Coevolution of Law and Science: A Clean Water Act Case Study

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Despite recent political attacks, science is integral to environmental law and other regulatory regimes that are informed by new scientific research. It is inaccurate, however, to view the relationship between law and science as static. Traditionally, science is either seen as a servant of the legal system, responding to and supporting the applicable statutes and regulations; or we expect the legal system to respond or "catch up" to scientific advances. A more useful model, borrowed from evolutionary biology, is coevolution, an ongoing process in which law and science interact over time in an iterative process. A case study from the Clean Water Act ("CWA") biocriteria program illustrates this dynamic process and suggests ways in which law and science can interact more effectively in the CWA and other regulatory regimes. It also highlights the conceptual difference between "scientific knowledge" and "regulatory knowledge," and the importance of that distinction for separation of powers and democratic governance in the administration and enforcement of complex regulatory statutes.

I. INTRODUCTION

A. Science and Regulation

It would hardly require saying that science is integral to environmental law,[1] except that the integrity of science and its relationship to government regulation is currently under attack.[2] Politics partially explains the current dynamic. The Trump Administration has a strong anti-regulatory agenda,[3] and the

1. *See generally* Robert L. Glicksman & Mathew R. Batzel, *Science, Politics, Law, and the Arc of the Clean Water Act: The Role of Assumptions in the Adoption of a Pollution Control Landmark*, 32 WASH. U. J.L. & POL'Y 99 (2010); Carol M. Rose, *Environmental Law Grows Up (More or Less), and What Science Can Do to Help*, 9 LEWIS & CLARK L. REV. 273 (2005); Oliver A. Houck, *Tales from a Troubled Marriage: Science and Law in Environmental Policy*, 17 TUL. ENVTL. L.J. 163 (2003); Robert W. Adler, *The Supreme Court and Ecosystems: Environmental Science in Environmental Law*, 27 VT. L. REV. 249 (2003).

2. *See* Coral Davenport, *In the Trump Administration, Science is Unwelcome. So is Advice.*, N.Y. TIMES, June 9, 2018, at A1.

3. *See* Linda Qiu, *Trump Says 'No President Has Ever Cut So Many Regulations.' Not Quite.*, N.Y. TIMES (Feb. 23, 2018), https://www.nytimes.com/2018/02/23/us/politics/trump-

President has both denied climate change science[4] and displayed a limited understanding of science.[5] President Trump's first U.S. Environmental Protection Agency ("EPA") Administrator initially took steps to prohibit public statements by EPA scientists about their research,[6] and later issued a rule to alter the manner in which EPA addresses scientific information.[7] In Congress, the proposed "HONEST" Act[8] seeks to impose what some science policy experts believe are untenable barriers to the use of scientific research to support regulatory policy, such as a requirement to rely only on

says-no-president-has-ever-cut-so-many-regulations-not-quite.html [https://perma.cc/L6P7-LCK7].

4. *See* Clare Foran, *Donald Trump and the Triumph of Climate-Change Denial*, THE ATLANTIC (Dec. 25, 2016), https://www.theatlantic.com/politics/archive/2016/12/donald-trump-climate-change-skeptic-denial/510359/ [https://perma.cc/NG4B-X5CC].

5. Bill Gates reported that he had to explain to President Trump that HPV virus was different from HIV. Bess Levin, *Bill Gates: Trump is Even Dumber Than You Thought*, VANITY FAIR (May 8, 2018, 11:25 AM), https://www.vanityfair.com/news/2018/05/donald-trump-bill-gates-hiv-hpv [https://perma.cc/BDV4-3CY8]. John Holdren, the former Science Advisor to President Obama, reportedly referred to President Trump as "a science and technology talent repellent." David Meyer, *'That's Not a Good Use of My Time:' Bill Gates Says He Turned Down a Job Offer from Donald Trump*, FORTUNE (May 1, 2018), http://fortune.com/2018/05/01/bill-gates-donald-trump-job-offer/ [https://perma.cc/DC8H-LGWW].

6. Brady Dennis & Juliet Eilperin, *'Let Us Do Our Job': Anger Erupts Over EPA's Apparent Muzzling of Scientists*, WASH. POST (Oct. 23, 2017), https://www.washingtonpost.com/news/energy-environment/wp/2017/10/23/let-us-do-our-job-anger-erupts-over-epas-muzzling-of-scientists/?utm_term=.1ffb3c92b181 [https://perma.cc/MBZ4-LNBR]. Mr. Pruitt apparently later reversed that ban. *See* Lisa Friedman, *Scott Pruitt, E.P.A. Chief, Says Agency Scientists Are Free to Discuss Their Work*, N.Y. TIMES (Dec. 6, 2017), https://www.nytimes.com/2017/12/06/climate/scott-pruitt-epa.html [https://perma.cc/7QTU-DGMF].

7. *See* Gretchen Goldman, *Scott Pruitt Will Restrict the EPA's Use of Legitimate Science*, SCI. AM.: OBSERVATIONS (Mar. 20, 2018), https://blogs.scientificamerican.com/observations/scott-pruitt-will-restrict-the-epas-use-of-legitimate-science/ [https://perma.cc/UZ5M-9QUU]; Lisa Friedman, *E.P.A. Announces a New Rule. One Likely Effect: Less Science in Policy-Making.*, N.Y. TIMES (Apr. 24, 2018), https://www.nytimes.com/2018/04/24/climate/epa-science-transparency-pruitt.html [https://perma.cc/TH6R-M4AN]. Mr. Pruitt subsequently resigned as EPA Administrator. *See* Coral Davenport, Lisa Friedman & Maggie Haberman, *E.P.A. Chief Scott Pruitt Resigns Under a Cloud of Ethics Scandals,* N.Y. TIMES (July 5, 2018), https://www.nytimes.com/2018/07/05/climate/scott-pruitt-epa-trump.html [https://perma.cc/R6G8-2K9V].

8. H.R. 1430, 115th Cong. (2017) (prohibiting the EPA from using, for regulatory purposes, any science that is not "transparent or reproducible" as defined in the bill). The bill passed the House of Representatives but was not adopted by the Senate.

studies for which all data are made publicly available, even where the studies rely on confidential health information.[9]

Efforts to thwart the implications of scientific research for legislation and regulation, however, predate the current Administration.[10] This suggests a more deep-seated explanation for anti-science (and anti-regulatory) backlash. New scientific research often sheds light on previously unknown or poorly understood problems for which a regulatory response may be warranted. Even where the net societal benefits of regulation are positive, regulation often restricts liberty and imposes other costs on some members of society. That naturally provokes resistance. It is legitimate to question the nature, magnitude, and costs of regulation and who should bear those costs. That inquiry, however, should reflect a sound understanding and application of the relevant science, balanced properly against other policy considerations.

Science rarely produces firm information and explanations quickly, and no science is ever definitive. Science is an evolutionary process—an incremental pursuit of knowledge that does not always produce perfect results but trends toward enhanced understanding of various natural phenomena.[11] Scientific methodology relies on the generation and analysis of competing hypotheses and the use of empirical tests to falsify, refute, or support those hypotheses.[12] Revised hypotheses and more experimentation then provide explanations that best fit the observed data.

The inherent uncertainty of science and the evolutionary nature of the scientific process sometimes provide ammunition for opponents of regulation. Generation of competing hypotheses—and, therefore, *doubt*—forces rigorous debate and a quest for

9. *See* Goldman, *supra* note 7; Rebecca Worby, *What Scientists Are Saying About the EPA's 'Secret Science' Rule*, PAC. STANDARD (Apr. 26, 2018), https://psmag.com/environment/what-scientists-are-saying-about-epa-secret-science-rule [https://perma.cc/J778-3TBD].

10. *See generally* NAOMI ORESKES & ERIK M. CONWAY, MERCHANTS OF DOUBT: HOW A HANDFUL OF SCIENTISTS OBSCURED THE TRUTH ON ISSUES FROM TOBACCO SMOKE TO GLOBAL WARMING (2010).

11. *See* DAVID L. HULL, SCIENCE AS A PROCESS: AN EVOLUTIONARY ACCOUNT OF THE SOCIAL AND CONCEPTUAL DEVELOPMENT OF SCIENCE 26 (1st ed. 1988) ("Science is not a process by which we go from no knowledge to some knowledge, or from some knowledge to total knowledge. Rather it is a process by which scientists go from some knowledge to more knowledge. The important feature of science is not that it *always* produces increased knowledge but that *sometimes* it does. Science is not a perfect machine for grinding out true claims about the world in which we live, but it is the best of all the imperfect machines developed to date.") (emphasis in original).

