoting Rep. Eckhardt's and Sen. John Tunney's criticism that, by giving "any such person the right to a de novo trial in Federal district court" the Citizen Petition provision failed to give weight "to the Administrator's discretion and expertise").

5. EPA's Interpretation of Section 21 Would Place Insurmountable Burdens on Petitioners Effectively Negating the Public Remedy Congress Established

While exaggerating the impacts of successful Section 21 petitions on its own resources, EPA ignores the significant burdens that its interpretation of Section 21 would place on petitioners; burdens that would eviscerate the plain language and purpose of Section 21. As Plaintiffs' petition in this case demonstrates, comprehensively evaluating the risks of a just a single chemical use is a sizable undertaking requiring the review of hundreds of scientific citations and a complex analysis of hazard and exposure.[44] The magnitude of this task would expand exponentially if all the many conditions of use of a chemical were required in that evaluation. Furthermore, citizen petitioners will rarely be adequately positioned to identify each and every condition of use for widely used industrial chemicals. This may explain why the Act defines "conditions of use" as being "the circumstances, *as determined by the Administrator*, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4) (emphasis added). The Administrator, and not a citizen petitioner, is best situated to comprehensively identify *all* conditions of use of a chemical, particularly since TSCA requires EPA to collect chemical use information from industries that manufacture and process chemical substances. *See* 15 U.S.C. § 2607(a).

The effort required to conduct a complete risk evaluation is underscored by Section 6(b), which directs EPA to:

> integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator; (ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration; (iii) not consider costs or other nonrisk factors; (iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and (v) describe the weight of the scientific evidence for the identified hazard and exposure.

[44] Plaintiffs' petition included over 2,400 pages of supporting documentation, including 196 studies published since 2006, which have investigated fluoride's effects on the brain.

15 U.S.C. § 2605(b)(4)(F). These requirements are amplified in EPA's risk evaluation rule, which contains detailed requirements for each step in the risk evaluation process, including scoping, hazard assessment, exposure assessment, risk characterization and risk determination. *See* Sections 702.41-43. Further, Section 6(b)(4)(G) provides three years[45] for the completion of risk evaluations by EPA (with an extension of up to six months) – a clear indication of the time, effort and resources the job would take. In a report to Congress, EPA estimated that a single risk evaluation would cost $3.7 million.[46]

Members of the public who petition for rulemaking under Section 21 have limited resources and even the evaluation of a single condition of use demands a significant commitment of time, money and effort. Greatly increasing these burdens to address *all* conditions of use would make the petition process cost-prohibitive in nearly all instances and discourage the public from exercising the remedies that Congress provided to citizens in Section 21.

C. EPA'S INTERPRETATION OF SECTION 21 IS NOT ENTITLED TO DEFERENCE

EPA argues that its interpretation of Section 21 is entitled to deference under the principles expressed in *Chevron v. Natural Resources Defense Council*, 467 U.S. 837 (1984), which held that reviewing courts should defer to an Agency's interpretation of ambiguous statutory provisions if they represent a permissible construction of the law. There are several reasons why *Chevron* is inapplicable in this case. First and foremost, the precondition for *Chevron* deference is lack of clarity in the statute itself. Where, as here, the statutory language is unambiguous, the agency and court must give it effect. Here, EPA's interpretation of Section 21 is contrary to its plain meaning. As discussed above, the statute contains no basis for EPA's claim that petitioners must conduct a risk evaluation for *all* of a chemical's

[45] By contrast, EPA has 90 days to respond to a Citizens Petition. 15 U.S.C. § 2620(b)(4)(A). In light of the much longer length of time Congress has given EPA to conduct complete Section 6(b) risk evaluations, Congress's decision to retain the 90-day review period for Citizen Petitions underscores the much more targeted and limited scope of Citizen Petitions vis-à-vis EPA initiated risk evaluations.

[46] EPA, Initial Report to Congress on the EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (January 2017), at 4. Available at https://www.epa.gov/sites/production/files/2017-01/documents/tsca_report_to_congress.pdf

conditions of use. Instead, it requires evidence that the chemical presents an unreasonable risk under its "conditions of use"—a requirement that, as a matter of logic, is met where the evidence demonstrates that at least one condition of use presents an unreasonable risk.

