

FOR PUBLICATION

In the
United States Court of Appeals
For the Eleventh Circuit

No. 25-10515

CENTER FOR BIOLOGICAL DIVERSITY,

Petitioner,

versus

U.S. ENVIRONMENTAL PROTECTION AGENCY,
ADMINISTRATOR, U.S. ENVIRONMENTAL
PROTECTION AGENCY,

Respondents,

MOSAIC FERTILIZER, LLC,

Intervenor.

Petition for Review of a Decision of the
Environmental Protection Agency
Agency No. FRL-12519-01-0A

Before ROSENBAUM, LAGOA, and MARCUS, Circuit Judges.

MARCUS, Circuit Judge:

The Center for Biological Diversity, a nonprofit membership organization, petitions this Court for review of the Environmental Protection Agency's Notice of Approval for Other Use of Phosphogypsum. The Notice approved a request submitted by Mosaic Fertilizer, LLC, a Delaware-based mining and chemical company, to use a radioactive byproduct of fertilizer production (phosphogypsum) in a road on the company's privately owned New Wales Facility in Polk County, Florida. After a multi-year review of the application, the EPA concluded that Mosaic's proposed road was a permissible use of phosphogypsum pursuant to the EPA's regulations promulgated under the Clean Air Act.

The Center asks us to vacate or remand the Notice of Approval because it claims the EPA's decision violates the controlling regulatory text or, alternatively, because the decision was arbitrary and capricious in violation of the Administrative Procedure Act. The EPA and Mosaic disagree, asserting that this Court is obliged to dismiss the Center's petition for want of jurisdiction and that it also fails on the merits.

After thorough review, and with the benefit of oral argument, we conclude that the petition must be denied. We are satisfied that we have jurisdiction because the Center has associational standing and the matter has not become moot. However, this application fails on the merits. The EPA did not violate the Agency's regulations, and its review and technical methodology were well supported, appropriately tailored, and fully explained. Accordingly, we deny the Center's petition.

25-10515

Opinion of the Court

3

I.

At the New Wales Facility (the “Facility”), Intervenor Mosaic Fertilizer, LLC, (“Mosaic”) mines and processes phosphate ore into phosphoric acid, which is subsequently used in the production of agricultural fertilizer. During this mining and conversion process, approximately five tons of phosphogypsum -- a radioactive solid-waste byproduct -- are produced for each ton of phosphate fertilizer. Pursuant to federal regulations, Mosaic then stores phosphogypsum in large, open-air pyramidal stacks at the Facility.

Even when the byproduct is stored in stacks, phosphogypsum naturally decays and emits dangerous radon gas, which is a radionuclide long associated with cancer, genetic abnormalities, and serious illness. On account of these health risks, the EPA has long regulated the production, disposal, and storage of phosphogypsum through federal regulations promulgated under the Clean Air Act. We recount the winding history of the regulatory scheme to better understand the nature and resolution of this dispute.

A.

In 1970, Congress enacted the Clean Air Act (the “Act”), 42 U.S.C. §§ 7401–7671q, to “speed up, expand, and intensify the war against air pollution in the United States with a view to assuring that the air we breathe throughout the Nation is wholesome once again.” H.R. Rep. No. 91–1146, 91st Cong., 2d Sess. 1, 1, (1970); *see*

also 42 U.S.C. § 7401(b)(1) (the Act’s purpose is “to protect and enhance the quality of the Nation’s air resources so as to promote the public health and welfare”). Under Section 112 of the Act, Congress authorized the creation of the National Emission Standards for Hazardous Air Pollutants Program (the “NESHAP” Program). 42 U.S.C. § 7412, Pub. L. No. 91-604, § 112, 84 Stat. 1676, 1685 (1970). The NESHAP Program is twofold; it requires the EPA to publish “a list which includes each hazardous air pollutant for which [it] intends to establish an emission standard,” and then requires the EPA to identify sources of the listed pollutants and set emission standards for each source category at a health threshold level that “provides an ample margin of safety to protect the public health[.]” *Id.* § 112(b)(1)(A)–(B).

As far back as 1979, the EPA listed radionuclides, including radon, as a Hazardous Air Pollutant (“HAP”). 40 C.F.R. § 61.01(a); *see also* Addition of Radionuclides to List of Hazardous Air Pollutants, 44 Fed. Reg. 76738 (Dec. 27, 1979); 42 U.S.C. § 7412(b)(1). For most Americans, radon is the single greatest source of environmental radiation exposure. The EPA defines radon as a non-threshold pollutant, which means that once radon induces cancer -- typically lung cancer -- the severity of the disease “is independent of the dose.” National Emission Standards for Hazardous Air Pollutants; Radionuclides, 54 Fed. Reg. 51654, 51659 (Dec. 15, 1989) (codified as amended at 40 C.F.R. pt. 61) [hereinafter “1989 Rule”]. That is, any non-zero amount of radon exposure can cause cancer of any severity. *Id.* Moreover, the EPA estimates that each year, approximately 21,000 lung cancer deaths in the United States are radon-

25-10515

Opinion of the Court

5

related, making radon the second leading cause of lung cancer after smoking.

Consistent with the Clean Air Act's NESHAP Program, the EPA promulgated emission standards to control radionuclide emissions from various source categories, including from phosphogypsum, in 1989. *Id.*; 42 U.S.C. § 7412(b)(1) (listing "Radionuclides (including radon)" as an HAP). During the 1989 rulemaking process, the EPA analyzed several sources of radionuclide emissions, including from the fertilizer industry's practice of disposing of phosphogypsum in stacks and mines. 1989 Rule, 54 Fed. Reg. at 51675. The Agency concluded that the maximum lifetime risk associated with baseline emissions from stack and mine storage -- defined as the "maximum additional cancer risk of any person due to exposure to an emitted pollutant for a 70-year lifetime" -- was approximately 9×10^{-5} (9 in 100,000). *Id.* at 51655, 51660, 51675. Finding this risk acceptable and adequately protective of human health, the 1989 Rule (codified, as amended, in Subpart R) required that all phosphogypsum be disposed of in stacks or old phosphate mines without exception. *Id.* at 51675, 51701; *see also* 42 U.S.C. § 7412. The 1989 Rule barred all uses of phosphogypsum beyond permanent storage in stacks or mines because the Agency wanted to ensure that phosphogypsum could not be "incorporated into other products or otherwise diffused throughout the country, such that the Agency will be unable to ensure that the phosphogypsum's radon emissions do not present an unacceptable risk to public health." 1989 Rule, 54 Fed. Reg. at 51675.

Less than a year later, the EPA granted limited reconsideration of Subpart R and commenced an evaluation of the risks associated with the use of phosphogypsum in three scenarios: (1) agriculture; (2) road construction; and (3) research and development activities. NESHAPS for Radionuclides Reconsideration; Phosphogypsum, 55 Fed. Reg. 13480 (Apr. 10, 1990) (codified as amended at 40 C.F.R. pt. 61). Consistent with the results of its research, the Agency amended Subpart R in 1992 through the administrative rulemaking process. *See* National Emission Standards for Radon Emissions from Phosphogypsum Stacks, 57 Fed. Reg. 23305, 23312 (June 3, 1992) (codified at 40 C.F.R. pt. 61) [hereinafter “1992 Rule”].

In the preamble to the 1992 Rule (the “Preamble”) the EPA outlined the results of each of the three scenarios, and explained how that research informed its amendments to Subpart R. *See id.* at 23305–17. As for the use of phosphogypsum in roads, the Preamble explained that the amendments would not create a categorical exception, thereby allowing the distribution and use of phosphogypsum in road construction. The EPA’s decision was the product of an evaluation of modeled risks to road construction workers, road users, residents near the road, and to future residents living directly on the phosphogypsum road base, should the road ever be abandoned (the “reclaimer” scenario). The EPA concluded that each of the modeled risks exceeded the Agency’s health and safety thresholds, with the highest lifetime risk applying to reclaimers. *Id.* at 23310. The 1992 Preamble reads this way:

25-10515

Opinion of the Court

7

For the road construction scenarios analyzed, the use of phosphogypsum always resulted in a MIR [Maximum Individual Risk] greater than the outer bound of the presumptively safe level of approximately 1×10^{-4} [1 in 10,000]. Therefore, EPA has determined that the use of phosphogypsum in road construction presents an unacceptable level of risk to public health.

