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

ORDER DENYING DEFENDANT'S MOTION TO DISMISS

Docket No. 28

The Toxic Substances Control Act ("TSCA")'s Section 6(a) requires Defendant United States Environmental Protection Agency ("EPA") to regulate the use of certain chemical substances that it determines pose an unreasonable risk to health or the environment. 15 U.S.C. § 2605(a). Section 6(b) requires the EPA to perform its own *sua sponte* evaluation of the risks posed by certain chemical substances "under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). The statute defines the "conditions of use" 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." 15 U.S.C. § 2602(4). Section 21 of the TSCA permits any person to petition the EPA to initiate rule-making under Section 6(a) if the petitioner demonstrates a chemical substance poses an unreasonable risk of harm. *Id.* § 2620(a).

Plaintiffs petitioned the EPA under Section 21 to regulate the fluoridation of drinking water supplies under Section 6(a) because, they maintain, the ingestion of fluoride poses an unreasonable risk of neurotoxic harm to humans. After the EPA denied Plaintiffs' petition, Plaintiffs filed this suit seeking judicial review of the EPA's determination. The EPA argues that Plaintiffs' lawsuit should be dismissed because their administrative petition failed to address

conditions of use other than the fluoridation of drinking water, failed to specifically identify the chemicals at issue, and failed to justify treatment of those chemicals on a categorical basis. For the reasons stated herein, the Court finds a citizen petition need not evaluate all conditions of use; that Plaintiffs sufficiently identified the chemicals they sought to regulate; and that Plaintiffs presented an adequate basis, in their administrative petition, for requesting categorical treatment of the chemicals they identified. Defendant's motion is **DENIED**.

I. FACTUAL & PROCEDURAL BACKGROUND

Plaintiffs are a group of non-profit organizations and associations and individual parents who sue on behalf of themselves and their minor children.[1] They allege that fluoridation chemicals (specifically, hydrofluorosilicic acid, sodium silicofluoride, and sodium fluoride) are added to public water supplies across the United States in an attempt to reduce tooth decay. Compl. ¶ 3. The practice began in the 1940s "on the mistaken premise that fluoride's primary benefit to teeth comes from *ingestion*." *Id.* ¶ 4. More recent research, they argue, demonstrates that fluoride's "primary benefit comes from *topical* application" and therefore, ingestion is unnecessary to prevent tooth decay. *Id.* ¶ 5. Though water fluoridation has been "rejected or discontinued by the vast majority of European countries," it continues in the United States. *Id.* ¶ 7. Plaintiffs allege that the risks of fluoridation include a higher risk of dental fluorosis, a "hypominelarization of tooth enamel that produces noticeable discoloration of the teeth" and deleterious effects on the brain, including cognitive impairments and neurotoxicity. Compl. ¶¶ 8-16.

On November 22, 2016, Plaintiffs petitioned the EPA to issue a rule under Section 6(a) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2605, prohibiting the addition of "fluoridation chemicals" to drinking water supplies. Compl. ¶¶ 24, 105; *see also* 15 U.S.C. § 2620(a) (permitting "[a]ny person" to petition for such a rule).

[1] Plaintiff organizations are Food & Water Watch, Inc.; American Academy of Environmental Medicine, Fluoride Action Network; International Academy of Oral Medicine & Toxicology, Moms Against Fluoridation. The Individual Plaintiffs are Audrey Adams on behalf of herself and Kyle Adams; Kristin Lavelle on behalf of herself and Neal Lavelle; Brenda Staudenmaier on behalf of herself and Hayden Staudenmaier. *See* Compl. ¶ 1, 29-44.

Defendant attaches Plaintiffs' petition as Exhibit 1 to the Rave Declaration. *See* Docket No. 28-1 (hereinafter "Admin. Pet.").[2] In the first paragraph of the cover letter, the petition states that the signatories "hereby petition the U.S. Environmental Protection Agency to protect the public and susceptible subpopulations from the neurotoxic risks of fluoride by banning the addition of fluoridation chemicals to water." Admin. Pet. at 1. The petition is approximately 30 pages long and summarizes scientific studies Plaintiffs maintain demonstrate the neurotoxic effects of ingesting fluoride in low doses, as well as the heightened risks to vulnerable subpopulations. According to the Table of Contents, petitioners attached 45 pages of appendices identifying hundreds of scientific studies upon which their petition relies, but the EPA did not submit them to the Court with its motion.

The EPA denied the petition on February 17, 2017. *Id.* ¶¶ 25, 106. Defendant's denial, which is also published in the Federal Register, is attached as Exhibit 2 to the Rave Declaration. *See* Docket No. 28-1 and 82 Fed. Reg. 11,878 (Feb. 27, 2017) ("EPA Denial"). The denial contains a summary of EPA's interpretation of the applicable statutory and regulatory framework and a response to the merits of Plaintiffs' petition. The EPA stated that "[a]fter careful consideration, EPA denied the TSCA section 21 petition primarily because EPA concluded that the petition has not set forth a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S. through the purposeful addition of fluoridation chemicals to drinking water or otherwise from fluoride exposure in the U.S." *Id.* at 11,881, col. 3. "EPA also denied the petition on the independent grounds that the petition neither justified the regulation of fluoridation chemicals as a category, nor identified an adequate section 6 rule as the action sought. 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)." *Id.*

[2] Although Plaintiffs did not attach their administrative petition to their complaint, both the petition and the EPA's denial are clearly "incorporated by reference" into the complaint and therefore may be considered by the Court on a motion to dismiss. *See U.S. v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). Plaintiffs have not objected to such reference.

The remainder of the EPA's denial sets forth a substantive response to the scientific studies submitted by the petitioners. *See, e.g.*, 82 Fed. Reg. at 11,882 (noting that "the evidence did not adequately account for the possibility that the confounding factors themselves, rather than concurrent fluoride exposure, were partly or wholly responsible for the health effects observed.'"); *id.* (criticizing petitioners' reliance on a study whose authors, the EPA states, "conclu[ded their data] . . . are unsuitable for evaluating levels of fluoride associated with neurotoxic effects and for deriving dose-response relationships necessary for risk assessment"); *id.* (noting that "[t]he petition suggested that a dose-response relationship between urinary fluoride and IQ is seen in several studies," but arguing that "it is not possible to determine whether effects on IQ were due to fluoride or to malnutrition (i.e., nutritional status may be an uncontrolled confounding factor)"); *id.* (citing a study to conclude that "the petitioner's use of fluorosis levels as a surrogate for evidence of neurotoxic harm to the U.S. population is inappropriate evidence to support an assertion of unreasonable risk to humans from fluoridation of drinking water"); *id.* (criticizing use of another study because "[i]mportant issues such as the timing and methods of sample collection were also often not reported in the studies"). While the scientific merits of the dispute are not material to Defendant's motion, the fact that the EPA engaged in a substantive merits analysis despite the alleged procedural flaw in the petition is noteworthy.