12. *See, e.g.,* Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593 (1993).

additional data and explanations.[13] The ongoing interaction between science and regulation is healthy because additional scientific understanding can reduce the risk of poorly targeted regulation. It can also help to avoid regulation of harms that turn out to be less severe than initially believed. Solutions to an identified problem (through regulation or other means) may generate net benefits or otherwise warrant a regulatory response.[14] Determining where along this spectrum regulation is appropriate involves both science and factors that transcend science, such as economics, feasibility, and societal values.

B. Competing Models of Science and Regulation

One might posit three different models for the relationship between law and science in the arena of government regulation. By "models," I mean alternative ways to explain the iterative interactions between law and science in a particular statutory and regulatory scheme. I do not mean them to reflect different *categories* of interactions; that is, I do not mean that some statutes fit within one "model" and others fit within another (although that may also be true in some cases). Two of the models are static and unidirectional and assume a fixed relationship in which one of the two disciplines—law or science—reacts to the other over time. The third model is bidirectional and dynamic, and it better explains the ongoing relationship between law and science.

In the first model, scientific information alerts society to a problem, such as water pollution. This induces the government to forge a regulatory response, in this case the federal Clean Water

13. *See* Karen Locke, Karen Golden-Biddle & Martha S. Feldman, *Perspective—Making Doubt Generative: Rethinking the Role of Doubt in the Research Process*, 19 ORG. SCI. 907, 908–11 (2008).

14. Logically, there is a reciprocal relationship between the degree of certainty necessary to justify regulation and the magnitude of potential harm the regulation seeks to avoid or mitigate. As the magnitude of harm increases, one might accept the legitimacy of preventive regulation with a lower standard of scientific proof. *See* Ethyl Corp. v. EPA, 541 F.2d 1, 18 (D.C. Cir. 1976) ("Danger . . . is not set by a fixed probability of harm, but rather is composed of reciprocal elements of risk and harm, or probability and severity. That is to say, the public health may properly be found endangered both by a lesser risk of a greater harm and by a greater risk of a lesser harm. Danger depends upon the relation between the risk and harm presented by each case, and cannot legitimately be pegged to 'probable' harm, regardless of whether that harm be great or small.") (internal citations omitted).

Act ("CWA").[15] The regulatory solutions chosen may then require scientific support to identify and prove the feasibility of effective control measures, such as the technology-based pollution controls in the CWA.[16] In this model, law drives the regulatory process, and science is expected to "catch up" to the legal mandate.

A second model reflects the opposite dynamic, in which law needs to "catch up" to science. One subset of this scenario occurs when scientific advances themselves become the target of government regulation. Nuclear power, artificial intelligence, and the Internet are examples of scientific developments that may require government regulation. The other subset occurs when new scientific knowledge suggests that existing regulatory regimes should be amended to address previously unknown or unforeseen problems. For water pollution, an example is the discovery of endocrine disruptors after Congress adopted the CWA, leading to statutory amendments to require increased focus on toxic pollutants.[17] In both subsets of the second model, science drives

15. See ROBERT W. ADLER, JESSICA C. LANDMAN & DIANE M. CAMERON, THE CLEAN WATER ACT: 20 YEARS LATER 5–6 (1993) for a brief history of the scientific information that prompted Congress to enact the Federal Water Pollution Control Act of 1972, commonly known as the Clean Water Act. Pub. L. No. 92-500, 86 Stat. 816 (1972) (codified as amended at 33 U.S.C. §§ 1251–1388 (2018)).

16. The CWA relies on engineering to develop better water pollution control technologies. *See* 33 U.S.C. §§ 1311(b), 1314(b) (2018) (requiring EPA to adopt water pollution control regulations for various categories of discharger based on determinations of the "best" technologies available to control those discharges). See *infra* Part III.B.5 for an explanation of the manner in which Congress intended this statutory mandate to stimulate science to develop increasingly better technologies until discharges could be eliminated entirely to fulfill the "zero discharge" goal of the CWA. *See* 33 U.S.C. § §1251(a)(1) (2018) (establishing a "national goal that the discharge of pollutants into the navigable waters be eliminated by 1985"). *See also id.* § 1311(b)(2)(A) (requiring "the elimination of discharges of all pollutants" where "technologically and economically achievable for a category or class of point sources"). Likewise, the CWA relies on biological science and other scientific disciplines to develop water quality standards to determine what levels of water quality are needed to support and protect various beneficial uses of water and aquatic ecosystems. *See id.* §§ 1313, 1314(a) (requiring U.S. EPA to adopt guidelines for the development of water quality standards, and individual states to adopt such standards subject to EPA review and approval, or for EPA to adopt substitute federal standards in the case of inadequate state action).

17. *See* Water Quality Act of 1987, Pub. L. No. 100-4, § 308, 101 Stat. 7, 38 (1987) (adding 33 U.S.C. § 1313(C)(2)(B) (requiring additional water quality standards for toxic pollutants) and *id.* § 1314(l) (requiring state identification, listing, and individual control strategies for "toxic hot spots" of water pollutants)); THEO COLBORN, DIANNE DUMANOSKI & JOHN PETERSON MYERS, OUR STOLEN FUTURE: ARE WE THREATENING OUR FERTILITY, INTELLIGENCE, AND SURVIVAL? A SCIENTIFIC DETECTIVE STORY (1996).

the need for regulation, and the law is expected to catch up to sometimes rapidly evolving science.

Both of these models of the relationship between law and science in the regulatory process are unidirectional. In one, legal developments drive science; in the other, scientific developments drive law. Both models are static in the sense that one set of factors drives another, with no ongoing or iterative feedback in the opposite direction.

I was prompted to consider a third, more iterative model of the interaction between law and science in connection with a presentation at the annual meeting of the Society for Freshwater Science ("SFS").[18] The presentation addressed the extent to which the law, in this case the CWA and its regulatory apparatus, has "caught up" to recent developments in a subset of water quality standards known as biological water quality, or "biocriteria."[19] I have written periodically about this set of issues for more than two decades,[20] largely to analyze the extent to which the law has caught up to the evolving science. It took quite a few years for EPA and states to use this form of water quality standards for monitoring and

18. The Society for Freshwater Science held its 2018 Annual Meeting in Detroit, Michigan on May 20–24, 2018. SFS describes itself as "an international scientific organization whose purpose is to promote further understanding of freshwater aquatic ecosystems (rivers, streams, lakes, reservoirs, and estuaries) and ecosystems at the interface between aquatic and terrestrial habitats (wetlands, bogs, fens, riparian forests, and grasslands.)." *What is SFS?*, SOC'Y FOR FRESHWATER SCI., https://freshwater-science.org/about [https://perma.cc/SJ3H-YS47] (last visited Dec. 31, 2018).

19. See *infra* Part II.B.2 for an explanation of biocriteria and how they fit into the CWA regulatory scheme.

20. *See* Robert W. Adler, *The Decline and (Possible) Renewal of Aspiration in the Clean Water Act*, 88 WASH. L. REV. 759 (2013) [hereinafter *Renewal of Aspiration*]; Robert W. Adler, *Resilience, Restoration, and Sustainability: Revisiting the Fundamental Principles of the Clean Water Act*, 32 WASH. U. J.L. & POL'Y 139 (2010) [hereinafter *Resilience, Restoration, and Sustainability*]; Robert W. Adler, *The Two Lost Books in the Water Quality Trilogy: The Elusive Objectives of Physical and Biological Integrity*, 33 ENVTL. L. 29 (2003) [hereinafter *The Two Lost Books in the Water Quality Trilogy*]; Robert W. Adler, *Integrated Approaches to Water Pollution: Lessons from the Clean Air Act*, 23 HARV. ENVTL. L. REV. 203 (1999) [hereinafter *Integrated Approaches to Water Pollution*]; Robert W. Adler, *Filling the Gaps in Water Quality Standards: Legal Perspectives on Biocriteria, in* BIOLOGICAL ASSESSMENT AND CRITERIA: TOOLS FOR WATER RESOURCE PLANNING AND DECISION MAKING 345 (Wayne S. Davis & Thomas P. Simon eds., 1995) [hereinafter *Legal Perspectives on Biocriteria*].

assessment, and later for regulatory and enforcement purposes.[21] That gap is now beginning to be filled.[22]

Conversely, advances in regulatory uses of biocriteria required additional scientific progress. "While biocriteria remain largely untouched by lawyers and judges thus far, this innocence likely will be lost as biocriteria move from the realm of science to the reality of regulation. Therefore, program managers would be wise to anticipate and to insulate their biocriteria programs from such legal challenges."[23] Here, I urged the traditional approach of ensuring that regulators develop the scientific foundation sufficiently to defend biocriteria and their regulatory uses against inevitable legal challenges.[24]

Neither of these static, unidirectional models properly depict and explain the dynamic, ongoing relationship between law and science in environmental law and other complex regulatory fields. Fittingly, in the context of biocriteria, evolutionary biology provides the concept of *coevolution* that can be used as a third model to better explain this relationship. Coevolution is an ongoing, iterative process whereby two or more species evolve in a reciprocal or mutually dependent manner.[25] Simple examples come from predator-prey relationships. As cheetahs become swifter, antelopes must become either faster or more evasive in response, requiring cheetahs to become even swifter or better at stalking.[26] As hawks

21. *See* Adler, *The Two Lost Books in the Water Quality Trilogy*, *supra* note 20, at 74 (describing the "significant untapped potential" for the use of biocriteria at the time).

