United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 27, 2023 Decided May 9, 2023

No. 20-1335

NATURAL RESOURCES DEFENSE COUNCIL,
PETITIONER

v.

MICHAEL S. REGAN, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY AND ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENTS

AMERICAN WATER WORKS ASSOCIATION,
INTERVENOR

On Petition for Review of a Final Action
of the Environmental Protection Agency

Sarah V. Fort argued the cause for petitioner. With her on the briefs was *Charles R. Corbett*.

David J. Berger was on the brief for *amici curiae* Academic Scientists in support of petitioner.

Sarah A. Buckley, Senior Attorney, U.S. Department of Justice, argued the cause for respondents. With her on the brief was *Todd Kim*, Assistant Attorney General.

Corinne Snow argued the cause for respondent-intervenor American Water Works Association. With her on the brief was *Ronald J. Tenpas*. *Jeremy C. Marwell* entered an appearance.

Annie S. Amaral and *Thomas C. Roberts* were on the brief for *amici curiae* American Chemistry Council and Western Growers in support of respondents.

Before: PAN, *Circuit Judge*, and SENTELLE and TATEL, *Senior Circuit Judges*.

Opinion for the Court filed by *Senior Circuit Judge* SENTELLE.

Opinion concurring in the judgment filed by *Circuit Judge* PAN.

SENTELLE, *Senior Circuit Judge*: In 2011, the Environmental Protection Agency ("EPA") issued its "final determination to regulate perchlorate in drinking water" under the Safe Drinking Water Act. Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7,762, 7,762 (Feb. 11, 2011). That determination started a clock under the Safe Drinking Water Act requiring EPA to propose regulations within twenty-four months and promulgate regulations within eighteen months of the proposal. *See* 42 U.S.C. § 300g-1(b)(1)(E). But EPA never promulgated perchlorate regulations. Instead, nine years later, the agency purported to withdraw its regulatory determination. *See* Drinking Water: Final Action on Perchlorate, 85 Fed. Reg. 43,990, 43,991 (July 21, 2020). Natural Resources Defense Council ("NRDC")

petitions for review of this action, arguing that EPA lacks the authority to withdraw a regulatory determination under the Act and that, even if EPA possesses such authority, it acted arbitrarily and capriciously by doing so. EPA, joined by Intervenor American Water Works Association, defends its action. Because the Safe Drinking Water Act does not permit EPA to withdraw a regulatory determination, we grant NRDC's petition, vacate EPA's withdrawal of its regulatory determination, and remand to the agency for further proceedings.

I. Background

a. Statutory Framework

The Safe Drinking Water Act authorizes EPA to regulate potentially harmful contaminants in the nation's drinking water. *See* 42 U.S.C. § 300g-1(b)(1)(A). First enacted in 1974, the Act has since undergone several amendments. The 1986 amendments required EPA to select at least twenty-five new contaminants for regulation every three years. Pub. L. No. 99-339, § 101(b)(3)(C), (D), 100 Stat. 642, 644 (1986). Congress apparently created this strict regulatory scheme, at least in part, because it believed EPA had failed to regulate a sufficient number of contaminants under the Act's prior structure. *See* S. Rep. No. 104-169, at 8, 12 (1995). When Congress amended the Act in 1996 to create the present scheme, it replaced the strict three-year regulatory requirement with a discretionary scheme that allows EPA to determine when contaminants warrant regulation. 42 U.S.C. § 300g-1(b)(1)(A); S. Rep. No. 104-169, at 12–13.

Under the current Act, every five years EPA must publish a list of unregulated contaminants that may require future regulation (the "Contaminant Candidate List") and make a

preliminary determination, subject to notice and comment, of whether to regulate at least five listed contaminants. 42 U.S.C. § 300g-1(b)(1)(B)(i)(I), (ii)(I). After the comment period ends, EPA must make its final regulatory determination. *Id.* § 300g-1(b)(1)(B)(ii)(I). The agency can only determine to regulate a contaminant if it finds, based upon the "best available public health information," *id.* § 300g-1(b)(1)(B)(ii)(II), that:

> (i) the contaminant may have an adverse effect on the health of persons; (ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and (iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems,

id. § 300g-1(b)(1)(A)(i)–(iii).

The Act frontloads EPA's discretion, allowing the agency to create the list of contaminants that may require future regulation, *id.* § 300g-1(b)(1)(B)(i)(I), select which of those listed contaminants to consider for regulation, *id.* § 300g-1(b)(1)(B)(ii)(I), and determine whether the selected contaminants meet the statutory criteria for regulating, *id.* § 300g-1(b)(1)(A)(iii). Once EPA makes its regulatory determination, however, the Act balances that discretion with a strict, mandatory scheme governing the regulatory process. It instructs that, after determining the statutory criteria are met, the EPA Administrator "*shall*, in accordance with the procedures established by this subsection, publish a maximum contaminant level goal and promulgate a national primary drinking water regulation." *Id.* § 300g-1(b)(1)(A) (emphasis

added). The maximum contaminant level goal ("MCLG") is an unenforceable, aspirational level and is defined as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." *Id.* § 300g-1(b)(4)(A). The national primary drinking water regulations also normally include an enforceable maximum contaminant level ("MCL") that must be set "as close to the maximum contaminant level goal as is feasible." *Id.* § 300g-1(b)(4)(B). In limited circumstances, EPA can issue an alternative enforceable standard. *See id.* § 300g-1(b)(6)(A), (7)(A). EPA must propose the MCLG and national primary drinking water regulations within twenty-four months of making its determination to regulate and must publish the MCLG and promulgate the regulations within eighteen months of the proposal, subject to a nine-month extension. *Id.* § 300g-1(b)(1)(E).