Plaintiffs now seek an order compelling the EPA to initiate the process for the rule they requested. *See* 15 U.S.C. § 2620(b)(4)(B) (permitting judicial review of EPA's denial of petition).

II. STATUTORY CONTEXT

This motion turns on interpretation of the Toxic Substances Control Act, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016) ("LCSA"). Congress enacted the TSCA, codified at 15 U.S.C. § 2601, *et seq.*, in 1976, motivated by findings that "human beings and the environment are being exposed each year to a large number of chemical substances and mixtures," 15 U.S.C. § 2601(a)(1), and that, "among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment." *id.* § 2601(a)(2).

The relationship between three provisions of the Act are at issue here. Section 6(a), codified at 15 U.S.C. § 2605(a), requires the EPA to regulate harmful substances; Section 6(b), codified at 15 U.S.C. § 2605(b), requires the EPA to conduct "risk evaluations" of certain substances; and Section 21, codified at 15 U.S.C. § 2620, authorizes citizens to petition the EPA to initiate rulemaking under Section 6(a). The question is whether a Section 21 citizen petition must include all information necessary for the EPA to perform a Section 6(b) risk evaluation,[3] and, if so, whether it must include all such information for *all* conditions of use or may be limited to only those of interest to the citizen petitioner. The EPA also claims Plaintiffs' claims must be dismissed because their administrative petition did not sufficiently identify the chemical substances they sought to regulate and did not justify treating them as a category. Each argument is discussed below, but the Court first sets forth the statutory background.

A. Section 6(a): Regulation of Chemical Substances Posing Unreasonable Risk of Harm

The TSCA requires the EPA to regulate the use of certain chemical substances that pose an unreasonable risk of harm health or the environment. Under Section 6(a) of the TSCA, codified at 15 U.S.C. § 2605(a),

> [i]f the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk . . . .

15 U.S.C. § 2605(a). In particular, if the EPA finds a risk of unreasonable harm, it must

[3] The statute states that "[i]n conducting a risk evaluation under this subsection, the Administrator shall—(i) 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." 15 U.S.C. § 2605(b)(4)(F).

promulgate a rule imposing one or more of the following requirements:

- prohibiting, restricting, or limiting the amount of such substance that may be manufactured, processed, or distributed in commerce, *id.* § 2605(a)(1);
- prohibiting, restricting, or limiting such manufacture, processing, or use in connection with "a particular use" or "a particular use in a concentration in excess of a level specified by the Administrator," *id.* § 2605(a)(2)(A);
- labeling requirements for such substance, *id.* § 2605(a)(3);
- record-keeping requirements for manufacturers or processors of the substance, *id.* § 2605(a)(4);
- commercial-use regulations, *id.* § 2605(a)(5);
- disposal requirements, *id.* § 2605(a)(6); and,
- notice requirements, *id.* § 2605(a)(7).

The EPA may limit the application of such requirements to "specified geographic areas." *Id.* § 2605(a).

After the LCSA amendments in 2016, there are now three possible pathways to obtaining a Section 6(a) rule regulating substances:

1) After an EPA risk evaluation of a chemical which the EPA has *sua sponte* designated as "high priority," *see* 15 U.S.C. § 2605(c)(1), which results in a finding of unreasonable risk;

2) After an EPA risk evaluation of a chemical at the request of a manufacturer, *see* 15 U.S.C. § 2605(b)(4)(C)(ii), which results in a finding of unreasonable risk; or,

3) Upon granting a Section 21 citizen petition, *see* 15 U.S.C. § 2620(a), § 2620(b)(3).

Each pathway is discussed below.

B. EPA's *Sua Sponte* Designation of High-Priority Chemicals

Both parties agree that the LCSA's most significant amendments to the TSCA relate to Section 6(b), codified at 15 U.S.C. § 2605(b). These amendments require the EPA to designate chemical substances as "high-priority" or "low-priority" based on a risk screening process. *See* 15 U.S.C. § 2605(b)(1). "High-priority" chemicals are those that "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). A "low-priority" substance, in contrast, is one that the Administrator "concludes, based on information sufficient to establish . . . does not meet the standard" to be designated a high-priority substance. *Id.*§ 2605(b)(1)(B)(ii).

Once the EPA has designated a chemical substance "high-priority," it must initiate a Section 6(b) "risk evaluation." *Id.* § 2605(b)(3)(A); *id.* § 2605(b)(4)(C)(i). A risk evaluation is not required for a "low-priority" substance. *Id*. § 2605(b)(1)(A). The EPA must pursue these risk evaluations at a minimum pace established by statute: within 6 months, risk evaluations must be underway on at least 10 substances drawn from the 2014 TSCA Work Plan for Chemical Assessments, *id.* § 2605(b)(2)(A); within three and a half years, risk evaluations must be underway on "at least 20 high-priority substances," *id.* § 2605(b)(2)(B); a new high-priority substance must be designated anytime a risk evaluation has been completed (other than those commenced at the request of a manufacturer), *id.* § 2605(b)(3)(C); and, generally, the EPA must continue designating substances and conducting evaluations "at a pace consistent" with its ability to meet the 3-year deadline to complete each risk evaluation, *id.* § 2605(b)(2)(C).

The procedure for and scope of a "risk evaluation" are discussed below. If, upon completion of a Section 6(b) risk evaluation, the EPA determines that a chemical substance presents an unreasonable risk, it must initiate rulemaking to address that risk under Section 6(a). *See* 15 U.S.C. § 2605(c)(1).

C. Section 6(b) Risk Evaluations

The purpose of a risk evaluation is to:

> 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).

Within six months of initiating a Section 6(b) risk evaluation, the EPA must publish a scope document that describes "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." *Id.*

§ 2605(b)(4)(D). The completed risk evaluation must "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." *Id.* § 2605(b)(4)(F)(i). Additional requirements must also be satisfied. *Id.* § 2605(b)(4)(F)(ii)-(v). The parties agree that the requirements are substantial. Accordingly, Congress provided the EPA with a three-year period to complete a Section 6(b) risk evaluation, with the possibility of a 6-month extension. *Id.* § 2605(b)(4)(F)-(G).

