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10 UNITED STATES DISTRICT COURT FOR THE
11 NORTHERN DISTRICT OF CALIFORNIA

12	FOOD & WATER WATCH, INC., et)	Case No. 17-cv-02162 EMC
13	al.,)	
14)	[Proposed] Amicus Curiae Brief of
15	Plaintiffs,)	Natural Resources Defense Council and
16	v.)	Safer Chemicals, Healthy Families in
17)	Support of Neither Party
18	U.S. ENVIRONMENTAL)	
19	PROTECTION AGENCY, et al.)	
20)	
21	Defendants.)	
22)	
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INTRODUCTION

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2 Section 21 of the Toxic Substances Control Act (TSCA) authorizes any person to
3 petition the U.S. Environmental Protection Agency (EPA) to promulgate a rule to
4 regulate, under section 6(a) of the Act, chemicals that pose unreasonable risks of injury
5 to health or the environment. 15 U.S.C. §§ 2620(a), 2605(a). Section 21 deputizes the
6 public to “ensure that bureaucratic lethargy does not prevent the appropriate
7 administration of [TSCA’s] vital authority.” *Env’tl. Def. Fund v. Reilly*, 909 F.2d 1497, 1499
8 (D.C. Cir. 1990). To that end, Congress empowered citizens to petition EPA to address
9 *known* unreasonable risks from chemicals, without waiting for the agency to evaluate
10 whether all uses of the chemical present unreasonable risks.

11 Congress imposed only one substantive requirement for a section 21 “citizen
12 petition”: the petition must “set forth the facts which it is claimed establish that [the
13 section 6(a) rule] is necessary.” 15 U.S.C. § 2620(b)(1). Section 6(a), in turn, provides for
14 EPA to issue a rule restricting or otherwise regulating the use of a chemical upon a
15 finding that the chemical presents “an unreasonable risk” of injury to health or the
16 environment. *Id.* § 2605(a). Consistent with this standard, section 21(b) provides that, if
17 EPA denies such a section 21 petition, a district court may order EPA to initiate the
18 rulemaking if the petitioner “demonstrates to the satisfaction of the court” in a “de novo
19 proceeding” that the chemical presents “an unreasonable risk” to health or the
20 environment. *Id.* § 2620(b)(4)(B). Read together, section 21 and section 6(a) require that a
21 petition for a new section 6(a) rule includes “the facts which [the petitioner] claim[s]
22 establish that,” *id.* § 2620(b)(1), the chemical presents “an unreasonable risk” to health
23 or the environment, *id.* §§ 2605(a), 2620(b)(4)(B)(ii). TSCA requires nothing more.

24 EPA asks this Court to read into section 21 an extra requirement: that the petition
25 evaluate all potential risks posed by other uses of the chemical—including uses that the
26 petitioner neither contends pose an unreasonable risk nor asks EPA to restrict. Section
27
28

1 21 does not require that information, however, because these are not facts the petitioner
2 “claim[s] establish that [the section 6(a) rule] is necessary.” *Id.* § 2620(b)(1).

3 Reading into section 21 an additional requirement that petitioners undertake
4 comprehensive risk evaluations like those EPA must conduct under section 6(b) would,
5 by judicial fiat, alter the “meticulously described” petitioning scheme that Congress set
6 out. *Reilly*, 909 F.2d at 1502. Requiring section 21 petitions to evaluate all of a chemical’s
7 uses for risk would also make the petition process essentially unavailable to a member
8 of the public who lacked the resources of a large federal agency. Rather than checking
9 EPA’s “bureaucratic lethargy,” *id.* at 1499, section 21 would become a dead letter.

10 Although EPA requests *Chevron* deference for its revisionary approach to section
11 21, such deference is not warranted where “Congress has expressly established the
12 Judiciary and not the [agency] as the adjudicator of private rights of action arising
13 under” the provision. *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990). But “[e]ven for
14 an agency able to claim all the authority possible under *Chevron*, deference to its
15 statutory interpretation is called for only when the devices of judicial construction have
16 been tried and found to yield no clear sense of congressional intent.” *Gen. Dynamics*
17 *Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004) (citing *Chevron U.S.A. v. Nat. Res. Def.*
18 *Council, Inc.*, 467 U.S. 837, 843 n.9 (1984)). “An agency is not entitled to deference simply
19 because it is an agency.” *Meister v. U.S. Dep’t of Agric.*, 623 F.3d 363, 367 (6th Cir. 2010).
20 To earn that respect, the agency “must apply—rather than disregard—the relevant
21 statutory and regulatory criteria.” *Id.* EPA’s brief fails to do that: it disregards statutory
22 text, ignores structural obstacles, and overlooks judicial precedent that is inconveniently
23 inconsistent with its approach.