Id. at 23312 (emphasis added).

As for the other use categories -- agricultural and research purposes -- the Agency concluded that subject to certain restrictions, those uses carried estimated maximum individual lifetime cancer risks no higher than 3×10^{-4} (3 in 10,000). *Id.* at 23311–12. The EPA explained that this risk was acceptable for agricultural and research purposes and thus amended Subpart R to categorically allow for (1) the distribution and use of phosphogypsum for outdoor agricultural purposes, 40 C.F.R. § 61.204; and (2) the distribution and use of phosphogypsum for indoor research and development, 40 C.F.R. § 61.205. 1992 Rule, 57 Fed. Reg. at 23311–12, 23315–19.

Finally, the 1992 Rule provided for a process by which entities could, on a case-by-case basis, request Agency approval for the use of phosphogypsum for any other purpose. *Id.* at 23316. The “other purpose” provision requires that an applicant submit a written proposal to the Agency, which must include information about how the phosphogypsum would be used, in what amounts, the risks posed by the proposed use, and the intended pollution control

measures. 40 C.F.R. § 61.206(a)–(b). An application may be approved by the EPA if “the proposed distribution and/or use is at least as protective of public health, in both the short term and the long term, as disposal of phosphogypsum in a stack or a mine.” *Id.* § 61.206(c). After an application is approved, the applicant still must prepare and maintain additional records to confirm that the applicant’s reported radium concentration remains consistent with previously reported levels. *Id.* § 61.207.

The next relevant development to the regulatory framework occurred in 2005, when the EPA published a workbook to “provide information on how to prepare a complete petition to the U.S. EPA for the distribution and use of phosphogypsum for ‘other purposes’ that is consistent with the requirement of [the EPA’s] regulations for radon emissions.” Radiation Prot. Div., Env’t Prot. Agency, Applying to EPA for Approval of Other Uses of Phosphogypsum: Preparing and Submitting a Complete Petition Under 40 C.F.R. § 61.206, at 1 (2005) [hereinafter “2005 Workbook”], https://www.epa.gov/system/files/documents/2025-04/wrkbk_sub-r_appl_1105_508-d.pdf. Notably, the 2005 Workbook discussed the use of phosphogypsum in roads on three occasions, articulating the EPA’s position that an application to use phosphogypsum in road construction projects may be approved under Subpart R.¹

¹ On page six, the Workbook reads: “[i]f you were proposing to use phosphogypsum in a way that would bring it into contact with the surface of the ground, such as using it for a road base, we might require you to establish a

Further, and relevant to the requirements an entity like Mosaic must satisfy when applying to use phosphogypsum for an other purpose, the 2005 Workbook provided guidance on the collection of radium-226 (“Ra-226”)² samples under 40 C.F.R. § 61.207(a). Section 61.207(a) explains that prior to removing phosphogypsum from a stack for use in an other purpose project, the stack’s average Ra-226 concentration “shall” be measured, and that the “[m]easurements shall be performed for each [stack] prior to the initial distribution . . . and at least once during each calendar year while distribution of phosphogypsum removed from the location continues.” *Id.* The 2005 Workbook explains that consistent with § 61.207, an application should also include Ra-226 sampling data collected within the last year. 2005 Workbook at 30. Even so, the EPA repeatedly said in the Workbook that this does “not replace or change the final rule” and this is intended only to “help [an applicant] submit a complete petition . . . but [the Workbook] is not intended to be a technical guidance document.” *Id.* at 1.

ground-water monitoring program.” 2005 Workbook at 6. Two pages later, the EPA writes: “[s]everal possible ‘other uses’ of phosphogypsum have been explored over the years. These include . . . [r]oad base material[.]” *Id.* at 8. Finally, the Workbook explains again, in near identical language, “if you are proposing to use phosphogypsum in a way that would bring it into contact with the surface of the ground, such as using it for a road base, we will probably require you to establish a ground-water monitoring program.” *Id.* at 16.

² Radium-226 is a naturally occurring uranium isotope, which the EPA generally uses to assess the potential risks associated with proposed projects involving the use and distribution of phosphogypsum.

Finally and most recently, in October 2020 the EPA granted conditional approval of a 2019 other use application to use phosphogypsum in road projects, submitted by The Fertilizer Institute, an agricultural trade association. Approval of the Request for Other Use of Phosphogypsum by the Fertilizer Institute, 85 Fed. Reg. 66550 (Oct. 20, 2020) [hereinafter “Approval of Institute Request”]. The EPA’s decision marked the first time it had approved an application to use phosphogypsum in a road project, and the conditional approval explained the Agency’s position that it “did not approve road construction as a categorical use of phosphogypsum” in 1992, but rather established “a process to request approval” for other uses, including in road construction. *Id.* at 66551.

Several environmental groups, including the Center, petitioned the United States Court of Appeals for the District of Columbia for direct review of the Agency’s decision and submitted a request to the EPA asking the Agency to reconsider. *See* Withdrawal of Approval for Use of Phosphogypsum in Road Construction, 86 Fed. Reg. 35795 (July 7, 2021). Subsequently, and “[o]n its own initiative,” the EPA withdrew its approval on procedural grounds and without prejudice on July 7, 2021, explaining that its conditional approval was premature because the Institute had not met the information requirements for an “other purpose application” under 40 C.F.R. § 61.206(b). *Id.*

B.

This decades-long regulatory history provides the backdrop for this dispute. In March 2022, Mosaic submitted an application

to use phosphogypsum -- for what it called a “Small-scale Road Pilot Project on Private Land in Florida” (the “Road Project”) -- to the EPA pursuant to the other use provision found in § 61.206. Request For Approval of Additional Uses of Phosphogypsum Pursuant to 40 C.F.R. § 61.206 at 1, *Ctr. For Biological Diversity v. EPA*, No. 25-10515 (11th Cir. July 7, 2025), Dkt. No. 26-1 [hereinafter “Mosaic Application”]. Mosaic presented a revised request in August 2023 containing only modest alterations to the original proposal. Request from The Mosaic Company to Use Phosphogypsum in Road Construction Pilot (August 2023), *Ctr. For Biological Diversity v. EPA*, No. 25-10515 (11th Cir. Aug. 12, 2025), Dkt. No. 30.

Mosaic’s application proposed to construct a pilot road (the “Road”) comprised of four 500-foot test sections, each containing a different concentration of phosphogypsum in the road base. *Id.* at 4. Mosaic estimated that the Project would use 1,200 tons of phosphogypsum -- taken from Mosaic’s on-site phosphogypsum stacks -- across 3,200 feet of roadway. *Id.* The original application further explained that the Road would be located on Mosaic’s private Facility without any public access points. Mosaic Application at 7–8. Finally, Mosaic reported that it had partnered with the University of Florida to conduct additional evaluations of the Road, including laboratory studies, to show that phosphogypsum “when appropriately blended with other aggregate or cementitious materials, can meet the performance criteria for engineered road base.” *Id.* at 11.

As part of Mosaic’s proposal, it included summary data from sampling completed in 2019 -- more than three years before the

2023 revisions -- measuring the average concentration of Ra-226 in the phosphogypsum to be used. *Id.* at 12. Using those Ra-226 concentrations, Mosaic’s application included an analysis of the exposure pathways and risks to road construction workers and truck drivers transporting the phosphogypsum for the Road Project over a “period of a few weeks to a month.” *Id.* at 6–7. Mosaic concluded that the radioactive exposure to those individuals would be negligible compared to the dose humans are exposed to from naturally occurring background radiation. *Id.* However, Mosaic declined to evaluate the risk the Road Project posed to utility workers, motorcycle and bicycle road users, residents living near the road, and potential reclaimers. It offered that these scenarios were inapplicable because there would be “no public access” to the Road. *Id.* at 7–8.

More broadly, Mosaic described its Road Project as a logical outgrowth of the Fertilizer Institute’s 2019 application and it explained that the additional information and research would demonstrate that phosphogypsum could be used beneficially and safely in road construction. *Id.* at 2, 10. Thus, throughout the Road Project proposal, Mosaic repeatedly referenced the risks and assumptions discussed by the Fertilizer Institute in its 2019 proposal and in the EPA’s conditional approval of that application.

