United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 11, 2020 Decided August 14, 2020

No. 19-1139

POET BIOREFINING, LLC, ET AL.,
PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY AND ANDREW WHEELER, ADMINISTRATOR,
RESPONDENTS

On Petition for Review of an Action of the
United States Environmental Protection Agency

Seth P. Waxman argued the cause for petitioners. With him on the briefs were *Brian M. Boynton*, *David M. Lehn*, *Paul Vanderslice*, *Ethan G. Shenkman*, *Jonathan S. Martel*, *William C. Perdue*, and *Sally L. Pei*.

Paul E. Salamanca, Attorney, U.S. Department of Justice, argued the cause for respondents. On the brief were *Jonathan D. Brightbill*, Principal Deputy Assistant Attorney General, and *Kate R. Bowers*, Attorney. *Perry Rosen*, Attorney, entered an appearance.

Before: HENDERSON, GARLAND, and PILLARD, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* PILLARD.

Opinion concurring in part and dissenting in part filed by *Circuit Judge* HENDERSON.

PILLARD, *Circuit Judge*: Cellulosic biofuel is a renewable fuel derived from plant fibers like switchgrass or the husks of corn kernels, and it produces the least lifecycle greenhouse gas emissions of the four renewable fuels promoted by the Clean Air Act's Renewable Fuel Standard program. *See* 42 U.S.C. § 7545(o)(1). Quantifying how much cellulosic biofuel companies produce becomes complicated when they make ethanol from partially cellulosic feedstocks like corn kernels. Biochemically processing the kernels produces ethanol representing both conventional biofuel from the starchy innards and, in some fraction, cellulosic biofuel from the husks. The challenge is finding an accurate method to measure the amount of cellulosic biofuel in the homogenous ethanol yielded by the whole kernels.

Recognizing the difficulty of ascertaining the cellulosic fraction, the U.S. Environmental Protection Agency (EPA) adopted a regulation known as the Pathways II Rule, allowing renewable-fuel producers to use a measurement method (1) "certified by a voluntary consensus standards body" (VCSB), or a method (2) "that would produce reasonably accurate results as demonstrated through peer reviewed references." 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3). EPA soon noticed what it considered to be troublingly wide variation in producers' measurements, so it issued "Guidance on Qualifying an Analytical Method for Determining the Cellulosic Converted Fraction of Corn Kernel Fiber Co-Processed with Starch" (the Cellulosic Guidance, or Guidance) to explain its interpretation of the applicable regulatory requirements and clarify the types of analyses and

demonstrations that might meet them. The Guidance elaborated the support needed before EPA could deem a VCSB-certified or peer-reviewed method acceptable under the Pathways II Rule.

POET Biorefining, LLC, and ten of its operating subsidiaries (collectively, POET) now petition us for review of the Cellulosic Guidance, contending that it is a legislative rule invalidly promulgated without notice and comment, conflicts with the Pathways II Rule it purports to interpret, and imposes arbitrary requirements that are impossible to meet. We conclude that POET's challenge to the Guidance's treatment of VCSB-certified methods is unripe because no such method yet exists and POET's registration efforts rely on the peer-reviewed alternative. As for POET's challenge to the Guidance's discussion of peer-reviewed methods, we hold the Guidance announces a final, interpretive rule that lawfully construes the underlying regulation. We therefore dismiss in part and deny in part the petition for review.

I. BACKGROUND

The Clean Air Act's Renewable Fuel Standard program charges EPA with increasing the domestic supply of four types of renewable fuel: cellulosic biofuel, biomass-based diesel, advanced biofuel, and total renewable fuel (which includes conventional biofuel that is not one of the three other types). *See* 42 U.S.C. § 7545(o). The four fuel types are partially "nested," meaning that cellulosic biofuel is a subcategory of advanced biofuel, which in turn is a subcategory of total renewable fuel. *See Alon Refining Krotz Springs v. EPA*, 936 F.3d 628, 635-36 (D.C. Cir. 2019) (per curiam). Each year, based on annual quotas set for each of the four statutorily defined renewable fuels, *see* 42 U.S.C. § 7545(o)(2), EPA identifies what percentage of the total amount of transportation

fuel marketed in the United States should consist of each of the four types, *see id*. § 7545(o)(3)(B). To meet those goals, EPA annually requires refiners and importers to introduce each type of renewable fuel in an amount proportionate to their overall fossil-fuel business. *See* 40 C.F.R. § 80.1407(a). EPA uses Renewable Identification Numbers (RINs) to track the type and volume of renewable fuels introduced into the U.S. economy. *See id*. § 80.1425.

RINs make the Renewable Fuel Standard program credit-based: Refiners and importers of fossil fuels satisfy their annual obligations by acquiring and submitting to EPA a quantity of RINs in requisite proportion to the fossil fuel they supplied the U.S. transportation market that year. *See id*. § 80.1427(a)(1); *see also* 42 U.S.C. § 7545(o)(5). The refiners and importers need not themselves produce or introduce renewable fuels, but instead can purchase and submit to EPA the necessary RINs from renewable-fuel producers like POET. *See Ams. for Clean Energy v. EPA*, 864 F.3d 691, 699 (D.C. Cir. 2017). Because RINs play a central role in tracking individual compliance and the volume of the overall renewable-fuel market, they must accurately reflect the volume and type of renewables produced or imported. To promote accuracy, EPA requires renewable-fuel producers to include certain information with their applications to generate RINs and, once registered with EPA, to comply with various reporting and recordkeeping requirements. *See* 40 C.F.R. § 80.1426(a)(1)(iii).

EPA's statutory duty to assign each batch of renewable fuel "an appropriate amount" of RINs, 42 U.S.C. § 7545(o)(5)(A)(i), becomes more complicated when a producer biochemically processes partially cellulosic feedstocks (like POET's corn kernels) into ethanol, a fraction of which the producer asserts is derived from the kernels' husks

so appropriately designated as cellulosic biofuel. One difficulty is the absence of "any ready test that could be used to identify the amount of a finished fuel that was derived from cellulosic versus non-cellulosic components," the relative amounts of which vary significantly depending on the producer's fuel-making process. Regulation of Fuels and Fuel Additives: RFS Pathways II, and Technical Amendments to the RFS Standards and E15 Misfueling Mitigation Requirements, 79 Fed. Reg. 42,128, 42,132 (July 18, 2014) (Pathways II Rule).

Here, POET challenges the procedural and substantive lawfulness of the Cellulosic Guidance, which explains, in view of additional data and experience, EPA's understanding of the Pathways II Rule's requirement that any method of measuring the proportion of cellulosic biofuel must do so with "reasonabl[e] accura[cy]." 40 C.F.R.80.1450(b)(1)(xiii)(B)(3).

A. Pathways II Rule & Memo

To address the problem of allocating RINs to the portion of cellulosic biofuel, if any, produced together with conventional biofuel from partially cellulosic feedstocks like corn kernels, EPA finalized the Pathways II Rule in July 2014. *See* Pathways II Rule, 79 Fed. Reg. at 42,132. Because they are triple-counted (as reflected in cellulosic biofuel's position nested within two larger categories), cellulosic-biofuel RINs are more valuable than conventional-biofuel RINs both in terms of satisfying annual regulatory obligations and generating revenue in the RIN market. *See* 40 C.F.R. § 80.1427(a)(2)-(3) (providing that RINs corresponding to cellulosic biofuel simultaneously count toward cellulosic biofuel, advanced biofuel, and total renewable fuel totals, while conventional-biofuel RINs count only as total renewable fuel).

In the Pathways II Rule, EPA describes assignment of cellulosic-biofuel RINs to a portion of the renewable fuel produced from partially cellulosic feedstocks in terms of what it calls the "cellulosic converted fraction"—the "portion of the feedstock that is converted" into cellulosic biofuel through an applicant's chosen fuel-making process. 40 C.F.R. § 80.1426(f)(3)(vi); *see also* Pathways II Rule, 79 Fed. Reg. at 42,132, 42,134. The Pathways II Rule requires that producers like POET, seeking to register with EPA to begin generating cellulosic-biofuel RINs from biochemically processing partially cellulosic feedstocks, identify "[t]he cellulosic converted fraction (CF) that will be used for generating [cellulosic-biofuel] RINs." 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(2). To enable EPA to determine whether a producer's cellulosic converted fraction is a sufficiently reliable basis for EPA to award cellulosic-biofuel RINs, the Pathways II Rule requires producers to supply the data "used to calculate the cellulosic CF." *Id.* § 80.1450(b)(1)(xiii)(B)(3); *see also* Pathways II Rule, 79 Fed. Reg. at 42,135.