24 This Court should not accept EPA’s invitation to revise section 21. Amici take no
25 position on the remaining issues raised by EPA’s motion to dismiss or the specific
26 petition at issue in this litigation.

STATUTORY BACKGROUND

1
2 Congress enacted the Toxic Substances Control Act in 1976 to grant EPA the
3 ability “to regulate chemical substances and mixtures which present an unreasonable
4 risk of injury to health or the environment.”¹ 15 U.S.C. § 2601(b)(2). To implement this
5 mandate, TSCA section 6(a) directs EPA to adopt restrictions and other regulations as
6 necessary to prevent such chemicals from posing unreasonable risks. *Id.* § 2605(a).

7 Following a quarter century during which EPA had not regulated a single
8 chemical under section 6(a), S. Rep. No. 114-67, at 4 (2015), Congress amended TSCA in
9 2016. *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No.
10 114-182, 130 Stat. 448 (2016). As amended, EPA’s duty to promulgate a section 6(a) rule
11 may arise in one of at least three ways.

12 First, under section 6(b), EPA must conduct comprehensive “risk evaluations” to
13 decide whether chemicals present unreasonable risks to health or the environment
14 under the chemicals’ “conditions of use.”² 15 U.S.C. § 2605(b)(4)(A). However, contrary
15 to the implication of EPA’s brief, *compare* Mot. to Dismiss 2, EPA’s section 6(b) risk
16 evaluations are conducted not only on chemicals that EPA has identified as high
17 priority, *see* 15 U.S.C. § 2605(b)(1), but also on non-priority chemicals that
18 manufacturers ask EPA to evaluate, *see id.* § 2605(b)(4)(C)(ii). Indeed, up to half of the
19 risk evaluations that EPA conducts must be in response to such a manufacturer request.
20 *Id.* § 2605(b)(4)(E)(i).

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23 ¹ Although TSCA applies to “chemical substances,” 15 U.S.C. § 2602(2)(A), and
24 “mixtures,” *id.* § 2602(10), this brief refers to both as “chemicals” for brevity.

25 ² “Conditions of use” means “the circumstances . . . under which a chemical
26 substance is intended, known, or reasonably foreseen to be manufactured, processed,
27 distributed in commerce, used, or disposed of.” 15 U.S.C. § 2602(4). This brief refers to
28 “uses” of a chemical when referring to such conditions of use.

1 When EPA finds that a use of a chemical presents an unreasonable risk following
2 a comprehensive section 6(b) risk evaluation, EPA must restrict that use under section
3 6(a). *Id.* § 2605(a)(1), (c)(1). If EPA finds that a chemical does *not* present any
4 unreasonable risk to health or the environment, however, that finding can trigger
5 preemption of state-law regulation of the chemical. *Id.* § 2617(a)(1)(B)(i). This is one
6 reason that a manufacturer might ask EPA to evaluate a non-priority chemical—and
7 pay for the evaluation. *Cf. id.* § 2605(b)(4)(E)(ii).

8 Second, EPA’s duty to promulgate a section 6(a) rule may arise because Congress
9 has directed the agency to regulate that chemical. For example, Congress has directed
10 EPA to restrict polychlorinated biphenyls (PCBs), *id.* § 2605(e), and certain persistent
11 and bioaccumulative toxics, *id.* § 2605(h). For these chemicals, Congress has effectively
12 substituted its own evaluation of chemical risks for a section 6(b) risk evaluation.

