JEFFREY H. WOOD
Acting Assistant Attorney General
U.S. Department of Justice
Environment & Natural Resources Division
NORMAN L. RAVE, JR. (D.C. 431602)
Environmental Defense Section
601 D Street, NW, Suite 8000
Washington, DC 20004
Tel. (202) 616-7568
norman.rave@usdoj.gov

Attorneys for Defendants

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

FOOD & WATER WATCH, INC, et al., Plaintiffs, v. U.S. Environmental Protection Agency, et al., Defendants.	Case No.: 17-cv-02162-EMC DEFENDANTS' REPLY IN FURTHER SUPPORT OF MOTION TO DISMISS DATE: November 30, 2017 TIME: 1:30 pm Courtroom: 5, 17th Floor

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Defendants United States Environmental Protection Agency, et al., ("EPA"), submit this Reply in Further Support of EPA's Motion to Dismiss the Complaint in this action. In this case, Plaintiffs seek judicial review of EPA's denial of their administrative petition under section 21 of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2620, which requested that the Agency promulgate a regulation pursuant to TSCA section 6(a), 15 U.S.C. § 2605(a), to ban the introduction of "fluoridation chemicals" into drinking water. EPA denied that petition because it did not meet the minimum statutory requirements to form the basis of a regulation under TSCA section 6(a) and because the petition did not demonstrate that the addition of fluoridation chemicals to drinking water poses an unreasonable risk of injury to health or the environment. 82 Fed. Reg. 11,878 (Feb. 27, 2017) (ECF No. 28-1 Att, 2). EPA's Motion, ECF No. 28, addresses only the first basis for EPA's denial, which presents purely questions of law. Specifically, EPA's Motion demonstrates that the Complaint should be dismissed for failure to state a claim because (1) Plaintiffs' administrative petition failed to specifically identify the chemical substances for which they wanted EPA to initiate a rulemaking and (2) Plaintiffs' administrative petition did not contain information comparable in scope and quality to a risk evaluation under TSCA section 6(b)(4), and thus cannot serve as the basis for the requested rule under TSCA section 6(a).

I. PLAINTIFFS' PETITION DOES NOT ADEQUATELY IDENTIFY THE CHEMICAL SUBSTANCES AT ISSUE

With regard to the issue of whether Plaintiffs' petition adequately identifies the chemical substances at issue, Plaintiffs argue, first, that because a parenthetical on page 28 of their petition mentions *two* specific chemicals and four of the 196 studies attached to their petition mention *three* specific chemicals, Plaintiffs adequately identified the chemical substances at issue. ECF No. 32 at 9. Even if one were to credit these references as constituting Plaintiffs' request for which chemical substances it seeks to regulate, these conflicting references are ambiguous, and thus do not clearly specify what chemical substances Plaintiffs seek to have EPA regulate. Are Plaintiffs seeking to

regulate two chemical substances or three? Or are these chemicals merely examples of a broader group of "fluoridation chemicals"? Furthermore, one parenthetical reference in the petition and scattered references among the exhibits are not sufficient for Plaintiffs to meet the basic requirement to identify what chemical substances Plaintiffs are requesting EPA to regulate. Tellingly, neither the formal request for rulemaking on page 1 of the petition nor the petition's conclusion on page 29 specifically identify the chemical substances that Plaintiffs are seeking to have EPA regulate.

Plaintiffs' second argument, that they do not have to identify the specific chemical substances they seek to have EPA regulate because EPA has recognized "fluoridation chemicals" as a category, ECF No. 32 at 9-10, has no basis in fact. First, that EPA may regulate a category of chemical substances under TSCA section 26(c), 15 U.S.C. § 2625(c), does not mean that EPA can promulgate such a regulation without specifying what chemical substances fit into the category. A regulation must clearly specify what is covered by it. *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 252-54 (2012). It would not be possible for either EPA or a petitioner to show, as required by TSCA section 26(c)(2), that the chemical substances in the purported category meet the criteria for categorization without identifying the actual substances. Moreover, the fact that a group of chemicals might qualify for category treatment does not mean that they should be treated as a category under TSCA. It is not possible to evaluate whether a group of chemicals should be treated as a category without knowing what the chemicals are. Thus, Plaintiffs must specify what chemical substances they seek to have EPA regulate as the category of "fluoridation chemicals."