22. Biocriteria have, in fact, moved from assessment to regulatory targeting to regulation and enforcement. *See, e.g.*, Ohio Valley Envtl. Coal., Inc. v. Fola Coal Co., 82 F. Supp. 3d 673 (S.D.W. Va. 2015), *aff'd*, 845 F.3d 133 (4th Cir. 2017) (involing a citizen enforcement suit relying on biocriteria violations); Ohio Valley Envtl. Coal., Inc. v. Pruitt, 893 F.3d 225, 231 (4th Cir. 2018) (reversing the decision of the District Court that West Virginia had constructively submitted TMDLs, and requiring regulation based on biocriteria violations); Bd. of Comm'rs. of Fairfield Cty. v. Koncelik, 2013 WL 2422905, at *13 (Ohio Ct. App. May 23, 2013) (upholding stricter permit conditions based on biocriteria).

23. Adler, *Legal Perspectives on Biocriteria*, *supra* note 20, at 345.

24. Indeed, the targets of regulatory action based on biocriteria violations have begun to mount legal challenges to the credibility of the underlying science and therefore the legitimacy of regulation. *See, e.g.*, Las Virgenes Mun. Water Dist.–Triunfo Sanitary Dist. v. McCarthy, 2016 WL 393166 (N.D. Cal. Feb. 1, 2016); *Koncelik*, 2013 WL 2422905.

25. *See* SCOTT NUISMER, INTRODUCTION TO COEVOLUTIONARY THEORY 1-4 (2017).

26. More accurately, faster cheetahs or better stalkers are more likely to survive to pass along the genes that convey those superior traits to their offspring, causing the cheetah gene pool to evolve accordingly. Likewise, those antelope best able to avoid becoming a cheetah's dinner will survive to pass their genes along to their offspring. *See id.*

develop keener eyes, their prey might develop more effective camouflage, requiring the hawks to become craftier.

Although the analogy is not perfect,[27] law and science are different epistemological "species" that interact with one another in the development and implementation of regulatory law. In a complex regulatory setting—as in a complex ecosystem—each discipline adapts to the other's developments in an iterative process. This bolsters the regulatory process by ensuring that regulation is both effective (serves the intended societal goals) and fair (tailored appropriately to those goals). In particular, it suggests that agencies should have a more intentional process whereby relevant scientific developments are followed by appropriate regulatory actions. Likewise, administrative agencies should adopt or heed existing processes to guide scientific research to best support the regulatory agenda. More importantly, this article will discuss ways in which the coevolution of law and science has implications for the appropriate role—and limits to the role—of each discipline in ensuring that key societal decisions are made democratically and reflect diverse views and interests. Science can provide answers to some kinds of regulatory questions, but others involve value judgments that require input from other disciplines, policymakers who are accountable to the public, and interested and affected members of the public.

This article explains and critiques the manner in which the coevolution of law and science has occurred through the example of biocriteria in the CWA. Part II sets the background by explaining how biocriteria fit within the regulatory structure of the CWA. Part III presents five examples of coevolution in the biocriteria program as implemented by EPA and the States. Part IV concludes by exploring the potential implications of legal and scientific coevolution in terms of CWA implementation and more generally.

27. Neither law nor science literally has a gene pool that changes in response to effective adaptations, resulting in superior survival and transmission of associated traits to future generations of lawyers or scientists.

II. THE ROLE OF BIOLOGICAL WATER QUALITY CRITERIA ("BIOCRITERIA") IN THE CLEAN WATER ACT

A. The Statutory Background

Although the CWA is a phenomenally complex statute and difficult to summarize compactly, some background is necessary to understand the role of biocriteria in the statutory scheme and why they pose a useful example of the coevolution of law and science. The immediate predecessor to the current CWA, the Water Quality Act of 1965,[28] focused on the development and application of ambient water quality standards ("WQS") to define the levels of water quality necessary to support various uses of water bodies.[29] Thus, water quality science drove pollution control requirements, but controls were limited to those deemed necessary to achieve WQS. In part due to the limits of water quality science at the time,[30] and the resulting failure of the 1965 law to reduce water pollution significantly,[31] the 1972 Act (referred to hereinafter, as amended, as the CWA) shifted to a preventive approach centered primarily on technology-based controls, which imposed discharge limits determined by what level of control was possible, irrespective of ambient water quality.[32]

28. Pub. L. No. 89-234, 79 Stat. 903 (1965). Dean William Hines authored a series of three articles outlining the history of pre-1972 water pollution control law. *See* N. William Hines, *Nor Any Drop to Drink: Public Regulation of Water Quality, Part I: State Pollution Control Programs*, 52 IOWA L. REV. 186 (1966); N. William Hines, *Nor Any Drop to Drink: Public Regulation of Water Quality, Part II: Interstate Arrangements for Pollution Control*, 52 IOWA L. REV. 432 (1966); N. William Hines, *Nor Any Drop to Drink: Public Regulation of Water Quality, Part III: The Federal Effort*, 52 IOWA L. REV. 799 (1967).

29. *See* WILLIAM H. RODGERS, JR., ENVIRONMENTAL LAW 253 (2d ed. 1994). An "ambient" environmental standard refers to a standard of quality in the environment as a whole relative to pollution from multiple sources, as distinct from a standard imposed on an individual discharger at the point of pollutant release. *See* David M. DRIESEN, ROBERT W. ADLER & KIRSTEN H. ENGLE, ENVIRONMENTAL LAW: A CONCEPTUAL AND PRAGMATIC APPROACH 91 (3d ed. 2016).

30. *See* Nat. Res. Def. Council v. U.S. EPA, 915 F.2d 1314, 1316 (9th Cir. 1990) ("Regulators had to work backward from an overpolluted body of water and determine which entities were responsible; proving cause and effect was not always easy.").

31. The 1971 Senate Subcommittee on Air and Water Pollution "conclude[d] that the national effort to abate and control water pollution [was] inadequate in every vital aspect," and "[m]any of the Nation's navigable waters [were] severely polluted, and major waterways near the industrial and urban areas [were] unfit for most purposes." S. REP. NO. 92-414, at 7 (1971), as *reprinted in* 1972 U.S.C.C.A.N. 3668, 3674.

32. *See* RODGERS, JR., *supra* note 29, at 259–62; 33 U.S.C. §§ 1311(b), 1314(b), 1316, 1317 (2018).

However, the final 1972 CWA retained WQS in a secondary role to measure the effectiveness of technology-based standards, and to determine whether any supplemental controls were needed to protect water quality after technology-based discharge limits were imposed. The dual approach was wise. Fueled in part by the development and implementation of biocriteria over the past twenty years, WQS are now playing a renewed role in meeting the CWA's statutory goals and objectives.

1. CWA Statutory Objective and Subsidiary Goals

In the CWA, Congress articulated broad and ambitious goals. The overriding objective of the Act is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[33] The statutory definition of water "pollution" uses nearly identical language: "the man-made or man-induced alteration of the chemical, physical, biological, or radiological integrity of water."[34] The statute does not define the term "integrity," although legislative history sheds some light on the concept.[35]

Congress supplemented the overarching statutory objective with a series of subsidiary goals and policies that guide EPA and the states in implementing the statute.[36] For purposes of this analysis, the most important goals are known colloquially (but imprecisely) as "zero discharge," "fishable and swimmable waters," and "no toxics in toxic amounts." The "zero discharge" goal[37] is implemented primarily through the technology-based approach of mandating increasingly advanced pollution control technology to eventually eliminate discharges of pollutants into the nation's waters irrespective of their impacts on ambient water quality.[38] The

33. 33 U.S.C. § 1251(a) (2018).