13 Finally, TSCA section 21 allows the public to petition EPA to promulgate a
14 section 6(a) rule upon a showing by the petitioner that the chemical presents “an
15 unreasonable risk” to health or the environment. *Id.* §§ 2620(a), (b)(4)(B)(ii). Congress
16 “meticulously described” a “comprehensive” process by which EPA, and if necessary
17 the courts, should address such petitions. *Reilly*, 909 F.2d at 1502. Compared to general
18 federal administrative law standards, section 21 “elevate[s] effective judicial review to a
19 degree perhaps unattainable otherwise.” *Id.* at 1505.

20 By statute, a section 21 petition must meet two requirements. Procedurally, it
21 must “be filed in the principal office of the Administrator.” 15 U.S.C. § 2620(b)(1).
22 Substantively, it must “set forth the facts which it is claimed establish that it is necessary
23 to issue” the requested rule. *Id.* That is all. And while the 2016 legislative amendments
24 made small conforming amendments to section 21, Congress intended “[n]o substantive
25 or policy change.” S. Rep. No. 114-67, at 29 (2015).

26 Once a section 21 petition is filed with EPA, the agency has ninety days to decide
27 whether to grant it. 15 U.S.C. § 2620(b)(3). During that time, the agency may hold a
28

1 public hearing or investigate the petition's claims. *Id.* § 2620(b)(2). If EPA denies the
 2 petition, the petitioner may sue "to compel [EPA] to initiate a rulemaking proceeding as
 3 requested in the petition." *Id.* § 2620(b)(4)(A).

4 A section 21 judicial proceeding following EPA's denial of a petition for a new
 5 section 6(a) rule is conducted "de novo." *Id.* § 2620(b)(4)(B). If the petitioner persuades
 6 the court by "a preponderance of the evidence" that the chemical "presents an
 7 unreasonable risk of injury to health or the environment . . . under the conditions of
 8 use," then the court "shall order [EPA] to initiate the [rulemaking] action requested by
 9 the petitioner." *Id.* § 2620(b)(4)(B)(ii).

10 ARGUMENT

11 I. Section 21 does not require that a petition evaluate every use of a chemical

12 Section 21 requires a petition to "set forth the facts which it is claimed establish"
 13 the need for the rule. 15 U.S.C. § 2620(b)(1). If EPA denies the petition, then the
 14 petitioner may sue. *Id.* § 2620(b)(4). In that suit, the petitioner must "demonstrate to the
 15 satisfaction of the court," by "a preponderance of the evidence," *id.* § 2620(b)(4)(B), that
 16 the chemical "presents an unreasonable risk of injury to health or the environment . . .
 17 under the conditions of use," *id.* § 2620(b)(4)(B)(ii).

18 Nothing in this statutory scheme requires a section 21 petition to evaluate every
 19 potential risk posed by every use of a chemical. Congress could easily have written such
 20 a requirement into section 21. It did not do so. EPA's contrary reading would therefore
 21 result, "'not [in] a construction of [the] statute, but, in effect, an enlargement of it by the
 22 court.'" *Lamie v. U.S. Tr.*, 540 U.S. 526, 538 (2004) (quoting *Iselin v. United States*, 270 U.S.
 23 245, 251 (1926)). Revising TSCA is Congress's job, not EPA's or this Court's.

24 To be sure, a court in a section 21 proceeding must determine whether the
 25 petitioner has shown the chemical poses "an unreasonable risk . . . under the conditions
 26 of use." 15 U.S.C. § 2620(b)(4)(B)(ii). The phrase "the conditions of use" is plural and—
 27 because introduced by the definite article "the"—encompassing. *See, e.g., Am. Bus Ass'n*
 28

1 *v. Slater*, 231 F.3d 1, 4-5 (D.C. Cir. 2000); *Kaufman v. Allstate N.J. Ins. Co.*, 561 F.3d 144, 155
2 (3d Cir. 2009). EPA argues that this Court must therefore evaluate all the chemical's
3 conditions of use before finding that one of them presents an unreasonable risk. But
4 section 21 does not require such a comprehensive inquiry (unlike EPA's section 6(b) risk
5 evaluation, *see infra* pp. 7-9); instead, section 21 provides that "the court shall order the
6 Administrator to initiate the action requested by the petitioner" if it finds that the
7 petitioner shows, by a preponderance of the evidence, that the chemical poses "*an*
8 unreasonable risk . . . under the conditions of use." 15 U.S.C. § 2620(b)(4)(B)(ii)
9 (emphasis added).

