

**IN THE UNITED STATES COURT OF APPEALS  
FOR THE FIFTH CIRCUIT**

United States Court of Appeals  
Fifth Circuit

**FILED**

March 1, 2021

Lyle W. Cayce  
Clerk

\_\_\_\_\_  
No. 17-60836  
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TEXAS ASSOCIATION OF MANUFACTURERS; TEXAS CHEMICAL  
COUNCIL; TEXAS ASSOCIATION OF BUSINESS; NATIONAL  
ASSOCIATION OF MANUFACTURERS; AMERICAN CHEMISTRY  
COUNCIL,

Petitioners

v.

UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION,

Respondent

\_\_\_\_\_  
On Petition for Review of an Order of the  
Consumer Product Safety Commission  
\_\_\_\_\_

Before OWEN, Chief Judge, and SOUTHWICK and HIGGINSON, Circuit  
Judges.

PRISCILLA R. OWEN, Chief Judge:

Pursuant to the Consumer Product Safety Improvement Act (CPSIA), the Consumer Product Safety Commission was tasked with studying the effects of phthalates in children's toys and child care articles. The Commission issued a final rule prohibiting the manufacture and sale of any children's toy or child care article that contains concentrations of more than 0.1 percent of any one of five phthalates. Petitioners seek direct review in this court, arguing

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that the Commission failed to give an adequate opportunity for comment, failed to apply the proper procedural standards, redefined the substantive standards, and arbitrarily and capriciously applied the scientific data. The Commission moves to dismiss or transfer the case for lack of jurisdiction. We hold that we have jurisdiction to review the rule and that the Commission procedurally erred in promulgating the final rule. In other respects, we affirm, and we remand to the Commission.

**I**

In 1972, Congress enacted the Consumer Product Safety Act (CPSA)<sup>1</sup> in order to “protect the public against unreasonable risks of injury associated with consumer products.”<sup>2</sup> The CPSA established the Consumer Product Safety Commission,<sup>3</sup> which “promulgate[s] consumer product safety standards”<sup>4</sup> and declares when a product is a “banned hazardous product.”<sup>5</sup>

In 2008, Congress enacted the Consumer Product Safety Improvement Act (CPSIA),<sup>6</sup> which, among other things, directed the Commission to promulgate rules banning or regulating the use of phthalates in children’s toys and child care articles.<sup>7</sup> Phthalates are “a class of organic compounds used primarily” to soften and add flexibility to plastic.<sup>8</sup> Some phthalates have antiandrogenic effects—that is, they affect the male reproductive system and can suppress the production of testosterone and normal development.<sup>9</sup>

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<sup>1</sup> Consumer Product Safety Act, Pub. L. No. 92-573, 86 Stat. 1207 (codified as amended at 15 U.S.C. §§ 2051-2089).

<sup>2</sup> 15 U.S.C. § 2051(b).

<sup>3</sup> 15 U.S.C. § 2053.

<sup>4</sup> 15 U.S.C. § 2056.

<sup>5</sup> 15 U.S.C. § 2057.

<sup>6</sup> Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, 122 Stat. 3016 (codified as amended in scattered sections of 15 U.S.C. §§ 2051-2089).

<sup>7</sup> *See, e.g.*, 15 U.S.C. §§ 2056a, 2056b, 2057c.

<sup>8</sup> Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates, 79 Fed. Reg. 78,324, 78,324 (December 30, 2014) (“Proposed Rule”).

<sup>9</sup> Proposed Rule at 78,324; 78,326.

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Congress addressed phthalates in three relevant ways. First, the CPSIA made it unlawful to “manufacture for sale, offer for sale, distribute in commerce, or import into the United States any children’s toy or child care article that contains concentrations of more than 0.1 percent” of three phthalates: di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP).<sup>10</sup> Second, the CPSIA included an interim prohibition on “any children’s toy that can be placed in a child’s mouth or child care article that contains concentrations of more than 0.1 percent” of three other phthalates: diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP).<sup>11</sup> Third, the CPSIA directed the Commission to promulgate a final rule regarding phthalates.<sup>12</sup> By its terms, the interim prohibition remained in place until the Commission promulgated a final rule.<sup>13</sup>

To aid the rulemaking process, Congress directed the Commission to appoint a Chronic Hazard Advisory Panel (CHAP) to “study the effects on children’s health of all phthalates and phthalate alternatives as used in children’s toys and child care articles.”<sup>14</sup> The CHAP was charged with examining “the full range of phthalates that are used in products for children”<sup>15</sup> and then preparing a report for the Commission with its findings and recommendations.<sup>16</sup> After receiving the CHAP’s report, the Commission was directed to:

(A) determine, based on such report, whether to continue in effect [the interim prohibition], in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety; and

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<sup>10</sup> 15 U.S.C. § 2057c(a).

<sup>11</sup> *Id.* § 2057c(b)(1).

<sup>12</sup> *Id.* § 2057c(b)(3).

<sup>13</sup> *Id.* § 2057c(b)(1).

<sup>14</sup> *Id.* § 2057c(b)(2)(A).

<sup>15</sup> *Id.* § 2057c(b)(2)(B).

<sup>16</sup> *Id.* § 2057c(b)(2)(C).

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(B) evaluate the findings and recommendations of the [CHAP] and declare any children's product containing any phthalates to be a banned hazardous product under section 8 of the [CPSA], as the Commission determines necessary to protect the health of children.<sup>17</sup>

Pursuant to the CPSIA, the Commission appointed a CHAP,<sup>18</sup> which assessed the risks of phthalates in combination and in isolation.<sup>19</sup> For its cumulative risk assessment, the CHAP employed a hazard index (HI).<sup>20</sup> To determine the HI, the CHAP first calculated the hazard quotient (HQ) for each phthalate by dividing the actual exposure to a particular phthalate by an estimate of the level of exposure that would generally be acceptable.<sup>21</sup> An HQ greater than one might cause "concern for antiandrogenic effects in the exposed population due to the effect of an individual phthalate."<sup>22</sup> Then, the CHAP combined the HQs of the individual phthalates to determine the cumulative HI.<sup>23</sup> The effects of active phthalates are additive in that doses of different phthalates can combine to produce effects.<sup>24</sup> Accordingly, if an individual's cumulative HI is greater than one, "there may be concern for antiandrogenic effects."<sup>25</sup>

To determine the level of exposure that is acceptable or "negligible," the CHAP relied on three case studies examining the effects of phthalates in rodents.<sup>26</sup> Next, the CHAP divided the no-effect level in rodents by ten to

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<sup>17</sup> *Id.* § 2057c(b)(3).

<sup>18</sup> Proposed Rule at 78,325.

<sup>19</sup> Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, 82 Fed. Reg. 49,938, 49,957 (Oct. 27, 2017) (codified at 16 C.F.R. § 1307) ("Final Rule").

<sup>20</sup> Proposed Rule at 78,327.

<sup>21</sup> *Id.* at 78,328.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.* at 78,326.

<sup>25</sup> Final Rule at 49,957.