34. *Id.* § 1362(19).

35. *See infra* notes 160–61 and accompanying text.

36. 33 U.S.C. § 1251(a)(1)–(7) (2018).

37. "[I]t is the national goal that the discharge of pollutants into the navigable waters be eliminated by 1985." *Id.* § 1251(a)(1). The 1985 zero discharge goal was not met and is now long past. *See* Lawrence S. Bazel, *The Clean Water Act at Thirty: A Failure After All These Years?*, 18 NAT. RESOURCES & ENV'T 46, 47 (2003) (asserting that "the goal of zero discharge turned out to be hopeless"); Adler, *Renewal of Aspiration*, *supra* note 20, at 776–77.

38. *See* Oliver A Houck, *Ending the War: A Strategy to Save America's Coastal Zone*, 47 MD. L. REV. 358, 372, 389–90 (1988) (discussing the rationale behind best available technology standards and explaining: "In 1972 Congress explicitly concluded that the state of the art should be advanced by 'action-forcing' technology and that the guidelines for this technology, as well as the permits issued under them, should not be limited to the means of

interim goal of "fishable and swimmable waters"[39] reflects the philosophy that science can guide the development of ambient water quality standards to define what levels of water quality suffice to support specific beneficial uses of water and water bodies. The "no toxics in toxic amounts" goal[40] falls in between the other two, as it envisions the elimination of pollutant discharges to serve the ultimate goal of ending toxic impacts.

2. The Qualified Discharge Ban

Congress matched the CWA's broad statutory goals and objectives with specific, but unfortunately narrow, statutory tools.[41] The sharpest of those tools, and arguably the central implementing mechanism in the statute, is the qualified discharge ban in section 301(a).[42] That provision prohibits the discharge of any pollutant except pursuant to a National Pollutant Discharge Elimination System ("NPDES") permit issued by EPA or a State with the delegated authority to do so.[43] Permits for discharges of dredged or fill material are issued by the U.S. Army Corps of Engineers or a State with the delegated authority to do so.[44]

individual applicants. This process was, and remains, an effective way to clean up pollution.") (internal citation omitted). For a description of technology-based standards generally, see DRIESEN, ADLER & ENGLE, supra note 29, at 151–96; Wendy E. Wagner, *The Triumph of Technology-Based Standards*, 2000 ILL. L. REV. 83; Sidney A. Shapiro & Thomas O. McGarity, *Not So Paradoxical: The Rationale for Technology-Based Regulation*, 1991 DUKE L.J. 729.

39. "[I]t is the national goal that wherever attainable, an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water be achieved by July 1, 1983." 33 U.S.C. §1251(a)(2) (2018). This goal also was not met by 1983, and still has not been for many of the Nation's waters. *See National Summary of State Information*, U.S. ENVTL. PROTECTION AGENCY, https://ofmpub.epa.gov/waters10/attains_nation_cy.control [https://perma.cc/2QMV-RZX6] (last visited Jan. 1, 2019) (providing information on water quality impairment nationally, and by state). An ambiguity in this statutory goal is whether the words "wherever attainable" stand alone or are modified by the words "by July 1, 1983." In one reading, Congress intended all water bodies to meet this goal eventually, but "wherever attainable . . . by 1983." A less stringent reading, preferred by EPA, is that the goal must be met for all water bodies for which the goal is attainable, and for those waters, by 1983. *See* 40 C.F.R. §§ 131.10(g), (j), 131.3(g) (2018) (allowing states to provide for uses that do not meet the goal of CWA section 101(a)(2) if supported by a use attainability analysis). No court has reviewed this interpretation.

40. "[I]t is the national policy that the discharge of toxic pollutants in toxic amounts be prohibited." 33 U.S.C. § 1251(a)(3) (2018).

41. *See generally* Adler, *Renewal of Aspiration*, *supra* note 20.

42. 33 U.S.C. § 1311(a) (2018).

43. *Id.* § 1342.

44. *Id.* § 1344.

Section 301(a), however, is limited to discharges of pollutants *from point sources* and to discharges *into the waters of the United States.*[45] Three categories of water pollution are therefore excluded from this qualified discharge ban. First, the "point source" qualification leaves all diffuse sources of water pollutants, such as runoff, infiltration, and air deposition of pollutants, to be governed by the considerably weaker provisions of CWA section 319.[46] Second, section 301(a) applies only to discharges into the "waters of the United States," which does not include all water bodies and remains the subject of considerable dispute.[47] Therefore, some of the "Nation's waters" are excluded from the Act's strictest implementing mechanism despite being included in its overall objective.[48] Third, although the CWA defines the term "pollutant" broadly, the even broader definition of "pollution" encompasses aquatic ecosystem stressors that are not covered by section 301(a),

45. These qualifications stem from the statutory definition of "discharge of a pollutant" as "any addition of any pollutant to navigable waters from any point source." *Id.* § 1362(12). The term "navigable waters," in turn, is redefined as the "waters of the United States, including the territorial seas." *Id.* § 1362(7). A "point source" is limited to "any discernible, confined, and discrete conveyance" from which pollutants may be discharged. *Id.* § 1362(14).

46. Section 319 requires individual states to identify water bodies that cannot reasonably be expected to meet WQS absent controls on nonpoint source pollution, and to identify and develop and implement a plan to control them through "best management practices" for various categories of diffuse pollution. *Id.* § 1329. An intermediary category of pollutant sources includes diffuse urban and industrial storm water which is then channelized prior to discharge, and regulated under the more specific provisions of section 401(p). *Id.* § 1342(p). However, those controls do not apply to "agricultural stormwater discharges and return flows from irrigated agriculture." *See id.* § 1362(14) (excluding those sources from the definition of "point source," thus categorizing them as nonpoint sources to be controlled pursuant to section 319).

47. The exact scope of this definition remains the subject of unresolved litigation and regulatory disputes. *See* Rapanos v. United States, 547 U.S. 715 (2006); *In re* E.P.A., 803 F.3d 804, 808 (6th Cir. 2015), *vacated sub nom. In re* U.S. Dep't of Def., 713 F. App'x 489, 490–91 (6th Cir. 2018) (dismissing for lack of jurisdiction pursuant to U.S. Supreme Court ruling in *National Ass'n of Manufacturers v. Department of Defense*, 138 S. Ct. 617 (2018)).

48. The overall statutory objective of restoring and maintaining the chemical, physical, and biological integrity applies to the "Nation's waters" (33 U.S.C. § 1251(a) (2018)), as distinct from the "waters of the United States" subject to the qualified discharge ban in section 301(a) (*id.* § 1311(a)). The distinction is not explained by the legislative history of the CWA, but the "Nation's waters" would appear logically to be broader than the "waters of the United States, especially given the structure of the CWA and its division of pollution control responsibility between the federal and state governments. *See, e.g., id.* § 1288(b)(2) (requiring state comprehensive management plans to address groundwater as well as surface water pollution).

such as hydrological modification, habitat loss or alteration, climate change, and other stressors.[49]

For those sources of pollution that are covered by section 301(a), the provision is qualified further because point source pollutant discharges can still be allowed through permits issued under sections 402 and 404 of the statute.[50] Section 402 NPDES permits issued by state agencies or EPA are required for most pollutant discharges, and are subject to both technology-based effluent limitations ("TBELs") and water quality-based effluent limitations ("WQBELs"), among other conditions.[51] Technology-based standards reflect a preventive approach to water pollution in which EPA or states identify the best pollution control methods available for a particular source or category of sources based on engineering science. For this purpose, water quality science is largely irrelevant,[52] because the statutory goal is zero discharge of point source pollutants irrespective of water quality impacts.[53] Supplemental WQBELs are required where technology-based discharge limits do not suffice to attain WQS for specific water bodies.[54]

Thus, WQS remain an important component of the CWA scheme despite the preeminence of technology-based standards. In addition to serving as an important check to ensure that section 402 and 404 permits advance the goals and objective of the Act, they also play an important role in identifying impaired waters, including waters impaired by forms of water pollution not addressed by the section 301(a)'s controls on point source pollution.[55]

49. *Id.* § 1362(6).

50. *Id.* §§ 1342, 1344.

51. *See id.* §§ 1311(b), 1342(b).