10 A court may find *an* unreasonable risk without evaluating every use of the
11 chemical. A court could, for example, find that a chemical poses an unreasonable risk of
12 cancer when used in, say, air freshener, even if the court did not evaluate whether the
13 same chemical also posed an unreasonable risk when used in, say, manufacturing
14 airplane parts. The court in that scenario would have identified *an* unreasonable risk
15 under the conditions of use, without necessarily identifying all possible risks under all
16 conditions of use.

17 TSCA does not require the court to go further. It does not require a court to
18 evaluate every use of the chemical—or indeed, any of the chemical's uses other than the
19 one that the plaintiff contends presents an unreasonable risk. As we discuss below, this
20 is different from EPA's obligations when preparing a comprehensive risk evaluation
21 under section 6(b).

22 **II. EPA's claim that a section 21 petition must evaluate conditions of use that the**
23 **petitioner has not asked EPA to regulate is neither reasoned nor reasonable**

24 Although EPA argues that a section 21 petition generally must address all
25 conditions of use of a chemical, *see* Mot. to Dismiss 10, the agency points to no statutory
26 language that imposes such a requirement. EPA instead attempts to hang this argument
27 on the fact that the phrase "conditions of use" appears both in section 21(b)(4)(B), which
28 governs judicial proceedings following EPA's denial of a rulemaking petition, and

1 section 6(b), which governs EPA's risk evaluations. *See* Mot. to Dismiss 5, 8, 10. But
2 Congress's conforming addition of "conditions of use" to section 21 is a vanishingly
3 thin reed from which to suspend EPA's attempt to impose requirements that Congress
4 omitted. *See* 15 U.S.C. § 2620(b)(1); *see also* S. Rep. No. 114-67, at 29 (2015) (stating that
5 the 2016 amendments to section 21 were intended to effect "[n]o substantive or policy
6 change").

7 EPA appears to contend that a section 21 petition *should* be required to evaluate
8 all uses of a chemical (or, at least, all uses that are not "insignificant," *see* Mot. to
9 Dismiss 10) because the agency's *section 6(b) risk evaluations* must evaluate all (or at least
10 some³) conditions of use of a chemical, *see* Mot. to Dismiss 4-6, 8. Despite considerable
11 hand waving, however, EPA's argument is more one of policy than statutory exegesis.
12 For while section 21 and section 6(b) contain some overlapping language, the two
13 provisions are not identical, do not involve the same determinations, and serve quite
14 different functions.

15 When a person petitions EPA under section 21 to issue a new section 6(a) rule,
16 the petition asks EPA to eliminate "an" unreasonable risk from a chemical by
17

18 ³ Shortly before EPA denied the citizen petition at issue in this case, EPA asserted
19 that a TSCA section 6(b) risk evaluation "must encompass all known, intended, and
20 reasonably foreseen activities associated with the subject chemical substance."
21 Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control
22 Act: Proposed Rule, 82 Fed. Reg. 7562, 7565 (Jan. 19, 2017) (Proposed Rule). EPA has since
23 reversed course, announcing its belief that it "may . . . exclude [from a section 6(b) risk
24 evaluation] certain activities that EPA has determined to be conditions of use in order to
25 focus . . . on those exposures that are likely to present the greatest concerns." Procedures
26 for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act: Final
27 Rule, 82 Fed. Reg. 33,726, 33,729 (July 20, 2017); *see also* Mot. to Dismiss 9. Amici do not
28 believe that limiting interpretation is permissible, and have challenged it. *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) (transfer pending
to 4th Circuit).

1 promulgating restrictions that remove “such” risk. 15 U.S.C. § 2605(a). If EPA does not
2 grant the petition, a petitioner then has a chance to demonstrate to a court that “an”
3 unreasonable risk from the chemical exists. *Id.* § 2620(b)(4)(A)-(B). If, at the end of the
4 section 21 proceeding, the court finds “an” unreasonable risk, then the court directs
5 EPA to initiate a section 6(a) rulemaking to remove that risk. *Id.* § 2620(b)(4)(B). A
6 chemical may present “an” unreasonable risk under its conditions of use, *id.*, if even a
7 single condition of use presents such a risk. EPA has recognized this. *See* Proposed Rule,
8 82 Fed. Reg. at 7568 (“EPA recognizes that under certain circumstances it may be
9 necessary to expedite an evaluation for a particular condition of use to move more
10 rapidly to risk management under TSCA section 6(a) . . . this could include a situation
11 in which a single use presented an unreasonable risk of injury for the population as a
12 whole or for a susceptible subpopulation . . .”).