On October 9, 2024, the EPA published its proposed approval of Mosaic’s Road Project in the Federal Register and solicited public comment. Notice of Pending Approval for Other Use of Phosphogypsum, 89 Fed. Reg. 81910 (Oct. 9, 2024) [hereinafter “Pending Approval”]. The Agency also made its technical review

25-10515

Opinion of the Court

13

of Mosaic’s application available on its website. *See id.* at 81912; Radiation Prot. Div., Env’t Prot. Agency, Review of the Small-Scale Road Pilot Project on Private Land in Florida Submitted by Mosaic Fertilizer, LLC (2024) [hereinafter “Agency Review”], https://www.epa.gov/system/files/documents/2024-10/1-mosaic_risk_technical_summary_final_508_0.pdf. The Pending Approval and Agency Review explained that Mosaic’s request included all necessary information and was complete under 40 C.F.R. § 61.206(b), that Mosaic’s risk assessments were technically acceptable, and that the potential radiological risks from the proposed Project posed no greater risk than maintaining the phosphogypsum in a stack or mine as required under § 61.206(c). Pending Approval, 89 Fed. Reg. at 81911; Agency Review at 2–3.

The Agency added that Mosaic’s 2019 sampling was acceptable because “the risk assessment scenarios reviewed by [the] EPA are based on Ra-226 activity concentration values that are roughly double the average value reported by Mosaic.” Agency Review at 11. The EPA concluded that its “risk assessment [would] remain valid even if the Ra-226 activity in the phosphogypsum that is used turns out to be higher.” *Id.* The Agency nevertheless required that additional sampling be completed upon final approval of the Project and before construction could begin, pursuant to the data collection requirements of § 61.207. *Id.*

On a more technical level, the EPA analyzed the risks the Road Project posed to certain individuals and compared those risks against the individual lifetime cancer risk threshold of 3 in 10,000.

For each category of individual the Agency assessed -- construction workers, truck drivers transporting phosphogypsum, road users, and nearby residents -- it concluded that the associated risks fell well below the applicable threshold. *Id.* at 14, 18–19.

As for the reclaimer scenario, the EPA concluded that the proposed Project would not alter the site characteristics because the Facility already included an existing phosphogypsum stack in the immediate vicinity of the Road. Accordingly, the Agency declined to consider the reclaimer scenario, which it determined to be inapplicable. *Id.* at 20–21. Finally, the EPA expressly noted that its review of Mosaic’s proposal “does not imply any conclusions about the risks to future reclaimers at other sites which may be further from phosphogypsum stacks and may lack the institutional controls present at the Mosaic facility.” *Id.* at 21.

The EPA’s review also included an analysis of the water pathway and the impact the Road Project might have on surface and groundwater supplies. *Id.* at 21–22. The Agency concluded that the potential risk arising from radionuclides leaching into surface or groundwater was low compared to the risks posed by direct exposure and inhalation of radon gas. *Id.* Nevertheless, the EPA required Mosaic to monitor the groundwater following the construction of the Road for a minimum of eighteen months. *Id.* The Agency again limited its findings to Mosaic’s Project, explaining that “the eighteen-month sampling duration proposed by Mosaic may not necessarily be sufficient to support conclusions about longer term use in a full-scale project.” *Id.* at 22.

The Center submitted a detailed technical comment on November 23, 2024, opposing the Agency’s Proposed Approval. *See* Comment Submitted by the Center for Biological Diversity, *Ctr. For Biological Diversity v. EPA*, No. 25-10515 (11th Cir. Mar. 13, 2025), Dkt. No. 9 Exh. C [hereinafter “Center’s Comment”]. It argued that: (1) the proposed approval violated Subpart R because the regulation forbade the use of phosphogypsum in road construction; (2) the Agency’s decision to apply a 3 in 10,000 safety threshold was violative of the text of Subpart R; and (3) the Agency arbitrarily limited the scope of its risk analysis and improperly accepted Mosaic’s outdated Ra-226 samples. *Id.* at 1, 4–9.

The EPA responded to public comment on December 11, 2024. Radiation Prot. Div., Env’t Prot. Agency, Request for Approval of Use of Phosphogypsum in a Small-Scale Road Pilot Project on Private Land in Florida Submitted by Mosaic Fertilizer, LLC: Response to Comments, (2024) [hereinafter “Response to Comments”], https://www.epa.gov/system/files/documents/2024-12/response-to-comments_12-12-2024.pdf. As for the Center’s claims, the Agency explained that road construction was an appropriate other use for phosphogypsum under Subpart R, that the 3 in 10,000 safety threshold was the appropriate standard to evaluate other use applications, and that its risk analysis was supported and appropriately tailored to Mosaic’s application. *Id.* at 6–11. The EPA made no change to its Proposed Approval, and, on December 23, 2024, the Agency published its Final Approval of Mosaic’s application. Agency’s Notice of Approval for Other Use of

Phosphogypsum, 89 Fed. Reg. at 104535 (Dec. 23, 2024) [hereinafter “Notice of Approval”].

The Center timely petitioned this Court for direct review of the Notice of Approval on February 19, 2025, under § 307(b)(1) of the Clean Air Act. The Center reprises substantially the same arguments it had raised in its November 2024 comment to the Agency, asserting that the EPA’s approval violated the plain language of Subpart R and that the Agency’s risk assessment was arbitrary and capricious. The EPA and Mosaic (collectively, “Respondents”) disagree, claiming that we must dismiss the petition for want of jurisdiction, and that in any event, the EPA’s action was consonant with the applicable regulations and was neither arbitrary nor capricious.

II.

Before proceeding to the merits of the Center’s petition, we consider whether we have jurisdiction. *Aguirre v. Seminole County*, 158 F.4th 1276, 1291 (11th Cir. 2025) (“Without jurisdiction the court cannot proceed at all in any cause.” (quoting *Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 514, 19 L.Ed. 264 (1868))). The EPA and Mosaic argue that this Court must dismiss for want of jurisdiction because the Center does not have associational standing; Mosaic also claims that the matter has become moot. After thorough review, however, we are satisfied that we have the power to entertain this petition.

25-10515

Opinion of the Court

17

A.

We begin with the claim that the Center lacks associational standing to challenge the EPA's approval of Mosaic's Road Project.

Article III of the Constitution limits this Court's jurisdiction to "cases" and "controversies." U.S. Const. art. III, § 2. As part of Article III's case-or-controversy requirement, any party seeking relief must have standing to litigate its claim. *See Bischoff v. Osceola County*, 222 F.3d 874, 878 (11th Cir. 2000) ("[S]tanding is perhaps the most important of [the jurisdictional] doctrines." (quoting *United States v. Hays*, 515 U.S. 737, 742 (1995) (alteration added by *Bischoff* court))). The central question asked by the standing doctrine is "whether [this] litigant is entitled to have the court decide the merits of the dispute or of particular issues." *Warth v. Seldin*, 422 U.S. 490, 498 (1975).

As the party invoking our jurisdiction, the Center bears the burden of establishing standing. *Ga. Republican Party v. SEC*, 888 F.3d 1198, 1201–02 (11th Cir. 2018). Under *Hunt v. Washington State Apple Advertising Commission*, 432 U.S. 333 (1977), an association like the Center has standing to challenge an Agency's action when: "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.* at 343; *see also Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Engineers*, 781 F.3d 1271, 1279–80 (11th Cir. 2015). When associational standing is invoked, the essential question is

whether the organization's members themselves have Article III standing, *Riverkeeper*, 781 F.3d at 1279–80, and here the parties disagree only as to that issue.

To establish that at least one of its members has standing to sue in his own right, the Center filed sworn declarations from two of its members, Michael Lexner and Elise Pautler Bennett. Lexner lives a little less than five miles from the Facility and Bennett lives some fifty miles away. Because the Center need only show that one of its members would have standing to sue in his individual capacity, we focus only on Lexner. *See Hunt*, 432 U.S. at 343.