Second, Plaintiffs have not pointed to any instance where EPA has regulated "fluoridation chemicals." The two regulations cited by Plaintiffs were promulgated under the Safe Drinking Water Act, 42 U.S.C. § 300f *et seq.*, and set limits on the amount of fluoride that may be in drinking water, regardless of whether the fluoride comes from natural sources or treatment chemicals. *See* 40 C.F.R. § 141.2 (defining a maximum contaminant level under the SDWA as the "maximum permissible level of a contaminant

in water which is delivered to any user of a public water system"). Those rules thus do not specifically regulate the treatment chemicals as Plaintiffs request here. Furthermore, neither of the EPA statements cited by Plaintiffs demonstrate that EPA has established a category of fluoridation chemicals. In the first, 78 Fed. Reg. 48,845, 48,846 (Aug. 12, 2013), EPA was characterizing a study performed by the Centers for Disease Prevention, and in the second, EPA was characterizing Plaintiffs' petition. Neither statement absolves Plaintiffs of the responsibility to clearly identify the subject of their petition.

Finally, EPA is not elevating form over substance. Plaintiffs request that EPA promulgate a regulation. A fundamental requirement of any regulation is that it clearly identify the activities or chemical substances it covers. For Plaintiffs' petition to serve as an adequate basis for a regulation, it must, at a minimum, specifically identify the chemical substances the Plaintiffs are asking EPA to regulate.

II. PLAINTIFFS' PETITION DOES NOT PROVIDE A SUFFICIENT BASIS TO JUSTIFY THE REQUESTED REGULATION UNDER TSCA SECTION 6(a) BECAUSE IT FAILS TO ADDRESS THE CONDITIONS OF USE THAT ARE NECESSARY TO DETERMINE WHETHER THE CHEMICAL SUBSTANCES PRESENT AN UNREASONABLE RISK AS REQUIRED BY TSCA

In their Opposition, Plaintiffs contend that they do not have to identify any conditions of use other than the risk of fluoridating drinking water identified in their petition or evaluate any risks from those conditions of use for which they do not seek a TSCA 6(a) rule because (1) the petition provisions of TSCA section 21 do not impose those requirements on them and (2) EPA's position here is inconsistent with its regulations interpreting TSCA sections 6(a) and 6(b). ECF No. 32 at 11-20. These arguments are without merit.

A. TSCA Section 21 Does Not Confer Authority On The Public to Compel EPA To Undertake A Rulemaking That Does Not Conform To The Substantive Requirements Of Section 6.

In this case, Plaintiffs seek to compel EPA to exercise its authority under TSCA section 6(a) to regulate the use of "fluoridation chemicals." As explained in EPA's

motion, the recent amendments to TSCA significantly altered the conditions under which EPA exercises that authority. In particular, the statute requires EPA to conduct a risk evaluation of a chemical substance as a predicate for exercising its section 6(a) authority to regulate that substance, and then to regulate it under section 6(a) to eliminate any identified unreasonable risks. There is no basis to Plaintiffs' claim that TSCA section 21 provides a mechanism to bypass those requirements.[1]