Establishing the converted fraction of cellulosic biofuel produced through biochemical processing of partially cellulosic feedstocks is not straightforward. A producer that processes partially cellulosic whole corn kernels into renewable fuel cannot directly measure how much of the resultant fuel was derived from the cellulose and how much from the starch. Measuring the proportion of cellulosic biofuel derived from corn kernels is additionally challenging when the producer's conversion process is biochemical rather than thermochemical, as POET's is: Whereas a thermochemical process yields cellulosic biofuel in "proportion[] to the cellulosic content of the organic fraction of the feedstock material" from which the fuel is made, biochemical fuel-making processes "convert different fractions of the cellulosic

and non-cellulosic carbohydrates to finished fuel." Pathways II Rule, 79 Fed. Reg. at 42,134.

In general, EPA estimates (and POET does not dispute) that some 5-9% of a corn kernel's total mass is fiber, and that biochemical processing may convert only about 20% of that fiber into cellulosic biofuel. *See* EPA Br. 5-6. By contrast, EPA estimates that about 70% of the kernel's mass is starch and that biochemical processing can convert approximately 88-93% of that starch into non-cellulosic biofuel. *See id*. Based on those estimates, it appears that a very small fraction of the resulting ethanol is cellulosic, with the precise fraction both difficult to pin down and subject to significant variation depending on the specific feedstocks used, and the type and efficiency of the producer's biochemical fuel-making process. *See* Pathways II Rule, 79 Fed. Reg. at 42,134.

Because there is no way of directly monitoring what proportion of ethanol made from whole kernels derives from kernel husks, producers must obtain the data necessary to calculate the cellulosic converted fraction indirectly by devising some method of assessing the cellulosic content of the biomass that goes into and is left over from their biochemical fuel-making process. Recognizing that no easy or universally accepted method exists, the Pathways II Rule requires producers to show in their registrations to generate cellulosic-biofuel RINs that their method accurately measures the cellulosic output of their fuel-making process. *See* Pathways II Rule, 79 Fed. Reg. at 42,132 & n.12, 42,134-35. The Rule relies on third parties' expertise to evaluate methodological soundness, requiring that, when calculating the cellulosic converted fraction, producers use data that are "representative and obtained [1] using an analytical method certified by a voluntary consensus standards body, or [2] using a method that would produce reasonably accurate results as demonstrated

through peer reviewed references provided to the third party engineer performing the engineering review." 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3). The producer must also describe how it uses the data produced by its VCSB-certified or peer-reviewed measurement method to calculate the cellulosic converted fraction. *See id*. § 80.1450(b)(1)(xiii)(B)(4).

To accompany publication of the Pathways II Rule, EPA prepared a memorandum—the Pathways II Memo—discussing several measurement methods the agency thought might be sufficiently rigorous "to determine the [cellulosic] converted fraction" in support of a successful application to register for cellulosic-biofuel RINs. *Id*. at 42,132 n.12. One method it identified is to measure "the starch content of the feedstock and [of the] residual material after conversion"—the portion of the incoming feedstock that was not converted to ethanol—to determine "how much starch was converted to fuel" and then use that estimate to "determine the cellulosic converted fraction." EPA-HQ-OAR-2012-0401-0242, Additional Detail on the Calculation of the Cellulosic Converted Fraction, and Attribution of Batch RINs for D-Code Dependent Feedstocks 8 (July 1, 2014) (Pathways II Memo) (J.A. 101). Such an estimate would presumably rest on the assumption that non-starch elements in the feedstock going into the fuel-making process, as well as in the residual material coming out, must be cellulosic. The parties use "mass closure" to refer to such a method of measuring all non-cellulosic components of the inputs and outputs of the producer's fuel-making process—"such as starch, lipids, proteins, ash, and free sugars"—and treating the balance of inputs and outputs as cellulosic. EPA Br. 13 & n.7; *see* POET Br. 19.

When releasing the Pathways II Memo, EPA cautioned that such an indirect method of estimating by process of elimination the proportion of fiber converted to fuel must

satisfy regulatory "requirements," including reasonable accuracy. Pathways II Rule, 79 Fed. Reg. at 42,132 n.12. To help EPA assure the integrity of registrations for cellulosic-biofuel RINs, the Pathways II Rule requires producers to collect new data and report an updated cellulosic converted fraction to EPA on a regular basis and in response to significant data variation. *See* 40 C.F.R. § 80.1451(b)(1)(ii)(U).

In the years following the Pathways II Rule's promulgation, EPA "observed data showing very high variability in results reported for various facilities for the cellulosic converted fraction" and received requests from stakeholders for additional guidance, prompting the agency to reexamine its approach. Compliance Div., EPA Office of Transp. & Air Quality, *Guidance on Qualifying an Analytical Method for Determining the Cellulosic Converted Fraction of Corn Kernel Fiber Co-Processed with Starch* 3, 8 (May 2019) (Cellulosic Guidance) (J.A. 85, 90). To study that variability, EPA undertook a statistical analysis—a Monte Carlo (random number) simulation using unspecified industry data—to examine how converted fractions varied across a range of possible data. *Id.* at 9 (J.A. 91).

Around the time EPA conducted its Monte Carlo simulation, POET applied to EPA to register for cellulosic-biofuel RINs using the cellulosic converted fraction it calculated using a peer-reviewed method of quantifying through mass closure the cellulosic content of the inputs and outputs of its biochemical process of making renewable fuel from whole corn kernels. After EPA objected to the large data variability in POET's original application, a POET subsidiary from South Dakota, POET Biorefining–Hudson, LLC, submitted a revised application.

B. Cellulosic Guidance & Hudson Letter

On May 7, 2019, POET-Hudson received a letter from Assistant EPA Administrator Bill Wehrum following up on POET-Hudson's meeting with EPA Administrator Andrew Wheeler (the Hudson Letter). The Hudson Letter explained EPA's interpretation of the Pathways II Rule's requirements, and its then-current view of the shortcomings in POET-Hudson's pending registration application. *See* Letter from William L. Wehrum, Assistant Adm'r, EPA Office of Air & Radiation, to Jeff Broin, Chairman & CEO, POET, LLC (May 7, 2019) (Hudson Letter) (J.A. 107-15). Within a day, the Compliance Division of EPA's Office of Transportation and Air Quality released nationally applicable guidance—the Cellulosic Guidance—reproducing almost verbatim the Hudson Letter's interpretation of the Pathways II Rule. EPA appended to both the Cellulosic Guidance and the Hudson Letter the results from its Monte Carlo simulation showing high variability, so likely unreliability, of data presented under the Rule.

The parties agree that the Cellulosic Guidance and Hudson Letter's discussion of the requirements for VCSB-certified and peer-reviewed methods of obtaining cellulosic data has several components, all but one of which deal with what counts as a reasonably accurate peer-reviewed method. The documents clarify EPA's position that a producer cannot demonstrate "reasonably accurate results" through peer review without using a "known, representative reference material." Cellulosic Guidance at 3 (J.A. 85). A reference material is a sample of "corn grain biomass" assessed both before and after biochemical processing that experts have determined contains a certain amount of cellulose. *Id*. at 3 n.7 (J.A. 85). A producer can rely on a reference material with known cellulosic content to test the accuracy of its own "analytical method" of

measuring cellulose. *Id.* at 3 (J.A. 85). Applying the producer's analytical method to the reference material to show how close its method comes to the known result for the reference material can bolster EPA's confidence that the same method can, in turn, accurately measure the cellulosic content in the producer's own fuel-making process. *See id.* at 3 & n.8 (J.A. 85). According to the Guidance and the Letter, any method thus verified can be a suitable basis on which to assign RINs. *See id.* at 5 (J.A. 87).