For just under two decades, Lexner, along with his wife and children, have lived at their Florida home located less than five miles “as the crow flies” from Mosaic’s Facility. Lexner attests that he is a member of the Center for Biological Diversity and that the Center represents his interest in protecting his health and the environment. Specifically, he avers that his family has experienced, and continues to experience, harm to their recreational interests and the use and enjoyment of their property because of substantial concerns about radioactive contamination coming from the Facility. Lexner and his family grew and harvested peas, potatoes and myriad other vegetables at home, but they have ceased gardening on the property on account of their concern about phosphogypsum contamination of the groundwater. Lexner likewise stopped raising horses on the property and no longer drinks the well water available at his home. To protect his family’s health, Lexner says that he is forced to purchase jugs of water from local stores and

25-10515

Opinion of the Court

19

haul the water to his home for drinking and food preparation. He explains that he first began avoiding drinking and using the well water on his property in 2016. In that year, a sinkhole opened up in one of Mosaic's phosphogypsum stacks, resulting in "hundreds of millions of gallons of radioactive, toxic waste" collapsing into the aquifer from whence the Lexner family drew their water. Lexner also cites and attaches to his declaration a 2018 research study conducted by the University of Central Florida concluding that the 2016 sinkhole carried a potential to contaminate Floridian groundwater far beyond the Facility.

Lexner further attests that Mosaic's Road Project will exacerbate these harms and injuries. He explains that the EPA's approval of the Road Project "once again threatens [his] health" by constructing still another source of phosphogypsum pollution which he asserts will "lead to additional radioactive particulate matter exposure, groundwater contamination, or sinkholes[.]" This, he says, will "further harm [his] ability to use [his] property, recreate in ways such as gardening, and protect [his] health and the health of [his] family." These injuries, he adds, are likely to affect the value of his property, causing him additional economic harm. Finally, Lexner observes that his immediate concerns are based upon "a long history of pollution events" at the Facility, notably including the "2016 sinkhole and other pollution events."

Under the law of this Circuit, to establish that Lexner would have standing in his own right, his declaration must show that:

“(1) [he] has suffered an injury in fact that is (a) concrete and particularized and (b) actual or imminent, (2) there is a causal connection between the injury and the conduct complained of, and (3) it is likely that the injury will be redressed by a favorable decision of the court.” *Sierra Club v. Johnson*, 436 F.3d 1269, 1276 (11th Cir. 2006) (citation modified). We address each in turn.

In an environmental case, an injury in fact may be established through evidence of concrete and particularized harm to aesthetic or recreational interests. Thus, for example, an individual plaintiff can demonstrate injury by attesting that he uses -- or would use more often -- an area affected by the alleged violation and that the challenged conduct harms his aesthetic or recreational enjoyment of that area. See *Sierra Club v. Tennessee Valley Auth.*, 430 F.3d 1337, 1344 (11th Cir. 2005); see also *Friends of the Earth, Inc. v. Laidlaw Env’t Services (TOC), Inc.*, 528 U.S. 167, 183 (2000). In addition, an environmental organization may establish standing by showing that its members use the affected areas and face environmental or health-related harm resulting from the challenged conduct. See *Riverkeeper*, 781 F.3d at 1279–83; see also *Parker v. Scrap Metal Processors, Inc.*, 386 F.3d 993, 1003–04 (11th Cir. 2004).

The Center says that Lexner’s alleged injuries are concrete and particularized because they stem from threats of radiation exposure and aquifer contamination, which carry increased individual health risks. In addition, the Center points out that Lexner has attested to significant degradation in the enjoyment of his property and that Mosaic’s Facility has a longstanding and extensive history

of creating environmental issues, which will plausibly be exacerbated by the Road Project. The Respondents reply that the declaration fails to establish an injury resulting from the Road Project, because Lexner has asserted only “generalized concerns about living near the Mosaic facility, *not* concerns regarding the Road Pilot Project at issue here.”

We are satisfied Lexner has presented enough to establish that he has suffered a concrete and particularized injury in fact. The harms he describes, including the loss of enjoyment of his own private property and the manifestation of plausible health risks, are sufficient. Thus, for example, Lexner attests to the cessation of all vegetable gardening and the removal of horses from his property. He adds that he has taken significant steps and continues to act in a manner designed to avoid using well water otherwise drawn from the property in order to avoid continued exposure to radioactive particulate matter.

While these injuries were evident before the Road Project commenced, the allegations plausibly and concretely assert that the Road Project exacerbates Lexner’s injuries. Lexner has attested in no unclear terms -- and has cited to supporting scientific literature -- that his injuries are plausibly made worse by the Road Project, because the Road will create an additional source of radioactive air pollutants, beyond the contaminants emanating from the phosphogypsum stacks at the Facility.

These claims are sufficient for standing purposes to establish an injury in fact. Time and again, the federal courts have concluded that a concrete and particularized harm arising from a party's proximity to radioactive materials constitutes an injury in fact. See, e.g., *Duke Power Co. v. Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 74 (1978) (“[T]he emission of non-natural radiation into appellees’ environment would also seem a direct and present injury[.]”); *Texas v. Nuclear Regul. Comm’n*, 78 F.4th 827, 836 (5th Cir. 2023) (owning property within four miles of facility “sufficient to establish injury . . . [i]n the context of radioactive materials” (citation modified)), *rev’d on other grounds. by, Nuclear Regul. Comm’n v. Texas*, 605 U.S. 665 (2025); see also *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1266 (D.C. Cir. 2004) (petitioner living eighteen miles from facility had standing); *Kelley v. Selin*, 42 F.3d 1501, 1509 (6th Cir. 1995) (finding injury resulting from storage of nuclear waste where petitioners asserted “harm to their aesthetic interests and their physical health” and “that the value of his or her property will be diminished by the storage of nuclear waste”).

The Supreme Court’s decision in *Duke Power* is illuminating. There, the High Court concluded that “the environmental and aesthetic consequences of the thermal pollution of the two lakes in the vicinity of the disputed [nuclear] power plants is the type of harmful effect which has been deemed adequate in prior cases to satisfy the injury in fact standard.” 438 U.S. 73–74. The Court explained that “the health and genetic consequences of even small emissions like those concededly emitted by nuclear power plants” are injuries in fact. *Id.* at 74. In this case, as alleged, the emission of additional

non-natural radon into Lexner's environment on account of Mosaic's Road Project -- which Lexner observes will harm his aesthetic, recreational, and financial interests -- is enough to assert a direct and present injury.

Lexner has also met the requirements of causation and redressability. Under the law of this Circuit, "[i]n environmental suits, the injury-in-fact inquiry tends to be more searching than the causation or redressability considerations." *Ouachita Watch League v. Jacobs*, 463 F.3d 1163, 1170 (11th Cir. 2006) (citing, *inter alia*, *Johnson*, 436 F.3d at 1277–78). Even so, when the alleged injury arises from the government's regulation of a third party, as is the case for the EPA's regulation of Mosaic, the standing inquiry is more demanding: the Center must demonstrate that the decisions of both the regulator and the regulated party will operate "in such manner as to produce causation and permit redressability of injury." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992).

As for causation, Mosaic's ability to complete the Road Project is entirely predicated on the EPA's approval of its application. Subject to Subpart R, Mosaic is categorically barred from removing phosphogypsum from its stacks for use in road construction unless and until it receives authorization from the EPA. See 40 C.F.R. § 61.206. The regulatory scheme thus makes the Agency's approval a necessary prerequisite to the Road Project. Absent the EPA's express approval, Mosaic could not lawfully proceed with the Road Project at all. Thus, there is a direct causal connection

between the challenged agency action and Mosaic’s completion of the Road Project.

For similar reasons, the injuries alleged are traceable to the EPA’s approval of the Project. As we’ve explained, Lexner alleges that the Road Project will further restrict the use and enjoyment of his property, diminish its value, and expose him to increased health risks. These claimed injuries do not arise in a vacuum; they result from a Project that could not go forward without the EPA’s authorization. The Agency’s decision is therefore not just a background condition or an attenuated link in the causal chain. Rather, it is the legal and practical cause that enables Mosaic to undertake the challenged activity that plausibly gives rise to Lexner’s claimed injuries.

Finally, Lexner’s injury is redressable by this Court. “Redressability is established . . . when a favorable decision ‘would amount to a significant increase in the likelihood that the plaintiff would obtain relief that directly redresses the injury suffered.’” *Harrell v. Fla. Bar*, 608 F.3d 1241, 1260 n.7 (11th Cir. 2010) (quoting *Utah v. Evans*, 536 U.S. 452, 464 (2002)). The redressability inquiry “generally assesses whether [a personal] interest exists at the outset.” *Uzuegbunam v. Preczewski*, 592 U.S. 279, 282 (2021). Thus, we consider whether Lexner had a concrete and particularized injury, redressable at the time the Center filed its petition in February 2025. *See id.* We conclude that he did.