Plaintiffs correctly point out that EPA interprets TSCA to allow the Agency to proceed to section 6(a) rulemaking to regulate one or more specific conditions of use that EPA has found to present unreasonable risk prior to completion of the evaluation of the remaining conditions of use. 40 C.F.R. § 702.41(a)(9); 82 Fed. Reg. 33,726, 33,740 (July 20, 2017). However, EPA's regulations also provide that, where EPA does so, it must "complete the risk evaluation of the chemical substance addressing *all* of the conditions of use within the scope of the evaluation" within the three to three-and-a-half-year timeframe established by TSCA section 6(b)(4)(G) for completion of risk evaluations. 40 C.F.R. § 702.41(a)(9) (emphasis added). EPA must then complete a section 6(a) rulemaking for that chemical substance, within the two- to four-year timeframe provided by section 6(c)(1), to address any unreasonable risks identified. Thus, EPA must finalize any section 6(a) rules needed to ensure that the chemical substance does not present an unreasonable risk for all its conditions of use within the seven years provided by statute for EPA to complete both chemical risk evaluations and the section 6(a) rules necessary to address any unreasonable risks. 15 U.S.C. §§2605(b)(4)(G), 2605(c)(1). In contrast, Plaintiffs do not acknowledge any obligation whatsoever on their part to provide information remotely comparable to a risk evaluation and they deny that their petition triggers any EPA obligation to complete a risk evaluation for fluoridation chemicals, ECF

---

[1] Plaintiffs' claim that EPA's interpretation of TSCA is not entitled to deference, ECF No. 32 at 20-22, is misplaced because the issue presented by this motion is whether Plaintiffs' administrative petition met the statutory prerequisites for EPA to exercise its rulemaking authority under section 6(a), and that is a matter on which EPA's interpretation is entitled to deference. ECF No. 28 at 11 n.6.

No. 32 at 16-18. Rather, they assert that they can compel EPA to conduct a section 6(a) rulemaking on the basis of a single condition of use without addressing any others. *Id.* at 13-15.

Thus, as Plaintiffs interpret section 21, a petitioner can compel EPA to undertake a course of action that the Agency would have *no authority to undertake on its own*. If EPA were to determine on its own that the addition of certain chemicals to drinking water presented an unreasonable risk, it would have no authority to address that risk through a section 6(a) rulemaking unless that rulemaking were a component of the statutorily-required, time-limited process to identify the range of unreasonable risks presented by the chemicals and regulate them as needed. While EPA acknowledges that the section 21 petition process may result in EPA addressing chemical substances sooner than it might have addressed them on its own, it should not be interpreted as expanding the Agency's statutory authority by empowering petitioners to compel action the Agency *could not* have taken. In light of the detailed provisions concerning risk evaluations that Congress enacted in the TSCA amendments, it is not plausible that Congress intended to give private citizens power to compel action to address risks of concern to them that EPA could not have taken had it independently identified the same risks.[2]

That Congress did not intend this result is demonstrated, as explained in EPA's motion to dismiss, by the amendment to section 21(b)(4)(B)(ii) that requires that the determination a court must make in order to compel section 6(a) rulemaking track the finding EPA must make in a risk evaluation to proceed to section 6(a) rulemaking. This change in language shows that Congress intended a section 21 petition requesting a section 6(a) rulemaking to serve a function comparable to that of a section 6(b) risk evaluation – that is to say, to provide a basis to identify any unreasonable risks presented by a chemical substance, which EPA would then be required to eliminate through one or

[2] Moreover, EPA is not powerless to address risks from individual conditions of use. For example, EPA can take action to abate imminent hazards under TSCA section 7. 15 U.S.C. § 2606. However, Congress did not provide authority in section 21 for citizens to petition for EPA to take action under section 7.

more section 6(a) rulemakings. In particular, Congress used the plural "conditions of use" to require that a petitioner assess chemical substances, under the conditions of use – rather than a selected individual use – as the basis to compel the exercise of section 6(a) authority.

The judicial review provision of section 21 is a waiver of the United States' sovereign immunity, and thus must be "construed strictly in favor of the sovereign . . . and not enlarge[d] . . . beyond what the language requires." *United States Dep't of Energy v. Ohio*, 503 U.S. 607, 615 (1992) (citations and quotations omitted). Plaintiffs' claim that section 21 imposes obligations on EPA beyond the statutory requirements of section 6 fails this test. Nothing in section 21 authorizes the court to require EPA to initiate a rulemaking pursuant to section 6(a) under circumstances other than those specified by section 6.