<sup>26</sup> Proposed Rule at 78,326; *see* Final Rule at 49,951.

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extrapolate from rodents to humans.<sup>27</sup> Due to the differences in how members of the same species may react to a chemical, the CHAP divided that number by ten again.<sup>28</sup> As a result, the CHAP used a no-effect level for humans that was 100 times lower than that for rodents.

The CHAP used data from three surveys to determine how much exposure humans actually have to phthalates, two involving human-biomonitoring (HBM) and one involving exposure scenario analysis.<sup>29</sup> First, the CHAP used the Department of Health and Human Services' National Health and Nutrition Examination Survey (NHANES).<sup>30</sup> The NHANES is an HBM survey that measures phthalates and other chemicals in human urine and blood based on spot sampling of pregnant women.<sup>31</sup> For the second study, the CHAP used the Study for Future Families (SFF), an HBM study of mother-child pairs before and after birth by the National Institutes for Health and the Environmental Protection Agency.<sup>32</sup> Finally, the CHAP relied on a scenario-based method to provide information on sources of exposure.<sup>33</sup>

The Commission responded to general comments about its use of HBM data collected via spot sampling, concluding that it could extrapolate average daily exposure based on the spot sampling data.<sup>34</sup> More specifically, the Commission maintained that the spot samples were collected at different sites, at different times of day, and on different days of the week, and participants were selected randomly, and therefore, the data is representative of "estimated

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<sup>27</sup> Final Rule at 49,952.

<sup>28</sup> *Id.*

<sup>29</sup> Proposed Rule at 78,327.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> Final Rule at 49,955.

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population per capita phthalate exposure across the 2-year NHANES cycle.”<sup>35</sup> Spot tests cannot differentiate between sources of phthalates, and most studies conclude that “food, rather than children’s toys or child care articles, provides the primary source of exposure.”<sup>36</sup> Moreover, phthalates are metabolized quickly and the amount of phthalates detected “depends to a large extent on . . . how long it has been since the last meal.”<sup>37</sup> Applying the NHANES and SFF data, the CHAP determined that “up to 10 percent of pregnant women and up to 5 percent of infants” had an HI greater than one.<sup>38</sup>

The CHAP recommended that the Commission lift the interim prohibition on two phthalates—DIDP and DnOP.<sup>39</sup> Those phthalates did not contribute to the HI.<sup>40</sup> However, the CHAP recommended that the Commission (1) issue a permanent prohibition for DINP at levels greater than 0.1 percent in all children’s toys and child care articles, not just toys that can be placed in a child’s mouth;<sup>41</sup> and (2) issue a permanent prohibition on children’s toys and child care articles containing diisobutyl phthalate (DIBP), di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), and dicyclohexyl phthalate (DCHP) at levels greater than 0.1 percent.<sup>42</sup> DIBP, DPENP, DHEXP, and DCHP were not prohibited by the CPSIA, but the CHAP

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<sup>35</sup> *Id.*

<sup>36</sup> Proposed Rule at 78,327.

<sup>37</sup> Minutes of Commission Meeting Re: Final Phthalates Rules, Index No. 462 (Oct. 18, 2017) (Statement of Comm’r A. Buerkle), [https://www.cpsc.gov/s3fs-public/ACHBuerklesPhthalatesfinalrulestatement10302017.pdf?1N0bigFnYyn\\_CGtgCEGQ\\_ZJrjTnsjv3RO](https://www.cpsc.gov/s3fs-public/ACHBuerklesPhthalatesfinalrulestatement10302017.pdf?1N0bigFnYyn_CGtgCEGQ_ZJrjTnsjv3RO); see also CHAP at 75, <https://www.cpsc.gov/s3fs-public/CHAP-REPORT-With-Appendices.pdf>.

<sup>38</sup> Proposed Rule at 78,328.

<sup>39</sup> *Id.* at 78,329-30.

<sup>40</sup> *See id.*

<sup>41</sup> *Id.* at 78,329.

<sup>42</sup> *Id.* at 78,330.

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concluded that “they contribute to the cumulative risk” and should be prohibited permanently.<sup>43</sup>

The Commission issued a proposed rule (Proposed Rule) that implemented the CHAP’s recommendations.<sup>44</sup> In explaining its rationale for the Proposed Rule, the Commission agreed with the CHAP that “the acceptable risk is exceeded when the HI is greater than one.”<sup>45</sup> Accordingly, the Commission decided that an HI less than one “is necessary ‘to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.’”<sup>46</sup> The Commission found it particularly pertinent that the HI was greater than one for ten percent of pregnant women, and the HI at the 95th percentile was five.<sup>47</sup>

After publication of the Proposed Rule, the NHANES released updated data sets.<sup>48</sup> Using the new data, the Commission had its staff “replicate the CHAP’s methodology.”<sup>49</sup> However, unlike the CHAP, which studied pregnant women, the staff “used women of reproductive age” (WORA) due to a lack of data on pregnant women.<sup>50</sup> The staff found that the risk decreased with the updated data.<sup>51</sup> The HI at the 95th percentile was now less than one.<sup>52</sup> The staff estimated that, using the updated data, between 98.8 and 99.6 percent of WORA had HIs less than or equal to one.<sup>53</sup> The staff was “unable to estimate

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<sup>43</sup> *Id.* It also appears that DPENP, DHEXP, and DCHP were not included in the HI metric. *Id.* at 78,328 (Table 1 “summarized” the CHAP’s findings and did not include those phthalates.).

<sup>44</sup> *Id.* at 78,343.

<sup>45</sup> *Id.* at 78,334.

<sup>46</sup> *Id.*

<sup>47</sup> *See, e.g., id.* at 78,328, 78,332-33.

<sup>48</sup> Final Rule at 49,939.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at 49,958.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*; *see also id.* at 49,963 (“CPSC staff determined that approximately 99 percent of WORA in the U.S. population now have an HI less than or equal to one.”).

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the percentage of WORA with an HI greater than one,”<sup>54</sup> but noted that “between two and nine real women from the sample of 538 WORAs had an HI greater than one.”<sup>55</sup>

The Commission concluded that “phthalate exposures and risks in WORA probably underestimate the risks to infants and children” because “infants’ exposures generally are two- to threefold greater than adults.”<sup>56</sup> The Commission also noted that exposure to DINP increased “approximately five-fold” since the CHAP’s report, despite the decrease in exposure to phthalates on the whole.<sup>57</sup> Based on the new data, the Commission, by a 3-2 vote,<sup>58</sup> promulgated a final rule (Final Rule) substantively identical to the Proposed Rule.<sup>59</sup> The Final Rule prohibits “the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any children’s toy or child care article that contains concentrations of more than 0.1 percent of [DINP], [DIBP], [DPENP], [DHEXP], and [DCHP].”<sup>60</sup> To summarize, the Final Rule (1) makes the CPSIA’s interim prohibition on DINP permanent, (2) extends the scope of the CPSIA’s interim prohibition on DINP to “any children’s toy or child care article,” and (3) prohibits four phthalates not prohibited by the CPSIA: DIBP, DPENP, DHEXP, and DCHP.<sup>61</sup>

Petitioners, trade associations representing chemical manufacturers, now seek direct review in this court. Natural Resources Defense Council, Inc., Environmental Justice Health Alliance for Chemical Policy Reform, and

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<sup>54</sup> *Id.* at 49,958.