If the EPA failed to comply with § 61.206 or the Administrative Procedure Act, we have the authority to vacate or remand the

Agency's Notice. At the time the Center filed its petition -- before construction of the Road Project had begun -- this relief would have provided precisely the redress the Center sought. Vacatur would have invalidated the Notice on which the Project depended, and remand would have required the EPA to reconsider its action in compliance with the governing legal requirements before the Project could proceed. Either form of relief would have prevented or, at a minimum, delayed construction of the Road Project until the EPA could ensure that the Project sufficiently protects the public health. We are therefore satisfied that Lexner's injuries were redressable when the action was filed.

The Center has shown that at least one of its members would have standing in his individual capacity. And because the environmental interests the Center seeks to protect are also germane to its purpose and neither the claim asserted nor the relief sought requires the participation of individual members in the lawsuit, *see Johnson*, 436 F.3d at 1276, we are satisfied that the Center has associational standing.

B.

Mosaic, alone, also argues that even if the Center has standing, we still must dismiss for want of jurisdiction because the matter has become moot.³ Mosaic maintains that the matter became

³ At oral argument, counsel for the EPA clarified that while it maintains we lack jurisdiction because the Center does not have associational standing, the

moot in November 2025 when it completed construction on the test sections of the Road. We are not persuaded.

The standing requirement is only “one strand” of this Court’s jurisdictional inquiry. *United States v. Ross*, 963 F.3d 1056, 1062 (11th Cir. 2020) (en banc) (citation modified). Another strand is mootness, which may offer a separate reason for dismissing the Center’s petition. A petition becomes moot “when it no longer presents a live controversy with respect to which the court can give meaningful relief.” *Sheely v. MRI Radiology Network, P.A.*, 505 F.3d 1173, 1183 (11th Cir. 2007) (quoting *Toriano v. Supervisor of Elections*, 382 F.3d 1276, 1281–82 (11th Cir. 2004)). While redressability and mootness are related, mootness “considers whether [a personal interest] exists throughout the proceedings.” *Uzuegbunam*, 592 U.S. at 282. “[I]f in the course of litigation a court finds that it can no longer provide a plaintiff with any effectual relief, the case generally is moot.” *Id.* However, unlike the standing inquiry, the “heavy burden” of proving that a claim is moot falls on the party seeking dismissal. *Norwegian Cruise Line Holdings Ltd. v. State Surgeon Gen., Fla. Dep’t of Health*, 55 F.4th 1312, 1315 (11th Cir. 2022) (citation modified). Mosaic has not met its burden.

Mosaic’s application explains that its Road Project has two phases: first, the company would construct the Road; then, Mosaic would coordinate with the University of Florida to “test and monitor the road.” Mosaic says that the initial construction phase began

Agency does not agree with Mosaic’s claim that we lack jurisdiction because the matter is moot.

in August 2025; phosphogypsum was removed from the Facility’s on-site stacks and applied to the Road beginning on October 7, 2025, and the application of all of the phosphogypsum was complete by November 4, 2025. Although some control sections of the Road remained under construction at the time of oral argument, Mosaic represents that the portions of the Project involving phosphogypsum are complete and “[n]o additional phosphogypsum will be removed from any stack in connection with the pilot project approval.”

Thus, according to Mosaic, its “remaining obligations under the terms of the approval involve only (1) completing ‘control’ sections of the road that do not contain any phosphogypsum and (2) testing and monitoring the already-constructed road and reporting the results to EPA, thus providing valuable data on the road’s environmental performance and suitability.” While Mosaic acknowledges that the Notice of Approval contains post-construction monitoring, it says that the Center did not challenge those conditions, that the Court cannot modify these discretionary conditions, and that the Center has not shown how revising monitoring obligations would redress its alleged injuries. It reasons that because the Center “has not asserted that testing or monitoring harm[s] its members,” vacatur or remand of the Agency’s action can no longer offer the Center redress, rendering the matter moot.

Mosaic cites several cases in support of its claim that the lawsuit has become moot. *See, e.g., Nat’l Parks Conservation Ass’n, Inc. v. U.S. Army Corps of Eng’rs*, 574 F. Supp. 2d 1314, 1322 (S.D. Fla.

2008) (first citing *Save the Bay, Inc. v. U.S. Army*, 639 F.2d 1100, 1103 (5th Cir. 1981); then citing *Fla. Wildlife Fed’n v. Goldschmidt*, 611 F.2d 547, 548 (5th Cir. 1980) (per curiam)).⁴ Mosaic also claims that under out-of-circuit precedent, lawsuits seeking to stop an agency-authorized construction project are mooted by the completion of the project. See, e.g., *Knaust v. City of Kingston*, 157 F.3d 86, 88 (2d Cir. 1998); *Bayou Liberty Ass’n, Inc. v. U.S. Army Corps of Eng’rs*, 217 F.3d 393, 398 (5th Cir. 2000); *City of Romulus v. Wayne County*, 634 F.2d 347, 348 (6th Cir. 1980); *One Thousand Friends of Iowa v. Mineta*, 364 F.3d 890, 892–94 (8th Cir. 2004); *Neighborhood Transp. Network, Inc. v. Pena*, 42 F.3d 1169, 1172 (8th Cir. 1994).

The cases are inapposite. They address claims of mootness where the petitioner sought only injunctive relief, or declarative relief in the form of an advisory opinion. See *Knaust*, 157 F.3d at 88 (“Because this appeal thus seeks to enjoin the future occurrence of events that are already in the past, we lack appellate jurisdiction.”); *City of Romulus*, 634 F.2d at 347 (same); *Mineta*, 364 F.3d at 892 (same); *Pena*, 42 F.3d at 1172; *Bayou Liberty Ass’n*, 217 F.3d at 397–98 (same for declaratory judgment). Those requests for equitable relief were rendered moot after construction was completed.

In this case, however, the Center seeks a vacatur or remand of the Agency decision approving Mosaic’s application, relief that

⁴ In *Bonner v. City of Prichard*, 661 F.2d 1206 (11th Cir. 1981) (en banc), the Eleventh Circuit adopted as binding precedent all decisions handed down by the former Fifth Circuit before October 1, 1981. *Id.* at 1209.

could be granted even if the Project has been completed. The Center observes that the EPA's Notice of Approval imposes ongoing monitoring and testing obligations, which could be altered markedly by a favorable decision from this Court. Thus, in the Center's view, a vacatur or remand could still provide meaningful relief; it would require the EPA to reconsider its approval and the ongoing monitoring protocols it has imposed.

We agree. A decision in the Center's favor could still affect the legal relationship between the parties, notwithstanding Mosaic's progress in building the Road. By way of example, if we were to conclude that the EPA applied the wrong risk calculus in reviewing the application, subsequent Agency review could result in heightened monitoring requirements, capping the road, or indeed, even tearing the road out. *Cf. Airport Neighbors All., Inc. v. United States*, 90 F.3d 426, 427–29 (10th Cir. 1996) (“[W]e could order that the runway be closed or impose restrictions on its use until Respondents complied with NEPA.”). These remedies remain available. This matter has not become moot. Thus, we deny Mosaic's motion.

III.

We proceed to the merits of the Center's petition. The Center raises two main arguments: first, that the Agency's approval misinterprets the demands of Subpart R and violates the text, and, second, that even if Subpart R was correctly construed, the approval of the Road Project was arbitrary and capricious. We remain unpersuaded.

A.

The Administrative Procedure Act (“APA”), 5 U.S.C. § 706(2)(A), requires that “courts, not agencies, will decide ‘all relevant questions of law’ arising on review of agency action -- even those involving ambiguous laws -- and set aside any such action inconsistent with the law as they interpret it.” *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 392 (2024) (quoting 5 U.S.C. § 706). If an agency’s final action fails to meet statutory requirements or violates federal regulations, the court must vacate the challenged action. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 413–14 (1971), *abrogated on other grounds by*, *Califano v. Sanders*, 430 U.S. 99 (1977).