Recognizing that no "representative reference material" is yet available, EPA notes that another federal agency, the National Institute of Standards and Technology (NIST), is developing "a reference material containing both starch and cellulose" in known proportions that reflect corn kernels' composition at various stages in a biochemical fuel-making process. *Id.* at 3 (J.A. 85). The documents also clarify that producers "cannot" show an analytical method to be "reasonably accurate" under the Pathways II Rule if the method relies solely on starch-based measurements and then infers the proportion of cellulose through mass closure. *Id.* at 4 (J.A. 86). Instead, the method should "directly" measure cellulose. *Id.*

Turning to the requirements for VCSB-certified methods, the Cellulosic Guidance and Hudson Letter acknowledge that no such method yet exists. *See id.* at 2 (J.A. 84). Nonetheless, the documents voice EPA's skepticism about the ongoing effort of one VCSB, the American Society for Testing and Materials (ASTM), to certify a method that "derive[s] the cellulosic converted fraction by directly measuring the conversion of starch," not cellulose. Hudson Letter at 6 (J.A. 112); *accord* Cellulosic Guidance at 6 (J.A. 88). Given EPA's judgment that a solely starch-based method "cannot" produce accurate results, both the Guidance and the Letter recommend that, if ASTM votes to certify the method under

consideration, producers using that method "should be prepared to demonstrate" reasonable accuracy in the same way as they would for a peer-reviewed method. *Id.*

After discussing how peer-reviewed and VCSB-certified methods must establish "reasonably accurate" results, the Hudson Letter proceeds to discuss POET-Hudson's request to generate cellulosic-biofuel RINs. POET-Hudson's peer-reviewed methodology relied on mass closure to estimate the cellulosic converted fraction of renewable fuel produced from biochemically processing corn kernels—measuring "all non-cellulosic components" and assuming "the remaining fraction that is not measured is 'cellulosic.'" Hudson Letter at 7 n.17 (J.A. 113). EPA commended POET-Hudson's effort to "limit variability," but expressed "significant concerns with relying on reference materials that do not contain both starch and cellulose." *Id.* at 9 (J.A. 115). Because it deemed POET-Hudson's proposed method to be incapable of "reasonably approximat[ing] the amount of cellulose that is actually being converted into fuel," EPA explained that it would have to further evaluate POET-Hudson's registration request "once a representative reference material with reportable starch and cellulosic values has been produced by NIST." *Id.*

POET-Hudson petitioned the Eighth Circuit for review of the Hudson Letter's consideration of its registration application. *See POET Biorefining – Hudson, LLC v. EPA*, No. 19-2429 (8th Cir. argued June 16, 2020). That petition remains pending. POET and various subsidiaries, including POET-Hudson, petitioned for our review of the Cellulosic Guidance, which they contend is a "nationally applicable" EPA action that (unlike the adjudication of POET-Hudson's application) is reviewable in this court. 42 U.S.C. § 7607(b)(1).

Specifically, POET argues that the Cellulosic Guidance is a legislative rule improperly promulgated without an opportunity for notice and comment. Alternatively, even if the Guidance is a procedurally proper interpretive rule, POET contends that it substantively conflicts with the Pathways II Rule by "arrogat[ing]" from third-party reviewers and VCSBs to EPA the power to decide what constitutes a reasonably accurate method of measuring a biochemical fuel-making process' cellulosic production. POET Br. 45. According to POET, EPA has exercised that power in a way that, due to the lack of a VCSB-certified method and a NIST-approved reference material, leaves producers unable to generate the cellulosic-biofuel RINs that the Pathways II Rule affords them.

II. JURISDICTION

Before reaching the merits, we must determine whether we have jurisdiction, which here requires deciding whether POET's petition is ripe under Article III of the U.S. Constitution and whether the challenged EPA Guidance is a "final" agency action under the Clean Air Act, 42 U.S.C. § 7607(b)(1).

A. POET's Challenge to the Guidance's VCSB Discussion Is Unripe

"The ripeness doctrine generally deals with when a federal court can or should decide a case." *Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 386 (D.C. Cir. 2012). We conclude that POET's challenge to the Cellulosic Guidance's discussion of VCSB-certified methods is unripe, but that the challenge to the Guidance's interpretation of the regulatory requirements for peer-reviewed methods, which EPA has already applied and which presents a purely legal question, is ripe for our review.

Constitutional ripeness "is subsumed into the Article III requirement of standing, which requires a petitioner to allege *inter alia* an injury-in-fact that is 'imminent' or 'certainly impending.'" *Id.* (quoting *Nat'l Treasury Emps. Union v. United States*, 101 F.3d 1423, 1427-28 (D.C. Cir. 1996)). Standing—and thus constitutional ripeness—is "not evaluated 'in gross,'" so a petitioner challenging distinct components of an agency's guidance must show that we have jurisdiction to consider each claim. *Sierra Club v. EPA*, 873 F.3d 946, 951 (D.C. Cir. 2017) (quoting *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996)); *see also Del. Dep't of Nat. Res. & Envtl. Control v. EPA*, 785 F.3d 1, 10 (D.C. Cir. 2015). Nobody disputes that the Pathways II Rule distinguishes VCSB-certified and peer-reviewed methods as separate, alternative ways to gain EPA approval and generate cellulosic-biofuel RINs, so we evaluate the Guidance's ripeness as to each method. *See* 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3); POET Br. 20-21; EPA Br. 16-17.

Because POET has not sought to rely on any VCSB-certified method, it has no "actual or imminent" injury in fact that is "fairly traceable to the challenged" interpretation regarding such methods, so cannot show that portion of its petition is ripe. *Kan. Corp. Comm'n v. FERC*, 881 F.3d 924, 929 (D.C. Cir. 2018) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). "A petitioner that asserts a harm that may occur 'some day,' with no 'specification of *when* the some day will be,' does not establish its standing." *Id.* at 930 (quoting *Defs. of Wildlife*, 504 U.S. at 564). Uncertainty over whether, let alone when, a VCSB might approve a method of obtaining data to calculate the cellulosic converted fraction renders POET's challenge to the Guidance's treatment of VCSB-certified methods constitutionally unripe. We therefore dismiss POET's premature challenge to the Cellulosic Guidance insofar as it addresses VCSB-certified methods.

By contrast, the Guidance's interpretation of the Pathways II Rule's requirements for peer-reviewed methods has already had real-world effects. Most concretely, EPA has relied on the Guidance in declining to grant POET-Hudson's application to register for cellulosic-biofuel RINs using a peer-reviewed method of obtaining cellulosic data. That part of the petition, which presents a "purely legal claim in the context of a facial challenge" to the Guidance, is ripe for our review. *Nat'l Ass'n of Home Builders v. U.S. Corps of Eng'rs*, 417 F.3d 1272, 1282 (D.C. Cir. 2005).

B. The Guidance's Interpretation Is Final Action

The Clean Air Act's requirement of "final action" tracks the Administrative Procedure Act's finality requirement, *see* 5 U.S.C. § 704, except that—in contrast to APA finality—"finality is jurisdictional" under the Clean Air Act. *Valero Energy Corp. v. EPA*, 927 F.3d 532, 536 (D.C. Cir. 2019). An agency's action is final "if two independent conditions are met: (1) the action 'mark[s] the consummation of the agency's decisionmaking process' and is not 'of a merely tentative or interlocutory nature;' and (2) it is an action 'by which rights or obligations have been determined, or from which legal consequences will flow.'" *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (alteration in *Soundboard Ass'n*)).

"The consummation prong of the finality inquiry requires us to determine 'whether an action is properly attributable to the agency itself and represents the culmination of that agency's consideration of an issue,' or is, instead, 'only the ruling of a subordinate official, or tentative.'" *NRDC v. Wheeler*, 955 F.3d 68, 78 (D.C. Cir. 2020) (quoting *Soundboard Ass'n*, 888 F.3d at 1267). The Guidance

consistently speaks in EPA's voice, setting forth the "interpretation" and "guidance" of the agency. Cellulosic Guidance at 1 (J.A. 83). EPA does not dispute that the Guidance was approved by Assistant EPA Administrator Bill Wehrum, who was then EPA Administrator Wheeler's "principal advisor . . . in matters pertaining to air and radiation programs," *Cal. Cmtys. Against Toxics v. EPA*, 934 F.3d 627, 636 (D.C. Cir. 2019) (quoting 40 C.F.R. § 1.41), and whom we have described in the context of finality analysis as "no mere subordinate" within EPA, *id.*

EPA contends that the Guidance's explication of how peer-reviewed methods might be shown to be "reasonably accurate" does not represent the consummation of agency decision making because it is "explicitly premised on the agency's current understanding of the science, which itself is expressly recognized as under development." EPA Br. 32. The possibility of revision "is a common characteristic of agency action, and does not make an otherwise definitive decision nonfinal." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1814 (2016); *see also Safari Club Int'l v. Jewell*, 842 F.3d 1280, 1289 (D.C. Cir. 2016); *Nat'l Envtl. Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1006-07 (D.C. Cir. 2014); *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 380 (D.C. Cir. 2002); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022 (D.C. Cir. 2000). Even though agency action taken at scientific frontiers is especially susceptible to future alteration, that fact alone does not alone defeat finality. EPA's considered Guidance, based on its best scientific understanding at the time, consummated its decision making regarding which currently available, peer-reviewed measurement methods are "reasonably accurate" for the purpose of assigning cellulosic-biofuel RINs. 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3).