<sup>55</sup> *Id.* at 49,961.

<sup>56</sup> *Id.* at 49,958.

<sup>57</sup> *Id.* at 49,963.

<sup>58</sup> *Id.* at 49,938 n.1.

<sup>59</sup> *Id.* at 49,982.

<sup>60</sup> *Id.*

<sup>61</sup> *Compare id.*, with 15 U.S.C. § 2057c(b)(1).



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Breast Cancer Prevention Partners (Intervenors) intervened in support of the Final Rule.

II

As a threshold matter, we address two challenges to our jurisdiction. Intervenors assert that the Petitioners lack standing to pursue these claims. The Commission also moved to dismiss this action, arguing that we lack jurisdiction because the Final Rule is not a “consumer product safety rule,” and we therefore lack statutory authorization for direct review.

A

Petitioners bear the burden of showing they have standing for each type of relief sought.<sup>62</sup> To establish standing to seek injunctive relief, the plaintiff must show

(1) it has suffered an “injury in fact” that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.<sup>63</sup>

Petitioners are five trade associations that seek to establish standing using a theory of associational standing. Associations may assert the standing of their own members.<sup>64</sup> “An association has standing to bring a suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization’s purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.”<sup>65</sup> The only issue in this case is whether

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<sup>62</sup> *Summers v. Earth Island Institute*, 555 U.S. 488, 493 (2009).

<sup>63</sup> *Friends of the Earth, Inc. v. Laidlaw Env’tl Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)).

<sup>64</sup> *Summers*, 555 U.S. at 494.

<sup>65</sup> *Friends of the Earth*, 528 U.S. at 181.

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any member of the Petitioner associations has standing to bring the claim in its own right.

According to Intervenors, Petitioners have not established that “at least one identified member ha[s] suffered or would suffer harm” from the Final Rule. In response, Petitioners attached to their Reply Brief an additional affidavit by Christopher Wallace, an employee of ExxonMobil Chemical Company (EMCC). EMCC is a member of Texas Chemical Council (TCC), one of the Petitioners. Even without the additional affidavit, the record demonstrates that EMCC is a producer of DINP. It is less clear, however, whether EMCC manufactures DINP for the use in products that will become children’s toys or child care articles. The record does not contain any indication that EMCC’s products are used or have been used in children’s toys or child care articles. The injury need not be actualized; a threatened injury suffices if it is “real, immediate, and direct.”<sup>66</sup> A high risk of economic injury is sufficiently real, immediate, and direct.<sup>67</sup> The Supreme Court routinely recognizes probable economic injury resulting from governmental actions that alter competitive conditions.<sup>68</sup> While the issue is a close one, we are satisfied that the threat of reduced sales to companies that manufacture children’s toys and child care articles is sufficiently concrete that EMCC, and by proxy TCC, has standing to challenge the Final Rule as it relates to DINP.

Petitioners further argue that they have standing because of the “stigma” inflicted by the Final Rule. According to one affidavit, in response to pressure from groups citing the Commission’s rulemaking process, major flooring retailers announced they would no longer carry flooring tile that

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<sup>66</sup> *Davis v. Federal Election Com’n*, 554 U.S. 724, 734 (citing *Los Angeles v. Lyons*, 461 U.S. 95 (1983)).

<sup>67</sup> *Pac. Gas & Elec. Co. v. FERC*, 106 F.3d 1190, 1195 (5th Cir. 1997).

<sup>68</sup> *Clinton v. City of New York*, 524 U.S. 417, 433 (1998) (quoting 3 K. Davis & R. Pierce, *Administrative Law Treatise* 13-14 (3d ed. 1994)).

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contains phthalates. EMCC experienced losses in its flooring market revenue that it attributes to the Final Rule. Petitioners argue that we should apply the same standards as the D.C. Circuit when assessing whether these facts support standing.<sup>69</sup> In *Tozzi*, the Department of Health and Human Services published a revised list of substances known or reasonably anticipated to cause cancer and upgraded the chemical “dioxin” from “reasonably anticipated” to “known.”<sup>70</sup> The petitioner, a manufacturer of medical devices that emit dioxin when incinerated, sued to vacate the rule.<sup>71</sup> The D.C. Circuit held that the petitioner had standing because the agency’s action was a “substantial factor” in the decisions of purchasers to reduce or end purchases of PVC plastics contained in the petitioner’s devices.<sup>72</sup> Further, the court noted that “[w]hen the government attaches an inherently pejorative and damaging term such as ‘carcinogen’ to a product, the probability of economic harm increases exponentially.”<sup>73</sup>

According to Petitioners, CPSC’s decision to prohibit certain phthalates from children’s toys and child care articles is likewise a “substantial factor” in causing EMCC’s economic injury. We agree. EMCC’s evidence of lost sales sufficiently demonstrates an injury in fact traceable to the Final Rule. Accordingly, TCC has demonstrated that it has standing to challenge the Final Rule as it relates to DINP. Even though the other petitioners have not named members that manufacture the prohibited phthalates, the presence of one petitioner with standing is sufficient for Article III purposes.<sup>74</sup>

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<sup>69</sup> See *Tozzi v. United States Dep’t of Health and Human Servs.*, 271 F.3d 301 (2001).

<sup>70</sup> *Id.* at 303.

<sup>71</sup> *Id.* at 306-08.

<sup>72</sup> *Id.* at 309.

<sup>73</sup> *Id.*

<sup>74</sup> *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 52 n.2 (2006).

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However, standing is not dispensed in gross; plaintiffs must demonstrate standing “for each claim [t]he[y] seek[] to press” and “for each form of relief that is sought.”<sup>75</sup> Defining a “claim” in this context is somewhat elusive.<sup>76</sup> For example, the Supreme Court in *Blum v. Yaretsky* held that plaintiffs had standing to challenge one aspect of the Medicaid Act but not others.<sup>77</sup> In *Blum*, nursing home patients brought suit after the state of New York determined that they no longer needed the care they were receiving and should be transferred to a lower level of care.<sup>78</sup> The Court agreed that the patients had standing to challenge the decision to transfer them to a lower level of care but held that they could not challenge the procedures for transferring patients to higher levels of care because “[n]othing in the record . . . suggest[ed] that any of the individual respondents [had] been” transferred to higher care, and “assessing the possibility now would ‘tak[e] [the Court] into the area of speculation and conjecture.’”<sup>79</sup>

On the other hand, in *Davis v. Federal Election Commission*, a candidate had standing to challenge both the asymmetrical contribution limitations under § 319(a) of the Bipartisan Campaign Reform Act of 2002<sup>80</sup> and the disclosure requirements under § 319(b) when the record indicated that the limits likely would have applied to the candidate.<sup>81</sup> Section 319 created rules

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<sup>75</sup> *Davis v. Federal Election Comm’n*, 554 U.S. 724, 734 (2008) (internal quotation marks omitted) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006)).