The statute also contains an "anti-backslide" provision that ensures that, once issued, a regulation can only be revised in a way that will "maintain . . . or provide for greater" health protections. *Id.* § 300g-1(b)(9). In all decisions the agency makes that are based on science, EPA is instructed to use "the best available, peer-reviewed science." *Id.* § 300g-1(b)(3)(A)(i).

b. Factual and Procedural Background

Perchlorate, the contaminant at issue in this case, is a naturally occurring and manufactured chemical commonly used in the aerospace and defense sectors. When ingested, perchlorate can inhibit the thyroid's ability to absorb iodide. 85 Fed. Reg. at 43,994. An iodide-deficient thyroid, in turn, disrupts the production of thyroid hormones. *Id.* And disruptions in thyroid hormone production can lead to adverse neurodevelopmental outcomes in sensitive populations whose

brains are still developing, including fetuses and children of lactating women. *Id.*

Recognizing the potential health risks associated with perchlorate, EPA added perchlorate to its Contaminant Candidate List in 1998, categorizing it as a chemical "needing additional health effects, treatment research, and occurrence information." Announcement of the Drinking Water Contaminant Candidate List, 63 Fed. Reg. 10,274, 10,275, 10,282 (Mar. 2, 1998). The agency published its first Unregulated Contaminant Monitoring Rule ("UCMR-1") in 1999, requiring all large water systems and a sample of small water systems to collect data on perchlorate contamination between 2001 and 2005. 85 Fed. Reg. at 43,993.

In 2008, after applying a health reference level (the "level of concern") of 15 μg/L and evaluating the frequency of perchlorate contamination at that level using the UCMR-1 data, EPA issued a preliminary determination not to regulate perchlorate after determining that regulation "would not present a meaningful opportunity for health risk reduction" and sought comment on that proposed action. Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60,262, 60,269, 60,280–81. (Oct. 10, 2008). EPA issued a supplemental notice seeking comment on alternative health reference levels the following year. *See* Drinking Water: Perchlorate Supplemental Request for Comments, 74 Fed. Reg. 41,883, 41,889 (Aug. 19, 2009). Deviating from its preliminary determination, the agency issued its "final determination to regulate perchlorate" in 2011. 76 Fed. Reg. at 7,762. That determination "initiate[d] the process to develop a national primary drinking water regulation . . . for perchlorate" and started the clock for EPA to propose the MCLG and regulations within twenty-four months and to promulgate the final MCLG and regulations within the

following eighteen months. 76 Fed. Reg. at 7762–63; 42 U.S.C. § 300g-1(b)(1)(A), (E).

Consistent with its statutory obligation, *see id.* § 300g-1(e), EPA consulted with the Science Advisory Board as it worked to develop perchlorate regulations, National Primary Drinking Water Regulations: Perchlorate, 84 Fed. Reg. 30,524, 30,527–28 (June 26, 2019). At the Board's urging, EPA revised the model it used to predict the effects of perchlorate exposure, developing a "broader and more comprehensive framework" that directly links iodide uptake inhibition to changes in thyroid hormone levels, allowing the agency to better analyze the neurodevelopmental effects caused by perchlorate exposure. *Id.*

After EPA missed the statutory deadlines for proposing and promulgating the MCLG and regulations, NRDC sued the agency in 2016, seeking to compel the agency to regulate. 84 Fed. Reg. at 30,526. The parties entered a consent decree requiring EPA to propose and promulgate the MCLG and final regulations by 2020. *NRDC v. EPA*, No. 1:16-cv-01251-ER, ECF Nos. 38, 60 (S.D.N.Y.); 84 Fed. Reg. at 30,526. In June 2019, EPA proposed setting the MCLG and MCL at 56 μg/L or, in the alternative, at 18 μg/L or 90 μg/L. 84 Fed. Reg. at 30,525. Alternatively, the agency also considered withdrawing its 2011 regulatory determination and not promulgating an MCLG or national primary drinking water regulations. *Id.* The agency sought comment on its proposal and the three alternatives. *Id.*

In July 2020, after the comment period ended, EPA announced it was withdrawing its determination to regulate and issuing a "final determination not to regulate perchlorate." 85 Fed. Reg. at 43,991. The agency explained that it had "re-evaluated" whether perchlorate satisfied the statutory criteria

for regulating using its updated model and concluded that "perchlorate does not occur at a frequency and at levels of public health concern" and that regulation "does not present a meaningful opportunity for health risk reduction." *Id.* at 43,998. In EPA's view, because its "re-evaluat[ion]" showed that the statutory criteria were not met, it lacked the authority to regulate. *Id.*

II. Analysis

a. Statutory Authority

EPA makes two primary arguments in support of its authority to withdraw a regulatory determination. First, it argues that its withdrawal of the 2011 regulatory determination was consistent with the statute. Its second argument is premised on its "inherent authority" to change positions and withdraw a determination to regulate, which it claims the Safe Drinking Water Act does not abrogate. Resp. Br. at 22.

We start with EPA's second argument, which rests on a faulty premise. While we have often referred to agencies' "inherent authority," *see, e.g., Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 86 (D.C. Cir. 2014), the term "inherent" is misleading because "it is 'axiomatic' that 'administrative agencies may act only pursuant to authority delegated to them by Congress,'" *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) (quoting *Verizon v. FCC*, 740 F.3d 623, 632 (D.C. Cir. 2014)). Thus, "the more accurate label" for the power EPA describes "is 'statutorily implicit.'" *HTH Corp. v. NLRB*, 823 F.3d 668, 679 (D.C. Cir. 2016) (quoting *Ivy Sports Med.*, 767 F.3d at 93 (Pillard, J., dissenting)). And although the power to decide is normally accompanied by the power to reconsider, "Congress . . . undoubtedly can limit an agency's discretion to reverse itself." *New Jersey v. EPA*, 517 F.3d 574, 582–83

(D.C. Cir. 2008); *see Ivy Sports Med.*, 767 F.3d at 86 ("[A]ny inherent reconsideration authority does not apply in cases where Congress has spoken.").