52. *See supra* note 38. The only reason that receiving water quality impacts are not entirely irrelevant to technology-based standards is that Congress adopted several variances that require EPA to consider receiving water quality. *See, e.g.*, 33 U.S.C. § 1311(g) (2018) (allowing modifications for nonconventional pollutants where modification will not interfere with attainment and maintenance of WQS).

53. *See supra* note 37.

54. *See* 33 U.S.C. §§ 1311(b)(1)(C), 1313(d) (2018); 40 C.F.R. § 122.44(d) (2018).

55. *See, e.g.*, 33 U.S.C. §§ 1313(d)(1) (requiring identification and listing of waters for which technology-based effluent limitations will not meet applicable WQS), 1319(a) (authorizing "federally assumed enforcement" of effluent permit conditions or limitations when EPA Administrator finds, "on the basis of information available to him," widespread violations of such permits), 1314(l) (2018) (requiring the listing of and a control strategy for any water that, after the application of effluent limitations, does not "assure protection of

B. Water Quality Standards

1. Water Quality Standards Generally

Unlike technology-based standards imposed on individual pollution sources and measured at the point of discharge, WQS define the desired quality of the water bodies Congress sought to restore and protect.[56] WQS consist of three major components.[57] First, they define the "designated uses," such as drinking water, aquatic life protection, or swimming and other recreation, for which particular water bodies are to be protected.[58] Congress specified in the CWA's statutory goals that the minimum uses for which water bodies are to be protected are "the protection and propagation of fish, shellfish, and wildlife . . . [and] recreation in and on the water . . . ."[59] Although the goals provisions of statutes generally articulate legislative aspirations rather than enforceable provisions of law,[60] the CWA converts this goal into operative law by providing that WQS must, *inter alia*, "serve the purposes of this [Act]."[61]

Second, WQS include water quality criteria ("WQC"), which are measures of water body characteristics deemed necessary to support the designated uses.[62] Designated uses define real-world end goals for water body protection, while WQC establish the water quality measurements or indicators used to measure attainment of those end goals, based on the best available—but frequently

public health, public water supplies, agricultural and industrial uses, and the protection and propagation of a balanced population of shellfish, fish and wildlife, and allow recreational activities in and on the water").

56. As discussed in Part III.B.5, *infra*, the scope of waters addressed by the CWA remains in dispute, but also varies with the portion of the Act being implemented.

57. *See generally* PUD No. 1 of Jefferson Cty. v. Wash. Dep't of Ecology, 511 U.S. 700, 704–05 (1994).

58. 33 U.S.C. § 1313(c)(2)(A) (2018); 40 C.F.R. §§ 130.2(d), 130.3, 131.2, 131.10 (2018).

59. 33 U.S.C. § 1251(a)(2) (2018).

60. *See* Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350–51 (1989); Rodriguez v. United States, 480 U.S. 522, 525–26 (1987) (per curiam); Nat'l Wildlife Fed'n v. Gorsuch, 693 F.2d 156, 178–79 (D.C. Cir. 1982). *But see* Donovan v. Dewey, 452 U.S. 594, 602 n.7 (1981); Kennecott Copper Corp. v. EPA, 612 F.2d 1232, 1236 (10th Cir. 1979); Am. Petroleum Inst. v. EPA, 540 F.2d 1023, 1028 (10th Cir. 1976).

61. 33 U.S.C. § 1313(c) (2018). *See also* 40 C.F.R. §§ 130.3, 131.2 (2018) (reflecting EPA's regulatory confirmation of this principle). As discussed below, however, EPA appears to have applied this rule too narrowly, applying it to one of the subsidiary statutory goals but not to the overall statutory objective. *See infra* notes 174–77 and accompanying text.

62. 33 U.S.C. § 1313(c)(2)(A) (2018); 40 C.F.R. §§ 130.2(d), 130.3, 131.2, 131.11 (2018).

evolving—scientific knowledge. A WQC, for example, might specify that a water body should have no more than X milligrams per liter of a particular pollutant, or a temperature no warmer than Y degrees, to support the resident fish population.

Third, EPA regulations require states to adopt and implement antidegradation rules and policies as essential components of WQS.[63] Antidegradation policy requires, with limited exceptions, the maintenance and protection of existing water quality and designated uses. It also requires the protection of existing uses of water bodies, whether or not such uses are formally designated.[64]

The CWA incorporates a presumption that individual states will adopt differing WQS. This recognizes the diversity of environmental conditions around the country, and the fact that states have differing philosophies on water body uses and the degree of protection needed to support them (balanced against economic, social, and other factors).[65] Through EPA, however, the federal government retains a key function in the WQS program by establishing water quality criteria "guidance"[66] to set minimum requirements for state WQS. Moreover, states are required to submit their WQS to EPA for review and approval at least once every three years.[67] EPA can insist on revisions to state WQS and has the authority to adopt federal WQS where a state fails to adopt

63. *See* 33 U.S.C. § 1313(d)(4)(B) (2018); 40 C.F.R. §§ 131.6(d), 131.12 (2018).

64. *See id. See also* OFFICE OF WATER, U.S. ENVTL. PROT. AGENCY, EPA-823-B-12-002, WATER QUALITY STANDARDS HANDBOOK—CHAPTER 4: ANTIDEGRADATION 6 (2012), https://www.epa.gov/sites/production/files/2014-10/documents/handbook-chapter4.pdf [https://perma.cc/YD9P-JN47] (explaining that "[n]o activity is allowable under the antidegradation policy which would partially or completely eliminate any existing use whether or not that use is designated in a State's water quality standards").

65. *See* 33 U.S.C. § 1251(b) (2018) (recognizing the "primary responsibilities and rights of States to prevent, reduce, and eliminate pollution, [and] to plan the development and use (including restoration, preservation, and enhancement) of land and water resources . . ."); Miss. Comm'n on Nat. Res. v. Costle, 625 F.2d 1269, 1275 (5th Cir. 1980) (noting that "the legislative history [of the CWA] reflects congressional concern that the Act not place in the hands of a federal administrator power over zoning watershed areas. The varied topographies and climates in the country call for varied water quality solutions.").

66. 33 U.S.C. § 1314(a) (2018). Although the statute refers to these EPA promulgations as "guidance," some resulting regulations are legally binding, see 40 C.F.R. pt. 131, while others are more traditional guidance documents, see OFFICE OF WATER, U.S. ENVTL. PROT. AGENCY, EPA-823-B-94-005a, WATER QUALITY STANDARDS HANDBOOK—APPENDIX I: LIST OF EPA WATER QUALITY CRITERIA DOCUMENTS (2d. 1994), https://www.epa.gov/sites/production/files/2014-10/documents/handbook-appendixi.pdf [https://perma.cc/Y5S7-RLXW].

67. 33 U.S.C. § 1313(c)(1) (2018).

WQS that comply with the CWA and EPA regulations.[68] Generally speaking, courts have afforded states more latitude in establishing designated uses of water bodies, because of the land use and economic policy implications of such choices. Courts have afforded EPA more latitude in the scientific judgment as to the WQC necessary to protect those uses.[69]

2. Forms of Water Quality Standards

Many different characteristics of water and aquatic ecosystems may affect the degree to which water body uses are supported. For example, aquatic species may be adversely affected by high levels of chemical pollutants, altered physical characteristics such as high temperatures or low dissolved oxygen levels, or by ecological changes such as loss of streamside vegetation. As a result, WQC come in multiple forms.[70] Narrative WQC qualitatively describe those conditions deemed necessary to support designated uses, usually expressed in the form: "free from toxic pollutants that [cause a specified adverse effect]."[71] This form of WQC is extremely flexible, providing pollution control agencies and courts with latitude to address water quality problems that may not be covered by more precisely stated forms of WQC, or for which the scientific basis for numeric criteria is not sufficiently developed. Although accepted by the courts as a valid form of regulation,[72]

68. *Id.* § 1313(c)(3)–(4).

69. *See Miss. Comm'n on Nat. Res.*, 625 F.2d at 1276 (recognizing that while the states have primary responsibility for zoning watershed areas, "EPA's role also is more dominant when water quality criteria are in question. . . . The criteria set for a specific use are more amenable to uniformity. Congress recognized this distinction by placing with EPA the duty to develop and publish water quality criteria reflecting the latest scientific knowledge . . . ."); Nw. Envtl. Advocates v. EPA, 268 F. Supp. 2d 1255, 1265–66 (D. Or. 2003) (upholding EPA's scientific determination of water temperature criteria for the designated use of rearing salmonids under a "rational basis" standard but noting "[t]hese criteria are meaningful and enforceable only if the state is able to designate when and where these particular uses may occur").