<sup>76</sup> See 13B CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FED. PRACTICE & PROC. § 3531.16 Scope Of Standing, (3d ed.) (“It is easy enough to agree that a challenge to a state tax abatement is a claim separate from a challenge to a municipal tax abatement. Equally easy distinctions will be drawn in other cases. But still other cases will present difficult line-drawing challenges.”).

<sup>77</sup> 457 U.S. 991 (1982).

<sup>78</sup> *Id.* at 995.

<sup>79</sup> *Id.* at 1001 (third alteration in original) (quoting *O’Shea v. Littleton*, 414 U.S. 488, 497 (1974)).

<sup>80</sup> 116 Stat. 109 (codified at 52 U.S.C. § 30117).

<sup>81</sup> *Davis*, 554 U.S. at 733-35.

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that applied to self-funding candidates contributing more than \$350,000 of their own funds to the campaign.<sup>82</sup> The candidate intended to contribute more than \$350,000 and made the disclosures required by subsection (b), giving him standing to challenge that provision.<sup>83</sup> The Federal Election Commission argued that the candidate did not have standing to challenge the asymmetrical contribution limits because they did not apply at the outset of the suit or at any point in time during the race at issue.<sup>84</sup> The Court held that there was a sufficient probability that the asymmetrical contribution limits would apply, and accordingly the candidate could challenge both provisions.<sup>85</sup>

The Ninth Circuit has held that an Americans with Disabilities Act plaintiff who was impeded by obstacles at one store could challenge all the obstacles to his mobility at that store, even the ones he was not aware of at the time he brought the suit.<sup>86</sup> That decision relied partially on the Supreme Court's instructions that courts take a "broad view of constitutional standing in civil rights cases," but the decision focused on whether the plaintiff had a sufficient personal stake "as to assure that concrete adverseness which sharpens the presentation of issues" upon which the court must rule.<sup>87</sup>

In an analogous case, the D.C. Circuit held that plaintiffs had standing to challenge every aspect of a Bureau of Land Management (BLM) decision that aggrieved them.<sup>88</sup> In *WildEarth Guardians*, an environmental group challenged the BLM's decision to issue a lease to mine federal lands in Wyoming, arguing that the mine would injure their aesthetic and recreational

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<sup>82</sup> 52 U.S.C. § 30117(a)(1).

<sup>83</sup> *Davis*, 554 U.S. at 733.

<sup>84</sup> *Id.* at 734.

<sup>85</sup> *Id.* at 734-35.

<sup>86</sup> *Doran v. 7-Eleven, Inc.*, 524 F.3d 1034, 1041-44 (9th Cir. 2008).

<sup>87</sup> *Id.* at 1043 (citations omitted).

<sup>88</sup> *WildEarth Guardians v. Jewell*, 738 F.3d 298, 309 (D.C. Cir. 2013)

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interests.<sup>89</sup> Plaintiffs claimed a procedural injury, alleging that the Environmental Impact Statement (EIS) was deficient in its consideration of local pollution and global greenhouse gas emissions.<sup>90</sup> The district court and the D.C. Circuit agreed that plaintiffs had standing to challenge the EIS with respect to local pollution because “the local pollution that causes their members’ aesthetic and recreational injuries follows inexorably from the decision to authorize leasing” on the tract.<sup>91</sup> The district court held that the organization did not have standing to challenge the global greenhouse emissions because those emissions did not affect the aesthetic and recreational interests; the circuit court disagreed.<sup>92</sup> According to the D.C. Circuit, the plaintiffs could challenge any alleged deficiencies in the EIS because their injuries were “caused by the allegedly unlawful [lease] and would be redressed by vacatur of the [lease] on the basis of any of the procedural defects identified in the [EIS].<sup>93</sup>

Applying these principles, EMCC has standing to bring its challenge to the Final Rule. The possibility of reduced sales of DINP along with the stigmatic effect of the rule provides standing to pursue its claim. Those injuries were caused by an allegedly unlawful rule and would be redressed by vacatur of the rule on the basis of any of the grounds raised. Further, the claim that CPSC violated various procedural requirements, if successful, would require us to grant relief that would apply to the entirety of the Final Rule, as the portions of the Final Rule pertaining to each individual phthalate are the result of the same administrative decision-making process.

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<sup>89</sup> *Id.* at 302.

<sup>90</sup> *Id.* at 305-06.

<sup>91</sup> *Id.* at 306.

<sup>92</sup> *Id.* at 306-07.

<sup>93</sup> *Id.* at 308.

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**B**

Federal courts of appeals are courts “of limited subject matter jurisdiction . . . authorized to review decisions and orders of administrative agencies only as provided by acts of Congress.”<sup>94</sup> Section 2060(a) of the CPSA provides that “[n]ot later than 60 days after a consumer product safety rule is promulgated by the Commission,” a person may file a petition for “judicial review of such rule” in the court of appeals.<sup>95</sup> The parties contest whether the Final Rule is a “consumer product safety rule” subject to the § 2060(a)’s procedure for judicial review.

Section 2052(a)(6) of the CPSA defines a “consumer product safety rule” as “a consumer products safety standard described in section 2056(a) of this title, or a rule under this chapter declaring a consumer product a banned hazardous product.”<sup>96</sup> In its phthalate provisions, the CPSIA provides that “any rule promulgated under [§ 2057c](b)(3) shall be considered consumer product safety standards under the [CPSA].”<sup>97</sup> The Final Rule was promulgated under § 2057c(b)(3),<sup>98</sup> so, pursuant to the CPSIA, it is a consumer product safety standard under the CPSA.<sup>99</sup> As a consumer product safety standard, the Final Rule is a consumer product safety rule as defined in § 2052(a)(6). The Final Rule is consequently subject to the procedures for judicial review established by § 2060(a).<sup>100</sup> We have jurisdiction to review the Final Rule.

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<sup>94</sup> *Xavier Univ. v. Nat’l Telecomms.*, 658 F.2d 306, 307 (5th Cir. Unit A 1981) (citations omitted).

<sup>95</sup> 15 U.S.C. § 2060(a).

<sup>96</sup> 15 U.S.C. § 2052(a)(6).

<sup>97</sup> 15 U.S.C. § 2057c(f).

<sup>98</sup> Final Rule at 49,940.

<sup>99</sup> *See* 15 U.S.C. § 2057c(f).

<sup>100</sup> 15 U.S.C. § 2060(a).