EPA, then, has no inherent authority. It has only the authority given it by the Safe Drinking Water Act. The question, then, is whether that authority includes the authority to withdraw a regulatory determination.

To answer that question, we look to the statutory text. The Act instructs that "[t]he [EPA] Administrator *shall*, in accordance with the procedures established by this subsection, publish a maximum contaminant level goal and promulgate a national primary drinking water regulation for a contaminant . . . if the Administrator determines that" the statutory criteria have been met. 42 U.S.C. § 300g-1(b)(1)(A) (emphasis added). Elsewhere in the statute, Congress repeated the directive three additional times that EPA "shall" regulate. "For each contaminant that the Administrator determines to regulate under subparagraph (B), the Administrator *shall* publish maximum contaminant level goals and promulgate, by rule, national primary drinking water regulations . . . ." *Id.* § 300g-1(b)(1)(E) (emphasis added). Within 24 months of making the determination to regulate, "[t]he Administrator *shall* propose the maximum contaminant level goal and national primary drinking water regulation." *Id.* (emphasis added). And within 18 months of proposing the MCLG and regulations, "[t]he Administrator *shall* publish a maximum contaminant level goal and promulgate a national primary drinking water regulation." *Id.* (emphasis added).

It is well established that "[t]he word 'shall' generally indicates a command that admits of no discretion on the part of the person instructed to carry out the directive." *Assoc. of Civilian Technicians, Mont. Air Chapter No. 29 v. FLRA*, 22

F.3d 1150, 1153 (D.C. Cir. 1994). That is even more true where, as here, the statute explicitly grants the agency significant discretion at the outset but later instructs the agency that it "shall" act. *Cf. Anglers Conservation Network v. Pritzker*, 809 F.3d 664, 671 (D.C. Cir. 2016) ("[W]hen a statutory provision uses both 'shall' and 'may,' it is a fair inference that the writers intended the ordinary distinction."). In 2011, EPA determined that perchlorate satisfied the statutory criteria for regulating. 76 Fed. Reg. at 7,763. Under the statute, then, EPA has one authorized course of action: it "shall" propose and promulgate the MCLG and regulations, and it "shall" do so by the statutory deadlines. *See* 42 U.S.C. § 300g-1(b)(1)(A), (E). EPA recognized as much when it issued its 2011 "final regulatory determination." *See* 76 Fed. Reg. at 7,763 ("Once EPA makes a determination to regulate a contaminant in drinking water, [the Act] *requires* that EPA issue a proposed [regulation] within 24 months and a final [regulation] within 18 months of proposal." (emphasis added)). Intervenors likewise admit the statute imposes "a duty to issue regulations where the Administrator has determined to regulate." Intervenor's Br. at 35. To read into the statute another course of action—one that allows EPA to withdraw its regulatory determination entirely and decide that it "shall not" regulate—would be to contravene the statute's clear language and structure and "nullif[y] textually applicable provisions meant to limit [EPA's] discretion." *New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008) (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 485 (2001)). Because EPA lacked the authority to withdraw its regulatory determination in the first instance, its argument that its authority to do so is not time-limited by the statutory deadlines for proposing and promulgating regulations is of no import.

EPA urges the Court to overlook the statute's clear language, first by arguing that its 2011 determination to

regulate was only a preliminary, interlocutory step in the regulatory process that did not bind the agency to issue future regulations. This argument contradicts the plain language of the statute and is easily disposed of. The Safe Drinking Water Act does anticipate that the agency will make a preliminary regulatory determination. *See* 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I) ("[T]he Administrator shall, after notice of the preliminary determination and opportunity for public comment, . . . make determinations of whether or not to regulate such contaminants."). But the preliminary determination precedes the notice and comment period. Once that period ends, the agency makes its regulatory determination, and that determination is final. *See id.* § 300g-1(b)(1)(E). EPA issued its preliminary determination in 2008 and then, after the period for public comments, issued its final determination in 2011. *Compare* 73 Fed. Reg. at 60,263 (presenting "EPA's preliminary regulatory determination on perchlorate"), *with* 76 Fed. Reg. at 7,762 (presenting "EPA's final determination to regulate perchlorate").

EPA cites several other provisions of the statute that it argues implicitly give the agency the authority to withdraw a regulatory determination. None of these provisions, however, negate the statute's clear directive that the agency "shall" propose and promulgate regulations after making a regulatory determination. The first provision EPA cites requires the agency to consider the "best available public health information" when evaluating whether the statutory criteria for regulating are met, *id.* § 300g-1(b)(1)(B)(ii)(II), while a similar provision requires it to apply "the best available, peer-reviewed science" to all decisions it makes that are based on science, *id.* § 300g-1(b)(3)(A)(i). EPA argues, and Intervenor agrees, the statute required the agency to use its new model, which it considers to be the "best available public health information,"

to re-evaluate whether the statutory criteria for regulating were satisfied. Because it did so and concluded that two of the criteria were no longer met—specifically, that "perchlorate does not occur at a frequency and at levels of public health concern, and that regulation of perchlorate does not present a meaningful opportunity for health risk reduction"—EPA and Intervenor argue the agency lacked the authority to regulate and had to withdraw its regulatory determination. 85 Fed. Reg. at 43,998.

This argument rests on a faulty dichotomy: that EPA must either disregard the statutory requirements and issue the regulations, or that it can adhere to the statutory requirements but is then required to withdraw its regulatory determination. Instead, the statute compels a third option. EPA must apply the "best available public health information" to determine whether the statutory criteria for regulating are satisfied. *Id.* § 300g-1(b)(1)(B)(ii)(II). Once that determination is made, it is final. EPA's obligation then is to consider and apply the "best available, peer-reviewed science," including any new developments, to set the substance of the regulations—not to reevaluate *whether* to regulate. *See id.* § 300g-1(b)(3)(A)(i).