70. *See* 40 C.F.R. § 131.3(b) (2018) (providing that WQC can be "expressed as constituent concentrations, levels, or narrative statements"); Adler, *Renewal of Aspiration*, *supra* note 20, at 803–06.

71. OFFICE OF WATER, U.S. ENVTL. PROT. AGENCY, EPA-823-B-17-001, WATER QUALITY STANDARDS HANDBOOK—CHAPTER 3: WATER QUALITY CRITERIA § 3.2.2 (2017), https://www.epa.gov/sites/production/files/2014-10/documents/handbook-chapter3.pdf [https://perma.cc/LTA2-WLUS] [hereinafter WQS HANDBOOK CHAPTER 3]. *See also* 40 C.F.R. § 131.11(b)(2) (2018).

72. *See* Envtl. Def. Fund, Inc. v. Costle, 657 F.2d 275, 288 (D.C. Cir. 1981) ("Water quality criteria may be, and often are, totally narrative.").

however, narrative criteria are more challenging to implement and enforce than numeric WQC. Unlike narrative WQC, numeric WQC define specific and quantifiable targets for ambient water quality (such as no more than x milligrams per liter of a particular contaminant),[73] and therefore can be incorporated into NPDES permits in a more straightforward way.

Neither narrative nor numeric WQC, however, address all of the adverse effects of pollutants on water bodies. For example, multiple pollutants may have cumulative or synergistic effects not captured by WQC for individual chemical pollutants. "Whole effluent toxicity" ("WET") criteria fill this gap by measuring the differential mortality of designated test species (or other adverse effects on them) to assess the overall toxicity of *in situ* water to aquatic life, allowing a more holistic assessment of the toxicity of aggregate pollution to aquatic life.[74] As is true for narrative criteria, it is not intuitively obvious how WET criteria can be implemented in NPDES permits for individual dischargers of pollutants. As a result, the development of WET criteria reflected a process of scientific and regulatory coevolution in which the underlying science progressed, and EPA developed appropriate methodologies for application of the science.[75] Affected dischargers challenged those methodologies in court, arguing that the CWA only allows the regulation of discrete pollutants, but the courts rejected that argument as unduly restrictive of EPA's authority in the face of evolving science.[76]

3. Biological Water Quality Criteria ("Biocriteria")

The broad and ambitious objective of the CWA presents a particularly challenging target from the perspective of WQC development and effectiveness. WQC designed to measure chemical integrity alone are insufficient to assess attainment of the

73. *See* 40 C.F.R. § 131.11(b)(1) (2018); WQS HANDBOOK CHAPTER 3, *supra* note 71, § 3.2.1.

74. WET criteria are now specifically recognized in the CWA. *See* 33 U.S.C. §§ 1313(c)(2)(B), 1314(a)(8) (2018). They are also the subject of specific EPA regulations. *See* 40 C.F.R. §§ 122.44(d), 131.11(b)(2) (2018).

75. *See National Pollutant Discharge Elimination System (NPDES): Whole Effluent Toxicity (WET)*, U.S. Envtl. Protection Agency, https://www.epa.gov/npdes/whole-effluent-toxicity-wet [https://perma.cc/PSM6-XASD] (last visited Jan. 1, 2019).

76. *See* Am. Paper Inst. v. U.S. EPA, 996 F.2d 346, 348 (D.C. Cir. 1993) (approving WET methodology as "necessary gap-filling in CWA statutory scheme").

statutory objective to "restore and maintain the chemical, physical, *and* biological integrity of the Nation's waters."[77] Although biological integrity (or even just "integrity") is not defined directly in the CWA, legislative history suggests that Congress intended water quality agencies to focus on the structure and function of healthy aquatic ecosystems,[78] and not simply water sufficiently "clean" to prevent more acute forms of harm such as fish kills or dangers to human health.

The distinction between WQC for individual chemical pollutants and the applicability of WQS to a wider range of aquatic ecosystem impairments is underscored in section 304(a) of the Act.[79] Under this provision, EPA develops and publishes water quality criteria guidance for use by states in adopting state-specific criteria or by EPA in adopting federal WQC for a state. Section 304(a) directs EPA to develop and publish scientifically supportable "criteria for water quality" reflecting "all identifiable effects" of water *pollutants* on health and welfare, including impacts to aquatic life and aquatic-dependent life and other resources.[80] Although those impacts include "the effects of pollutants on biological community diversity, productivity, and stability,"[81] the sources of impairment addressed by this subsection are limited to pollutants. The following subsection, however, also requires EPA to develop and publish:

> . . . *information* (A) on the factors necessary to restore and maintain the chemical, physical, and biological integrity of all navigable waters, ground waters, waters of the contiguous zone, and the oceans; [and] (B) on the factors necessary for the protection and propagation of shellfish, fish, and wildlife for classes and categories of receiving waters and to allow recreational activities in and on the water . . . .[82]

77. 33 U.S.C. § 1251(a) (2018) (emphasis added).

78. *See* Adler, *Legal Perspectives on Biocriteria*, *supra* note 20, at 348–49. See also *infra* Part III.B.2 for a more extensive discussion of the relevant language in the House and Senate Reports on the 1972 legislation.

79. 33 U.S.C. § 1314(a) (2018).

80. *Id.* § 1314(a)(1).

81. *Id.*

82. *Id.* § 1314(a)(2) (emphasis added). Because courts assume Congress uses different terms intentionally, see *Bailey v. United States*, 516 U.S. 137, 146 (1995), presumably Congress intended to distinguish between the "criteria for water quality" applicable to pollutants in subsection (a)(1), and the "information" applicable to the broader goals and objectives of the CWA in subsection (a)(2). But the significance of that difference is not clear. Neither

The breadth of this language supported the gradual development and implementation of biocriteria. Recognizing that full implementation of the CWA objective required a more sophisticated understanding of the concept of integrity, EPA held a symposium three years after passage of the CWA in which one researcher proposed to define biological integrity as "the capability of supporting and maintaining a balanced, integrated, adaptive community of organisms having a composition and diversity comparable to that of the natural habitats of the region."[83] Researchers in the early 1980s developed biological assessment methods to measure the biological health—or integrity—of aquatic ecosystems by comparing a potentially degraded system to a reference water body of the same ecological type. Reference water bodies were selected if they exhibited comparatively unimpaired or "natural" conditions, or as close thereto as existed in the region.[84]

EPA responded to this new science in 1990 by developing guidance for states to use to develop biocriteria based on the particular types of aquatic ecosystems and conditions in each state.[85] Since then, guidance from EPA has become increasingly more detailed and sophisticated in parallel with the evolution of biocriteria science.[86] Moreover, as the methodology became more

provision standing alone resulted in enforceable standards, as opposed to guidance to the states. Given that Congress directed EPA to issue both categories of criteria and information to the states, to publish them in the Federal Register, and otherwise make them available to the public, see *id.* § 1314(a)(3), the significance of the different terminology is not apparent. It may reflect the fact that, as of 1972, neither scientists nor regulators had an available methodology for measuring and establishing "criteria" for the latter category of impairment, and Congress logically chose not to use that term as a result.

83. *See* David G. Frey, *Biological Integrity of Water—An Historical Approach*, *in* U.S. ENVTL. PROT. AGENCY, THE INTEGRITY OF WATER: A SYMPOSIUM 127, 128 (R. Kent Ballentine & Leonard J. Guarraia eds., 1977).

84. *See* James R. Karr, *Assessment of Biotic Integrity Using Fish Communities*, 6 FISHERIES 21 (1981); James R. Karr & Daniel R. Dudley, *Ecological Perspective on Water Quality Goals*, 5 ENVTL. MGMT. 55 (1981).

85. OFFICE OF WATER, U.S. ENVTL. PROT. AGENCY, EPA-440/5-90-004, BIOLOGICAL CRITERIA: NATIONAL PROGRAM GUIDANCE FOR SURFACE WATERS (1990) [hereinafter 1990 BIOCRITERIA PROGRAM GUIDANCE].