Contrary to Plaintiffs' assertions, the legislative history does not support their claims and, in fact, supports EPA's interpretation. The Senate Report that Plaintiffs and proposed amici refer to is based on Senate Bill 697 as it was drafted a year prior to the Lautenberg Act that became law on June 22, 2016. Senate Bill 697 did not contain the language in section 21 that the parties are now discussing. S. 114-67 (June 18, 2015). And to the extent the Report is relevant to the final language of amended TSCA, it confirms Congress' intent that the standards to be applied to citizen petitions for section 6(a) rules under section 21 continued to be consistent with section 6(a)'s substantive requirements for EPA to take similar action. The addition of the phrase "under the conditions of use" maintains that approach by making the section 21 standard consistent with the new standard in section 6. This conclusion is supported by a colloquy on the House floor discussing the final version of the Lautenberg Act in which Congressman Pallone, one of the House authors of the legislation as Ranking Member of the House Energy and Commerce Committee, stated:

> On 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. . . citizen petitions*. I would have preferred to leave those

> tools intact, but, hopefully, the new tools we are giving the Agency will more than make up for those changes.

162 Cong. Rec. at H3026 col. 1 (May 24, 2016) (emphasis added).

Thus, Congress acknowledged that the substantive changes made to section 6, and the conforming changes made to section 21, could make it more difficult to make the showing required to compel EPA to promulgate a rule under section 6(a). Further, Congress recognized that the new tools it gave EPA to address the risks of chemicals under section 6, as well as clearly delineating a minimum pace for EPA's process of prioritizing and evaluating the 85,000 existing TSCA chemicals, would be more than sufficient to offset any resulting substantive impacts to the citizen petition process in section 21.

Plaintiffs characterize EPA's position as establishing an impossibly high bar to compel section 6(a) rulemaking. ECF No. 32 at 11, 19-20. EPA disagrees. While, TSCA imposes significant requirements for a petitioner to demonstrate that their request to compel such rulemaking should be granted, those requirements are no different than the requirements EPA must meet to regulate a chemical substance under section 6(a). This is entirely appropriate. Section 21 creates a powerful remedy for private citizens: the opportunity to petition EPA to commence rulemaking and to seek a court order to compel that rulemaking for chemical substances that the Agency has not identified as high-priority and for which it has not conducted a risk evaluation, and to conduct that rulemaking in addition to the rulemakings required by section 6 for high-priority chemicals. Thus, it is not surprising that Congress set a high bar. Indeed even prior to the 2016 TSCA amendments, section 21 set a high bar to compel section 6(a) rulemaking. Before the 2016 amendments, a section 6(a) rule could be justified only if the benefits of the rule would justify the costs. EPA interpreted section 21 as requiring petitioners to make this demonstration, despite the extensive economic analysis obligation imposed on petitioners (and EPA) to make the required showing. *See, e.g.*, 80 Fed. Reg. 60,577, 60,581 (Oct. 7, 2015) (denying a section 21 petition to regulate carbon dioxide under

TSCA section 6(a), in part due to petitioners' failure to provide a cost-benefit analysis of a specific requested regulation).

Accordingly, Plaintiffs' claim that they were not required to present to EPA a basis for action that is reasonably comparable to a risk evaluation by EPA under TSCA section 6 in order to compel EPA to undertake rulemaking is not a reasonable interpretation of TSCA.

B. EPA's Denial Of The Petition Is Consistent With Its Risk Evaluation Rule.

Plaintiffs' argument that EPA's risk evaluation rule is inconsistent with the position it took in denying the petition because the rule identifies specific circumstances when EPA can proceed to substantive rulemaking without first having completed a risk evaluation of the conditions of use is without merit.