EPA claims that this reading of the statute will "hamstr[i]ng" its decision-making and result in outdated, scientifically unsupported regulations. 85 Fed. Reg. at 43,992. But this takes an "all-or-nothing" approach and ignores the statutory requirements. If the science changes after the agency makes its determination to regulate but before it issues the regulations, EPA can—and must—account for those changes when setting the appropriate regulatory level.

Undeterred, EPA argues that several other provisions militate against our understanding that "shall" means "shall." One such provision, known as the "anti-backslide" provision,

requires EPA to review regulations at least every six years and only permits revisions to those regulations that will "maintain, or provide for greater, [health] protection." *Id.* § 300g-1(b)(9). In EPA's view, because this provision applies only to existing regulations, the agency is free to withdraw a regulatory determination at any time before it promulgates final regulations. EPA also argues that another provision that renders a determination not to regulate subject to judicial review, *see id.* § 300g-1(b)(1)(B)(ii)(IV), implicitly means that a determination to regulate is not subject to judicial review and can be withdrawn. Both arguments ignore the rigidity of the statute, which creates only two possible courses of action after the agency considers a contaminant for regulation: EPA can either determine not to regulate, or it can determine to regulate and then promulgate the regulations. If EPA takes the first approach, there are no regulations to which the anti-backslide provision can apply, and its determination is subject to judicial review. If EPA takes the second approach, it must promulgate regulations, to which the anti-backslide provision applies, and which are themselves subject to judicial review. EPA's attempt to create a third option, one in which there are no regulations to which the anti-backslide provision applies but whereby the agency still evades judicial review, is inconsistent with the statutory scheme.

Having run out of provisions in the statute that it views as favorable, EPA flips the script and cites to the absence of a provision governing how the agency must withdraw a regulatory determination, arguing that because the agency did not "contravene any express statutory command" or "avoid any otherwise applicable statutory process" for withdrawing a determination to regulate, its withdrawal was permissible. Resp. Br. at 26–27 (internal citation omitted). But this just repackages the already rejected argument that the agency possesses an "inherent" authority to change its mind. Congress

did not create a process for EPA to withdraw a regulatory determination because it seemingly did not want EPA to have the power to do so. "Regardless of how serious the [purported] problem an administrative agency seeks to address, . . . it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000) (quoting *ETSI Pipeline Project v. Missouri*, 484 U.S. 495, 517 (1988)). Further, EPA's withdrawal of its regulatory determination did contravene an express statutory command: the command that the agency "shall" regulate.

EPA eventually abandons the statute altogether, turning instead to the Act's legislative history. In its view, allowing the agency to withdraw a regulatory determination would be consistent with Congress's intent in passing the 1996 amendments, which it argues was to grant the agency additional discretion to decide when regulation is warranted and to eliminate wasteful spending on regulations without significant health benefits. EPA runs into two problems with this argument. First, and most fundamentally, EPA's interpretation of what Congress intended in the statute cannot overcome the statute's directive that the agency "shall" regulate. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1815 (2019) ("[M]urky legislative history . . . can't overcome a statute's clear text and structure."). And second, the history EPA cites is not inconsistent with our interpretation. The 1996 amendments undoubtedly gave the agency more discretion in determining which contaminants to consider for regulation and whether to regulate them in the first instance. But they also balanced that discretion with a mandatory scheme requiring EPA to regulate after it determines to do so.

Because the Safe Drinking Water Act requires that the agency "shall" regulate after making a regulatory

determination, EPA lacks authority to withdraw that determination and decide that it "shall not" regulate.

b. Arbitrary and Capricious Challenges

NRDC also challenges EPA's decision-making process that led to the withdrawal of its regulatory determination, arguing that EPA acted arbitrarily and capriciously by setting "levels of public health concern" that fail to protect against adverse health effects and by relying on selectively updated data to assess the frequency of perchlorate contamination. Because we conclude that EPA lacked statutory authority to withdraw its regulatory determination, we do not reach these issues. *See New York Stock Exch. LLC v. SEC*, 962 F.3d 541, 559 (D.C. Cir. 2020). Having been apprised of NRDC's contentions and our concurring colleague's views, EPA is, of course, free to take those into consideration when it develops perchlorate regulations.

III. Conclusion

We grant NRDC's petition, vacate EPA's withdrawal of its determination to regulate, and remand to the agency for further proceedings.

PAN, *Circuit Judge*, concurring in the judgment: In 2011, the EPA determined that perchlorate met the statutory factors for regulation under the Safe Drinking Water Act. For unexplained reasons, the agency missed the 24-month deadline to propose the required regulation and the 42-month deadline to promulgate it. Eight years passed. When the EPA finally commenced the notice-and-comment process to limit perchlorate in drinking water, the agency proposed establishing a Maximum Contaminant Level Goal ("MCLG") associated with a two-point drop in the average IQ of the most sensitive population. The agency also sought comments about alternative MCLGs associated with one- or three-point drops in the benchmark IQ. Moreover, the EPA requested comments about whether perchlorate should be regulated at all, "in light of new considerations . . . including information on lower levels of occurrence of perchlorate than the EPA had previously believed to exist and new analysis of the concentration [of perchlorate] that represents a level of health concern." National Primary Drinking Water Regulations: Perchlorate, 84 Fed. Reg. 30,524, 30,525 (June 26, 2019). After the notice-and-comment period expired, the EPA decided that the statutory factors for regulation were not met, and therefore "withdr[e]w" its 2011 determination to regulate perchlorate, based on an updated understanding of the "best available public health information." Drinking Water: Final Action on Perchlorate, 85 Fed. Reg. 43,990, 43,992 (July 21, 2020). The agency's withdrawal of its regulatory determination relied on a MCLG associated with a one-point drop in the average IQ of the most sensitive population, and on a partial update of the data that the agency used to measure the prevalence of perchlorate in the nation's drinking water.