Proceeding to the second question under *Bennett*, "whether an agency action has direct and appreciable legal consequences," we "pragmatic[ally]" focus on "the concrete consequences [the] action has or does not have as a result of the specific statutes and regulations that govern it." *Cal. Cmtys.*, 934 F.3d at 637 (internal quotation marks omitted). The Guidance carries legal consequences because it withdraws some of the discretion the Pathways II Rule afforded EPA in evaluating the reliability of peer-reviewed methodologies. In contrast to EPA's suggestion at the time of the Pathways II Rule that producers could "indirectly determine the cellulosic converted fraction" by measuring "starch content," Pathways II Memo at 8 (J.A. 101), EPA has since concluded with the benefit of additional information that solely starch-based measurements "cannot ensure that resulting estimates of cellulosic conversion are reasonably accurate," Cellulosic Guidance at 4 (J.A. 86). The Guidance also imposes obligations by directing applicants for cellulosic biofuel registration to demonstrate to EPA the reliability of their methods via a representative reference material. Those elaborations on what counts as a "reasonably accurate" method of obtaining cellulosic data, 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3), have concrete consequences for producers like POET seeking to show EPA that their method meets the Pathways II Rule's requirements, *see Gen. Elec.*, 290 F.3d at 380; *Appalachian Power*, 208 F.3d at 1023.

The unequivocal language of the Guidance also signals that EPA has "definitively interpreted" the Pathways II Rule's reasonable-accuracy requirement to demand use of a cellulosic reference material. *NRDC v. EPA*, 643 F.3d 311, 320 (D.C. Cir. 2011). For example, the Guidance document declares that "it is not possible" to assess whether a method satisfies the regulatory standard—reasonable accuracy—without evaluating the performance of the method on a "known,

representative reference material" that includes cellulose. Cellulosic Guidance at 3 (J.A. 85). By declaring that achieving reasonable accuracy is impossible without using such material, the Guidance makes the "permissibility" of methods not using a cellulosic reference material a "closed question," at least for now. *NRDC*, 643 F.3d at 320. EPA's Cellulosic Guidance "leads private parties . . . to believe that it will declare [registrations] invalid unless they comply with the terms of the document." *Appalachian Power*, 208 F.3d at 1021.

Indeed, EPA has already applied the Guidance as if it were binding in the context of the Hudson Letter. The Hudson Letter's use of the Cellulosic Guidance to analyze POET-Hudson's registration application reinforces the Guidance's finality and is properly part of our finality analysis. For example, we have examined an agency directive's role in a separate "permit decision" to conclude it was final. *Clean Air Project*, 752 F.3d at 1007. The Hudson Letter explained that, despite POET-Hudson's effort to tweak its methodology to reduce data variability, the company could not register for cellulosic-biofuel RINs without proving its method's accuracy using "a representative reference material with reportable starch and cellulosic values." Hudson Letter at 9 (J.A. 115). The Hudson Letter illustrates the firmness of the Guidance's demand that producers use a cellulosic reference material to show reasonable accuracy.

Contending the Cellulosic Guidance is nonfinal, EPA unsuccessfully analogizes to Clean Air Act cases in which, unlike here, challenged guidance did not affect "the amount of discretion permitting authorities retain," *Sierra Club*, 955 F.3d 56, 64 (D.C. Cir. 2020); "d[id] not impose any requirements in order to obtain" agency approval, *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014); and was never applied in a "binding" manner, *Sierra Club*, 873 F.3d at 952.

EPA also asserts the Cellulosic Guidance is nonfinal because it "merely interpret[s] existing requirements" instead of "creating new ones." EPA Br. 24. But we recently reiterated that an interpretive rule construing existing law can constitute final action under 42 U.S.C. § 7607(b)(1) even though, standing alone, it would lack "the force and effect of law" carried by an underlying legislative rule or statute. *Cal. Cmtys.*, 934 F.3d at 635 (quoting *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 103 (2015)).

Finally, EPA contends that we need not exercise jurisdiction over the Guidance because producers like POET-Hudson can still petition regional circuits to challenge individual RIN registration decisions based on the Guidance. That argument proves too much. The Clean Air Act "specifically provides for 'preenforcement' review" of nationally applicable actions like the Guidance even if parties could also seek review in connection with individual adjudications. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 479-80 (2001) (construing 42 U.S.C. § 7607(b)(1)). In contrast to the cases EPA cites, there is no alternative judicial-review provision applicable here that might suggest we should not exercise jurisdiction under section 7607(b)(1). *Cf. Cal. Cmtys.*, 934 F.3d at 639 (holding guidance to be nonfinal under section 7607(b)(1) in view of section 7661d's judicial-review regime); *Valero*, 927 F.3d at 538 (similar, in view of the opportunity for review under section 7604(a)(2)). The substantial investment, research, and development required to generate cellulosic biofuels compliant with the Renewable Fuel Standard program underscores why the prospect of eventual review of an application disapproval is no reason to deny here the opportunity for pre-enforcement review the Act provides.

As in *Appalachian Power*, "[t]he short of the matter" here is that the Guidance's interpretation of the Pathway II Rule's

peer-review requirements "is final agency action, reflecting a settled agency position which has legal consequences both for" EPA officials allocating RINs and "for companies like those represented by petitioners" who must obtain EPA approval to generate RINs. 208 F.3d at 1023. Having confirmed our jurisdiction over the Cellulosic Guidance's treatment of peer-reviewed methods of obtaining cellulosic data, we proceed to review the merits of its interpretation.

III. MERITS

The first step in our merits analysis is to determine whether the Guidance is a legislative rule or an interpretive one, because if it is legislative we must invalidate it at the outset as never having been subjected to notice and comment. *See* 42 U.S.C. § 7607(d) (incorporating 5 U.S.C. § 553(b)); *NRDC*, 955 F.3d at 85. Only if the Guidance is an interpretive rule need we address petitioners' substantive challenge to the Guidance as contrary to the Pathways II Rule it purports to interpret.

A. The Guidance is an Interpretive Rule

"[T]he critical feature of interpretive rules is that they are issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Perez*, 575 U.S. at 97 (internal quotation marks omitted). In contrast to legislative rules, which "effect[] a substantive change in existing law or policy," interpretive rules "clarify a statutory or regulatory term, remind parties of existing statutory or regulatory duties, or 'merely track[]' preexisting requirements and explain something the statute or regulation already required." *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014) (quoting *Nat'l Family Planning & Reprod. Health Ass'n v. Sullivan*, 979 F.2d 227, 237 (D.C. Cir. 1992)). To decide whether a rule is interpretive or legislative, we look to the rule's "language" and "ask whether the agency intended

to speak with the force of law," including "whether the agency has published the rule in the Code of Federal Regulations and whether it explicitly invoked its general legislative authority." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 18 (D.C. Cir. 2019) (per curiam) (internal quotation marks omitted); *see also Gen. Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc). We also consider whether the challenged rule comports with or changes the text of whatever prior rule it professes to interpret. *See, e.g.*, *Perez*, 575 U.S. at 103-04.

The Cellulosic Guidance could hardly be clearer that it interprets the regulatory requirement that biofuel producers' methodologies yield "reasonably accurate results as demonstrated through peer reviewed references." 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3). The title, "Interpretation of the 'Reasonable Accuracy' Requirement," identifies the function of the Guidance: to explain what the Pathways II Rule requires when a company seeks to show the accuracy of its peer-reviewed method of measuring how much of its ethanol produced from whole corn kernels derives from cellulosic material in support of its registration for cellulosic-biofuel RINs. Cellulosic Guidance at 2 (J.A. 84). Without ever invoking EPA's legislative authority or deviating from the Pathways II Rule's text, it explains how biofuel producers must "demonstrate[]" their method's reasonable accuracy using "a known, representative reference material" capable of producing a "true value" of the renewable fuel's cellulosic content against which accuracy can be reliably assessed. *Id.* at 3 & n.8 (J.A. 85). In short, the Guidance interprets the "reasonable accuracy" regulatory requirement in light of EPA's accumulated experience in this particular context.