The statute requires the EPA to "establish, by rule, a process to conduct [such] risk evaluations" no later than June 22, 2017. *Id.* § 2605(b)(4)(B). The EPA has now completed that rule-making process. The rules regarding risk evaluations are codified at 40 C.F.R. § 702.31, *et seq.* An aspect of the new administrative rule concerns the key dispute on this motion, the meaning of the term "under the conditions of use." The statute defines "conditions of use" 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." 15 U.S.C. § 2602(4). Notably, the statute states only that a Section 6(b) risk evaluation must "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." *Id.* § 2605(b)(4)(A). It does not state that the evaluation must address "*all* the conditions of use," the interpretation favored by the EPA on this motion. In January 2017, the EPA proposed a rule that adopted that construction, interpreting Section 6(b) to require EPA's risk evaluations to cover *all* "conditions of use." *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7562-01, 7565 (Jan. 19, 2017) ("[A] risk evaluation must encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance."). However, the EPA received considerable commentary regarding its proposed interpretation. For example, "[c]oncerns were raised . . . 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." Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33726-01, 33728 (Jul. 20, 2017). Concerns were also raised about "ensuring that EPA can act promptly to address any unreasonable risks identified for particular conditions of use." *Id.* In contrast, other commenters argued that "the law in a number of locations signals the intent that EPA evaluate all activities associated with the chemical" under consideration. *Id.*

As explained in the final rule, the EPA ultimately sided with those commenters who argued that a risk evaluation need not cover *all* conditions of use. Thus,

> EPA went back to the direction on risk evaluation provided in section 6(b) of the statute and legislative history, and developed an approach to the term, 'the conditions of use' that is firmly grounded in the law, while accounting for the various policy considerations necessary for effective implementation of section 6. 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. See, June 7, 2016 Cong. Rec. S3519-S3520.

Id.

In its final rule, the EPA affirmed that, in identifying "the conditions of use" of a chemical substance, it "will be guided by its best understanding, informed by legislative text and history, of the circumstances of manufacture, processing, distribution in commerce, use and disposal Congress intended EPA to consider in risk evaluations." *Id.* The EPA explained, however, that the scope of a section 6(b) risk evaluation could be narrower than *all* the conditions of use:

> [I]n developing the scope of the risk evaluation, TSCA section 6(b)(4)(D) requires EPA to identify 'the conditions of use that the Agency expects to consider in a risk evaluation,' suggesting that EPA is not required to consider all conditions of use. 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 [in a risk evaluation] on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination.

Id. at 33729. As non-exhaustive examples, the EPA explained that it might exclude conditions of use which involve only "de minimis" exposures or "a condition of use that has been adequately

assessed by another regulatory agency." *Id.* The conditions of use the EPA intends to include within the scope of a risk evaluation (as well as those it intends to exclude) would then be published for public comment, as required by the statute. *Id.*; *see also* 15 U.S.C. § 2605(b)(4)(D). Thus, the EPA's July 2017 final rule adopts the position that the TSCA does *not* require the EPA's Section 6(b) risk evaluations to cover *all* conditions of use. *See also* 40 C.F.R. § 702.41(c)(1) (scope document will include "[t]he condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation").

For those "conditions of use" that the EPA elects to include within the scope of a risk evaluation, the EPA has also explained that it may "conduct its risk evaluations in stages." 82 Fed. Reg. at 33729. Accordingly, "in cases where EPA has sufficient information to determine whether or not the chemical substance presents an unreasonable risk under particular conditions of use, the Agency may issue an early determination for that subset of conditions of use, while EPA continues to evaluate the remaining conditions of use." *Id.* Thus, even when the EPA has determined to perform a risk evaluation on some but not all conditions of use, it affords itself the discretion to issue partial risk determinations on particular conditions of use while it continues to assess other conditions of use within its defined scope.

D. Manufacturer Requests

In addition to the Section 6(b) risk evaluation required for chemicals *sua sponte* designated by the EPA as "high priority," the TSCA also requires a Section 6(b) risk evaluation to be performed upon the request of the manufacturer of a chemical substance. *See* 15 U.S.C. § 2605(b)(4)(C)(ii). The manufacturer's request must be presented "in a form and manner and using the criteria prescribed by the Administrator" according to a promulgated rule. *Id.*

The EPA has, pursuant to § 2605(b)(4)(C)(ii), promulgated a rule governing the required form, manner, and criteria for a manufacturer's request for risk evaluation. In its proposed rule, the EPA required manufacturers to address *all* conditions of use in their requests for a risk evaluation. *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7562-01, 7569 (Jan. 19, 2017) ("EPA is proposing to require a manufacturer to submit a list (e.g., citations) of the reasonably available information on hazard and

exposure for all the conditions of use."). However, the agency received significant opposition from manufacturers, including complaints that "manufacturers are not always privy to every downstream use [of a chemical substance], and therefore would find it very difficult to obtain all the required information," that "the bar set in the proposed rule overall was too high and would make it extremely difficult for manufacturers to submit a compliant request," and that it "could create a disincentive to submit requests for risk evaluation." *See* Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33726-01, 33735-36 (Jul. 20, 2017).

In response, the EPA modified its position. The final rule thus states that "EPA agrees with many of these concerns in opposition to the proposed approach." *Id.* at 33736. Accordingly, "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*." *Id.* (emphasis added). Although the manufacturer's request may focus on only those uses that interest the manufacturer, the EPA itself "intends to conduct the risk evaluation in the same manner as any other risk evaluation conducted under section 6(b)(4)(A)." *Id.* In particular:

> EPA intends to conduct a full risk evaluation that encompasses both the conditions of use that formed the basis for the manufacturer request, and any additional conditions of use that EPA identifies, just as EPA would if EPA had determined the chemical to be high priority. However, rather than require the manufacturer to identify any additional conditions of use that EPA will evaluate, EPA will determine the additional conditions of use during the process of determining whether to grant or deny the manufacturer request.

Id. Thus, "[u]pon receipt of a [manufacturer] request, EPA will evaluate whether the circumstances of manufacture, processing, distribution in commerce, use, and/or disposal identified by the submitter constitute conditions of use that warrant risk evaluation and whether additional conditions of use need to be included in the risk evaluation." *Id.*

Accordingly, under the final rule, a manufacturer need not address *all* conditions of use, but rather only those that interest it. *See* 40 C.F.R. § 702.37(b)(4) ("The request must also include a list of all the existing information that is relevant to whether the chemical substance, *under the circumstances identified by the manufacturer(s)*, presents an unreasonable risk of injury to health

or the environment.") (emphasis added); *see also* 82 Fed. Reg. at 33736 (manufacturer must "include all of the information necessary for EPA to conduct the evaluation for *the requested conditions of use*, consistent with [statutory] requirements") (emphasis added). The EPA, in reviewing the manufacturer's request, will then determine whether its own Section 6(b) risk evaluation of the chemical substance should address additional conditions of use it deems appropriate. *See* 40 C.F.R. § 702.37(e)(3) ("EPA will also assess what, if any, additional conditions of use that [sic] warrant inclusion within the scope of the risk evaluation for the chemical substance."). It then remains to the EPA to assemble the information necessary to evaluate the risks posed with respect to other conditions of use not identified by the manufacturer.