Second, *Chevron* deference is most appropriate where the Agency is exercising substantive rulemaking authority and its interpretation was developed in the course of a notice-and-comment rulemaking. *See,* e.g., *Christensen v. Harris Cty*., 529 U.S. 576, 587 (2000); *Price v. Stevedoring Servs. of Am., Inc*., 697 F.3d 820, 826-31 (9th Cir. 2012); *Doe v. Mutual of Omaha Ins. Co*., 179 F.3d 557, 563 (7th Cir. 1999); *Smiley v. Citibank*, 517 U.S. 735, 741 (1996); *In re Appletree Markets, Inc*., 19 F. 3d 969 (5th Circ. 1994). Here, by contrast, Congress did not give EPA authority to interpret Section 21 through rulemaking and the interpretation it offers in this case was not developed through a notice-and-comment process.

Third, although EPA claims reliance on EPA's risk evaluation rule to support its interpretation, the rule was promulgated on July 20, 2017, several months after the petition denial on February 17, 2017. The rule changed in important respects between what was proposed in January and what was promulgated in July; in fact, as promulgated, the rule actually conflicts with the basis EPA has cited for denying the petition. For example, while the proposed rule provided that EPA will address all conditions of use in risk evaluations,[47] the final rule asserts broad discretion to select the conditions of use that evaluations will consider.[48] The final rule also (1) concludes that EPA can limit risk evaluations conducted in response to industry requests to the specific uses identified by manufacturers,[49] (2) makes clear that EPA can and will make determinations of unreasonable risk for specific conditions of use,[50] and (3) recognizes that such determinations trigger rulemaking under Section 6(a) for the use in

[47] 82 Fed. Reg. at 7565.
[48] 82 Fed. Reg. at 33728-29.
[49] 82 Fed. Reg. at 33736.
[50] 82 Fed. Reg. at 33728-29.

question.[51] While EPA may be entitled to deference for reasonable constructions of its own regulations, no weight should be extended to interpretations that are "plainly erroneous or inconsistent with the regulation." *Kentuckians for the Commonwealth, Inc. v Rivenburgh*, 317 F.3d 425, 439 (4th Cir. 2001); *see also Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012) (stating that deference is "unwarranted when there is reason to suspect that the agency's interpretation 'does not reflect the agency's fair and considered judgment on the matter in question,'" such as "when the agency's interpretation conflicts with a prior interpretation").

Lacking any basis in the risk evaluation rule, EPA's interpretation is essentially a litigating position advanced by counsel and, as such, does not warrant deference. *Bowen v Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988) ("Deference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate."); *see also Price*, 697 F.3d at 830 ("[D]eferring to agencies' litigating positions interpreting statutes they are charged with administering would create a danger that agencies would avoid promulgating regulations altogether, given the comparative ease of announcing a new statutory interpretation in a brief rather than through formal rulemaking. This result would severely undermine the notice and predictability to regulated parties that formal rulemaking is meant to promote.").

Finally, EPA's interpretation of Section 21 speaks to the standards under which *district courts* are empowered to provide relief to petitioners under a provision that requires the *court* to make a *de novo* determination of the petitioners' entitlement to relief. It is well-established that *Chevron* deference does not apply whether the agency's position relates not to its own regulatory authority but the jurisdiction of a federal court. *See, e.g., B & H Med., LLC v. United States*, 116 Fed. Cl. 671, 680 (2014) ("A federal court owes no deference to an agency's interpretation of the court's subject matter jurisdiction.").

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[51] 82 Fed. Reg. at 33744.

V. CONCLUSION

Contrary to EPA's claims, Plaintiffs made it abundantly clear in their Petition what chemical substances were at issue. Further, EPA's contention that Plaintiffs were required to identify all conditions of use is incompatible with the plain meaning and congressional intent of Section 21, as well EPA's own prior interpretation of Section 6. As such, EPA's statutory interpretation does not warrant any deference from this Court, *Chevron* or otherwise. EPA's motion should be denied.

Date: October 25, 2017

Respectfully submitted,

By: _____

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by Notice of Electronic Filing this 25th day of October, 2017, upon all ECF registered counsel of record using the Court's EM/ECF system.

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