When we review whether an agency’s action complies with the applicable text of the agency’s own regulations, we defer to the agency’s interpretation only if the regulation is “genuinely ambiguous.” *Kisor v. Wilke*, 588 U.S. 558, 563 (2019); *see also United States v. James*, 135 F.4th 1329, 1333 (11th Cir. 2025) (“[O]nly if we are left with real uncertainties about a regulation’s meaning do we [defer].” (citation modified)), *cert. denied*, No. 25-6267, 2026 WL 922527 (U.S. Apr. 6, 2026); *Hayes v. Dir.*, OWCP, 172 F.4th 1263, 1266 (11th Cir. 2026) (“We review *de novo* the administrative interpretation of the regulations implementing the Act, but we defer to agencies’ reasonable readings of genuinely ambiguous regulations.” (citation modified)). To discern whether a regulation is really ambiguous we “carefully consider the text, structure, history, and purpose of a regulation, in all the ways [the Court] would if it

25-10515

Opinion of the Court

31

had no agency to fall back on.” *Rafferty v. Denny’s, Inc.*, 13 F.4th 1166, 1179 (11th Cir. 2021) (citing *Kisor*, 588 U.S. at 563).

The Center argues that the EPA’s Notice of Approval violates the unambiguous text of Subpart R in two ways. First, it says the text categorically prohibits the use of phosphogypsum in road projects, and so the EPA cannot interpret the other purposes provision to include road construction without a new rulemaking process. Next the Center argues Subpart R requires the Agency to evaluate other use projects using a maximum risk threshold of 9 in 100,000, and the Agency’s use of a 3 in 10,000 risk threshold was therefore violative of the regulatory text. We agree that Subpart R is unambiguous. But the Center’s interpretation of the regulatory text is wrong.

Again, Subpart R prohibits the distribution and use of phosphogypsum for “any purpose not expressly specified in § 61.204 or § 61.205 without prior EPA approval.” 40 C.F.R. § 61.206(a). The regulation provides that the EPA may approve an other use application so long as the proposed “use is at least as protective of public health, in both the short term and the long term, as disposal of phosphogypsum in a stack or a mine.” *Id.* § 61.206(c). Subpart R does not categorically prohibit the use of phosphogypsum in road construction; in fact, it does not mention road construction at all.

The Center nevertheless argues that Subpart R clearly forbids the EPA from approving an other use application to use phosphogypsum in road construction. It only relies on language drawn from the 1992 Rule’s Preamble, not from the regulation itself. The

Preamble declared that the EPA’s four modeled road use scenarios “always” exceeded the presumptively safe level. *See* 1992 Rule, 57 Fed. Reg. at 23312. Thus, the Center reasons that when Subpart R is read in concert with the 1992 Preamble, the regulatory text forbids the use of phosphogypsum in road construction.

The Respondents agree that the regulatory text is unambiguous, but they say that it permits the EPA to review and approve road projects under the other purposes provision of § 61.206(c). They assert that under our law we must first look to the text of the regulation (Subpart R) in order to resolve the dispute, and because that regulation permits the use of phosphogypsum in road construction (so long as EPA approval is obtained) we have no reason to consider the 1992 Preamble -- or any other extrinsic evidence -- in interpreting the regulation. Finally, the Respondents contend that even if we look beyond the text of Subpart R, the Center’s argument finds no solid footing.

For starters, we agree with the Respondents that regulatory interpretation begins with, must rely upon, and often ends with the text of the regulation itself. First, we ask whether the applicable regulatory language has a “plain and unambiguous meaning.” *Gose v. Native Am. Servs. Corp.*, 109 F.4th 1297, 1310 (11th Cir. 2024) (citation modified). We do that by examining “the language itself, the specific context in which that language is used, and the broader context of the statute [or regulation] as a whole.” *Id.* (citation modified). If the meaning is clear, “there is no need for further inquiry.” *Id.* (citation modified). Regulatory preambles may provide context

about an agency’s intent, *see, e.g., Watkins v. City of Montgomery, Ala.*, 775 F.3d 1280, 1284 (11th Cir. 2014) (relying on preamble to interpret Department of Labor regulations), but preambles “do not enjoy the force of law” and they cannot override the unambiguous terms of a regulation itself, *Blanco v. Samuel*, 91 F.4th 1061, 1076 (11th Cir. 2024) (citing *AT&T Corp. v. FCC*, 970 F.3d 344, 350 (D.C. Cir. 2020)).⁵

The plain text of Subpart R does not prohibit the use of phosphogypsum in road construction. Section 61.206 allows the EPA to approve an application for the distribution and use of phosphogypsum for “any other purpose,” so long as the applicant secures “prior EPA approval.” 40 C.F.R. § 61.206(b). The language of § 61.206 neither enumerates what other purposes would be permissible, nor excludes any particular use; instead, the regulation only employs the broad term “any.” The Supreme Court has emphasized that “the word ‘any’ has an expansive meaning.” *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 219 (2008) (citation modified); *see also Encino Motorcars, LLC v. Navarro*, 584 U.S. 79, 88 (2018) (reading “any” to “bespeak[] breadth”); *Harrison v. PPG Indus., Inc.*, 446 U.S. 578, 589 (1980) (explaining that “any” is “expansive language” that offers no indication that the text has a “limiting construction”).

⁵ Our sister Circuits have treated preambles in a similar way, viewing them as interpretive aids, if necessary, but declining to treat them as operative law. *See, e.g., Saint Francis Med. Ctr. v. Azar*, 894 F.3d 290, 297 (D.C. Cir. 2018) (preamble “lacks the force and effect of law”); *Peabody Coal Co. v. Dir., Off. of Workers’ Comp. Programs*, 746 F.3d 1119, 1125–27 (9th Cir. 2014); *Peabody Twentymile Mining, LLC v. Sec’y of Lab.*, 931 F.3d 992, 998 (10th Cir. 2019).

So have we. See *Merritt v. Dillard Paper Co.*, 120 F.3d 1181, 1186 (11th Cir. 1997) (“[T]he adjective ‘any’ is not ambiguous; it has a well-established meaning [A]ny means all.” (citation modified)); *United States v. Castro*, 837 F.2d 441, 445 (11th Cir. 1988) (concluding that “any” means “every” or “all”).

Undeniably, road construction falls into the broad any other purpose category for which the EPA may grant approval. The EPA did not violate Subpart R when it concluded that Mosaic’s Road Project was a permissible other purpose use of phosphogypsum.

Since the regulatory text is unambiguous, we need not look to the 1992 Rule’s Preamble in order to discern its meaning. See, e.g., *Azar*, 894 F.3d at 297 (declining to evaluate preamble language where the regulation itself is clear). But even if we did look beyond the Rule’s text, the 1992 Preamble offers the Center no support. The Center primarily relies on a single paragraph from the 1992 Preamble which, again, reads this way:

For the road construction scenarios analyzed, the use of phosphogypsum always resulted in a MIR [Maximum Individual Risk] greater than the outer bound of the presumptively safe level of approximately 1×10^{-4} [1 in 10,000]. Therefore, EPA has determined that the use of phosphogypsum in road construction presents an unacceptable level of risk to public health.

1992 Rule, 57 Fed. Reg. at 23312 (emphasis added). This language, the Center argues, confirms that the EPA intended to “unconditionally reject[] all road construction as an other purpose.”

We are unpersuaded. The 1992 Preamble explained that the Agency modeled and evaluated only four road construction scenarios. *Id.* Based on its analysis of those four scenarios, the EPA declined to categorically authorize road construction in the same way it did for agricultural and research uses. *See* 40 C.F.R. §§ 61.204–05. But nowhere in the regulatory text or in the 1992 Preamble can we discern any indication that the Agency’s decision not to authorize the use of phosphogypsum in those four road construction scenarios categorically prohibited the use of phosphogypsum in all road construction scenarios.

The Center also argues that even if the 1992 Rule permits road construction as an “other purpose,” the EPA violated Subpart R when it evaluated Mosaic’s application using a risk threshold of 3 in 10,000, because the regulation requires an evaluation using a 9 in 100,000 threshold. The Center says that because the other use provision requires projects to be “at least as protective of public health, in both the short term and the long term, as disposal of phosphogypsum in a stack or a mine,” the EPA could only approve projects that carry a risk below a 9 in 100,000 threshold, which is the maximum individual lifetime risk the EPA calculated for phosphogypsum stacks and mines in 1989. 1989 Rule, 54 Fed. Reg. at 51654, 51675.

The Respondents observe, however, that the risk threshold is ultimately irrelevant, because the Road Project’s risks fall well below *both* the EPA’s applied risk threshold (3 in 10,000) and the

Center's preferred risk threshold (9 in 100,000).⁶ So even if the EPA incorrectly applied a lower risk threshold -- and we draw no such conclusion -- that error would be harmless.