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Each of the Commission's arguments to the contrary is unavailing. First, the Commission argues that the Final Rule is not a consumer product safety standard *described in section 2056(a)*. That argument ignores that the Final Rule is statutorily defined to be a consumer product safety rule. The Commission's other main argument is that Congress only intended phthalate rules to be consumer product safety rules for purposes of preemption. The subsection of the CPSIA at issue is titled "Treatment as consumer product safety standards; effect on State laws."<sup>101</sup> The subsection's first sentence provides that "any rule[s] promulgated under subsection (b)(3)," including the Final Rule, "shall be considered consumer product safety standards."<sup>102</sup> The second sentence states that "[n]othing in this section or the [CPSA] shall be construed to preempt or otherwise affect any State requirement with respect to any phthalate alternative not specifically regulated in a consumer product safety standard under the [CPSA]."<sup>103</sup> Congress clearly contemplated that it was both defining phthalate rules as consumer product safety standards *and* expressing the scope of preemption. The Commission's argument to the contrary is without merit. Further, the Commission considers the Final Rule to be a consumer product safety standard for purposes of testing and certification requirements under the CPSA.<sup>104</sup> The Commission cannot have its cake and prevent our review by relying on the same provision. The Final Rule is defined by Congress as a consumer product safety standard, and we have jurisdiction to review it.

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<sup>101</sup> 15 U.S.C. § 2057c(f).

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> See 82 Fed Reg 49,767, 49,768 ("The Commission's phthalates rule is considered a 'consumer product safety standard.' 15 U.S.C. 2063c(f).") The Commission cited to 2063c(f) for this proposition but that statute does not exist. Presumably, the Commission meant to cite to § 2057c(f), which defines the phthalate rule as a consumer product safety standard.



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### III

Petitioners ask the court to set aside the Final Rule because, in their view, the Commission failed to give an adequate opportunity to comment on the rulemaking, failed to apply the proper procedural standards, redefined the substantive standards, and arbitrarily and capriciously applied the scientific data. We address each in turn and hold that the Commission procedurally erred by not providing an adequate opportunity to comment on the rule and by failing to consider the costs of a portion of the rule.

#### A

Petitioners argue that the Commission did not provide an adequate opportunity to comment on its use of data at the 99th percentile to justify its prohibition. The APA requires agencies to publish a notice of proposed rulemaking that includes “either the terms or substance of the proposed rule or a description of the subjects and issues involved.”<sup>105</sup> Final rules under APA notice-and-comment rulemaking must be the “logical outgrowth” of the proposed rule.<sup>106</sup> The objective is fair notice.<sup>107</sup> “If interested parties ‘should have anticipated’ that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period, then the rule is deemed to constitute a logical outgrowth of the proposed rule.”<sup>108</sup>

Petitioners do not object to a substantive change in the text of the Proposed Rule and the Final Rule, but to the change in the justification for the

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<sup>105</sup> 5 U.S.C. § 553(b)(3).

<sup>106</sup> *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007) (citations omitted); see also *ConocoPhillips Co. v. EPA*, 612 F.3d 822, 834 (5th Cir. 2010) (citation omitted).

<sup>107</sup> *Long Island*, 551 U.S. at 174.

<sup>108</sup> *American Coke & Coal Chemicals Inst. v. EPA*, 452 F.3d 930, 938-39 (D.C. Cir. 2006) (citing *City of Waukesha v. EPA*, 320 F.3d 228, 245 (D.C. Cir. 2003)).

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Proposed Rule and the justification for the Final Rule. The Commission's primary justification for the Proposed Rule was data demonstrating that ten percent of pregnant women had an HI greater than one, which exceeded the acceptable risk, and that the average HI was five at the 95th percentile.<sup>109</sup> However, when the Commission examined the updated data released after the publication of the Proposed Rule, it found that the risk of antiandrogenic effects had decreased, and that the HI at the 95th percentile had decreased from five to less than one.<sup>110</sup> The Commission could not determine exactly what percentage of the women studied had an HI greater than one,<sup>111</sup> but did state that "between two and nine real women from the sample of 538 WORAs had an HI greater than one."<sup>112</sup> The Commission relied on this new data when promulgating the Final Rule.<sup>113</sup>

According to Petitioners, the Commission did not provide fair notice when it changed its justification for the prohibition from data showing that the average HI was greater than one in the 95th percentile to data including individual spot samples with HIs greater than one.<sup>114</sup> We agree. The Commission's justification for the Proposed Rule was based on data showing that a statistically stable percentage of the women studied had an HI that indicated an unacceptably high risk of antiandrogenic effects. After new data became available, the Commission replicated the CHAP's methodology and determined that there were too few samples with an HI above one to estimate the number of women and children in the general population who are

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<sup>109</sup> Proposed Rule at 78,328, 78,334.

<sup>110</sup> Final Rule at 49,958.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.* at 49,961.

<sup>113</sup> *Id.*

<sup>114</sup> *Compare* Proposed Rule at 78,328, *with* Final Rule at 49,961.

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negatively affected by the phthalates at issue.<sup>115</sup> Because the Commission could no longer justify the rule based on the ten percent of women who had risky exposures, it justified the Final Rule because between two and nine individual samples had HIs deemed unacceptable.

The Commission provided some notice that it was relying on new data and asked for comments.<sup>116</sup> One commenter objected to the use of spot checks at the 99th percentile, and the Commission responded to that comment.<sup>117</sup> The Commission argues that the public was therefore aware that it was “considering the matter,” and the Commission provided sufficient notice under the APA.<sup>118</sup> We disagree. The agency’s rationale for the rule must be made clear and subjected to public comment.<sup>119</sup> In the notices to which the Commission refers, statements about statistically unstable data dominate, and any reference to spot samples is not clearly communicated as a new justification to support the rule and supplant the unstable statistical analysis.<sup>120</sup> Thus, while the Commission did provide some opportunity for comment on its reliance on spot samples, it did not make clear it was inviting comments on the use of spot samples as a new justification for why the Final Rule is necessary to protect the health of children. The fact that one commenter suggested that data above the 95th percentile is too unstable for rulemaking does not relieve the Commission of its burden to provide notice and

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<sup>115</sup> See 80 Fed. Reg. 35,938 (June 23, 2015); 82 Fed. Reg. 11,348 (Feb. 22, 2017).

<sup>116</sup> See 80 Fed. Reg. 35,938; 82 Fed. Reg. 11,348.

<sup>117</sup> Final Rule at 49,961.

<sup>118</sup> See *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 175 (2007).

<sup>119</sup> See *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1212 (5th Cir. 1991).

<sup>120</sup> See 80 Fed. Reg. 35,938; 82 Fed. Reg. 11,348.

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an opportunity to comment on the clearly articulated justification for its use of such data.<sup>121</sup>

Because it was justified with reference to individual spot samples rather than an estimable percentage of the population that had potentially harmful exposure to the phthalates in question, the Final Rule is not a logical outgrowth of the Proposed Rule. As one of the commissioners pointed out, that change in methodology—whether right or wrong—was not reasonably foreseeable based on the Proposed Rule.<sup>122</sup> Accordingly, the Commission violated the APA’s notice-and-comment procedures by not adequately allowing for comment after it changed its primary justification for the rule but before adopting a final rule.