E. Section 21: Citizen Petitions

The TSCA's Section 21 (15 U.S.C. § 2620) authorizes "[a]ny person" to request rulemaking by the EPA under various provisions of the statute, including Section 6 (15 U.S.C. § 2605). Section 21 has been called an "unusually powerful procedure[] for citizens to force EPA's hand." *Trumpeter Swan Soc. v. E.P.A.*, 774 F.3d 1037, 1039 (D.C. Cir. 2014). The EPA must grant or deny the petition within 90 days. *Id.* § 2620(b)(3). If the EPA grants the petition, it "shall promptly commence an appropriate proceeding in accordance with" the relevant statutory provision. *Id.* If it denies the petition, however, it must publish its reasons in the Federal Register. *Id.*

When the EPA denies a petition or fails to act within 60 days of the petition, a 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 actions, "the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding." *Id.* § 2620(b)(4)(B).

As passed in 1976, the reviewing court was to compel the EPA to initiate the action requested by the petitioner under Section 6(a) if the petitioner demonstrated by a preponderance of the evidence that "there is a reasonable basis to conclude that the issuance of such a rule or order is necessary to protect health or the environment against an unreasonable risk of injury." 15 U.S.C. § 2620(b)(4)(B)(ii) (1976). However, that language was amended by the LCSA in 2016.

Now, the reviewing court must determine whether the petitioner has demonstrated by a preponderance of the evidence that "the chemical substance or mixture to be subject to such rule or order 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 population, under the conditions of use." 15 U.S.C. § 2620(b)(4)(B)(ii) (2016).

If the court determines that the petitioner has satisfied that burden, then it "shall order the Administrator to initiate the action requested by the petitioner." 15 U.S.C. § 2620(b)(4)(B)(ii). The court may permit the EPA to defer initiating the action if it finds "that the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this chapter *and* there are insufficient resources available to the Administrator to take the action requested by the petitioner." *Id.* (emphasis added).

III. DISCUSSION

Defendant argues that Plaintiffs' lawsuit must be dismissed for three reasons. The Court first addresses Defendant's argument that the petition must be dismissed because it does not address all "conditions of use" for fluoride, but rather, only the one that interests petitioner, the fluoridation of drinking water supplies. The Court then reviews Defendant's argument that dismissal is required because the petition does not adequately identify the chemical substances Plaintiffs seek to regulate and because the petition does not provide adequate grounds to justify treating "fluoridation chemicals" as a category. For the reasons below, the Court rejects each of Defendant's arguments.

A. Plaintiffs Are Not Required to Identify *All* Conditions of Use for a Chemical Substance in Their Petition

The central dispute is whether Section 21 requires Plaintiffs to address *all* conditions of use in their petition as the EPA contends, or whether citizen petitions, such as the one filed in this case, may address only the conditions of use the petition seeks to regulate.

Statutory interpretation begins with the text of the statute. *See Los Angeles Lakers, Inc. v.*

Fed. Ins. Co., 869 F.3d 795, 802 (9th Cir. 2017). "When an examination of the plain language of the statute, its structure, and purpose clearly reveals congressional intent, our judicial inquiry is complete. But if the plain meaning of the statutory text remains unclear after consulting internal indicia of congressional intent, we may then turn to extrinsic indicators, such as legislative history, to help resolve the ambiguity." *Hernandez v. Williams, Zinman & Parham PC*, 829 F.3d 1068, 1073 (9th Cir. 2016) (quotations and citations omitted). Additionally, "when a statute is ambiguous and we have the benefit of an administrative agency's interpretation, we may defer to it if it is based on a permissible construction of the statute." *Eleri v. Sessions*, 852 F.3d 879, 882 (9th Cir. 2017).

1. Statutory Text and Structure

The text of Section 21 imposes only a procedural requirement that a petition must be filed with the Administrator and a substantive requirement that the petition "set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title." *See* 15 U.S.C. § 2620(b)(1). Section 21 does not explicitly impose any other substantive requirements for the administrative petition. *Cf. Trumpeter*, 774 F.3d at 1039 (holding that pre-amendment Section 21 imposes only same two statutory requirements on petitioners, and that satisfying those requirements entitles a petitioner to judicial review in case of denial).

Additional substantive requirements, if any, could arise therefore only through Section 21's incorporation of Section 6. In other words, Section 21 requires a petition to present "the facts" which "establish that it is necessary" to issue a Section 6(a) rule. *See* 15 U.S.C. § 2620(b)(1). The question then becomes, what facts require issuance of a Section 6(a) rule? Those would appear to be the only facts that Section 21 explicitly requires a petitioner to set forth in a citizen petition.

According to Section 6(a), a rule is required when "in accordance with subsection (b)(4)(A)" the EPA determines that a chemical substance "presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a). It follows that the "facts" required in a Section 21 citizen petition are the "facts" that would establish the existence of "an unreasonable

risk" under Section 6(a). *Id.* The statute uses the singular term "an" in describing an unreasonable risk, so it appears that a petitioner need only present facts establishing *one* unreasonable risk to trigger the EPA's rule-making obligations. Indeed, the sufficiency of *one* risk to trigger a rule corresponds with the fact that the EPA may issue a rule restricting only *one* use of a substance. *See* 15 U.S.C. § 2605(a)(2) (a Section 6(a) rule may regulate "a particular use" of a chemical substance).

Defendant rejects this literal and natural reading, claiming that a citizen petitioner must instead present the EPA with *all* information about *all* uses of a chemical substance (*i.e.*, about all the "conditions of use"), even those uses which are of no interest to the petitioner and which the petitioner does not contend pose an unreasonable risk.

This argument has no basis in the statutory text. Not only does it ignore Section 6(a)'s use of the singular article "an" in describing unreasonable risks, Section 21 does not itself use the term "conditions of use." *See* 15 U.S.C. § 2620(b)(1). Indeed, in describing the predicate trigger for a regulation, Section 6(a) does not use the term "conditions of use" either. *See* 15 U.S.C. § 2605(a). The phrase appears only in two other provisions: first, in Section 6(b), describing the EPA's obligation to conduct risk evaluations of chemicals designated "high priority" *sua sponte* and in response to manufacturer requests, *see* 15 U.S.C. § 2605(b)(4)(A);[4] and, second, in Section 21's judicial review provisions, describing the standard of review the Court must apply to a citizen petition, *see* 15 U.S.C. § 2620(b)(4)(B)(ii).[5] Neither provision supports the EPA's argument here.

With respect to Section 6(b), there is no good reason to believe that the term's appearance therein is to be imported into Section 21 such that it obligates all citizen petitioners to address all conditions of use.[6] Section 21 refers only generally to Section 6; it does not specifically refer to

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[4] The statute provides that "[t]he Administrator shall conduct risk evaluations' . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." 15 U.S.C. § 2605(b)(4)(A).

[5] The statute provides that the Court must determine whether a petition demonstrates that "the chemical substance . . . presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." 15 U.S.C. § 2620(b)(4)(B)(ii).