13 But when a court rules *against* a section 21 petitioner, the court does not make a
14 finding that the chemical does not present an unreasonable risk. The court finds only
15 that the petitioner has failed to “demonstrate[] [such a risk] to the satisfaction of the
16 court.” 15 U.S.C. § 2620(b)(4)(B).

17 Risk evaluations under section 6(b) work differently. When EPA finalizes a
18 section 6(b) risk evaluation, the agency must make one of two determinations: either
19 that the chemical “*presents an unreasonable risk*” or that the chemical “*does not present*
20 *an unreasonable risk.*” *Id.* § 2605(i) (emphases added). This is different from a section 21
21 court’s determination that the *petitioner* has or has not not *demonstrated* such a risk. *Id.* §
22 2620(b)(4)(B). The section 21 court’s determination is critically narrower than EPA’s,
23 *contra* Mot. to Dismiss 10; the court, unlike EPA, never would determine that a chemical
24 *does not* present an unreasonable risk.

25 Given the broader scope of EPA’s determination, Congress required EPA’s risk
26 evaluation under section 6(b) to be comprehensive, while a court’s adjudication under
27 section 21 is not. The finding that EPA (but only EPA) may make—that a chemical *does*
28

1 *not* present any unreasonable risk under any condition of use—logically can be made
2 only if all the chemical’s uses are evaluated.

3 This difference has an important legal consequence as well: an EPA finding that a
4 chemical “does not present an unreasonable risk” may preempt state-law restrictions of
5 the chemical. *See* 15 U.S.C. § 2617(a)(1)(B)(i). The same is not true for a judicial finding
6 that a petitioner has not demonstrated an unreasonable risk. It is thus no wonder that
7 Congress required EPA’s section 6(b) risk evaluations to consider all of a chemical’s
8 conditions of use, while requiring a court in a section 21 proceeding to decide the
9 narrower question of whether the petitioner “has demonstrated to the satisfaction of the
10 court . . . *an* unreasonable risk.” *Id.* § 2620(b)(4)(B) (emphasis added).

11 To the extent EPA now implies that every section 6(a) rule must address all
12 unreasonable risks that the chemical may present—and that, therefore, a section 21
13 petition must be denied unless it addresses every condition of use of the chemical, *see*
14 *Mot. to Dismiss 11*—the agency is arguing out of both sides of its mouth. EPA has
15 elsewhere explained that, in “a situation in which a single use presented an
16 unreasonable risk of injury”—for example, where “one use results in risks that EPA
17 would determine unreasonable *regardless of the risk posed by other uses*”—EPA may
18 “move more rapidly to risk management under TSCA section 6(a)” for that condition of
19 use. Proposed Rule, 82 Fed. Reg. at 7568 (emphasis added); *see also* Final Rule, 82 Fed.
20 Reg. at 33,744 (July 20, 2017) (reaffirming that in conducting a risk evaluation, EPA may
21 make an “early determination on one or more conditions of use”). Indeed, even in
22 denying plaintiffs’ section 21 petition here, EPA stated that “the amended TSCA
23 authorizes EPA to issue TSCA section 6 rules that are not comprehensive of the
24 conditions of use.”⁴ Fluoride Chemicals in Drinking Water; TSCA Section 21 Petition;
25 Reasons for Agency Response, 82 Fed. Reg. 11,878, 11,880 (Feb. 27, 2017).