In my view, under the circumstances presented, the EPA had authority to withdraw its initial regulatory determination based on changes in the best available, peer-reviewed science. But the agency's ultimate decision not to regulate perchlorate was arbitrary, capricious, and not in accordance with law,

because it relied on a MCLG that did not meet the statutory standard, as well as on a biased dataset that was selectively updated. I would vacate and remand on those alternative grounds, and therefore respectfully concur in the judgment.

I. Background

In 2011, the EPA published a final determination that perchlorate met the requirements for regulation under the Safe Drinking Water Act. *See* Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7,762 (Feb. 11, 2011). Specifically, it found that perchlorate (1) "may have an adverse effect on the health of persons"; (2) "is known to occur or there is a substantial likelihood that [perchlorate] will occur in public water systems with a frequency and at levels of public health concern"; and (3) "in the sole judgment of the Administrator[of the EPA], regulation of [perchlorate] presents a meaningful opportunity for health risk reduction for persons served by public water systems." *Id.* at 7,762–63; *see also* 42 U.S.C. § 300g-1(b)(1)(A)(i)–(iii). The statute required the agency to propose a MCLG and an accompanying regulation that would limit perchlorate in drinking water within 24 months after making that regulatory determination — *i.e.*, by February 11, 2013. *See* 42 U.S.C. § 300g-1(b)(E).

But the EPA missed that deadline. In February of 2016, the Natural Resources Defense Council ("NRDC") brought suit to compel the agency to issue the tardy perchlorate regulation. *See* Compl., *NRDC v. EPA*, No. 2:16-cv-1251 (S.D.N.Y. Feb. 19, 2016), ECF No. 7. The parties entered a consent decree that required the EPA to propose the MCLG and accompanying regulation by May 28, 2019, and to finalize the MCLG and accompanying regulation by June 19, 2020. *See* Consent Decree and Extensions, *NRDC v. EPA*, No. 2:16-cv-1251 (S.D.N.Y.), ECF No. 38, 57, 59, 60.

Pursuant to the consent decree, the EPA issued its proposal for limiting the amount of perchlorate in drinking water in 2019. *See* 84 Fed. Reg. at 30,565. The agency proposed setting both the MCLG and Maximum Contaminant Level ("MCL") at 56 micrograms per liter (μg/L), a level associated with "a 2 percent decrease in IQ" in the most sensitive population. *Id.* at 30,540. The proposal also requested public comments on three alternatives: (1) setting the MCLG and MCL at 18 μg/L, a level associated with a one-point drop in IQ; (2) setting the MCLG and MCL at 90 μg/L, a level associated with a three-point drop in IQ; or (3) withdrawing the agency's 2011 determination to regulate perchlorate altogether, "based on new information that indicates that perchlorate does not occur in public water systems with a frequency and at levels of public health concern and there may not be a meaningful opportunity for health risk reduction." *Id.* at 30,524, 30,541.

In 2020, the EPA withdrew the 2011 determination to regulate perchlorate. The agency based its decision on a new understanding of the scientific evidence regarding perchlorate's prevalence in drinking water and its effects on human health. The agency "recognize[d] that the [Safe Drinking Water Act] does not include a provision explicitly authorizing withdrawal of a regulatory determination," but concluded that "such authority is inherent in the authority to issue a regulatory determination . . . particularly given the requirement that such determination be based on the 'best available public health information.'" 85 Fed. Reg. at 43,992. The EPA explained that "new data and analysis developed by the Agency as part of the 2019 proposal demonstrate that the occurrence and health effects information used as the basis for the 2011 determination no longer constitute 'best available information,' are no longer accurate, and no longer support the Agency's prioritization of perchlorate for regulation." *Id.*

According to the EPA, the best available scientific evidence had changed in two ways. First, the EPA refined its understanding of the concentrations at which perchlorate causes health problems. In 2011, the agency identified "levels of public health concern" that "range[d] from 1 µg/L to 47 µg/L." *See* 76 Fed. Reg. at 7,764. But the publication of various studies in the following years shed further light on the relationship between exposure to perchlorate and iodide deficiencies in pregnant women that cause "a variety of adverse neurodevelopmental outcomes" in their fetuses, including decreases in IQ. *See* 84 Fed. Reg. at 30,531; 85 Fed. Reg. at 44,000 (identifying "the fetus of the iodide deficient pregnant mother" as the most sensitive population). Using a new study that the agency identified as "the most rigorous analysis available in the literature to date," *see* 84 Fed. Reg. at 30,534, the EPA developed a new model that caused it to reconsider the levels at which perchlorate is detrimental to health. Based on that model, the agency increased the relevant "levels of public health concern" from between 1 and 47 µg/L to between 18 and 90 µg/L. *See* 85 Fed. Reg. at 43,992.

Second, the EPA revised its data showing the prevalence of perchlorate in the nation's water supply. The agency based its 2011 determination to regulate in part on the UCMR-1 study, a nationwide survey of perchlorate occurrence in drinking water conducted between 2001 and 2005. *See* 76 Fed. Reg. at 7,764–65. After the 2001–2005 period of data collection for the UMCR-1 study, California and Massachusetts enacted enforceable state-level perchlorate drinking-water standards. *See* 85 Fed. Reg. at 43,995. The EPA used compliance-monitoring information from those states to update some of the UMCR-1 data points. *Id*. The updates for California, in particular, had the potential to disproportionately affect the national picture of perchlorate occurrence: "In the original UCMR 1 dataset . . . 320 of 540

samples in which perchlorate was detected were in California." EPA Br. 52; *see also* Env't Prot. Agency, EPA 816-R-19-003, *Perchlorate Occurrence and Monitoring Report* App. D at D-3 (May 2019). Based on the updated data, the EPA concluded that perchlorate did not occur in public water systems at the requisite levels of public health concern to justify regulation. *See* 85 Fed. Reg. at 43,992.