By "deriv[ing] a proposition from an existing document whose meaning compels or logically justifies the proposition,"

the Guidance's discussion of peer-reviewed methods qualifies as an interpretive rule. *Mendoza*, 754 F.3d at 1021 (quoting *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 494 (D.C. Cir. 2010)). Indeed, here the EPA has not even shifted its policy objective: The agency remains committed to issuing RINs to biofuel producers who can show with reasonable accuracy what portion, if any, of the fuel they make from partially cellulosic feedstocks actually derives from the cellulosic material. The Guidance does no more than account for data, accumulated since EPA issued the Pathways II Rule and Memo, suggesting that previously contemplated measurement methods are inaccurate. In spelling out what EPA believes it means to "produce reasonably accurate results" under the Pathways II Rule, thereby aiding industry to steer clear of demonstrated measurement problems, 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3), the agency cannot fairly be said to have substantively amended the regulation.

To the extent that the Cellulosic Guidance is a "new" and more detailed articulation of the Pathways II Rule's requirements for peer-reviewed methods, POET Br. 39, POET errs in asserting that such limited novelty makes the Guidance a legislative rule. If an agency's interpretation were a legislative rule simply because it drew "crisper and more detailed lines than the authority being interpreted," then "no rule could pass as an interpretation of a legislative rule unless it were confined to parroting the rule or replacing the original vagueness with another"—a regime we have squarely rejected. *Am. Mining Cong. v. MSHA*, 995 F.2d 1106, 1112 (D.C. Cir. 1993). Rules that are fairly drawn from underlying statutes or regulations may articulate even relatively detailed legal obligations without thereby becoming legislative rules subject to notice and comment.

We have, time and again, upheld interpretive rules that narrow or remove leeway afforded to regulated parties under a prior interpretation. Examples include a Program Policy Letter of the Mine Safety and Health Administration specifying the minimum opacity a chest X-ray needs to count as a reportable diagnosis under mine-safety regulations, *see id.*; a section of the Medicare Provider Reimbursement Manual advising how the Medicare statute and regulations work in particular reimbursement claims, *see Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 97-99 (1995); a new Federal Communications Commission order explaining how an existing order regarding portability would apply to wireless telephone carriers, *see Cent. Tex. Tel. Co-op., Inc. v. FCC*, 402 F.3d 205, 213-14 (D.C. Cir. 2005); and a letter from the Federal Aviation Administration's deputy counsel explaining how to calculate pilots' required rest periods under an FAA regulation imposing flight-time limitations, *see Air Transp. Ass'n of Am., Inc. v. FAA*, 291 F.3d 49, 56 (D.C. Cir. 2002). The common thread running through the cases is that even a consequential, "conduct-altering" rule remains interpretive so long as it can "fairly be viewed as interpreting—even incorrectly—a statute or regulation." *Cent. Tex.*, 402 F.3d at 212, 214.

Requiring EPA to undertake notice and comment whenever it refines an interpretation of its rules or statutory authorities would discourage the agency from synthesizing and documenting helpful and reliable advice like the Cellulosic Guidance. "[I]nformal communications between agencies and their regulated communities . . . are vital to the smooth operation of both government and business." *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004). After all, "[t]he agency that wrote the regulation will often have direct insight into what that rule was intended to mean" in a given context and "how it was supposed to apply to some problem." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2412 (2019)

(plurality opinion of Kagan, J.) (internal quotation marks omitted). Guidance offering "convenient notice" of an agency's interpretation of a statute or regulation it administers is often preferable to leaving regulated parties and the public to piece together interpretive strands reflected in individual adjudications. *Am. Mining Cong.*, 995 F.2d at 1112. The Cellulosic Guidance's discussion of what it means under the Pathways II Rule to demonstrate reasonable accuracy through peer review is the sort of clarifying elaboration interpretive rules legitimately provide.

POET asserts that the Cellulosic Guidance "repudiates or is irreconcilable with" the Pathways II Rule, so must be a legislative rule. POET Br. 39 (quoting *Ass'n of Flight Attendants-CWA v. Huerta*, 785 F.3d 710, 718 (D.C. Cir. 2015)). We conclude, however, that EPA's reasoned elaboration of what it means to demonstrate a peer-reviewed method's reasonable accuracy is consistent with the Pathways II Rule, and nothing like the kind of stark "*volte face*" necessary to support POET's argument. *Nat'l Family Planning*, 979 F.2d at 235 (quoting *Homemakers N. Shore, Inc. v. Bowen*, 832 F.2d 408, 412 (7th Cir. 1987)). Indeed, an agency may work even a "fundamental change in its interpretation of a substantive regulation," and yet the result may still constitute an interpretive rule that does not require notice and comment. *Perez*, 575 U.S. at 101 (internal quotation marks omitted). At bottom, EPA's interpretation of "[a]ccuracy" to mean "how closely the measured value approximates its true value," and its call for a reference material capable of supplying that true value, Cellulosic Guidance at 3 n.8 (J.A. 85), interprets the Pathways II Rule's reasonably-accuracy requirement. POET's argument that the Cellulosic Guidance reads the Pathways II Rule incorrectly relates not to the Guidance's classification as an interpretive rule, but to its substantive merits.

Our disagreement with our dissenting colleague over whether the Cellulosic Guidance is an interpretive or legislative rule is relatively limited: The dissent concludes that the Guidance is in part a legislative rule—only "with respect to the reference material requirement." Dissent at 1. Because no representative reference material presently exists, *see* Cellulosic Guidance at 3 n.7 (J.A. 85), the dissenting opinion argues that EPA substantively changed the regulation by "clos[ing] a regulatory pathway opened by the Pathways II Rule," Dissent at 7. There is no substantive change: The Pathways II Rule authorizes RIN registrations for cellulosic biofuel only in "certain circumstances," 79 Fed. Reg. at 42,132—namely, where producers utilize a measurement method that obtains "reasonably accurate results," 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3). EPA is under no obligation to approve applications that fail to meet this requirement, or to bend the science behind "reasonable accuracy" to ensure that producers are permitted to register. Certainly, if EPA took a view of "reasonable accuracy" contrary to that of "100 cellulosic fuel experts," Dissent at 6, its interpretation might be arbitrary. That counterfactual is not before us here, where the record includes unquestioned data and ample scientific support for EPA's doubts that an analytical method's accuracy can be established without a representative reference material. More fundamentally, differences of expert opinion would go to the substantive merits, to which we now turn.

B. The Guidance's Interpretation Is Reasonable

POET challenges the Cellulosic Guidance's construction of the Pathways II Rule as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," in violation of the Clean Air Act. 42 U.S.C. § 7607(d)(9)(A). "The arbitrary and capricious standard is deferential; it requires that agency action simply be 'reasonable and reasonably

explained.'" *Cmtys. for a Better Env't v. EPA*, 748 F.3d 333, 335 (D.C. Cir. 2014) (quoting *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009)). The parties dispute the precise level of deference EPA enjoys as the author of the Guidance and the regulation that it interprets, but because we conclude that EPA's interpretation is valid even under the less deferential "power to persuade" standard, *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 150 (2012) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001)), we need not resolve their dispute.

The Pathways II Rule's requirement that biofuel producers show that their methods of obtaining cellulosic data "would produce reasonably accurate results as demonstrated through peer reviewed references provided to the third party engineer performing the engineering review at registration," 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3), limits EPA to approving methods that have been favorably peer reviewed. Contrary to POET's contention, however, the Pathways II Rule does not "unambiguously delegate[]" reasonable-accuracy determinations to third-party engineers and peer reviewers. POET Br. 42. To the contrary, the regulation requires producers, supported by the specified professional analyses, to "demonstrate[]" to EPA that their methods of determining the cellulosic fraction of their biofuel are reasonably accurate. 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3).

Peer-reviewed references and the accompanying third-party engineer's report "must be submitted and accepted by EPA" before producers can register the corresponding RINs. *Id.* § 80.1450(b). Confirming that the agency retains the decisive role in choosing whether to "accept[]" peer reviewers' conclusions, *id.*, EPA explained that the Pathways II Rule's peer-review requirement "allow[s] EPA to verify that the [cellulosic converted fraction] is being applied appropriately

for cellulosic biofuel RIN generation," Pathways II Rule, 79 Fed. Reg. at 42,132. Like an academic journal that incorporates the results of peer review into the publication decisions its editorial board makes or a funder that looks to peer review to guide its grantmaking, EPA required peer review to help it "verify" methodological soundness without displacing the agency's ultimate approval authority or ability to say more precisely what it is looking for. *Id*.