86. *See, e.g.*, U.S. ENVTL. PROT. AGENCY, EPA 842-R-16-001, A PRACTITIONER'S GUIDE TO THE BIOLOGICAL CONDITION GRADIENT: A FRAMEWORK TO DESCRIBE INCREMENTAL CHANGE IN AQUATIC ECOSYSTEMS (2016) [hereinafter PRACTITIONER'S GUIDE TO THE BIOLOGICAL CONDITION GRADIENT]; U.S. ENVTL. PROT. AGENCY, EPA 820-R-13-001, BIOLOGICAL ASSESSMENT PROGRAM REVIEW: ASSESSING LEVEL OF TECHNICAL RIGOR TO SUPPORT WATER QUALITY MANAGEMENT (2013) [hereinafter BIOLOGICAL ASSESSMENT PROGRAM REVIEW]; U.S. ENVTL. PROT. AGENCY, EPA 810-R-11-01, A PRIMER ON USING BIOLOGICAL ASSESSMENTS TO

refined, EPA released guidance regarding the assessment of particular categories of water bodies (lakes and reservoirs, streams and wadable rivers, estuaries and near coastal waters, wetlands, and coral reefs) in addition to generic guidance for all kinds of waters.[87] However, state response has been variable, and it remains incomplete nationally.[88]

As is true for chemical-specific WQC, biocriteria can come in both narrative and numeric forms. Narrative biocriteria can be expressed in "free from" format, such as "free from contaminants or other stressors that interfere with natural aquatic life." They can also be expressed as affirmative conditions, such as "[a]quatic life shall be as naturally occurs," or "[a]mbient water quality sufficient to support all life stages of indigenous aquatic species," with varying degrees of specificity.[89]

Numeric biocriteria require more background data and analysis, thus demanding more time and agency resources to develop. As a result, however, they add quantitative rigor, can address different ecosystem types more specifically, and provide a more objective way to measure attainment. They typically use indices to statistically compare the abundance and diversity of organisms within designated taxa sampled in a test system to that of the reference condition.[90] One scientific assumption underlying biocriteria is that species within a taxonomic classification, and between taxa, respond differently to chemical pollutants and other environmental stressors. Thus, by comparing species abundance and composition within samples of collected organisms from test systems and reference systems, scientists can deduce insights into

SUPPORT WATER QUALITY MANAGEMENT (2011) [hereinafter PRIMER ON USING BIOLOGICAL ASSESSMENTS].

87. *See Biological Assessment—Technical Assistance Documents for States, Tribes and Territories*, U.S. ENVTL. PROTECTION AGENCY (Oct. 23, 2018), https://www.epa.gov/wqc/biological-assessment-technical-assistance-documents-states-tribes-and-territories [https://perma.cc/NLT5-FFSX].

88. *See infra* Part II.B.3.

89. *See* 1990 BIOCRITERIA PROGRAM GUIDANCE, *supra* note 85, at 15–16. Elsewhere, I have noted that one conceptual advantage of affirmative biocriteria is that they articulate "aims to achieve, not ills to avoid." *See* Adler, *Legal Perspectives on Biocriteria*, *supra* note 20, at 346; Adler, *Renewal of Aspiration, supra* note 20, at 806 ("Unlike other forms of water quality criteria, which describe what is bad, or those characteristics of water bodies we want to avoid, [biocriteria] describe more precisely and scientifically the characteristics of ecosystem health we aspire to achieve.").

90. *See* WQS HANDBOOK CHAPTER 3, *supra* note 71, § 3.7; PRIMER ON USING BIOLOGICAL ASSESSMENTS, *supra* note 86, at viii–ix.

the degree to which a system is biologically impaired, and potentially why.[91]

An intermediate option is the use of narrative criteria that can be translated into more specific permit limits through mathematical methods known as "translator procedures."[92] In this method, states do not include numeric criteria in the water quality standards themselves, but use numeric formulae to apply narrative standards to individual water bodies and permits for discharges to those waters.

Biocriteria science is evolving at a rapid pace.[93] Increasingly sophisticated versions of those methods continue to be developed and used, but new methods are also being developed to assess aquatic ecosystem integrity in other ways, for example, by measuring the metabolic condition[94] or traits[95] of organisms to assess the degree of environmental stress they experience compared to similar organisms in unstressed systems. Scientists also continue to search for more efficient methods to identify organisms collected in a water body segment, such as DNA testing of samples rather than the more subjective and labor-intensive species identification based on human observations of morphological differences.[96] Likewise, researchers continue to improve the statistical validity of sampling and analytical methods to increase the reliability of conclusions drawn from the data.[97]

What is most notable about biocriteria from the perspective of the coevolution of law and science is the unexpected ways in which

91. *See* OFFICE OF WATER, U.S. ENVTL. PROT. AGENCY, EPA-822-B-00-025, STRESSOR IDENTIFICATION GUIDANCE DOCUMENT (2000) [hereinafter STRESSOR IDENTIFICATION GUIDANCE].

92. *See* PRIMER ON USING BIOLOGICAL ASSESSMENTS, *supra* note 86, at 7–8. For a specific example, see U.S. ENVTL. PROT. AGENCY, EPA-820-S-10-001, USING STRESSOR-RESPONSE RELATIONSHIPS TO DERIVE NUMERIC NUTRIENT CRITERIA (2010).

93. For an assessment of needed improvements in biocriteria science, see CHARLES P. HAWKINS & DAREN CARLISLE, DISCUSSION DOCUMENT FOR PLANNING PURPOSES, ADVANCING AND REFINING THE DEVELOPMENT AND APPLICATION OF BIOLOGICAL CRITERIA FOR THE PROTECTION OF AQUATIC LIFE: OUTSTANDING TECHNICAL CHALLENGES AND THEIR POTENTIAL SOLUTIONS (on file with author) [hereinafter EPA BIOCRITERIA SCIENCE PLAN].

94. *See, e.g.*, Donald J. Baird et al., *Toward a Knowledge Infrastructure for Traits-based Ecological Risk Assessment*, 7 INTEGRATED ENVTL. ASSESSMENT & MGMT. 209 (2011).

95. *See, e.g.*, Elisabeth Berger et al., *Towards Stressor-Specific Macroinvertebrate Indices: Which Traits and Taxonomic Groups are Associated with Vulnerable and Tolerant Taxa?*, 619-620 SCI. OF THE TOTAL ENV'T 144 (2018).

96. *See* EPA BIOCRITERIA SCIENCE PLAN, *supra* note 93, at 4–5.

97. *See id.* at 5–6.

biocriteria differ from the kinds of WQC that were available and in use when Congress passed the CWA. Existing WQC were either extremely vague or too specific. Narrative criteria articulated very general goals for water bodies (for example, "free from" pollutants in amounts deleterious to aquatic life), but begged the question about the levels of pollution at which harm occurred, thus forcing a difficult case-by-case effort to ascertain a violation of WQC. Numeric, pollutant-specific WQC established a bright line between levels of pollutants in the water column deemed harmful to designated water body uses, but missed many sources and impacts of water pollution.

Biocriteria changed the game in fundamental ways that have challenged the legal and regulatory process to evolve in response. Chemical-specific numeric water quality criteria assumed that lower levels of individual pollutants in water bodies would suffice to restore the health of aquatic ecosystems. Those criteria were relatively easy to translate into pollution control requirements for individual dischargers through mathematical calculations of how much pollution could be released without exceeding the maximum pollutant levels in the water. They did not, however, actually measure the response of individual aquatic species, assemblages of species, or the ecosystem as a whole. Biocriteria measure aquatic ecosystem health directly, by comparing the health of aquatic organisms and the diversity and composition of species in the water body compared to unpolluted waters. There is no similarly simple method, however, to translate those kinds of holistic ecosystem measures into individual permit requirements.

C. Implementation of Water Quality Standards

Because biocriteria reflect such an innovative development, and a means of statutory application that the CWA's sponsors did not anticipate, they also pose challenges to the ways in which the CWA provides for the implementation and enforcement of WQS. This is because those statutory tools were designed with an eye toward more traditional forms of WQC.