II. Authority to Withdraw a Regulatory Determination

Under the Safe Drinking Water Act, the EPA's issuance of a regulatory determination triggers a duty to propose and promulgate an appropriate regulation. As my colleagues in the majority note, the statute imposes that duty by repeatedly using the word "shall." *See* Maj. Op. 9–10. Specifically, the EPA Administrator (1) "*shall*, in accordance with the procedures established by this subsection, publish a [MCLG] and promulgate a[n accompanying] regulation for a contaminant . . . if the Administrator determines that" the statutory factors are met, 42 U.S.C. § 300g-1(b)(1)(A) (emphasis added); (2) "*shall* publish [MCLGs] and promulgate, by rule," accompanying regulations "[f]or each contaminant that the Administrator determines to regulate," *id.* § 300g-1(b)(1)(E) (emphasis added); (3) "*shall* propose" the MCLG and accompanying regulation within 24 months of the determination to regulate, *id.* (emphasis added); and (4) "*shall* publish" the MCLG and accompanying regulation within 18 months of the proposal (with a possible nine-month extension), *id.* (emphasis added).

Based on this language, the majority concludes that when the EPA initially determined to regulate perchlorate in 2011, the issuance of regulations became mandatory — full stop. *See* Maj. Op. 9–10. But in my view, the question here is not whether the existence of a regulatory determination gives rise

to a duty to actually regulate. It undoubtedly does. Instead, the salient question is whether the agency may *withdraw* its determination to regulate based on changed circumstances, thereby vitiating the agency's obligation to proceed with regulation. It is the regulatory determination that kicks off all the statutory timelines and imposes on the agency a firm obligation to regulate; if that determination is withdrawn, those attendant requirements are no longer operative.

The withdrawal of a determination to regulate in this context appears to be unprecedented. This may be explained by the 24-month statutory deadline to propose a regulation: A significant change in the underlying science is unlikely to occur in that relatively short timeframe. But here, eight years passed after the EPA issued its initial determination. At that point, after undergoing a notice-and-comment procedure, the agency made a new determination based on updated information. The issue before us is not whether the EPA should have violated the Safe Drinking Water Act's statutory deadline — it should not have. But, now that it has, we must consider whether the EPA has the power to withdraw a regulatory determination when changed circumstances justify such a withdrawal. In my view, the agency surely has that authority.

Contrary to my colleagues' view, nothing in the Safe Drinking Water Act forbids the EPA from withdrawing a determination to regulate. The statute is silent on that issue. But reading such a prohibition into the Safe Drinking Water Act would force the EPA to violate another statutory provision. Specifically, the statute obligates the EPA to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" in every action under the Safe Drinking Water Act that "is based on science." 42 U.S.C. § 300g-1(b)(3)(A)(i). If new information comes to light before the EPA proposes a

MCLG and accompanying regulation, and the "best available, peer-reviewed science" makes clear that the initial regulatory determination is no longer supported by the evidence, then proceeding to regulate despite that new evidence would violate this provision. We obviously should not adopt an interpretation of the statute that discounts or ignores the EPA's duty to rely on the best available science. *See Loughrin v. United States*, 573 U.S. 351, 358 (2014) (explaining the "'cardinal principle' of interpretation that courts 'must give effect, if possible, to every clause and word of a statute'" (quoting *Williams v. Taylor*, 529 U.S. 362, 404 (2000))); *Del. Dep't of Nat. Res. & Env't Control v. EPA*, 895 F.3d 90, 99 (D.C. Cir. 2018) ("[W]e strive to construe statutes 'so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.'" (quoting *Corley v. United States*, 556 U.S. 303, 314 (2009))).

The majority asserts that the agency can reconcile these statutory mandates by "apply[ing] the 'best available, peer-reviewed science,' including any new developments, to set the substance of the regulations — not to reevaluate *whether* to regulate." Maj. Op. 12; *see also* NRDC Br. 34–35 (making a similar argument). But that fails to account for circumstances where, as here, the agency concludes that the best available, peer-reviewed science does not support regulating a contaminant at all. Under the majority's approach, the agency is forced to regulate anyway. The regulation of a contaminant entails setting a MCLG and a MCL, which in turn triggers potentially costly testing requirements. *See* 42 U.S.C. § 300g-3(c)(1)(A)(i) (requiring public water systems to notify customers of "any failure" to "comply with an applicable maximum contaminant level"); 40 C.F.R. § 141.23 (requiring water systems to "conduct monitoring to determine compliance with . . . maximum contaminant levels"). The majority's interpretation gives the agency no choice but to impose a

pointless burden on water systems to test for a substance that the agency does not even think should be regulated. Congress could not have intended "such an illogical result." *Tri-State Hosp. Supply Corp. v. United States*, 341 F.3d 571, 577 (D.C. Cir. 2003); *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998) (highlighting "the long-standing rule that a statute should not be construed to produce an absurd result," *i.e.*, a "result [that] is contrary to common sense" and "inconsistent with the clear intentions of the statute's drafters").

For its part, NRDC contends that the "best available, peer-reviewed science" provision requires the EPA to consider only the best evidence that was available "at the time" of the original determination, *i.e.*, in 2011. *See* NRDC Br. 35–36. Citing our decision in *Chlorine Chemistry Council v. EPA*, NRDC relies on our statement "that the action [should] be taken on the basis of the best available evidence *at the time* of the rulemaking." 206 F.3d 1286, 1291 (D.C. Cir. 2000) (emphasis in original). But *Chlorine Chemistry Council* involved very different facts. In that case, the EPA refused to establish a MCLG supported by the best available evidence "because of the possibility of contradiction in the future by evidence unavailable at the time of the action." *Id.* at 1290–91. In this case, the EPA is not arguing that the currently available evidence *might* be contradicted in the future, but that the currently available evidence *does* contradict the agency's past understanding of the science. Moreover, although the EPA made a regulatory determination in 2011, the "time of the rulemaking" in this case was in 2019, when the EPA sought comments about its proposed MCLG and accompanying regulation. *See* 5 U.S.C. § 551(5) ("'[R]ule making' means agency process for formulating, amending, or repealing a rule[.]"). If the best available evidence at that later time revealed that the statutory prerequisites for regulation were not met, then the agency's

only way forward was to withdraw its earlier decision to the contrary. Otherwise, the EPA would be simultaneously forbidden yet compelled to rely on "the best available, peer-reviewed science." 42 U.S.C. § 300g-1(b)(3)(A)(i).