POET claims support in the National Technology Transfer and Advancement Act of 1995 for its view that the Pathways II rule delegates the reasonable-accuracy determination to peer reviewers. But the provision POET cites, which directs federal agencies to "use technical standards that are developed or adopted by voluntary consensus standards bodies," Pub. L. No. 104-113, § 12(d)(2), 110 Stat. 775, 783 (1996) (codified at 15 U.S.C. § 272 note), deals with agencies' interactions with VCSBs, not their use of peer-reviewed methods—and even that directive is subject to agencies' direction, interests, and goals. POET also points to EPA's general policy on peer review, but that policy supports EPA's position, not POET's, insofar as it explains that peer review helps "ensur[e] that the EPA's decisions rest on sound science and data," not that the peer reviewers' determinations are themselves deemed to be EPA's. EPA Sci. & Tech. Pol'y Council, *Peer Review Handbook* § 1.3.1, at 25 (4th ed. Oct. 2015). Nor does the Guidance reduce peer reviewers to "mere fact checkers of a mathematical test," POET Br. 42; rather, the Guidance aids effective peer review by articulating benchmarks for reviewers' assessments whether a producer's method can accurately measure the cellulosic yield of its particular fuel-making process on a consistent basis.

Congress requires EPA to ensure RINs are "appropriate[ly]" assigned. 42 U.S.C. § 7545(o)(5)(A)(i). The

regulation at issue explicitly preserves EPA's authority to decide whether to "accept[]" a "demonstrat[ion]" that a peer-reviewed method produces reasonably accurate results. 40 C.F.R. § 80.1450(b). In that role, EPA appropriately issued the Cellulosic Guidance to help peer reviewers and applicants identify the kinds of data that EPA has determined are required in registrations for cellulosic-biofuel RINs. The Guidance explains what EPA deems necessary to verify the accuracy of producers' claims as to the quantity of fuel they derive from the small cellulosic portion of their corn-kernel feedstocks, as opposed to the larger starch component. In sum, we are unpersuaded by POET's contention that the Pathways II Rule's peer-review requirement somehow forces EPA into unquestioned deference to peer reviewers' conclusions and prevents it from requiring applicants to comply with its own understanding of reasonable accuracy.

POET next contends that three interpretations within the Guidance are arbitrary: that producers must demonstrate their method's accuracy both in theory and in fact; that producers must use a representative reference material to prove their method's accuracy; and that producers cannot rely on methods that measure a fuel's cellulosic content by process of elimination—*i.e.*, through mass closure. POET refers to those three interpretations as the Demonstration Requirement, the Reference Material Requirement, and the Mass Closure Prohibition. (POET understands the Demonstration and Reference Material Requirements also to "mandat[e]" that a measurement method "actually yield[] results within 20% of the known quantities of starch and cellulose in a representative reference material," but makes clear it is not "separately challeng[ing] that 20% standard." Reply Br. 8 n.1.) We conclude that all three survive arbitrary-and-capricious review.

Demonstration Requirement. The Cellulosic Guidance's Demonstration Requirement interprets the regulatory obligation on producers to show how their method "would produce reasonably accurate results as demonstrated through peer reviewed references." 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3). The Guidance construes that language to direct peer reviewers to evaluate both "the potential performance" of their method and "the accuracy of the results of that method." Cellulosic Guidance at 3 (J.A. 85). Because "demonstrate" ordinarily means "[t]o show . . . by operation, reasoning, or evidence," *Animal Legal Def. Fund, Inc. v. Perdue*, 872 F.3d 602, 616 (D.C. Cir. 2017) (quoting Black's Law Dictionary 432 (6th ed. 1990)), not merely to predict or hypothesize, EPA reasonably reads the regulatory requirement of "demonstrated" accuracy to require peer reviewers to pass on both the theoretical soundness of a producer's method, and whether its application "has, in fact, yielded a calculation of the cellulosic converted fraction that is reasonably accurate," Cellulosic Guidance at 3 (J.A. 85).

POET reads the regulation's use of conditional language—requiring that analytic methods "*would produce* reasonably accurate results," 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3) (emphasis added)—to stop short of calling for review of any results actually produced by the method. We understand the form "would produce" simply to reflect that producers seek peer review before they obtain EPA approval to generate RINs in compliance with the regulation. We are unpersuaded that the regulatory text bars EPA from requiring reviewers to examine data demonstrating a method's accuracy in practice. The Demonstration Requirement permissibly interprets "demonstrated" in line with its ordinary meaning.

Reference Material Requirement. The Cellulosic Guidance interprets accuracy to mean "how closely the

measured value approximates its true value." Cellulosic Guidance at 3 n.8 (J.A. 85). The Guidance explains that "accurately measuring how much of a cellulosic feedstock is converted into fuel" requires testing the measurement method on a "representative reference material," *id.* at 3 (J.A. 85), to see how closely the method's results approach such a material's known "cellulosic value," *id.* at 3 n.6 (J.A. 85). The Guidance's conception of accuracy parallels what EPA understands accuracy to mean in other environmental programs. *See, e.g.*, 40 C.F.R. § 72.2 (defining "Flow meter accuracy" and "Monitor accuracy" by "the closeness of the measurement . . . to the reference value"); *id.* § 80.47(a)(2) ("Accuracy means the closeness of agreement between an observed value from a single test measurement and an accepted reference value."); *id.* § 194.22(c)(1) (conceiving of "Data accuracy" as "the degree to which data agree with an accepted reference or true value"). The Guidance further observes that the absence of a known value against which to measure accuracy has caused unacceptable data variability, as manifested both in producers' reporting and EPA's own Monte Carlo simulation. *See* Cellulosic Guidance at 3-4 (J.A. 85-86).

POET seizes on EPA's acknowledgment that NIST has not yet made available the only suitable reference material identified in the Guidance, arguing that its current unavailability makes the requirement "impossible to fulfill and thus . . . arbitrary and capricious" under our decision in *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 940 (D.C. Cir. 1991). This case is readily distinguishable from *Cannabis Therapeutics*, however, where we invalidated an agency's interpretation of a provision in the Controlled Substances Act, 21 U.S.C. § 812(b)(2)(B), that created a seemingly permanent Catch-22: Parties seeking to reclassify marijuana as a Schedule II drug needed to show that marijuana "enjoys general 'availability' or 'use,'" but had to make that

showing during a period when marijuana remained a Schedule I drug, which by definition is not generally available. 930 F.2d at 940. The challenge posed by the Guidance's Reference Material Requirement, by contrast, flows not from intractably contradictory agency directives, but the ongoing effort to develop a suitable reference material that, once complete, will provide a path forward. Unlike the legally unachievable marijuana "general availability" requirement, ability to meet the Reference Material Requirement awaits scientific development by NIST or some other entity of a reference material capable of supplying a known, standard value against which the claimed accuracy of producers' methods can be tested. There is nothing arbitrary about EPA's refusal to approve a methodology to make measurements that nobody has yet shown can be made with reasonable accuracy.

POET also claims the Reference Material Requirement is unreasonable to the extent that it is unmet by synthetic reference materials. Notably, however, neither the Cellulosic Guidance nor the Hudson Letter's general discussion disallows synthetic materials as such, and EPA told us that "the Guidance does not foreclose a peer reviewer from concluding that the use of a synthetic reference material is appropriate" and persuading EPA to that effect. EPA Br. 44. The only discussion specific to synthetic rather than natural reference materials comes in the Hudson Letter's determination that POET-Hudson's proposed reliance on a synthetic reference material to validate its analytic method would not produce the requisite "reasonably accurate results." Hudson Letter at 9 (J.A. 115). Because POET's petition for review in this case is limited to the Cellulosic Guidance, with POET-Hudson having separately petitioned the Eighth Circuit for review of the Hudson Letter, the synthetic-material issue is not before us and we express no view on it here. We sustain the interpretation embodied in the Reference Material Requirement notwithstanding that no reference

material capable of establishing a true cellulosic value currently exists.

Mass Closure Prohibition. Flowing from the same proposition that ascertaining reasonable accuracy requires knowing how well a proposed method measures known cellulosic content, the Mass Closure Prohibition declares that methods of calculating cellulosic content "based on starch reference values alone cannot ensure that resulting estimates of cellulosic conversion are reasonably accurate." Cellulosic Guidance at 4 (J.A. 86). Recall that mass closure estimates cellulosic content indirectly by measuring all non-cellulosic components of the partially cellulosic inputs and outputs of the producer's fuel-making process and assumes the remainders must be cellulosic (kernel husk inputs on one hand, and cellulosic biofuel on the other). After five years of observing a "wide degree of variability in [renewable-fuel producers'] data" and conducting its own "statistical analysis," *id.* at 3-4 (J.A. 85-86), EPA recognized that mass closure's reliance on a series of non-cellulosic measurements—each with its own error rate—has had unacceptably distorting cumulative effects on the resulting measurement of cellulosic content. EPA's Guidance thus concludes that the agency lacks evidence that indirectly estimating cellulosic content by relying on mass closure's process of elimination can accurately measure the fuel's relatively small cellulosic content.