26 ⁴ Piecemeal determinations that particular uses do *not* present unreasonable risks
27 may overlook aggregate and cumulative risks from those different uses. For that reason,
28 amici disagree with EPA’s assertion that it can make piecemeal, “early determination[s]”
[Proposed] Amicus Br. of NRDC and SCHF
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1 This makes sense: Congress would not likely have barred EPA from addressing
 2 an *identified* and *unreasonable* risk simply because EPA had not finished evaluating
 3 other, less obvious potential risks. And read carefully, EPA’s motion to dismiss does not
 4 conflict with this view, for EPA asserts only that a section 6(a) rule “must eliminate any
 5 unreasonable risks *that have been identified*.” Mot. to Dismiss 11 (emphasis added). This
 6 assertion simply does not support EPA’s conclusion that all those risks must have been
 7 identified for a section 21 petition to succeed.⁵

8 **III. EPA’s inflated and unsubstantiated concerns about unmanageability do not**
 9 **justify reading additional requirements into section 21**

10 EPA offers two policy arguments for its revisionary reading of section 21, but
 11 neither survives a clear-eyed examination. Even if the policy arguments were
 12 persuasive, moreover, they would not give the court power to rewrite the statute. *Baker*
 13 *Botts L.L.P. v. ASARCO LLC*, 135 S. Ct. 2158, 2169 (2015).

14 First, Congress carefully guarded against EPA’s stated worry that petitioners will
 15 “promote chemicals of particular concern to them over other chemicals that may well
 16 present greater overall risk.” Mot. to Dismiss 12. Section 21 gives courts explicit power

17 _____
 18 that a chemical does not present an unreasonable risk under particular uses before
 19 completing a full section 6(b) risk evaluation. Final Rule, 82 Fed. Reg. at 33,729; *see also*
 20 *supra* n.3. That concern does not arise with respect to a section 21 petition to regulate only
 21 one use, because a court is asked only to adjudicate whether the petitioner has shown
 22 that a risk exists, not to determine that there is no risk for the chemical substance as a
 23 whole.

24 ⁵ Section 6(a)’s first clause (“If [EPA] determines in accordance with subsection
 25 (b)(4)(A) . . .”) reflects that EPA’s duty to issue a section 6(a) rule typically is triggered by
 26 an EPA risk evaluation under section 6(b)(4)(A). 15 U.S.C. § 2605(a). But as explained
 27 *supra*, that is not the only route to a section 6(a) rulemaking. Under section 21(b), when a
 28 court finds that a chemical presents “an unreasonable risk” to health or the environment,
 the *court* orders EPA to promulgate a section 6(a) rule. *Id.* § 2620(b)(4)(B). EPA
 acknowledges this. *See* Mot. to Dismiss 4 (“[A] petition . . . asks EPA to jump immediately
 to . . . promulgat[ing] a regulation,” without conducting a full risk evaluation.).

1 to allow EPA to defer a section 6(a) rulemaking if the risk identified by the petitioner “is
 2 less than” the risks “with respect to which [EPA] is taking action” and EPA lacks the
 3 resources to take both sets of actions. 15 U.S.C. § 2620(b)(4)(B)(ii). Courts need not let
 4 section 21 petitions push higher-priority chemicals aside.

5 Second, EPA likewise overstates the concern that petitions “based on analysis of
 6 a single condition of use” will force “‘catch-up’ risk evaluation[s]” and upset EPA’s
 7 “orderly” risk-evaluation process. Mot. to Dismiss 11. When a court grants a section 21
 8 petition for a section 6(a) rule, the court directs EPA “to initiate the action requested by
 9 the petitioner,” 15 U.S.C. § 2620(b)(2)(B)—that is, to initiate a section 6(a) rulemaking.
 10 The court does *not* order EPA to conduct a “catch up” section 6(b) risk evaluation of
 11 uses of the chemical that are not addressed by the petition. Nor does EPA have a duty
 12 to conduct such a comprehensive section 6(b) risk evaluation in response to a section 21
 13 order. *Cf. supra* pp. 6-8. Notwithstanding EPA’s puzzling implication that section 6(c)
 14 imposes such a duty, that subsection requires EPA to timely issue section 6(a) rules after
 15 section 6(b) risk evaluations, not the other way around. *Compare* Mot. to Dismiss 11,
 16 *with* 15 U.S.C. § 2605(c)(1). EPA’s overstated manageability concerns do not justify
 17 judicial imposition of requirements on section 21 petitions that Congress omitted.