[6] For that reason, it is irrelevant to this case whether the TSCA requires the EPA's *sua sponte* risk evaluations to cover *all* conditions of use, a question currently pending before the Fourth and

Section 6(b). *See* 15 U.S.C. § 2620(a) ("Any person may petition the Administrator to initiate a proceeding for the issuance . . . of a rule under section . . . 2605 . . . ."). That general reference to Section 6 cannot reasonably be read to import the entire risk evaluation process into Section 21. Indeed, Section 21's judicial review provision specifically identifies Section 6(a), suggesting that Section 6(a) (and not Section 6(b) discussing risk evaluations) is the only provision of Section 6 which pertains to citizen petitions. *See* 15 U.S.C. § 2620(b)(4)(B)(iii) (establishing judicial review standard "in the case of a petition to initiate a proceeding for the issuance of a rule under section 2605(a)").[7]

That makes sense in light of the fact that there are three different pathways to a Section 6(a) rule. The predicate for a rule is a finding of unreasonable risk. Section 6(b) governs two processes that may result in an unreasonable risk finding: risk evaluations based on EPA's *sua sponte* designation of a "high priority" chemical" and risk evaluations at the request of a manufacturer. Section 21 governs the third pathway, one that appears to be independent of the Section 6(b) risk evaluation process. Indeed, the TSCA explicitly requires a Section 6(b) "risk evaluation" to be performed for "high priority" chemicals and in response to manufacturer requests, but does not state that the same requirement applies to citizen petitions. *See* U.S.C. § 2605(b)(4)(C). Thus, the statutory text and structure suggest that Section 21 does not require a citizen petitioner to perform the functional equivalent of a Section 6(b) risk evaluation with

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Ninth Circuits. *See All. of Nurses for Healthy Env'ts v. EPA*, No. 17-1926 (4th Cir. filed Aug. 11, 2017); *Safer Chems. Healthy Families v. U.S. EPA*, No. 17-72259 (9th Cir. filed Aug. 10, 2017) (transferred to 4th Cir. on Oct. 20, 2017). Even if it did, the same requirement would not automatically carry over to Section 21 citizen petitions.

[7] This reading is supported by the statute's history. Prior to the 2016 LCSA, Section 6 did not mandate the EPA perform any risk evaluations. Rather, the statute related solely to rulemaking regarding chemical substances that pose an unreasonable risk of harm or health (though it also mandated quality control requirements for manufacturers which are not relevant here). *See* 15 U.S.C. § 2605 (2008). Accordingly, Section 21, prior to the 2016 LCSA, contained only a general reference to Section 6, likely because it was obvious that it referred to the only provision governing the issuance of a rule, Section 6(a). *See* 15 U.S.C. § 2620 (1986). There is no reason to think that by retaining the same general reference after the 2016 LCSA amendments to Section 21, Congress also intended to incorporate all of the *new* provisions of Section 6(b) related to the EPA's risk evaluations into the Section 21 process, particularly in light of the express limitation to Section 6(a) in Section 21's judicial review provisions.

respect to conditions of use that the petitioner does not seek to regulate.

Nor is there any reason to think that the term "under the conditions of use," as it appears in Section 21's judicial review provisions, *see* 15 U.S.C. § 2620(b)(4)(B)(ii), does so either. The use of the plural word "conditions" does not mean that a plaintiff must present scientific evidence regarding every single condition of use. That would make little sense in light of the fact that a single unreasonable risk is sufficient to trigger the EPA's rulemaking obligations. *See* 15 U.S.C. § 2605(a). In context, the phrase has a more straightforward meaning. As Plaintiffs and Amici persuasively argue, this phrase *limits* the rights of citizen petitioners. A petitioner must demonstrate *an* unreasonable risk of harm "*under* the conditions of use," *id.* § 2620(b)(4)(B)(ii), in other words, in a "circumstance[] . . . 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).[8] If the unreasonable risk only arises in some circumstance that does not constitute a "condition of use" as defined by statute, then the EPA is not obligated to take any action. As a limitation, there is no need to construe "conditions of use" as cross-referenced under Section 6(b) as expansively as the EPA argues.[9]

This reading also coheres with the statutory requirement that the "conditions of use" for a chemical substance are to be "determined by the Administrator," 15 U.S.C. § 2602(4), not by a citizen petitioner. If, as here, the EPA has not yet determined the "conditions of use" for a chemical substance, how can a citizen petitioner submit a compliant petition addressing yet-undetermined conditions of use? Petitioners would be required to gaze into a crystal ball and

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[8] Indeed, the EPA performs a similar threshold determination when reviewing a manufacturer's request for a risk evaluation. *See* 40 C.F.R. § 702.37(e)(3) ("EPA will assess whether the circumstances identified in the [manufacturer] request constitute condition[s] of use under § 702.33[.]"); *see also* 82 Fed. Reg. at 33736 (stating that, after receiving a manufacturer request, the EPA first "evaluate[s] whether the circumstances of manufacture, processing, distribution in commerce, use, and/or disposal identified by the submitter constitute conditions of use that warrant risk evaluation").

[9] The EPA argued that similar terms should be construed similarly in the same statute, and that this interpretation would not square with how the term "under the conditions of use" appears in Section 6(b)(4)(A). That argument is not persuasive. The EPA's performance of risk evaluations of conditions of use under Section 6(b) is structurally separate from the statutory provisions addressing Section 21 petitions.

make their best guess at what the Administrator will determine. That is not only unreasonable, but also an unnecessary complication in light of the natural reading discussed above. *See Ariz. State Bd. for Charter Schools v. U.S. Dept. of Educ.*, 464 F.3d 1003, 1008 (9th Cir. 2006) ("[W]ell-accepted rules of statutory construction caution us that statutory interpretations that would produce absurd results are to be avoided. When a natural reading of the statutes leads to a rational, common-sense result, an alteration of meaning is not only unnecessary, but also extrajudicial." (citations and quotations omitted)); *see also* 15 U.S.C. § 2601(c) ("It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner . . . .").

Moreover, the statutory timelines present another problem for the EPA's interpretation. The EPA has three-and-a-half years to complete a Section 6(b) risk evaluation; yet it must act on a citizen petition under Section 21 within 90 days. If the EPA is correct that a citizen petitioner must present *all* scientific information related to *all* conditions of use of a chemical substance, then the EPA would essentially be required to perform a potentially wide ranging plenary review within three *months* perhaps approximating what the EPA would otherwise have three-and-a-half *years* to complete. Thus, far from easing the EPA's burden, its interpretation requiring Section 21 petitions to tender and the EPA to evaluate all conditions of use would expand that burden exponentially. The structure of the statute thus suggests that a Section 21 petition is not intended to require citizen petitions to present all conditions of use, thus burdening the EPA with an expansive evaluative task which must be completed within 90 days.