As shown above, the risk evaluation rule does not provide authority for EPA to regulate under section 6(a) risks arising from particular conditions of use of a chemical substance except as a component of the statutorily-required, time-limited process to identify the range of unreasonable risks presented by the chemical substance and regulate them as needed. While an EPA risk evaluation may exclude conditions of use that are insignificant or otherwise unnecessary to determine whether a chemical substance does or does not present an unreasonable risk under TSCA section 6(b), EPA is statutorily required to identify the conditions of use it expects to consider in a risk evaluation, 15 U.S.C. § 2605(b)(4)(D), and EPA's justification for excluding conditions of use from the evaluation would be subject to judicial review under TSCA section 19(a)(1)(A), 15 U.S.C. § 2618(a)(1)(A). Plaintiffs make no attempt to explain why consideration of the conditions of use of fluoridation chemicals other than use to fluoridate drinking water would be unnecessary to conduct a risk evaluation on the chemicals. In fact, an integral part of their petition is that fluoridation chemicals in drinking water pose an unreasonable risk in part because of exposure to fluoride from other sources. *E.g.*, ECF 28-1 Att. 1 at 6-8.

While the risk evaluation rule provides that a manufacturer may request a risk evaluation based on a subset of the conditions of use of the chemical, the rule makes clear that the Agency will still perform the risk evaluation required by section 6(b) after identifying other conditions of use necessary to evaluate whether the chemical presents an unreasonable risk following a scoping and lengthy public notice and comment process, just as it would any other chemical substance undergoing a risk evaluation. 82 Fed. Reg. at 33,736 col. 1. Specifically, EPA stated:

> Although manufacturers may request that EPA conduct a risk evaluation based on a subset of the conditions of use, EPA intends to conduct the risk evaluation in the same manner as any other risk evaluation conducted under section 6(b)(4)(A). This is clear from subsections (A) and (C), and from section 6(b)(4)(E)(ii), which expressly directs that the Administrator shall not expedite or otherwise provide special treatment to manufacturer-requested risk evaluations. As such, 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.

Id. This follows from the fact that the statute gives manufacturers the ability to request a *risk evaluation*, subject to all of the requirements in section 6(b)(4). 15 U.S.C. § 2605(b)(4)(C)(ii). This situation is clearly distinguishable from that posed by Plaintiffs' petition where Plaintiffs seek to compel EPA to act under section 6(a) without considering any conditions of use other than fluoridating drinking water.

Plaintiffs also point out that EPA has proposed rules under section 6(a) for specific uses of three chemical substances whose assessments were begun prior to the TSCA amendments, ECF No. 32 at 14-15 & n.32. This provides no support to Plaintiffs' arguments. As Plaintiffs acknowledge, those rulemakings were proposed under a statutory provision that specifically excludes them from the section 6(b) requirements, 15 U.S.C. § 2625(*l*)(4). This authority was included in the law in recognition of the fact that the risk assessments for these chemicals "were not conducted *across all conditions of use*." 162 Cong. Rec. at S3519 col. 1 (June 7, 2016) (emphasis added). Thus, Congress' addition of this authority reinforces the point that EPA otherwise lacks authority to

conduct targeted section 6(a) rulemakings to address risks arising from specific conditions of use, except as part of the statutory time-limited process to address the range of unreasonable risks associated with a chemical.[3]

In short, while the risk evaluation rule recognizes that EPA requires flexibility to address specific circumstances, in all cases EPA must consider the full range of conditions of use that are necessary to determine whether the substance does or does not present an unreasonable risk, as required by the statute. In their petition, Plaintiffs failed to do so, and thus they failed to meet the minimum requirements for a rulemaking under section 6(a).

III. THE SCOPE OF REVIEW ISSUE RAISED BY PROPOSED AMICI IS INCORRECT AND THE COURT HAS ALREADY ESTABLISHED A PROCESS TO ADDRESS IT

Proposed amici base part of their argument on a claim that the de novo standard of review means that the Court can take evidence on other conditions of use during the review proceedings. ECF No. 30-1 at 11-13. This is incorrect. Section 21 empowers a citizen to submit to EPA a "petition" and, if the petition is denied, authorizes court action by the petitioner to seek rulemaking "as requested in *the petition*." 15 U.S.C. § 2620(b)(4)(A) (emphasis added). While the standard of review is de novo, that cannot mean that a petitioner can present wholly new arguments and analyses to the court that