18 **IV. Alternatively, because section 21 judicial review is de novo, a petition need not**
 19 **include all evidence the petitioner will introduce in court**

20 Even if EPA were correct (although it is not, *see supra*, Arguments I-III) that a
 21 section 21 judicial proceeding must evaluate risks from all uses of a chemical—
 22 including uses that the petitioner does not ask EPA to regulate—EPA would be wrong
 23 that a section 21 *petition* must include evidence evaluating those other uses.

24 EPA’s theory depends not only on its incorrect claim that a section 21 petitioner
 25 must evaluate risks from all uses of a chemical, but also on its premise that a section 21
 26 judicial proceeding is “limited to the administrative record.” Mot. to Dismiss 1 n.1. EPA
 27 provides no support for this premise, however, other than *ipse dixit*. *See id.* Yet the
 28 premise is essential to the agency’s claim that a court must dismiss a section 21

1 complaint unless the underlying petition “on its face” “provide[s] enough information
2 to allow . . . the [c]ourt to evaluate” the chemical. *Id.* at 8.

3 EPA’s assumption of record-review cannot be reconciled with section 21’s “de
4 novo” judicial review standard. 15 U.S.C. § 2620(b)(4)(B). While judicial review under
5 the Administrative Procedure Act (APA) must, “save in rare instances, . . . be conducted
6 on the administrative record,” section 21 does not incorporate that standard. *Reilly*, 909
7 F.2d at 1506. Instead, a court proceeding under section 21 decides for itself—“by a
8 preponderance of the evidence” and “de novo” —whether TSCA’s unreasonable-risk
9 standard is met. 15 U.S.C. § 2620(b)(4)(B).

10 EPA’s disregard for this statutory standard—and its failure to inform this Court
11 of appellate precedent that rejects the agency’s assertion that section 21 litigations are
12 limited to an administrative record, *compare* Mot. to Dismiss 1 n.1, *with Reilly*, 909 F.2d
13 at 1506—is troubling. EPA does not even try to explain why “de novo” in section 21
14 means anything other what it normally means: “a fresh, independent determination”
15 that “is not limited to or constricted by the administrative record.” *Doe v. United States*,
16 821 F.2d 694, 697-98 (D.C. Cir. 1987). Given this established meaning, appellate courts,
17 including the Ninth Circuit, do not find error when district courts consider extra-record
18 evidence in de novo proceedings. *See, e.g., Wong v. United States*, 859 F.2d 129, 132-33
19 (9th Cir. 1988); *see also, e.g., Saunders v. United States*, 507 F.2d 33, 36 (6th Cir. 1974). And
20 consistent with that meaning, TSCA’s legislative history confirms that Congress
21 understood that section 21 plaintiffs in de novo proceedings would introduce evidence,
22 rather than be limited to an administrative record. *See* S. Rep. No. 94-698, at 9 (1976)
23 (stating that in a section 21 case the court would make a decision “after gathering
24 evidence in a de novo procedure”); *cf.* H.R. Conf. Rep. No. 94-1679, at 98 (1976) (stating
25 that the de novo proceeding “affords greater rights to a person petitioning for the
26 issuance of a rule or order because in such a situation [EPA] will not previously have
27 addressed the issue”).

1 EPA's assertion that a section 21 *petition* must provide all information necessary
2 for a court to rule for the plaintiff, Mot. to Dismiss 8, runs headlong into the statute's de
3 novo standard. Because a section 21 plaintiff may introduce evidence in the court case,
4 the underlying administrative petition need not include all the petitioner's evidence. In
5 this sense, the petition acts more like a district court complaint than a summary
6 judgment filing: while the petition must state the "facts" that the petitioner "claim[s]"
7 are necessary to establish an unreasonable risk from the chemical, *see* 15 U.S.C.
8 § 2620(b)(1), the petition need not contain all the evidence supporting those claimed
9 facts. Evidence establishing that a chemical poses "an" unreasonable risk may instead
10 be submitted during a subsequent section 6(a) rulemaking proceeding (if EPA grants
11 the petition) or in a de novo court proceeding (if EPA does not).

12 **CONCLUSION**

13 For these reasons, the Court should not read into section 21 a requirement that a
14 petition for a section 6(a) rule must evaluate all of a chemical's conditions of use.

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Respectfully submitted,

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[Proposed] Amicus Br. of NRDC and SCHF

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