Thus, the text and structure of the statute do not support the EPA's contention that Section 21 requires a citizen petitioner who seeks to regulate a chemical substance to address all conditions of use. Rather, a natural reading suggests that a Section 21 petitioner need only present "the facts" which "establish that it is necessary" to issue a rule under Section 6(a), *see* 15 U.S.C. § 2620(b)(1), *i.e.*, facts showing that a chemical substance poses "an unreasonable risk." *See* 15 U.S.C. § 2605(a). That is sufficient to trigger the EPA's obligation to promulgate a rule under Section 6(a).

2. Purpose of the Statute

The EPA's interpretation would also undermine the role of Section 21 citizen petitions and

the purpose of the TSCA.

The purpose of citizen petitions is to ensure the EPA does not overlook unreasonable risks to health or the environment. *See Env. Def. Fund v. Reilly*, 909 F.2d 1497, 1499 (D.C. Cir. 1990) ("Citizen participation is broadly permitted [under the TSCA] to ensure that bureaucratic lethargy does not prevent the appropriate administration of this vital authority." (quotation and citation omitted)). Citizen petitions under Section 21 are intended to be an "unusually powerful procedure[] for citizens to force EPA's hand." *Trumpeter*, 774 F.3d at 1039.

The EPA's interpretation would undermine the purpose of Section 21 by permitting it to deny even a petition that successfully identifies an unreasonable risk of harm to health or the environment under a single condition of use simply because the petition does not also address all other conditions of use. The EPA would be permitted *not* to act despite knowledge of an unreasonable risk of harm, while simultaneously inoculating itself from judicial review of its refusal to act because of the petition's supposed deficiency. That a known unreasonable risk of harm could be ignored by the EPA is contrary to the TSCA's very purpose, as well as the statute's express command that the EPA "shall" promulgate regulations when "an" unreasonable risk is found. *See* 15 U.S.C. § 2605(a). *See also Rollins Env. Servs. (FS), Inc. v. St. James Parish*, 775 F.2d 627, 632 (5th Cir. 1985) ("The overall purpose of the Toxic Substances Control Act was to set in place a comprehensive, national scheme to protect humans and the environment from the dangers of toxic substances.").

Further, the EPA's interpretation creates a disparity between citizen petitions and manufacturer requests. Under the EPA's published rules, a manufacturer's request for a Section 6(b) risk evaluation may be limited to only those particular conditions of use of interest to the manufacturer. *See* 40 C.F.R. § 702.37(b)(4). The EPA recognized that requiring manufacturers to address *all* conditions of use would "create a disincentive to submit requests for risk evaluation." *See* 82 Fed. Reg. at 33735-36. It also recognized that "manufacturers are not always privy to every downstream use [of a chemical substance]" and that it would be "very difficult [for manufacturers] to obtain all the required information" for a compliant request identifying all conditions of use. *Id.* Requiring citizen petitioners to carry a burden that the EPA deemed was far

too high for manufacturers would clearly create a disincentive to making such requests. Citizen petitioners are likely to have less financial wherewithal and resources than manufacturers. There is no indication Congress intended citizens to encounter a burden not presented to manufacturers.[10] Discouraging citizen petitions would undermine the availability of this "unusually powerful procedure[] for citizens to force EPA's hand." *Trumpeter*, 774 F.3d at 1039.

Thus, the purpose of the statute is more consonant with a reading that Section 21 does not require a petitioner to address *all* conditions of use.

3. Legislative History

Although the text, structure, and purpose of the TSCA clearly demonstrate that a Section 21 petition does not need to address all conditions of use, the Court's interpretation is also bolstered by the legislative history. *See Hernandez*, 829 F.3d at 1073 (court may look to legislative history to ascertain Congress's intent if statute's internal indicia are insufficiently clear). The EPA's argument hinges on the notion that the addition of the term "under the conditions of use" to Section 21 in 2016 represents a sea change. However, the Senate Committee on Environment and Public Work's Report on the draft legislation states that "[n]o substantive or policy change is intended by these amendments" to the citizen petition provisions. S. Rep. 114-67 at 33 (114th Cong. 1st Sess., Jun. 18, 2015). That suggests that Congress did not understand the amendments to be imposing the type of significant burdens and hurdles that the EPA acknowledges its interpretation would place on citizen petitioners; nothing suggests Congress intended to weaken citizen petitions under Section 21, a powerful tool of enforcement.

The EPA argues that the Committee Report carries no weight because it referred to an earlier draft of the legislation that did not include the "conditions of use" language. That is incorrect. It is true that the phrase "conditions of use" did not appear directly in the citizen petition section of that draft. However, the draft referred to whether a citizen petition demonstrated that a chemical would not meet "the safety standard." S. 697 (114th Cong. 1st Sess.,

[10] If anything, Congress intended protections for citizen petitioners to be even greater. The requirements for a citizen petition are explicitly set forth by statute, *see* 15 U.S.C. § 2620, whereas Congress committed the required "form," "manner," and "criteria" for manufacturer requests to the EPA's discretion. *See* 15 U.S.C. § 2605(b)(4)(C)(ii).

Jun. 17, 2015). The term "safety standard," in turn, was defined in the draft to mean "a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance *under the conditions of use* . . . ." *Id*. (emphasis added). That is substantially identical to the language that ultimately ended up in Section 21, and, does, in fact, include the disputed term "under the conditions of use." Thus, the Senate Report can fairly be read to reflect the Committee's views about the import (or, more accurately, *lack* of import) of that term in Section 21.[11]

Accordingly, the legislative history also supports the view that citizen petitioners are not required to address all conditions of use.

4. Consistency With EPA Regulations

The Court's interpretation is also consistent with the EPA's regulations with respect to manufacturer requests and *sua sponte* risk evaluations under Section 6(b). (The EPA has not proposed or adopted any rule specifically addressing Section 21.) As explained above, EPA initially took the position that a Section 6(b) risk evaluation must address all conditions of use, but its final rule permits it to focus on fewer than all conditions of use. *Compare* 82 Fed. Reg. at 7565 *with* 82 Fed. Reg. at 33728-29. The EPA argued that its final rule was grounded in the statutory text. *See* 82 Fed. Reg. at 33729 (explaining that the statutory text "suggest[s] that EPA is not required to consider all conditions of use" and thus EPA "may" "exclude certain activities that EPA has determined to be conditions of use" from the scope of a Section 6(b) risk evaluation).

