Safer Chemicals, Healthy Families v. U.S. Environmental Protection Agency, ___ F.3d ___, 2019 WL 5997404 (9th Cir. Nov. 14, 2019)

The Ninth Circuit address a number of challenges to EPA's 2017 Risk Evaluation Rule issued under the Toxic Substances Act. In summary, the panel opinion (1) held that a challenge to the process by EPA will conduct determinations under the Rule was non-justiciable because it lacked constitutional ripeness; (2) rejected a challenge to the Rule as contravening the TSCA's requirement that EPA consider all of a chemical's "conditions of use" when conducting a risk evaluation; (3) upheld challenge to the Rule's excluding "legacy uses" and "associated disposals" from the TSCA's and the Rule's definition of "conditions of use"; and (4) rejected a challenge to the Rule's excluding "legacy disposal[s]" from the definition of "conditions of use."

Summary

Congress enacted the Toxic Substances Control Act, 15 U.S.C. §§ 2601 to 2629, in 1976 and designated EPA as the implementing agency. It amended TSCA 40 years later to establish "'a separate risk evaluation process for determining whether a chemical substance presents or will present an unreasonable risk of injury,' and prescribe[d] statutory deadlines by which EPA is required to complete such evaluations." EPA issued a Risk Evaluation Rule in 2017. Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726 (July 17, 2017) (codified at 40 C.F.R. §§ 702.31 to 702.51). Multiple groups sought judicial review of the Rule in the Ninth Circuit. The panel separated the challenges into three categories.

o The first category of challenges focused on the process prescribed by the Rule for conducting risk determinations—i.e., "Petitioners argue that several provisions in the Rule assert that EPA has authority to determine whether individual conditions of use, in isolation, pose unreasonable risks, rather than to evaluate the risks posed by a chemical substance holistically." EPA responded that this challenge was "nonjusticiable because it is based merely on a 'hypothes[i]s about how EPA may apply [the Rule] in the future,' and therefore Petitioners have not alleged 'a concrete or particularized injury.'" The panel agreed with EPA. It recognized that Petitioners possessed prudential ripeness as to the challenge given the presence of TSCA's judicial review provision (15 U.S.C. § 2618) but held that such provision "does not make a claim *constitutionally* ripe." It found Article III justiciability absent because "the ambiguous text of the Risk Evaluation Rule" made it uncertain "whether the Agency will actually conduct risk evaluations in the manner Petitioners fear." Thus, "[t]o the extent it is not clear how EPA will actually conduct risk evaluations under these rules, there is no concrete, imminent harm to Petitioners' interests that is caused by the challenged provisions." The panel stressed, however, "[i]f EPA *does*, in the future, fail to consider all conditions of use together in completing a risk evaluation, and if Petitioners are harmed by that failure, then Petitioners may, under TSCA, seek review of EPA's 'no unreasonable risk' determination."

o Petitioners second category of challenges asserted "that the Risk Evaluation Rule contravenes TSCA's requirement that EPA consider *all* of a chemical's conditions of use when conducting a risk evaluation." They based this challenge on "preambular language" to the Rule and several codified provisions denominated by the panel as "scope provisions." The panel deemed the preambular-language challenge component non-reviewable because that language did not

constitute final agency action insofar as it did "not bind the agency to ever exclude *any* conditions of use from consideration." Petitioners' challenge to the scope provisions failed on the merits. The panel explained:

> The problem with Petitioners' theory is that the meaning they attribute to these provisions is inconsistent with the provisions themselves. The phrase "the conditions of use within the scope of" an evaluation simply refers to the conditions of use that are applicable to any particular substance—and that therefore are included in the scope of that substance's evaluation—without excluding any conditions of use in forming that list. Likewise, the phrase that refers to the conditions of use "that the EPA plans to consider" simply refers to the Agency's role in determining what the conditions of use are for a particular substance. Petitioners effectively acknowledge as much in arguing that the similar language of TSCA itself referring to the conditions of use that the Administrator "expects to consider" does not grant EPA discretion to exclude conditions of use. ... We see no reason why "plans to consider" should be read differently than "expects to consider."

- The panel identified Petitioners' third category of challenges as the Rule's "categorical exclusion of legacy activities from the definition of 'conditions of use.'" TSCA (15 U.S.C. § 2602(4)) and the Rule (40 C.F.R. § 702.33) define "conditions of use" to mean "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." However, "[i]n the preamble to the Risk Evaluation Rule, EPA elaborated on this definition ... and stated that it does not consider what it now calls 'legacy activities'—consisting of 'legacy uses,' 'associated disposals,' and 'legacy disposals'—to be conditions of use." The preamble defined "legacy uses" as "the circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution." The term "'associated disposals' refer[red] to future disposals from legacy uses[,]" while the term "'legacy disposal[s]' [were] defined as 'disposals that have already occurred,' regardless of whether the substance disposed of is still manufactured for its pre-disposal use." In contrast to the earlier preambular language-based challenge, "EPA concede[d] that its 'preamble interpretation regarding legacy activities is reviewable because it is a binding statutory interpretation that EPA stated it intends to apply going forward.'"

The panel held EPA exclusion of "legacy uses" and "associated disposals" from "conditions of use" an unreasonable interpretation of TSCA. It reasoned that "TSCA's 'conditions of use' definition plainly addresses conditions of use of chemical substances that will be used or disposed of in the future, regardless of whether the substances are still manufactured for the particular use." The panel reached a different conclusion as to "legacy disposals":

> TSCA unambiguously does not require past disposals to be considered conditions of use. The statutory definition, once again, covers the circumstances "under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." ... A substance that has already been disposed of will not ordinarily be intended, known, or reasonably foreseen to be prospectively manufactured, processed, distributed in commerce, used, or (again) disposed of. Of course, there may be some substances that already have been disposed of yet are also "known ... to be ... distributed in commerce" or used. ... And TSCA's

> definition does ... clearly cover those substances and those prospective uses. But TSCA does not address a substance that has already been disposed of and remains so.

The panel therefore vacated the Rule's exclusion of "legal uses" and "associated disposals" from the "conditions of use" definition but denied the challenge to the exclusion of "legacy disposals."

The panel simultaneously issued an unpublished opinion in *Safer Chemicals, Healthy Families v. U.S. Environmental Protection Agency*, ___ F. App'x ___, 2019 WL 6041996 (9th Cir. Nov. 14, 2019). It (1) granted EPA's unopposed request to vacate and remand one challenged provision (40 C.F.R. § 702.31(d)) criminally penalizing submission of inaccurate or incomplete information; (2) granted EPA's request to remand without vacatur two information-gathering provisions (*id.* § 702.37(b)(4) and (b)(6)); and (3) rejected on the merits Petitioners' challenge to § 702.9(b) "as erecting a 'screen' that excludes some 'reasonably available information' from EPA's consideration" and to § 702.5(b) and (c) as "categorically prevent[ing] EPA from obtaining and considering sufficient information to conduct both a prioritization and a risk evaluation for each chemical substance."