Notably, Congress clearly knew how to limit the agency's ability to change its mind and chose to do so only later in the Safe Drinking Water Act's regulatory process. Specifically, the statute's anti-backsliding provision applies after promulgation of the MCLG and accompanying regulation. *See id.* § 300g-1(b)(9). It mandates that "[a]ny revision of a national primary drinking water *regulation* . . . shall maintain, or provide for greater, protection of the health of persons." *Id.* (emphasis added). That provision is inoperative here because the EPA made (and then withdrew) only a *determination* to regulate. Nevertheless, Congress's enactment of a specific limitation on the EPA's ability to revisit and alter drinking-water regulations under the Safe Drinking Water Act highlights the absence of any explicit limitation on changing regulatory determinations in this context. The statutory text thus strongly suggests that there is no implicit constraint on the agency's ability to reconsider a regulatory determination. *See Jama v. Immigr. & Customs Enf't*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.").

My conclusion that the EPA may withdraw a regulatory determination is consistent with the ordinary rule that agencies may "use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 101 (2015) (citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009));

Hickman & Pierce, Administrative Law Treatise § 4.5.1 (6th ed. 2019) ("In the ordinary course, legislative rules must be promulgated using notice and comment procedures and can only be modified or replaced using notice and comment procedures."). Indeed, it is a core principle of administrative law "that an agency must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.'" *See Motor Vehicles Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (citation omitted)). If Congress had intended to depart from these well-established principles in the present context, it would have spoken to that issue directly. *Cf. Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 86 (D.C. Cir. 2014). As it did not, the EPA changed its mind in the way that agencies routinely do: It made its 2011 determination to regulate after notice and comment; then, eight years later, it went through another round of notice and comment before deciding to change course.[1]

Finally, it bears mention that if, after "employing traditional tools of statutory construction," the Safe Drinking Water Act remained ambiguous about whether the EPA can withdraw a regulatory determination, the agency's interpretation ordinarily would be entitled to deference. *See*

---

[1] This case does not fall within the exception that applies when Congress, by providing an alternative statutory mechanism to correct mistakes, restricts the means through which an agency can change course. *See, e.g.*, *Ivy Sports*, 767 F.3d at 86 (holding that agency lacked authority to reconsider prior decision where Congress "creat[ed] . . . a specific statutory mechanism to correct alleged . . . errors"); *New Jersey v. EPA*, 517 F.3d 574, 582–83 (D.C. Cir. 2008) (similar); *Am. Methyl Corp. v. EPA*, 749 F.2d 826, 835 (D.C. Cir. 1984) (similar). To the contrary, denying the EPA the ability to withdraw its regulatory determination under the present circumstances leaves the agency with no mechanism at all to alter what it later concluded was an incorrect decision.

Chevron, U.S.A., Inc. v. NRDC, 467 U.S. 837, 843 n.9 (1984). But because the EPA did not cite *Chevron* in its brief and avoided relying on it at oral argument, *see* Oral Arg. Tr. 27:15–18, I decline to consider the applicability of *Chevron* here. *See HollyFrontier Cheyenne Refin., LLC v. Renewable Fuels Ass'n*, 141 S. Ct. 2172, 2180 (2021) ("[T]he government does not [invoke *Chevron*.] . . . We therefore decline to consider whether any deference might be due its regulation.").

In short, under the circumstances presented, it was permissible for the EPA to reconsider and withdraw a determination to regulate a contaminant under the Safe Drinking Water Act. The agency had not yet proposed and promulgated a final regulation when it made a new finding that the best available, peer-reviewed science no longer supported its prior regulatory determination. In my view, the EPA may appropriately reverse a decision to regulate based on a change in scientific evidence, after engaging in notice-and-comment procedures.

III. Withdrawal of the 2011 Determination to Regulate Perchlorate

Although the EPA was empowered to reconsider its initial regulatory determination based on changes in the best available, peer-reviewed science, the agency's ultimate decision not to regulate perchlorate in drinking water was arbitrary, capricious, and otherwise not in accordance with law. *See* 5 U.S.C. § 706(2)(A); *see also Fox Television Stations*, 556 U.S. at 514–16; *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1037–38 (D.C. Cir. 2012). An agency action is arbitrary or capricious "if the agency has 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." *State Farm*, 463 U.S. at 43. An agency action that "violates [a statute] is 'not in accordance with law' within the meaning of 5 U.S.C. § 706(2)(A)." *Chrysler Corp. v. Brown*, 441 U.S. 281, 318 (1979); *see also Ethyl Corp. v. EPA*, 306 F.3d 1144, 1150 (D.C. Cir. 2002) (holding that agency action that violated authorizing statute was "not in accordance with law").

A. *Proposed MCLGs*

The Safe Drinking Water Act requires the EPA to "set [the MCLG] at the level at which *no* known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." 42 U.S.C. § 300g-1(b)(4)(A) (emphasis added). But the EPA sought comments on MCLGs that permitted levels of perchlorate associated with one-, two-, and three-point decreases in the average IQ of the most sensitive population; and then used those MCLGs as the "levels of public health concern" by which it evaluated the need to limit perchlorate in drinking water. *See* 85 Fed. Reg. at 43,995 ("[T]he EPA used these potential MCLGs as the levels of public health concern in assessing the frequency of occurrence of perchlorate in this regulatory determination.").[2] The EPA

[2] The EPA characterizes its proposed MCLGs of 18 µg/L, 56 µg/L, or 90 µg/L as the levels of perchlorate that "avoid" IQ decreases of one, two, or three points, respectively. *See* 85 Fed. Reg. at 43,994, 43,995, 43,999; EPA Br. 2, 11, 16, 33, 34, 39, 45. That characterization is at best confusing and at worst misleading. The proposed MCLGs are the levels of perchlorate *associated with* decreases in IQ of one, two, or three points — not the levels at which those cognitive harms do not occur. *See* 84 Fed. Reg. at 30,536 (explaining that the agency based its calculations on the daily dose of perchlorate "associated with a 1, 2, or 3 point decrease from the

found that "even at the most stringent regulatory level considered in the 2019 proposal" — *i.e.*, the level associated with a one-point drop in IQ — "perchlorate does not occur in public water systems 'with a frequency and at levels of public health concern.'" *Id*. at 43,992.