[11] The EPA counters that there is also legislative history supporting its interpretation. *See* 162 Cong. Rec. H2989, at H3026, col. 1 (May 26, 2016) (testimony that "[o]n the substantive side, the bill could make it harder for the EPA and citizens to use some of the tools that have proven effective under current law, including significant new use rules and citizen petitions"). This vague statement, however, does not refer to any particular amendment to the citizen petition provisions and thus it is impossible to discern to what the House representative is referring. Moreover, the Supreme Court has held that "the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill," not "the passing comments of one Member" or "casual statements from the floor debates." *Garcia v. U.S.*, 469 U.S. 70, 76 (1984). Thus, particularly here, where there is no other reference to the citizen petition provision in the record, this singular and indirect passing remark does not outweigh the Committee Report. *Zuber v. Allen*, 396 U.S. 168, 186 (1969) ("A committee report represents the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation. Floor debates reflect at best the understanding of individual Congressmen. It would take extensive and thoughtful debate to detract from the plain thrust of a committee report[.]").

Similarly, the EPA backed away from a requirement that a manufacturer must address all conditions of use when requesting a Section 6(b) risk evaluation. *See* 82 Fed. Reg. at 33736.

If the term "under the conditions of use" does not impose an affirmative requirement that every manufacturer request or *sua sponte* review address *all* conditions of use in the Section 6(b) context, then there is no reason to think it does so in the context of Section 21 citizen petitions.

5. Deference to EPA's Interpretation

The EPA's litigation argument herein that citizen petitions must identify all conditions of use before they can be considered is not entitled to *Chevron* deference. As a threshold matter, as explained above, the statutory text, structure, and purpose strongly indicate that a Section 21 petition need not address all conditions of use. Arguably, there is thus no need to refer to the agency's interpretation given the clear statutory text. *Cf. Trumpeter*, 774 F.3d at 1039 (pre-2016 TSCA is unambiguous with respect to requirements for citizen petitions so EPA's interpretation was not entitled to deference).

Even if there is ambiguity, the agency's interpretation would not be entitled to *Chevron* deference. "Generally, *Chevron* deference is reserved for legislative rules that an agency issues within the ambit of the authority entrusted to it by Congress. Such rules are characteristically promulgated only after notice and comment." *Tablada v. Thomas*, 533 F.3d 800, 806 (9th Cir. 2008). The EPA's interpretation here was set forth for the first time in its denial of Plaintiffs' petition. The agency has never put that interpretation up for notice-and-comment nor enacted a formal rule adopting it. It does not represent a long-held consistent position of the EPA. Its argument in this lawsuit is not entitled to *Chevron* deference. *See 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."); *cf. Inv. Co. Inst. v. Camp*, 401 U.S. 617, 628 (1971) ("It is the administrative official and not appellate counsel who possesses the expertise that can enlighten and rationalize the search for the meaning and intent of Congress.").

At best, the EPA's interpretation may be entitled to *Skidmore* deference "proportional to its power to persuade." *Tablada*, 533 F.3d at 806. Under *Skidmore*, the deference owed to an agency's interpretation "depend[s] upon the thoroughness evident in its consideration, the validity

of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade." *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944); *see also The Wilderness Soc. v. U.S. Fish & Wildlife Serv.*, 353 F.3d 1051, 1068 (9th Cir. 2003). The *Skidmore* factors weigh against giving the EPA's interpretation significant weight here for the reasons explained above related to the statutory text, structure, purpose, and the legislative history. The persuasiveness of the EPA's interpretation is also undermined by the agency's inconsistent approach to Section 21 petitions compared to Section 6(b) risk evaluations undertaken in response to manufacturer requests or *sua sponte*. It has not offered any convincing explanation for imposing a higher burden on a Section 21 petition than it has imposed on itself or on manufacturers. Moreover, the EPA's argument fails to address problems such as the fact that a citizen petitioner cannot know whether it has addressed all conditions of use if the EPA Administrator has not yet determined what those conditions of use are consistent with the statutory definition of "conditions of use." *See supra* at 17-18.

Finally, the EPA's policy arguments in support of its interpretation are unavailing. It argues that citizen petitioners must present information about *all* conditions of use, otherwise, citizen petitioners would place a drain on agency resources and cut in line ahead of "high priority" chemical substances or those identified by manufacturers. Even so, that would not necessarily be inconsistent with the statute's purpose. A citizen petition must persuade the EPA that a chemical substance poses an unreasonable risk of harm before the EPA is required to issue a rule. It is not unreasonable that Congress would require the EPA to act in response to a known unreasonable risk of harm, regardless of whether the finding is prompted by a citizen petition, a manufacturer request, or a *sua sponte* evaluation by the agency. In any event, the statute contemplates the possibility that some citizen petitions may present evidence of harms that are nevertheless less pressing than other matters pending before the EPA. Reviewing courts are thus required to weigh the relative harm addressed by a citizen petition, as well as consider, and accommodate, any EPA resource constraints in fashioning relief. *See* 15 U.S.C. § 2620(b)(4)(B)(ii) (court "may permit the Administrator to defer initiating the action requested by the petitioner" if the court "finds that the extent of the risk . . . alleged . . . is less than the extent of risks . . . with respect to which the

Administrator is taking action under this chapter and there are insufficient resources available to the Administrator to take the action requested by the petitioner").[12] The EPA ignores this explicit statutory accommodation relative to Section 21 petitions. The EPA's policy argument is unpersuasive.

For those reasons, the EPA's interpretation in this litigation is entitled to minimal, if any, weight, and the Court rejects it.[13]

6. Conclusion

In sum, the statutory text does not support the EPA's interpretation. Rather, a natural reading of the language suggests a citizen petitioner need only present facts demonstrating that a chemical substance poses *an* unreasonable risk due to one or more conditions of use that are of concern to the petitioner. This construction is consistent with the language, structure, and purpose of the statute, the legislative history, the EPA's interpretation of similar provisions, and the policies Congress sought to advance. The Court therefore concludes that Section 21 does not require a petition under Section 6(a) to address *all* conditions of use, but rather, only those that the petitioner seeks to regulate. The EPA's motion to dismiss for failure to address *all* conditions of use is **DENIED**.

B. Plaintiffs Adequately Identified the Chemical Substances at Issue

Defendant also argues Plaintiffs' petition "does not provide enough information to allow the Agency or the Court to evaluate 'fluoridation chemicals' under th[e] statutory scheme because

[12] Indeed, looking at the broader structure of the statute, it is telling that Congress provided detailed quotas and timelines regarding the prioritization of the EPA's review of "high priority" chemicals and manufacturer requests, but left the determination regarding citizen petitions to the courts. *See, e.g.*, 15 U.S.C. (b)(2)(A) (at least 10 risk evaluations must be undertaken for chemicals on the TSCA Work Plan within 6 months); 15 U.S.C. § 2605(b)(2)(B) (within three and a half years, at least 20 risk evaluations of "high priority" substances must be underway, at least half taken from TSCA Work Plan); 15 U.S.C. § 2605(b)(3)(C) (whenever the EPA completes a risk evaluation of a "high priority" substance, other than those initiated by manufacturers, it must designate at least one new high-priority substance).