[3] The only other exception to the requirement for EPA to conduct a risk evaluation prior to section 6(a) rulemaking is for certain persistent, bioaccumulative and toxic ("PBT") chemicals for which Congress required expedited rulemaking under TSCA section 6(h), 15 U.S.C. § 2605(h), without a risk evaluation. Although section 6(a) is the vehicle for the PBT rules required by section 6(h), the rules are subject to a standard unique to these PBTs: the rules must address the risks identified by EPA and reduce exposure to the extent practicable. *Id*. § 2605(h)(4). This contrasts with the standard for ordinary section 6(a) rulemakings: the elimination of unreasonable risk identified through section 6(b) risk evaluation. *Id*. § 2605(a). EPA has identified seven PBT chemicals potentially subject to this authority. *See* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals-under. Proposed amici incorrectly assert that EPA can also regulate polychlorinated biphenyls ("PCBs") without risk evaluation under TSCA section 6(a). PCBs are regulated under TSCA section 6(e), which is specific to PCBs and provides no additional authority for EPA to undertake section 6(a) rulemaking. 15 U.S.C. § 2605(e)(1).

were not included in the petition. This would result in the court adjudicating a petition that was never submitted to or considered by the Agency thereby undermining the requirement that a petitioner exhaust the administrative remedy provided by section 21 prior to initiating court action. As EPA has acknowledged, the court may call for expert testimony to elucidate the scientific issues raised by the petition and EPA's denial. ECF No. 23 at 4-5. But Plaintiffs should not be allowed to use court proceedings to build from scratch a necessary element of their petition.

With respect to the specific contours of the de novo standard of review, the Court has established a process for addressing these issues, ECF No. 27, and that process is the appropriate avenue to address them. To the extent that points raised by proposed amicus are helpful to the Court in understanding those issues, EPA does not object to the Court taking those arguments into account during that process. At this point, though, EPA notes that the D.C. Circuit's decision in *Environmental Defense Fund v. Reilly*, 909 F.2d 1497 (D.C. Cir. 1990), does not, contrary to proposed amici's assertion, resolve these issues. The issue before the court in *Reilly* was whether an action for review of EPA's denial of a TSCA section 21 petition could be brought under the Administrative Procedure Act ("APA") as well as under section 21. (The district court had dismissed the plaintiffs' APA claims, and the section 21 claim had been resolved by settlement.) The D.C. Circuit held that no APA claim was available, and as part of its reasoning discussed the different standards of review. 909 F.2d at 1506 ("While the Section 21 court, proceeding de novo, is free to disregard EPA's reasoning and decision, APA review is restricted and highly deferential." (footnotes omitted)). The question of whether the district court could consider evidence beyond the administrative record was not before the court in *Reilly*. Moreover, in a more recent case, the D.C. Circuit indicated (albeit, in passing) that it considers judicial review in section 21 cases to be limited to the administrative record. *Trumpeter Swan Society v. EPA*, 774 F.3d 1037, 1042 (D.C. Cir. 2014) ("In the normal TSCA section 21 case, we would review the administrative record . . . ").

CONCLUSION

Plaintiffs' Complaint should be dismissed for failure to state a claim because their administrative petition to EPA, on its face, does not meet the statutory requirements to compel EPA to initiate a rulemaking under TSCA section 6(a).

Dated: November 8, 2017

Respectfully submitted,

JEFFREY H. WOOD
Acting Assistant Attorney General

/s/ *Norman L. Rave, Jr.*
NORMAN L. RAVE, JR.
Environmental Defense Section
601 D Street, NW, Suite 8000
Washington, DC 20004
Tel: (202) 616-7568
Email: norman.rave@usdoj.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by Notice of Electronic Filing this 8th day of November, 2017, upon all ECF registered counsel of record using the Court's CM/ECF system.

/s/ *Norman L. Rave, Jr.*
Norman L. Rave, Jr., Trial Attorney