While the Cellulosic Guidance's disapproval of mass closure methods retreats from EPA's earlier expressions of amenability to such methods, *see* Pathways II Memo at 8 (J.A. 101), agencies are free to shift interpretive positions, especially where, as here, they do so on a comprehensively updated record, *see Ark Initiative v. Tidwell*, 816 F.3d 119, 129-30 (D.C. Cir. 2016). Agencies may change interpretations without subjecting the new interpretive rule to "notice-and-

comment procedures," *Perez*, 575 U.S. at 101, or "to more searching [judicial] review," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514 (2009). EPA made clear when it promulgated the Pathways II Rule that it was open to, if not yet convinced of, the prospect that producers could reliably use mass closure to quantify the cellulosic component of renewable fuel produced from feedstocks like corn kernels that are predominantly non-cellulosic. *See* Pathways II Rule, 79 Fed. Reg. at 42,132 & n.12; Pathways II Memo at 5-6 (J.A. 98-99). Informed by the wildly variable data that mass closure methods have produced in the ensuing years and by its own statistical analysis, EPA has now reasonably decided to replace the Pathways II Memo's unstudied agnosticism with the Guidance's evidence-based understanding that mass closure cannot achieve reasonable accuracy. No further justification is required.

To the extent POET claims it presented evidence in connection with POET-Hudson's application to generate cellulosic-biofuel RINs that undermines the Mass Closure Prohibition, both the Guidance and EPA's briefing make clear that an individual applicant may gain EPA's approval of a method utilizing mass closure if it presents data or scientific developments that address the general concerns set forth in the Guidance. *See* Cellulosic Guidance at 1 (J.A. 83); EPA Br. 48. In light of that understanding, we uphold the interpretation embodied in the Guidance's Mass Closure Prohibition and leave the Eighth Circuit to determine whether the Hudson Letter's individualized consideration of POET-Hudson's proposed use of mass closure was lawful.

Throughout its briefing, POET contests various policy judgments underlying the Cellulosic Guidance's interpretation of the Pathways II Rule, such as the wisdom of explaining criteria that expert peer reviewers must account for, yet "[o]ur

review under the 'arbitrary and capricious' standard is narrow and does not permit us to substitute our policy judgment for that of [EPA]." *Maryland v. EPA*, 958 F.3d 1185, 1210 (D.C. Cir. 2020) (per curiam) (quoting *Bluewater Network v. EPA*, 370 F.3d 1, 11 (D.C. Cir. 2004)). We conclude the Cellulosic Guidance is an interpretive rule that reasonably explains how under the Pathways II Rule renewable-fuel producers must demonstrate that peer-reviewed methods of obtaining cellulosic data can yield "reasonably accurate results" that justify EPA awarding them cellulosic-biofuel RINs. 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3).

* * *

In sum, we dismiss the petition for review as unripe to the extent it challenges the Cellulosic Guidance's recommendations for RIN registrations relying on a VCSB-certified method to support calculation of the cellulosic converted fraction. We deny the balance of the petition because POET has not shown that the Guidance's discussion of the Pathways II Rule's registration requirements for peer-reviewed methods—a discussion that amounts to a final, interpretive rule—is arbitrary, capricious, or otherwise unlawful.

So ordered.

KAREN LECRAFT HENDERSON, *Circuit Judge*, concurring in part and dissenting in part: I agree with my colleagues that the VCSB portion of the Guidance is not ripe and that the remainder of the Guidance constitutes final agency action subject to our review. I disagree, however, with their conclusion that the Guidance is an interpretive rule. The Guidance's reference material requirement changes the regulatory scheme to register the in situ biofuel production process[1] by constricting biofuel producers' ability to show reasonably accurate results to a single possible means that is currently not possible. This change means that producers like POET are indefinitely foreclosed from successfully registering that type of biofuel production process. In my view, the Guidance is a legislative rule with respect to the reference material requirement because it limits and thus effectively amends the 2014 regulation, 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3) (codifying the Pathways II Rule). I would "invalidate [the Guidance] at the outset as never having been subjected to notice and comment." Majority Op. 20 (citing 42 U.S.C. § 7607(d)).

An agency's characterization of its rule as interpretive, "while relevant, is not dispositive." *Gen. Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc). And, although in deciding this question, we look to "whether the agency 'intended'" for its action "to speak with the force of

[1] The "in situ process" is the "biochemical hydrolysis treatment where cellulosic and non-cellulosic components of feedstocks (at least one of which is not predominantly cellulosic) are simultaneously hydrolyzed to fermentable sugars (e.g., corn starch and a crop residue)." Regulation of Fuels and Fuel Additives: RFS Pathways II, and Technical Amendments to the RFS Standards and E15 Misfueling Mitigation Requirements (Pathways II Rule), 79 Fed. Reg. 42128, 42134 (July 18, 2014). In short, it is a process by which the cellulosic fiber of a corn kernel is processed "simultaneously with the starch processing." POET Br. at 11; *see also* J.A. 94.

law," *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 18 (D.C. Cir. 2019) (per curiam) (citation omitted), agency intent alone is likewise not decisive. Were it otherwise, an agency could simply label—and intend—a regulatory overhaul that changes the permissible conduct of regulated parties as interpretive and avoid notice and comment requirements. *See Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1024 (D.C. Cir. 2000) ("It is well-established that an agency may not escape the notice and comment requirements . . . by labeling a major substantive legal addition to a rule a mere interpretation."). Thus, in determining whether a rule is legislative or interpretive, we consider the substantive effect of the rule in question. *See Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014) ("The court's inquiry in distinguishing legislative rules from interpretative rules 'is whether the new rule effects a substantive regulatory change to the statutory or regulatory regime.'" (quoting *Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.,* 653 F.3d 1, 6–7 (D.C. Cir. 2011))); *Office of Commc'n of United Church of Christ v. FCC*, 826 F.2d 101, 105 (D.C. Cir. 1987) ("Since the court reviews not the label but the agency pronouncement that underlies the label, it is that pronouncement itself that governs the determination of its status."); *cf. Strange ex rel. Strange v. Islamic Republic of Iran*, No. 19-7083, 2020 WL 3886202, at *8 (D.C. Cir. July 10, 2020) ("Substance, not name or label, is what matters here.").

In conducting this inquiry, we have held that a rule that "effectively amends" an existing regulation—i.e., a regulation created by a final rule promulgated through notice and comment rulemaking—is itself a legislative rule. *U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 34 (D.C. Cir. 2005); *see Ass'n of Flight Attendants-CWA v. Huerta*, 785 F.3d 710, 718 (D.C. Cir. 2015) ("[I]f a second rule repudiates or is irreconcilable with a prior legislative rule, the second rule must be an amendment of

the first; and, of course, an amendment to a legislative rule must itself be legislative." (quoting *Am. Mining Cong. v. MSHA,* 995 F.2d 1106, 1109 (D.C. Cir. 1993))). A "*volte face*" is unquestionably sufficient to effectively amend a preexisting regulation, *see* Majority Op. 24 (quoting *Nat'l Family Planning & Reprod. Health Ass'n v. Sullivan*, 979 F.2d 227, 235 (D.C. Cir. 1992)), but a 180-degree turn is not necessary. Rather, "[o]ur cases have formulated this 'effective amendment' test in a number of ways," including by concluding that "'new rules *that work substantive changes*,' or '*major substantive legal addition[s]*,' to prior regulations are subject to the APA's procedures." *U.S. Telecom Ass'n*, 400 F.3d at 34–35 (first quoting *Sprint Corp. v. FCC*, 315 F.3d 369, 374 (D.C. Cir. 2003); then quoting *Appalachian Power Co.*, 208 F.3d at 1024). Moreover, as the United States Supreme Court has explained, "if an agency adopts 'a new position *inconsistent with*' an existing regulation, or effects '*a substantive change in* the regulation,' notice and comment are required." *Id.* at 35 (quoting *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 100 (1995)). "Although these verbal formulations vary somewhat, their underlying principle is the same: fidelity to the rulemaking requirements of the APA bars courts from permitting agencies to avoid those requirements by calling a substantive regulatory change an interpretative rule."[2] *Id.*

The Guidance does just that. Its new reference material requirement effectively amends the 2014 regulation allowing biofuel producers to utilize the in situ process by indefinitely foreclosing that process while characterizing its indeterminate

[2] Granted, an agency need not provide notice and comment when it amends an earlier interpretive rule with a subsequent interpretive rule. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 101 (2015); Majority Op. 24. It must do so, however, if a subsequent rule labeled as interpretive "effectively amends" an existing regulation. *U.S. Telecom Ass'n*, 400 F.3d at 34.

halt as an interpretation of the 2014 regulation. Notwithstanding the EPA's label, the reference material requirement is not simply the EPA's interpretation of what constitutes "reasonably accurate results" under 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3). Rather, the Guidance changes the regulatory scheme for the in situ biofuel production process by indefinitely barring producers planning to utilize that process. Its reference material requirement forces producers to use a single approach to demonstrate reasonably accurate results instead of allowing the producers' peer reviewers to use their expertise on how best to demonstrate such results. And because that single method—the cellulosic reference material requirement—is not currently possible, *see* Hudson Letter at 9 (J.A. 115) ("It is EPA's intention to continue evaluating Poet's registration request for coprocessing corn kernel fiber and starch *once a representative reference material with reportable starch and cellulosic values has been produced by NIST* . . . ." (emphasis added)); EPA Br. at 12; POET Br. at 18, producers are indefinitely prevented from registering RINs using the in situ process, in contravention of the Pathways II Rule which permitted such registration. For these reasons, I believe the Guidance—to the extent it imposes the reference material requirement—is interpretive in name (label) only.