[13] Even if *Chevron* rather than *Skidmore* applied here, however, the EPA's interpretation still would not be entitled to deference because it is not "a permissible (or reasonable) construction of the statute," for the same reasons discussed above. *See Natural Resources Defense Council, Inc. v. Nat'l Marine Fisheries Serv.*, 421 F.3d 872, 879 (9th Cir. 2005) (rejecting agency's interpretation even where entitled to *Chevron* deference because it was "directly at odds with the text and purpose" of the statute).

it does not identify the specific chemical substances at issue . . . ." Mot. at 8. According to Defendant, the petition merely "allege[s] neurological effects of exposure to unspecified 'fluoridation chemicals.'" Mot. at 12.

This argument is not persuasive. The EPA did not deny Plaintiffs' petition on the grounds that it was not sufficiently specific for the EPA to evaluate. Rather, the EPA denied the petition on the merits. *See* 82 Fed. Reg. at 11,881, col. 3. (concluding petition did "not set forth a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S. through the purposeful addition of fluoridation chemicals to drinking water or otherwise from fluoride exposure in the U.S."). Like the EPA, the Court will be able to understand from the petition and supporting materials what chemicals are at issue.

Moreover, Plaintiffs' petition *does* identify the chemical substances they seek to regulate. A "chemical substance" is "any organic or inorganic substance of a particular molecular identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical." *See* 15 U.S.C. § 2602(2)(A). Plaintiffs' petition clearly states that it seeks regulation of "fluoride" used for "fluoridation of water" in the first paragraph of the cover letter. *See* Admin. Pet. at 1. The EPA itself simply refers to "fluoride" in notice-and-comment regarding water fluoridation, suggesting there is no reasonable dispute about the chemicals to which that term refers in this context.[14] Plaintiffs' petition also refers to "fluorosilic acid" and "sodium fluorosilicate," specific chemical compounds. Admin. Pet. at 28. The materials attached to the petition also identify the specific compounds that fall under the term "fluoride." *See, e.g.*, Connett Decl., Ex. 1, at 1091 ("Over 91% of US fluoridated water is treated with either sodium silicofluoride or fluosilicic acid . . . . Less than 10% is treated with simple sodium fluoride."). Although in other circumstances the reference to these compounds in the 317th exhibit to Plaintiffs' petition might

[14] *See, e.g.*, National Primary Drinking Water Regulations; Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment and/or Information on Related Issues, Jan. 11, 2017, 82 Fed. Reg. 3518-01, 3531-33 (discussing water fluoridation without identifying specific chemical substances); National Primary and Secondary Drinking Water Regulations, Apr. 2, 1986, 51 Fed. Reg. 11396 (final rule regulating fluoride in public drinking water without identifying specific chemical substances).

be insufficient, the EPA's denial of Plaintiffs' petition includes explicit references to all three chemicals, undermining any notion that the EPA was not adequately on notice. *See* 82 Fed. Reg. at 11887, col. 3, (referring to "silicofluoride"); *id.* ("fluorosilicic acid"); 82 Fed. Reg. at 11889, col. 2, n. 38 (referring to "sodium fluoride").

Plaintiffs' petition sufficiently identifies the chemicals at issue. This is not a case where Plaintiffs seek to regulate a chemical in litigation that the EPA did not realize was at issue in the administrative petition. Defendant's motion to dismiss on that basis is **DENIED.**

C. Plaintiffs' Reference to the Category "Fluoride" Does Not Require Dismissal

Relatedly, Defendant argues that Plaintiffs' petition fails to justify treatment of the three "fluoridation chemicals" as a "category" under 15 U.S.C. § 2625(c). That provision states that wherever the EPA may take action "with respect to a chemical substance or mixture," it may take the same action with respect to "a category of chemical substances or mixtures." 15 U.S.C. § 2625(c)(1). The statute defines "category of chemical substances" as:

> a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, *or* in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter. . . .

Id. § 2625(c)(2)(A) (emphasis added). The statute further provides that "[w]henever the Administrator takes action under a provision of this chapter with respect to a category of chemical substances or mixtures, any reference in this chapter to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category." *Id.* § 2625(c)(1).

Plaintiffs' petition plainly presents a basis for why the chemical substances are "similar" "in use" and "in mode of entrance into the human body": they are all allegedly used for fluoridation of water, and are all ingested through water consumption. Moreover, Plaintiffs claim that these chemicals all have similar "physical, chemical, or biological properties," insofar as they are all used for the same purpose (fluoridation of water to prevent tooth decay) and pose a similar risk of harm (neurotoxic effects). Thus, the petition plainly presents a basis for why it is made with respect to a "category" of chemicals under § 2625(c).

Defendant also argues the use of a category was problematic because Plaintiffs requested regulation of "several different chemicals" but "fail[ed] to distinguish between them," thus conveying "inadequate information about the properties or conditions of use of the individual chemical substances for EPA or the Court to determine whether they should be considered as a category for purposes of risk evaluation and any necessary regulation." Mot. at 13. This argument contradicts the record. The EPA did not deny Plaintiffs' petition because it had inadequate information to evaluate the petition, but rather because the petition did "not set forth a scientifically defensible basis" to conclude that "the purposeful addition of fluoridation chemicals to drinking water" causes harm. *See* 82 Fed. Reg. at 11,881, col. 3. Moreover, as discussed above, Plaintiffs were not required to identify all conditions of use for each of the compounds where they sought to regulate only one condition of use, fluoridation of drinking water.

At best, the EPA raises the question whether Plaintiffs will meet their burden in this litigation by showing by a preponderance of the evidence that each chemical substance in the category of "fluoride" or "fluoridation chemicals" poses an unreasonable risk of harm, as appears to be required under 15 U.S.C. § 2625(c)(1). However, that question is more appropriately resolved on summary judgment, after the parties have summarized and presented the scientific evidence supporting their positions, rather than at the motion to dismiss stage. Accordingly, Defendant's motion to dismiss for failure to justify treatment of fluoridation chemicals as a category is **DENIED**.

IV. CONCLUSION

Plaintiffs are entitled to judicial review of their petition on the merits because they complied with the two minimal statutory requirements: they filed their petition with the Administrator, and they set forth the facts they believe justify a rule under Section 6(a) regulating the fluoridation of drinking water supplies. Plaintiffs were not required to address other uses of fluoridation chemicals in their petition to the EPA. Moreover, Plaintiffs sufficiently identified the chemical substances at issue in their petition and explained why they seek to regulate that category

of substances. Whether they can meet their ultimate burden on the merits with respect to each chemical substance remains to be seen, but they are at least entitled to attempt to make that showing. Defendant's motion to dismiss is **DENIED**.

This order disposes of Docket No. 28.

IT IS SO ORDERED.

Dated: December 21, 2017

EDWARD M. CHEN
United States District Judge