The EPA's proposed MCLGs plainly violated the statutory mandate to reflect "the level at which no known or anticipated adverse effects on the health of persons occur." 42 U.S.C. § 300g-1(b)(4)(A). A decrease in average IQ of even one point is undoubtedly an "adverse effect[] on the health of persons." *Id.* Rather than debate that self-evident conclusion, the EPA chooses the path of obfuscation, essentially arguing that in this "complicated technical area," the court must defer to the agency's chosen approach to regulation. EPA Br. 34, 37. Specifically, the EPA says that we should defer to its reliance on the agency's "'Benchmark Dose Guidance,' which supported using a 1% effect [on IQ] as a starting point." *Id.* at 34. That guidance focuses not on "what individual levels [of a contaminant] can be considered adverse" but instead on "the level of change in the endpoint [here, IQ] at which the effect is considered to become biologically significant (as determined by expert judgment or relevant guidance documents)." *See* Env't Prot. Agency, *Benchmark Dose Technical Guidance* x (June 2012). In other words, the agency relied on its own judgment about whether an adverse health effect is

---

standardized mean IQ"). At oral argument, the EPA contended that setting MCLGs at these levels would "avoid" the relevant IQ decreases because regulating at those levels of perchlorate would prevent water from containing those levels of perchlorate. *See* Oral Arg. Tr. 37:24–38:14, 39:7–9. But the truth appears to be the opposite: Setting a maximum of 18 µg/L would not *avoid* water having that much perchlorate, it would *permit* that level of perchlorate — a level that, according to the EPA's own data, is associated with a one-point decline in IQ.

"biologically significant" instead of adhering to the statutory standard, which requires setting the MCLG "at the level at which [there are] no known or anticipated adverse effects on the health of persons." 42 U.S.C. § 300g-1(b)(4)(A). Notably, the EPA used the Benchmark Dose Guidance to replace the "NOAEL/LOAEL [no or low observed adverse effect level] approach," which had been "used for many years" and which mirrors what the statute requires. *See Benchmark Dose Technical Guidance* viii. One need not be a scientist to understand that by rejecting the "no observed adverse effect level" approach, the EPA eschewed what the Safe Drinking Water Act demands. *Compare id.*, *with* 42 U.S.C. § 300g-1(b)(4)(A).

Beneath the technical jargon and puffery about agency expertise, the EPA is not really arguing that it complied with the statute. Instead, the agency appears to contend that the statute's requirements are not the best way to go about making policy in this area, and that its own judgment should control. Of course, that position finds no support in the law. Congress directed the EPA to set MCLGs "at the level at which no known or anticipated adverse effects on the health of persons occur." 42 U.S.C. § 300g-1(b)(4)(A). The agency did not act in accordance with that law when it used a MCLG associated with a one-point drop in IQ — which plainly is an "adverse effect[] on the health of persons," *id.* — as the basis for withdrawing its determination to regulate perchlorate.

B. *UCMR-1 Data*

As previously noted, the EPA relied on data from the UCMR-1 — a nationwide sampling of public water systems for perchlorate — when it made its determination to regulate in 2011. *See* 76 Fed. Reg. at 7,764. The UCMR-1 survey detected "perchlorate at levels greater than or equal to 4 μg/L .

. . [in] approximately 1.9 percent of the" samples collected during the 2001–2005 study period. *Id*. After the UCMR-1 study, however, Massachusetts and California passed enforceable state-level standards on perchlorate in drinking water. As a result, statewide monitoring data of perchlorate have become available in those states. *See* 85 Fed. Reg. at 43,995.

When the EPA reconsidered its determination to regulate in 2019, it updated the UCMR-1 data to reflect some, but not all, of the newly available information from Massachusetts and California. Instead of replacing all the data points from Massachusetts and California in the UCMR-1 dataset, the agency updated only those samples where perchlorate was detected during the 2001–2005 data collection. *See id.* In other words, it revised any samples that were positive for perchlorate in the 2001–2005 data, but left untouched those samples that were negative for perchlorate. Thus, as NRDC argues, the "EPA set up a one-way ratchet: [C]ontaminated water could become clean, but clean water could not become contaminated." NRDC Br. 62. If the purpose of adjusting the UCMR-1 data was to obtain the most current systematic picture of perchlorate occurrence, there was no apparent reason (and the agency proffers none) to selectively update the data from Massachusetts and California instead of using all the new data from those states. The EPA's evident failure "to consider [that] important aspect of the problem" was arbitrary and capricious. *State Farm*, 463 U.S. at 43.

IV. Conclusion

For the foregoing reasons, I would hold that the EPA has authority to withdraw a determination to regulate a contaminant under the Safe Drinking Water Act, prior to the promulgation of a MCLG and accompanying regulation, when

the best available science supports the agency's conclusion that the required factors for regulation are no longer met. But in my view, the EPA's 2020 decision not to regulate perchlorate was arbitrary, capricious, and contrary to law because it was based on a MCLG that did not comply with a statutory directive, and relied on selectively updated data concerning the prevalence of perchlorate in drinking water. On those grounds, I would vacate the agency's withdrawal of its 2011 regulatory determination and remand for further proceedings. I therefore concur in the judgment.