**B**

Petitioners argue that the Final Rule declares five phthalates to be “banned hazardous products” under § 2057c and consequently should have complied with § 2057’s requirements for such a ban. This argument is premised on § 2057c(b)(3)(B), which empowers the Commission to “declare any children’s product containing any phthalates to be a banned hazardous product under Section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).”<sup>123</sup> We review the Commission’s actions under the familiar framework of *Chevron U.S.A. Inc. v. National Resources Defense Council, Inc.*<sup>124</sup>

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<sup>121</sup> See *Fertilizer Inst. V. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) (“The fact that some commenters actually submitted comments suggesting the creation of administrative exemptions is of little significance.”).

<sup>122</sup> Minutes of Commission Meeting Re: Final Phthalates Rules, Index No. 462, at 23 (Oct. 18, 2017) (Statement of Comm’r J. Mohorovic).

<sup>123</sup> 15 U.S.C. § 2057c(b)(3)(B).

<sup>124</sup> *Chevron U.S.A. Inc. v. Nat’l Res. Def. Council, Inc.*, 467 U.S. 837 (1984); *Michigan v. E.P.A.*, 135 S.Ct. 2699, 2707 (“*Chevron* directs courts to accept an agency’s reasonable resolution of an ambiguity in a statute that the agency administers.”).

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The Commission may ban a consumer product under § 2057 when it finds that the product presents an unreasonable risk of injury and “no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury associated with such product.”<sup>125</sup> Section 2057 in turn requires the Commission to comply with § 2058 when declaring products “banned hazardous products.”<sup>126</sup> The Commission indisputably did not comply with § 2058, which requires, among other things, findings as to: (1) “the degree and nature of the risk of injury,” (2) the approximate number of products subject to the rule, and (3) “any means of achieving the objective of the order while minimizing adverse effects on competition.”<sup>127</sup>

The Commission argues that it was not required to comply with § 2058 because it was authorized to promulgate the Final Rule by the CPSIA, which contains its own detailed requirements for rulemaking in § 2057c(b)(3). Section 2057c(b)(3) directs that “the Commission shall, pursuant to section 553 of Title 5, promulgate a final rule.”<sup>128</sup> Section 553 of Title 5 sets forth the general notice-and-comment rulemaking process under Administrative Procedures Act (APA).<sup>129</sup> In addition, § 2057c(b)(3)(B) directs the Commission to “evaluate the findings and recommendations of the [CHAP]” and ban products containing phthalates “as the Commission determines necessary to protect the health of children.”<sup>130</sup> According to the Commission, the specific

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<sup>125</sup> 15 U.S.C. § 2057.

<sup>126</sup> *Id.*

<sup>127</sup> 15 U.S.C. § 2058.

<sup>128</sup> 15 U.S.C. § 2057c(b)(3).

<sup>129</sup> *See* 5 U.S.C. § 553.

<sup>130</sup> 15 U.S.C. § 2057c(b)(3).

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controls over the general,<sup>131</sup> and the specific requirements contained in § 2057c(b)(3) are incompatible with the requirements imposed by § 2058. Further, the Commission argues that if there is ambiguity, its interpretation is entitled to *Chevron* deference.

The Commission's reading of § 2057c is correct. Rather than direct the Commission to follow its general rulemaking procedures, § 2057c(b)(3) authorizes rulemaking under the APA's notice-and-comment procedures. The standard for promulgating rules is also different—whereas § 2058 requires the Commission to find that a product poses “an unreasonable risk of injury” before promulgating a rule,<sup>132</sup> § 2057c(b)(3)(B) requires the Commission to promulgate a phthalate rule on a finding that the rule is “necessary to protect the health of children.”<sup>133</sup> Further, § 2057c(b)(3)(A) empowers the Commission to promulgate a rule continuing Congress's interim prohibition “to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.”<sup>134</sup> While there may be substantial overlap in the standards imposed by § 2057c(b)(3) and § 2058, Congress phrased the standards differently, indicating that Congress intended the standards in § 2057c(b)(3) to apply instead of the standards laid out in § 2058. The Commission did not procedurally err in promulgating the Final Rule pursuant to § 2057c(b)(3).

## C

Alternatively, Petitioners argue that the Commission ignored statutory standards for rulemaking and instead promulgated rules to provide “absolute

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<sup>131</sup> See *United States v. Marshall*, 798 F.3d 296, 318 (5th Cir. 2015) (“[I]t is familiar law that a specific statute controls over a general one.”) (internal quotation marks omitted) (quoting *Bulova Watch. Co. v. United States*, 365 U.S. 753, 758 (1961)).

<sup>132</sup> 15 U.S.C. § 2058.

<sup>133</sup> 15 U.S.C. § 2057c(b)(3)(B).

<sup>134</sup> *Id.* § 2057c(b)(3)(A).

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certainty of no risk.” Subsection (A) empowers the Commission to continue the interim prohibition on DINP “to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.”<sup>135</sup> Subsection (B) of § 2057c(b)(3) empowers the Commission to ban children’s products containing phthalates as “necessary to protect the health of children.”<sup>136</sup> According to Petitioners, the Commission misread these two separate standards together as a mandate to “demand an absolute certainty of no risk.”

In its description of the rationale behind the Final Rule, the Commission cited the standards in § 2057c(b)(3)(A) and (B).<sup>137</sup> In promulgating the specific prohibitions, it referred to the standards applicable to its decision on each phthalate. The Commission continued the prohibition on DINP because the prohibition is “still necessary to ‘ensure a reasonable certainty of no harm’ to children and pregnant women with an ‘adequate margin of safety.’”<sup>138</sup> The Commission also extended the prohibition to all “children’s toy and child care articles,” not just those “that can be placed in a child’s mouth,” because it found that such a rule was necessary both “to ensure a reasonable certainty of no harm and to protect the health of children.”<sup>139</sup> When the Commission determined that it was not necessary to continue the interim prohibition on DNOP and DIDP, it properly employed the “reasonable certainty of no harm” standard.<sup>140</sup> Finally, the Commission referred to the “necessary to protect the

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<sup>135</sup> *Id.*

<sup>136</sup> *Id.* § 2057c(b)(3)(B).

<sup>137</sup> Final Rule at 49,938; 49,957 (“to meet the CPSIA’s criteria of reasonable certainty of no harm and protection of the health of children, it is necessary to prohibit children’s toys and child care articles containing concentrations of more than 0.1 percent of . . . DINP, DIBP, DPENP, DHEXP, and DCHP”).

<sup>138</sup> *Id.* at 49,966.

<sup>139</sup> *Compare id.* at 49,966-67, with 15 U.S.C. § 2057c(b)(1).

<sup>140</sup> Final Rule at 49,968.

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health of children” standard when it finalized its ban on DIBP, DPENP, DHEXP, and DCHP.<sup>141</sup>

1

Petitioners contend that the Commission exceeded its mandate to protect against “harm” and instead issued a Final Rule that protected against “risk.” Risk is “the chance of injury, damage, or loss.”<sup>142</sup> Harm, on the other hand, is actual “[i]njury, loss, damage[,] [or] material or tangible detriment.”<sup>143</sup> According to Petitioners, the Commission overprotected consumers by prohibiting products with phthalates based on evidence of risk, not harm.