As the Guidance explains, "[i]n the 2014 Pathways II Final Rule, EPA added a pathway for the production of cellulosic ethanol from corn kernel fiber and promulgated the regulations necessary to implement this pathway." Guidance at 1 (J.A. 83) (footnotes omitted). In the Pathways II Rule, the EPA explained that, although at the time of the proposed rule, it was not aware of a "ready test" to determine the amount of fuel "derived from cellulosic versus non-cellulosic components," the comments it received indicated that "there are methods available for [that] purpose." 79 Fed. Reg. at 42,132. The EPA decided to utilize those methods, "believ[ing] it [was]

reasonable to require the use of these existing methods under certain circumstances . . . to verify that the [cellulosic and non-cellulosic] values . . . are as accurate as possible" and therefore "requir[ed] the use of these available test methods." *Id.* In other words, the EPA chose to allow the use of existing methods without defining a specific approach that must be used—either for the analytical methods themselves or for how those methods demonstrated reasonably accurate results. Regarding the latter, the EPA deferred to producers' peer-reviewed references in its additional registration requirements for the in situ process—namely, allowing a producer to use any non-VCSB method so long as "the method used is an adequate means of providing reasonably accurate results by providing peer reviewed references to the third party engineer performing the engineering review at registration." *Id.* at 42,135; *see* 40 C.F.R. § 80.1450(b)(1)(xiii)(B)(3). Although the EPA has the ultimate say on whether to accept a particular method for registration, *see* Majority Op. 26, the Pathways II Rule did not tell the peer reviewers how to demonstrate that a method would produce reasonably accurate results; instead it created a registration system that gave those reviewers flexibility in deciding how to do so.

Then, the EPA issued the 2019 Guidance, upending the registration scheme for producers using the in situ process. Questioning "the wide degree of variability in the data" it had reviewed, the EPA concluded that "it is not possible, as a technical matter, to assess whether a method is accurately measuring" the cellulosic content of fuel produced via the in situ method without using "a known, representative reference material." Guidance at 3 (J.A. 85). Thus, going forward, producers (and their peer reviewers) could demonstrate that a non-VCSB method would produce reasonably accurate results by using a cellulosic reference material only. The result? The in situ process pathway is closed.

The combination of the registration change wrought by the Guidance's reference material requirement for the in situ process and its effect in indefinitely foreclosing future registrations amounts, in effect, to an amendment of the 2014 regulation, thus making the Guidance a legislative rule. The Guidance takes the broad discretion given to peer reviewers to demonstrate that a method will produce reasonably accurate results and narrows it to one possible way: comparison to a cellulosic reference material. "To the applicant reading the [Guidance] . . . the message is clear: in reviewing applications the Agency will not be open to considering approaches other than [the one] prescribed in the [Guidance]," *Gen. Elec. Co. v. EPA.*, 290 F.3d 377, 384 (D.C. Cir. 2002), notably, an approach not included in the 2014 regulation, § 80.1450(b)(1)(xiii)(B)(3). Without a cellulosic reference material, a registration application based on an in situ process is dead on arrival. Although the 2014 regulation placed no restriction on how producers could show that a method produces reasonably accurate results, the Guidance "requires them to conform" to one technique, "that is, not to submit an application based upon a [different] way." *Gen. Elec. Co.*, 290 F.3d at 384. For example, even if a producer's application were supported by the top 100 cellulosic fuel experts who all confirmed that the method used would produce reasonably accurate results, that application would not be considered if it did not use a cellulosic reference material.[3]

[3] My colleagues say that if this hypothetical occurred, the EPA's interpretation might be "arbitrary" but that would go to the "substantive merits" of the Guidance. Majority Op. 25. But the point of the hypothetical involves something greater—what the Guidance in fact *is*, i.e., legislative or interpretive. In other words, the Guidance is clear that no matter the number of experts nor the how persuasive their analysis supporting an application, a reference material is required to show that a method produces reasonably

The practical effect of this regulatory change is that producers are indefinitely foreclosed from registering an in situ process. Because no VCSB-approved method exists, producers are limited to using non-VCSB methods to register an in situ biofuel process. But with the addition of the Guidance's reference material requirement, producers are barred from pursuing registration of the in situ process *in toto* because the reference material does not yet exist. And no alternative appears to exist—the Guidance makes clear starch-based reference materials will not do, *see* Guidance at 4 (J.A. 86), and the Hudson letter shows that synthetic reference materials will fare no better, *see* Hudson Letter at 9 (J.A. 115).[4] Thus, the Guidance closes a regulatory pathway opened by the Pathways II Rule, leaving producers utilizing the in situ process in limbo until a reference material requirement is created. The Guidance's substantive change and its practical effect do in fact manifest, in my view, a "stark '*volte face*,'" Majority Op. 24 (quoting *Nat'l Family Planning*, 979 F.2d at 235) that "runs 180 degrees counter to the plain meaning of the regulation," *Nat'l Family Planning*, 979 F.2d at 235.

Requiring a producer to compare its method to a cellulosic reference material may well be prudent, especially if the EPA's

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accurate results. That requirement substantively changes the scheme of the 2014 regulation; it does not simply interpret the regulation, whether arbitrarily or otherwise.

[4] Despite my colleagues' reliance on the EPA's assertion in its brief that "the Guidance does not foreclose a peer reviewer from concluding that the use of a synthetic reference material is appropriate," Majority Op. 31 (quoting EPA Br. 44), nothing in the Guidance itself suggests that the EPA will accept "approaches other than what EPA has laid out in the Guidance," EPA Br. 44. The Guidance message to producers is plain: use a representative cellulosic reference material or do not bother applying to register. *See Gen. Elec. Co.*, 290 F.3d at 384.

data questions about the amount of cellulose produced through the in situ process are accurate. Nevertheless, the EPA is not free to change its existing regulations to meet those concerns however it sees fit. It must follow the required procedures. Because the Guidance's reference material requirement effectively amends the 2014 regulation, the EPA was obligated to promulgate that requirement via notice and comment rulemaking. That Administrative Procedure Act obligation (incorporated here under the Clean Air Act)[5] protects regulated parties, like the producers, by ensuring their input and by requiring the Agency to consider and respond thereto before it effects a substantive change in the regulatory framework relied upon by those parties.[6] *See Make The Rd. N.Y. v. Wolf*, 962 F.3d 612, 634 (D.C. Cir. 2020) ("[A] central purpose of notice-and-comment rulemaking is to subject agency decisionmaking to public input and to obligate the agency to consider and respond to the material comments and concerns that are voiced."). Biofuel producers like POET were entitled to formally and publicly comment and have those comments considered and responded to by the EPA before it added a requirement that substantively amended the 2014 regulation and indefinitely foreclosed their ability to utilize the in situ process.

Because the EPA failed to follow that required procedure, I would vacate and remand the Guidance with respect to its

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[5] *See* 42 U.S.C. § 7607(d); 5 U.S.C. § 553.

[6] And because the Guidance's reference material requirement is more than a "clarifying elaboration," Majority Op. 23, the ease and efficiency of "offering 'convenient notice,'" *id.* at 24 (citation omitted), through issuance of a Guidance must yield to lawful procedure—a procedure designed to keep agency rule-making transparent and to give regulated parties a seat at the table.

reference material requirement. Accordingly, I respectfully dissent in part.