We agree with the Respondents. The doctrine of harmless error applies to administrative agency actions "when a mistake of the administrative body is one that clearly had no bearing on the procedure used or the substance of [the] decision reached." *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 215 (5th Cir. 1979) (citation modified); see also *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 659–60 (2007). The reviewing court generally conducts a case-specific inquiry involving "an estimation of the likelihood that the result would have been different . . . and a hesitancy to generalize too broadly about particular kinds of errors when the specific factual circumstances in which the error arises may well make all the difference." *Shinseki v. Sanders*, 556 U.S. 396, 411–12 (2009) (citation modified).

On this record, we are satisfied that the EPA would have reached the same result even if it had applied the Center's preferred safety threshold of 9 in 100,000. In fact, the Road Project's risks are often several orders of magnitude less than the Center's preferred threshold: for truck drivers moving phosphogypsum to the site of

⁶ The Respondents, however, do not concede that the EPA used the incorrect risk threshold in evaluating Mosaic's application. Instead, they argue that Subpart R requires only that the Project carry a maximum risk below 3 in 10,000, which is the threshold the Agency used in its 1992 rulemaking process.

the test road, the risk is 2.7×10^{-7} (2.7 in 10,000,000); for construction workers, the risk is less than 2×10^{-6} (2 in 1,000,000); for workers at the Facility not directly involved in the Road Project, the risk is less than 1×10^{-6} (1 in 1,000,000); and, finally, for nearby residents, the risk is less than 1×10^{-6} (1 in 1,000,000). Thus, even for construction workers experiencing the highest risk levels, their risk of developing fatal cancer is at least 45 times lower than the Center's preferred risk threshold of 9×10^{-5} (9 in 100,000). And for the others, the risks are even lower: for truck drivers the risk is approximately 333 times less than the Center's preferred threshold, and for workers at the Facility and nearby residents, the risk is at least 90 times less than that threshold.

The Center argues nevertheless that vacatur or remand is necessary because the EPA's application of an incorrect threshold is a serious procedural error that cannot be excused. Citing *United States Steel Corp. v. EPA*, 595 F.2d 207 (5th Cir. 1979), the Center claims that the EPA's "error plainly affected the procedure used" and therefore we "cannot assume that there was no prejudice to petitioners." *Id.* at 215. In that case, the former Fifth Circuit concluded that the EPA's failure to give notice and comment was not cured by acceptance of comments after the effective date, and that the procedural error could not be considered harmless. *Id.*

Steel Corp. is not analogous. The EPA did not commit a serious procedural error which deprived the Center or its members of an opportunity to participate in the administrative process, nor did the EPA's use of the 3 in 10,000 risk threshold prejudice the

Center in any way. The Agency’s approval would be justified even if it had used the Center’s preferred risk threshold. Here, vacatur or remand would require the Agency to repeat its Review of the Road Project only to reach the same result -- a significant and unnecessary use of administrative resources. The law does not support ordering so empty an exercise.

B.

Next, the Center argues that regardless of whether the EPA’s decision violated the text of Subpart R, vacatur or remand is still required because the Agency’s approval of Mosaic’s application was arbitrary and capricious. Again, we are unpersuaded.

Under the APA, a reviewing court must set aside an agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]” 5 U.S.C. § 706(2)(A); *see Johnson*, 436 F.3d at 1273. Review under the well-established arbitrary-and-capricious standard is deferential, but still meaningful. *See id.* An agency action would be arbitrary and capricious if the agency “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *BBX Capital v. FDIC*, 956 F.3d 1304, 1314–15 (11th Cir. 2020) (per curiam) (quoting *Miccosukee Tribe of Indians of Fla. v. United States*, 566 F.3d 1257, 1264 (11th Cir. 2009)); *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Finally, in

Clean Air Act cases, where Congress has “delegated to an administrative agency the critical task of assessing the public health and the power to make decisions of national import in which individuals’ lives and welfare hang in the balance,” the EPA has the “heaviest of obligations” to explain its reasoning. *Am. Lung Ass’n v. EPA*, 134 F.3d 388, 392 (D.C. Cir. 1998).

While the grounds on which the EPA acted must be clearly disclosed in and sustained by the record, *see State Farm*, 463 U.S. at 43, the Center bears the burden of proving that the EPA’s action was arbitrary and capricious. That showing carries a significant burden here because the Agency made complex scientific and technical judgments within its area of expertise. *See BBX Capital*, 956 F.3d at 1314–15. Under our law, the EPA’s risk assessment methodology is a matter of “technical judgment lying fully within the scope of the EPA’s agency discretion.” *Miami-Dade County v. EPA*, 529 F.3d 1049, 1070 (11th Cir. 2008) (per curiam). “The law does not require selection of the single best methodology in any case, but only a study based on a consideration of the relevant factors and in the construction of which there has been no clear error of judgment.” *Id.* at 1069 (citation modified). “Indeed, courts must be ‘extremely deferential’ when an agency’s decision rests on the evaluation of complex scientific data within the agency’s technical expertise.” *Id.* at 1065 (quoting *New York v. Reilly*, 969 F.2d 1147, 1152 (D.C. Cir. 1992)). Ultimately, we may not vacate the Agency’s decision if in fact the risk assessment methodology “was appropriate for the problem it addressed.” *Id.* at 1070.

The Center makes three claims: first, that the EPA evaluated the risks of the Project using arbitrarily short exposure durations; second, that the EPA arbitrarily failed to analyze applicable exposure pathways; and, third, that in assessing exposure pathways, the Agency accepted deficient and unverifiable sampling data. As a final refuge, the Center argues vacatur or remand is necessary because future road projects may be approved on the results of Mosaic's Project, which have been tainted by the Agency's deficient and arbitrary analysis. We are unpersuaded and conclude that we are obliged to defer to the EPA's well-supported and appropriately tailored risk assessment methodology, and the ultimate decision it yielded.

i.

The Center first says that the EPA's review arbitrarily limited the temporal scope of its risk analyses for exposed individuals. For construction workers and truck drivers transporting phosphogypsum, it argues that the EPA arbitrarily limited the analyzed exposure duration to approximately one month. The Center likewise disagrees with the Agency's decision to assume that a road user would traverse the Road Project for only 250 hours in a 2,000-hour work year, as well as its decision to limit the nearest residential exposure duration to approximately thirty years.

The Respondents counter that each of the Agency's methodological assumptions were well supported and in large part derived from the EPA's 1992 analysis and rulemaking process. Moreover, they explain that when evaluating applications for other uses

of phosphogypsum, the Agency's research parameters "should be commensurate with the level of risk associated with the application." 1992 Rule, 57 Fed. Reg. at 23315. Thus, the Respondents conclude that the EPA may adjust and evaluate its methodology based on the actual estimated duration risk from a specific project, and that it appropriately did so here. The Respondents have the better of the argument.

Each of the Agency's assumptions limiting the temporal duration of the likely exposure for individuals was well explained and fully aligned with the scope of Mosaic's Road Project. As for the construction workers and truck drivers transporting phosphogypsum, the Agency's estimated one-month exposure duration was entirely consistent with Mosaic's projected construction timeline. In fact, consistent with Mosaic's proposal, the construction on the test sections of the Road -- those sections containing phosphogypsum -- actually did conclude in less than a month. Phosphogypsum was applied to the road beginning on October 7, 2025, and the application of phosphogypsum was completed by November 4, 2025. Likewise, the Agency logically explained that because the Road is located on the Facility with no public access points, its review assumed that any individual user of the Road would be a truck driver who would have no more than 250 hours of exposure per year. This assumption was modeled on the methodology the EPA used in its 1992 rulemaking process to assess the risk to bikers and motorcyclists who each have less protection from the road than a truck driver. Finally, the EPA explained that its analysis of the risk to nearby residents of approximately thirty years also was derived

from the 1992 rulemaking process, when the EPA used the same exposure duration to assess the risks to a hypothetical resident living only one hundred meters from the road.