We disagree. Adopting the standard used in the CHAP report, the Commission interpreted the phrase “necessary to protect the health of children” to require “an HI less than or equal to one.”<sup>144</sup> The Proposed Rule explained:

If the HI is greater than one, there may be a concern for antiandrogenic effects in the exposed population due to the cumulative effects of phthalates. . . . Having a HI greater than one does not necessarily mean that adverse effects will occur; however, this possibility cannot be ruled out.<sup>145</sup>

Accordingly, the Commission determined that preventing exposure to an HI greater than one was necessary to ensure that adverse effects—i.e., harm—will not occur. The HI method itself is not controversial, though Petitioners argue that the Commission was overly conservative in setting the benchmark.

Petitioners also argue that Congress required only “reasonable certainty,” not “absolute certainty.” In Petitioners’ view, the Commission

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<sup>141</sup> *Id.* at 49,969-70.

<sup>142</sup> *Risk*, BLACK’S LAW DICTIONARY (10th Ed. 2014); *see Risk*, MERRIAM-WEBSTER COLLEGIATE DICTIONARY (11th Ed. 2009) (defining “risk” as “the possibility of loss or injury”).

<sup>143</sup> *Harm*, BLACK’S LAW DICTIONARY (10th ed. 2014).

<sup>144</sup> Final Rule at 49,968.

<sup>145</sup> Proposed Rule at 78,328 & n.8.



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exceeded this mandate when it (a) considered risks at or above the 99th percentile of spot samples, and (b) did not consider costs of the regulation to determine whether the regulation could prevent harm “with reasonable certainty.”

Both parties agree that statistical data above the 99th percentile is not stable, i.e., is not reliable.<sup>146</sup> Petitioners argue that the Commission initially relied on scientifically valid 95<sup>th</sup>-percentile data and then moved the goalposts when there was not significant risk at that level.<sup>147</sup> The Commission responded to this argument in its Final Rule, asserting that the instability at the 99th percentile “mean[s] that [the Commission is] precluded from estimating the precise number of WORA with HIs greater than one in the larger population from which the sample was selected.”<sup>148</sup> Instead, the Commission urges that the rule is “not based on any particular percentile, but on the observation that actual women from the NHANES sample have HIs greater than one.”<sup>149</sup>

In the abstract, protecting the 99th percentile from harm is not per se unreasonable and may be required by subsection (A). The Commission is required to continue the interim prohibition on DINP to “ensure a reasonable certainty of no harm . . . with an adequate margin of safety.”<sup>150</sup> The District of Columbia Circuit recently examined the meaning of a comparable requirement to provide an “ample margin of safety” in *Sierra Club v. EPA*.<sup>151</sup> The EPA had been authorized to set a health threshold for acid gases that included an

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<sup>146</sup> See Final Rule at 49,961.

<sup>147</sup> See Proposed Rule at 78,328, 78,332-33.

<sup>148</sup> Final Rule at 49,961.

<sup>149</sup> *Id.*

<sup>150</sup> 15 U.S.C. § 2057c(b)(3)(A).

<sup>151</sup> 895 F.3d 1, 12-13 (D.C. Cir. 2018).

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“ample margin of safety.”<sup>152</sup> The EPA employed a model based on conservative assumptions, including worst-case weather and worst-case population proximity, and set a standard that resulted in most of the country having a hazard quotient of below one (the level at which there was a risk to human health).<sup>153</sup> However, in the model, the EPA projected that some people would be exposed to the regulated gases if both worst-case scenarios came to pass.<sup>154</sup> The D.C. Circuit concluded that the EPA’s determination of how a margin of safety could be built into the emission standard deserved deference, but struck down the standard in question because it did not build in an any margin of safety.<sup>155</sup>

Applying the logic of *Sierra Club*, the Commission was arguably required to prohibit DINP if even a single person had an HI greater than one and the prohibition would prevent exposure and therefore “provide an adequate margin of safety.”<sup>156</sup> Petitioners analogize to cases interpreting the phrase “unreasonable risk” to show that Congress intended the cost of the regulation to be one factor in determining what is necessary to ensure a reasonable certainty of no harm.<sup>157</sup> The Commission considered the meaning of “reasonable certainty of no harm” in its Final Rule and rejected some commenters’ suggestion that the phrase meant “reasonably necessary to prevent or reduce an unreasonable risk of injury,”<sup>158</sup> ultimately concluding that the phrase “calls for a highly protective standard, but not 100 percent

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<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.* at 12.

<sup>155</sup> *Id.* at 13.

<sup>156</sup> *Compare id.* at 12-13, with 15 U.S.C. § 2057c(b)(3)(A).

<sup>157</sup> *See Forester v. CPSC*, 559 F.2d 774, 788-89 (D.C. Cir. 1977) (upholding regulations where the cost was slight); *Aqua Slide ‘N’ Dive Corp. v. CPSC*, 569 F.2d 831, 844 (5th Cir. 1978) (requiring the commission to consider costs and benefits to determine whether there was “reasonable necessity” for a standard).

<sup>158</sup> Final Rule at 49,944.

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certainty of no harm.”<sup>159</sup> Attempting to protect the 99th percentile from harm did not exceed the Commission’s mandate to “ensure a reasonable certainty of no harm.”<sup>160</sup>

However, the Commission ignored the first portion of the standard: it must be “reasonably necessary.” We have required regulations to use a cost-benefit analysis based on the word “reasonable.”<sup>161</sup> We interpreted the similar phrase “reasonable necessity” to require the Commission to “take a hard look, not only at the nature and severity of the risk, but also the potential the standard has for reducing the severity or frequency of the injury, and the effect the standard would have on the utility, costs or availability of the product.”<sup>162</sup> The Supreme Court rejected EPA regulations authorized if the agency found the regulation was “appropriate and necessary” because the EPA did not consider costs to determine whether the regulations were “appropriate.”<sup>163</sup> The Court rejected the EPA’s arguments that it need not consider costs because Congress used that language only because of its uncertainty about whether the regulation at issue would be needed.<sup>164</sup> The Court noted that “if uncertainty about the need for regulation were the *only* reason [Congress delegated authority to regulate], Congress would have required the Agency to decide only whether the regulation remains ‘necessary.’”<sup>165</sup> Accordingly, the Commission was required to at least consider the costs, as well as the effect on utility and availability of products containing DINP to determine whether to continue the interim prohibition to “ensure a reasonable certainty of no harm.”<sup>166</sup>

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<sup>159</sup> *Id.*

<sup>160</sup> *Id.* at 49,939.

<sup>161</sup> *Aqua Slide*, 569 F.2d at 844.

<sup>162</sup> *Id.*

<sup>163</sup> *Michigan v. E.P.A.*, 135 S.Ct. 2699, 2708-10 (2015).

<sup>164</sup> *Id.* at 2710.

<sup>165</sup> *Id.*

<sup>166</sup> 15 U.S.C. § 2057c(b)(3)(A).