The Center still claims that the EPA acted arbitrarily and capriciously by limiting the analyzed duration exposures when the “actual exposure will likely occur over a much longer duration.” But the Center’s argument that the EPA must assume a longer exposure period for construction workers, truck drivers transporting phosphogypsum, road users, and nearby residents is untethered from the actual parameters of Mosaic’s Road Project. Each of the EPA’s assumed duration exposures was fully explained and supported by the actual estimated exposure timelines for at-risk individuals.

Moreover, and as the Agency points out, even if it had assumed a significantly longer exposure duration for the at-risk individuals, the calculated risks were so low that even under the Center’s preferred exposure durations, the risks still would be negligible. Assuming a year-long construction period, the highest risk to construction workers would be 2.4 in 100,000, and assuming a seventy-year exposure for road users and nearby residents, the risks would be 7.7 in 1,000,000 and, at most, 4.125 in 100,000,000 respectively. Each of these risks fall well below even the Center’s preferred risk threshold of 9 in 100,000.

In short, the EPA thoroughly explained its decision to limit its risk assessments to “reflect the actual exposure times that are

25-10515

Opinion of the Court

43

expected to result from this pilot project,” and its review parameters were fully supported by the record. Agency Review at 15–16. The EPA’s methodological assumptions reflect a rational attempt to model real-world exposure, and those methodological decisions fell well within the EPA’s technical discretion. See *Miami-Dade County*, 529 F.3d at 1070 (accepting EPA modeling assumptions with a “rational relationship to the real world”).

ii.

The Center also argues that the EPA’s methodology was arbitrary and capricious because the Agency failed to analyze the reclaimer scenario -- where a future resident would build a home on land where the Road once existed. The Center says this failure was particularly “glaring” because in the 1992 Preamble, the EPA identified the reclaimer scenario as posing the highest lifetime risk of all analyzed phosphogypsum road construction scenarios. 1992 Rule, 57 Fed. Reg. at 23310.

The EPA’s decision to forgo a separate reclaimer analysis was neither arbitrary nor capricious. The Agency reasonably concluded and thoroughly explained that it excluded the reclaimer scenario in its review because the scenario did not plausibly reflect a likely exposure pathway posed by Mosaic’s Road Project. The EPA’s Notice of Approval explained that the Road would be constructed on Mosaic’s active industrial Facility, where phosphate ore mining, phosphoric acid production, and phosphogypsum storage already occur. Agency Review at 20–21. If the Facility were ever redeveloped for residential use, the site as a whole -- irrespective of

the Road -- would require the developer to undertake substantial remediation to address the radiological risks associated with the already existing radioactive residuals. The EPA explained that the Road Project “would not significantly change the site characteristics or create additional risk” to a future reclaimer and accordingly determined that a hypothetical scenario in which only the short road segment was reclaimed for residential use was not a meaningful or plausible basis for evaluating Mosaic’s application. *Id.*

We find that the Agency’s decision to forgo an analysis of the reclaimer scenario was well supported and consonant with the actual parameters of Mosaic’s Road Project and the surrounding Facility. The EPA offered a thorough account of its decision, and we can discern nothing arbitrary or capricious in the Agency’s decision to focus only on those exposure scenarios that realistically corresponded to the Road Project.

iii.

The Center next challenges the EPA’s acceptance of radium concentration values from samples of Mosaic’s phosphogypsum stacks that were over three years old when Mosaic revised its application.

The Center points to the EPA’s 2005 Workbook, which it says forbids the EPA from accepting Ra-226 samples that are more than one year old. The Workbook explains that an application for the distribution and use of phosphogypsum for other purposes must include “[t]he average concentration of radium-226 in the

25-10515

Opinion of the Court

45

phosphogypsum to be used” and that “[t]he sampling must have been done within the past 12 months.” 2005 Workbook at 30.

The Respondents acknowledge that the Agency accepted three-year-old data despite the Workbook’s language, but they say that the Workbook provides only non-binding guidance, and that the EPA’s decision to accept Mosaic’s Ra-226 sampling was well reasoned and not arbitrary and capricious. The Agency explains that it accepted Mosaic’s Ra-226 sampling because those measurements were consistent with the EPA’s own data collected from other phosphogypsum stacks in central Florida. Agency Review at 16–17. Even so, the EPA then based its analysis of the Road Project on an assumed Ra-226 concentration of more than two times Mosaic’s reported Ra-226 samples -- assuming an Ra-226 concentration of 35 pCi/g where Mosaic reported a concentration of only 15.1 pCi/g -- to reasonably overestimate the concentration of radium and arrive at conservative risk estimates. *Id.* These decisions, it says, were not arbitrary and capricious, but rather were well-explained and reasonable methodological assumptions.

We agree. Agency guidance, like the 2005 Workbook, does not provide binding, operative law. *See Lewis v. City of Union City, Ga.*, 934 F.3d 1169, 1182 (11th Cir. 2019) (agency guidance is “not binding”); *Nat’l Mining Ass’n v. Sec’y of Lab.*, 589 F.3d 1368, 1371 (11th Cir. 2009) (a guidance document “leaves the agency free to exercise its discretion to follow or not to follow that general policy in an individual case” (quoting *Ryder Truck Lines, Inc. v. United States*, 716 F.2d 1369, 1377 (11th Cir. 1983))). Thus, the Center’s

argument that the 2005 Workbook created a “regulatory obligation” that the EPA consider sampling from the past twelve months is not supported by the law.

The binding and applicable regulatory text in § 61.207(a) explains that prior to removing phosphogypsum from a stack for use in an “other purpose” project, the stack’s average Ra-226 concentration “shall” be measured with subsequent measurements performed “each calendar year while distribution of phosphogypsum removed from the location continues.” Thus, § 61.207 does not require the EPA to consider Ra-226 sampling from the past twelve months as part of the initial application.⁷ The EPA was free to accept older Ra-226 sampling in reviewing Mosaic’s application, so long as it offered a reasonable explanation.

The EPA provided a well-supported explanation of its decision. It explained that to account for the age of the samples, its analysis assumed a radium concentration that reflects the mean concentration of Ra-226 in phosphogypsum stacks in Florida, more than double the average of Mosaic’s samples. Agency Review at 11, 16. Moreover, the EPA’s approval was conditioned on Mosaic presenting additional radium sampling before construction began, in accordance with § 61.207. *Id.* By requiring further sampling, the

⁷ The regulatory text required Mosaic to conduct sampling before the Road Project commenced, and the EPA expressly imposed that requirement in its Review. *See* Agency Review at 11 (“Should the project be approved, § 61.206(d) requires that sampling that conforms with § 61.207 must be performed on the actual phosphogypsum used for the project, and repeated annually for the duration of phosphogypsum removal from the stack.”).

25-10515

Opinion of the Court

47

EPA left open the option to rescind or alter its decision upon the receipt of updated Ra-226 sampling. And as it points out, the EPA previously rescinded its conditional approval of the Fertilizer Institute's other use application for road construction projects based on information acquired after initial approval. *See* *Withdrawal of Approval for Use of Phosphogypsum in Road Construction*, 86 Fed. Reg. at 35795.

We are satisfied that the Agency acted within its discretion when it accepted the three-year-old test samples in its Review of Mosaic's Project.

iv.

The Center's final argument is that vacatur or remand is necessary because the Road Project generally will serve as an "intermediate step between laboratory testing and full-scale" approval of phosphogypsum in road construction, and these potential future regulatory amendments will be tainted by the EPA's arbitrary and capricious assessment of the Project.

This sweeping argument fails. The EPA's technical risk assessment methodology was thoroughly explained and well supported. And to the extent the Center argues that the EPA's decision improperly underlies a forthcoming regulatory shift, the argument is unsupported by the record. The EPA's Review expressly and appropriately limited the scope of its decision to Mosaic's Road Project, explicitly emphasizing that any future request to construct phosphogypsum roads anywhere else would require a separate application, a separate risk assessment, and separate approval.

Agency Review at 3, 21. Because the approval of Mosaic's Road Project does not directly bear on potential future projects, which will be subject to separate Agency action and independent analysis, we can discern no basis to vacate or remand the Agency's decision.

In short, the EPA's risk assessment articulated a coherent rationale for its approach. The Agency explained its methodology, identified the specific exposure pathways it evaluated, described its reasonable assumptions, and concluded that the Road Project fell within acceptable risk parameters. The Center may disagree with the EPA's methodological choices and its ultimate conclusion, but disagreement about technical methodology does not render an agency's reasoned determination arbitrary and capricious.

PETITION DENIED.