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The Commission expressly “did not prepare a regulatory analysis of the costs and benefits of the rule.”<sup>167</sup> It did give some thought to the costs of testing and responded to commenters about the costs of testing on small businesses.<sup>168</sup> That is not enough. Congress required the Commission to consider whether the regulation is “reasonably necessary,” and the Commission failed to undertake that analysis. Even under the deferential lens of *Chevron*, the Commission cannot ignore Congress’s directive. Accordingly, the Commission procedurally erred by failing to take a hard look at the costs and benefits of continuing Congress’s interim prohibition.

## 2

However, a different standard applied to the Commission’s expansion of the DINP prohibition and its prohibition on products containing DIBP, DPENP, DHEXP, and DCHP. Congress required the Commission to “declare any children’s product containing any phthalates to be a banned hazardous product . . . as the Commission determines necessary to protect the health of children.”<sup>169</sup> Congress did not add a “reasonable” qualifier to the Commission’s authority under subsection (B), nor was it required to provide any margin of safety. Accordingly, the Commission was entrusted with discretion to promulgate rules with the singular purpose of “protect[ing] the health of children.”<sup>170</sup>

Petitioners argue that the Commission only paid lip service to the statutory standards but failed to apply the standard in its reasoning and decision. Petitioners cite to *Natural Resources Defense Council v. Pritzker* as an analogous case.<sup>171</sup> In that case, the Ninth Circuit invalidated a regulation

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<sup>167</sup> Final Rule at 49,974.

<sup>168</sup> *See id.* at 49,967, 49,970.

<sup>169</sup> 15 U.S.C. § 2057c(b)(3)(B).

<sup>170</sup> *Id.*

<sup>171</sup> 828 F.3d 1125, 1135 (9th Cir. 2016)).

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by the National Marine Fisheries Service that it held did not satisfy the enabling legislation's "least practicable adverse impact standard."<sup>172</sup> The agency there stated that it had reviewed the proposed regulation and determined that it would "effect the least practicable adverse impact on marine mammals."<sup>173</sup> The Ninth Circuit held that agency did "not meaningfully discuss how the mitigation measures meet that 'stringent standard.'"<sup>174</sup>

Unlike the agency in *NRDC v. Pritzker*, the Commission here engaged in a thorough analysis of the health risks of phthalates. To start, the Commission reviewed the multi-year findings of the CHAP and discussed them in depth.<sup>175</sup> It then assessed those findings and adopted the Proposed Rule to mirror the recommendations of the CHAP.<sup>176</sup> The Final Rule justified the risks differently by referring to actual women exposed to HIs greater than one, but did give more than mere lip service to the statutory standards.<sup>177</sup> Accordingly, the Commission did not change the standard set by Congress.

Ultimately, the Commission applied the proper health standards to its rulemaking. It applied the "reasonable certainty of no harm" standard to continue its prohibition on DINP, and the "necessary to protect the health of children" to expand its prohibition on DINP and prohibit DIBP, DPENP, DHEXP, and DCHP. However, the Commission did not give an adequate opportunity to comment when it changed its underlying rationale for the final rule. It also erred by failing to consider the cost of continuing the interim prohibition of DINP.

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<sup>172</sup> *NRDC*, 828 F.3d at 1129.

<sup>173</sup> *Id.* at 1135 (quoting 77 Fed Reg. 50,290, 50,294).

<sup>174</sup> *Id.* (citation omitted).

<sup>175</sup> Proposed Rule at 78,326-34; Final Rule at 49,945-50.

<sup>176</sup> Proposed Rule at 78,339.

<sup>177</sup> Final Rule at 49,961.

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## IV

Petitioners argue that the Commission's Final Rule is arbitrary and capricious. Petitioners specifically mention six decisions. First, the Commission calibrated the HI according to the "most sensitive health effect," which Petitioners argue is not proven to be harmful. Second, the Commission used data that Petitioners deem unreliable. Third, the Commission assumed that humans are more sensitive to phthalates than rodents, which petitioners contend was erroneous. Fourth, the use of spot samples overestimated the actual exposure of individuals. Fifth, adding together the HIs of each individual phthalate resulted in an overestimation of the risk. Sixth, petitioners argue that the link between pre-natal exposure and antiandrogenic effects means that it is unreasonable to ban children's toys, which are certain to be used post-natal.

We are not free to second-guess the Commission's determinations as to statistical methods and scientific data.<sup>178</sup> In reviewing an agency decision, "[o]ur task is to determine whether the agency examined the pertinent evidence, considered the relevant factors, and articulated a 'reasonable explanation for how it reached its decision.'"<sup>179</sup> This standard is highly deferential; we apply a presumption of validity and may not substitute our judgment for that of the agency.<sup>180</sup> The Supreme Court has said that courts should "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned."<sup>181</sup> Having reviewed the record and the Final Rule, we can discern the Commission's path for each of the six decisions above. Its

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<sup>178</sup> *Sw. Elec. Power Co. v. E.P.A.*, 920 F.3d 999, 1019 (5th Cir. 2019).

<sup>179</sup> *Assoc'd Builders and Contractors of Texas v. NLRB*, 826 F.3d 215, 219-20 (5th Cir. 2016) (quoting *Tex. Office of Pub. Util. Counsel v. FCC*, 183 F.3d 393, 410 (5th Cir. 1999)).

<sup>180</sup> *Id.* (citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009)).

<sup>181</sup> *Fox Television*, 556 U.S. at 513 (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 286 (1974)).

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explanations are not “so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”<sup>182</sup>

V

Having found that the CPSC violated the APA by failing to allow proper notice-and-comment for its new justification and failing to consider the costs of continuing Congress’s interim prohibition on DINP, the only remaining question is what remedy is appropriate. Petitioners urge vacatur. We are required to “set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.”<sup>183</sup> However, “[o]nly in ‘rare circumstances’ is remand for agency reconsideration not the appropriate solution.”<sup>184</sup> Remand, not vacatur, is generally appropriate when there is at least a serious possibility that the agency will be able to substantiate its decision given an opportunity to do so.<sup>185</sup> In this case, there is a serious possibility that the CSPC will be able to remedy its failures.<sup>186</sup> The Commission must allow industry to comment and consider the new justification for the Final Rule. Further, it must consider the costs of continuing Congress’s interim prohibition on DINP to determine whether the rule is “reasonably necessary” to protect from harm.

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Accordingly, we retain jurisdiction and REMAND to the Commission to resolve the defects in its rule.

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<sup>182</sup> *Sw. Elec. Power Co.*, 920 F.3d at 1013 (quoting *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mutu. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)) (internal quotations omitted).

<sup>183</sup> 5 U.S.C. § 706(2).

<sup>184</sup> *O’Reilly v. U.S. Army Corps of Eng’rs*, 477 F.3d 225, 238-39 (5th Cir. 2007) (citation omitted).

<sup>185</sup> *Central and South West Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000).

<sup>186</sup> *Cf. Allied-Signal, Inc. v. N.R.C.*, 988 F.2d 146, 150-51 (D.C. Cir. 1993) (explaining that “[a]n inadequately supported rule . . . need not necessarily be vacated”).