The CWA requires the states (or in the event of inadequate state action, EPA) to implement WQS in several ways. First, the statute requires NPDES permit conditions sufficient to achieve, in addition to the various technology-based effluent limitations imposed on various categories of dischargers, "any more stringent limitation, including those necessary to meet water quality standards . . . established pursuant to any State law or regulations . . . or any other Federal law or regulation, or required to implement any applicable water quality standard established pursuant to this chapter."[98] Other provisions of the Act similarly authorize or require implementation of WQS in particular regulatory contexts.[99]

Second, through ongoing monitoring and assessment of water bodies against the measuring stick of WQS, states are required to identify "impaired" water bodies, which are water bodies that do not meet applicable WQC or that otherwise do not support their designated uses in whole or in part. States are then required to list and report impaired water bodies through a series of somewhat confusing and overlapping provisions.[100] Some of those provisions simply provide information about the health of a state's water bodies and progress toward attaining CWA statutory goals, including comprehensive water quality reports each state must submit to EPA every two years.[101] Although several other listing provisions apply to specific circumstances,[102] the two most significant listing requirements are sections 303(d) and 319(a).[103]

Section 303(d) is the broadest of the CWA listing provisions with regulatory significance. It requires every state to "identify those waters within its boundaries for which the effluent limitations required by [the technology-based provisions of the Act] are not stringent enough to implement any water quality standard applicable to such waters."[104] The state is then required to prioritize those waters according to the severity of the pollution

98. 33 U.S.C. § 1311(b)(1)(C) (2018). The statute identified an initial compliance date for such water-quality based effluent limitations of July 1, 1977. *See also id.* §§ 1312 (providing additional EPA authority for the adoption of stricter effluent limitations necessary to meet WQS), 1342(a) (requiring NPDES permits to impose conditions necessary to achieve both technology-based and water quality-based treatment requirements).

99. *See, e.g.*, *id.* §§ 1341 (requiring state water quality certifications for all federal licenses or permits), 1313(e)(3)(A) (requiring state continuing planning processes to provide for WQBELs).

100. *See id.* §§ 1313(d), 1313(e), 1314(l), 1315(b), 1329(a).

101. *Id.* § 1315(b) (requiring, *inter alia*, each State to report biennially on the water quality of all navigable waters relative to the objective of the CWA, the extent to which all navigable waters meet the interim "fishable and swimmable" goal of the Act).

102. *See id.* §§ 1314(l) (requiring identification and listing of water bodies not meeting WQC due to toxic pollutants), 1330(b) (requiring water quality monitoring and assessment in estuaries selected for remediation in the National Estuary Program).

103. *Id.* §§ 1313(d), 1329(a).

104. *Id.* § 1313(d)(1)(A).

and intended water body uses,[105] and for each water, to establish a "total maximum daily load" ("TMDL") "at a level necessary to implement the applicable water quality standards with seasonal variations and a margin of safety which takes into account any lack of knowledge concerning the relationship between effluent limitations and water quality."[106] A TMDL is essentially a "pollutant budget" through which aggregate sources of pollutants can be tallied mathematically, and the necessary control measures calculated, until pollutant levels fall below those established in the WQC.[107] As is true for the WQS and for discharge permits imposing water quality-based effluent limitations, EPA has a statutory duty to implement the TMDL provisions in the case of state default.[108]

Congress adopted section 303(d) before biocriteria science evolved, and before states began to adopt biocriteria. Thus, the language of this provision does not fit easily with biocriteria, which differ significantly from the kinds of WQC with which Congress and others were familiar in 1972. By using the term "total maximum daily load," Congress apparently conceptualized WQC as regulating chemical pollutants, the amounts of which may be discharged over a finite time period.[109] But reflecting the evolution of biocriteria, EPA regulations specify that "TMDLs may be established using a pollutant-by-pollutant or biomonitoring approach."[110] The

105. *Id.* Congress included no criteria for states to use in prioritizing water bodies.

106. *Id.* § 1313(d)(1)(C). Essentially identical requirements apply to thermal discharges (effluent at temperatures significantly different from those in receiving waters). *Id.* § 1313(d)(1)(B),(D).

107. *See* 40 C.F.R. § 130.7 (2018). *See also* Am. Farm Bureau Fed'n v. U.S. EPA, 792 F.3d 281, 290 (3d. Cir. 2015); Pronsolino v. Nastri, 291 F.3d 1123, 1126–28 (9th Cir. 2002); OFFICE OF WATER, U.S. ENVTL. PROT. AGENCY, EPA-820-B-15-001, WATER QUALITY STANDARDS HANDBOOK—CHAPTER 7: WATER QUALITY STANDARDS AND THE WATER QUALITY-BASED APPROACH TO POLLUTION CONTROL § 7.4 (2015), https://nepis.epa.gov/Exe/ZyPDF.cgi/P100ODEV.PDF?Dockey=P100ODEV.PDF [https://perma.cc/HC3N-9PDS] (citing guidance documents for TMDL development and implementation).

108. 33 U.S.C. § 1313(d)(2) (2018). For an overview of the TMDL program and its history, see *Am. Farm Bureau Fed'n*, 792 F.3d at 288–92.

109. The fact that Congress was so specific about the relevant time period—*daily* loads—raised different science-law coevolution issues regarding the appropriate time frame for the regulation of different kinds of pollutants into different ecosystems. *See* U.S. ENVTL. PROT. AGENCY, EPA 100-R-98-006, REPORT OF THE FEDERAL ADVISORY COMMITTEE ON THE TOTAL MAXIMUM DAILY LOAD (TMDL) PROGRAM 34 (1998) [hereinafter TMDL FACA REPORT] (recommending that EPA support alternatives to daily load calculations where appropriate to the kind of pollution addressed).

110. 40 C.F.R. § 130.7(c)(1)(i) (2018).

development of WQC that measure deviations from baseline environmental reference conditions, rather than pollutant concentrations in the environment, required flexibility in implementation of the TMDL program.[111]

In 1987, Congress added another broadly applicable water body listing provision to the CWA, section 319(a).[112] Section 319 was a response to the widespread failure of most states to take significant action to address, under existing statutory provisions,[113] nonpoint source water pollution, meaning all forms of water pollution other than discharges of pollutants from point sources.[114] Section 319(a) of the Act requires states to identify all "navigable waters within the State which, without additional action to control nonpoint sources of pollution, cannot reasonably be expected to attain or maintain applicable water quality standards or the goals and requirements of this chapter."[115] States were also to identify categories of nonpoint sources responsible for those cases of nonattainment,[116] as well as the public processes used to identify best management practices to control that pollution,[117] and applicable state and local nonpoint source pollution control programs.[118] All of this information guides the development of statewide nonpoint source pollution management programs, which each state was required to develop and to submit to EPA for review and approval.[119] The section 319 listing and remediation program is particularly relevant here because of the unique ability of biocriteria to detect aquatic

111. *See* TMDL FACA REPORT, *supra* note 109, at 30–34.

112. 33 U.S.C. § 1329(a) (2018).

113. The predecessor to section 319, section 208 of the 1972 Act, 33 U.S.C. § 1288, was widely considered to have failed to redress nonpoint source pollution to a significant degree. *See* William L. Andreen, *Water Quality Today—Has the Clean Water Act Been a Success?*, 55 ALA. L. REV. 537, 593 (2004); David Zaring, Note, *Agriculture, Nonpoint Source Pollution, and Regulatory Control: The Clean Water Act's Bleak Present and Future*, 20 HARV. ENVTL. L. REV. 515, 521–28 (1996); ADLER, LANDMAN & CAMERON, *supra* note 15, at 173–85.

114. The definition of "pollution" as the "man-made or man-induced alteration of the chemical, physical, biological, and radiological integrity of water," 33 U.S.C. § 1362(19) (2018), includes a wide range of stressors beyond the release of chemical pollutants.

115. *Id.* § 1329(a)(1)(A).

116. *Id.* § 1329(a)(1)(B).

117. *Id.* § 1329(a)(1)(C).

118. *Id.* § 1329(a)(1)(D).

119. *Id.* § 1329(b). By sharp contrast to the WQS, TMDLs, and the NPDES program, however, the CWA does not provide EPA with authority to develop and implement a state NPS management program in the event of inadequate state action. Rather, EPA's remedy is limited to program disapproval and denial of federal grant funding to implement the program. *Id.* § 1329(d),(g).

ecosystem impairment due to causes beyond the discharge of pollutants from point sources.[120] The development of biocriteria, therefore, was useful in the effort to implement the CWA, but not one that Congress anticipated in drafting the statute. Biocriteria added a more holistic method of measuring aquatic ecosystem health to a system of WQC that measured only levels of individual pollutants. The task of pairing cause and effect, that is, stressors to adverse water quality impacts, however, is facilitated by biocriteria but requires further coevolution of the relevant law and science. That ongoing process will be described in Part III.

III. BIOCRITERIA AS A CASE STUDY IN THE COEVOLUTION OF LAW AND SCIENCE

Biocriteria are an interesting and robust context in which to examine and explain the coevolutionary process of law and science due to the high degree of innovation in biocriteria science in the past three decades and the resulting incentive for responses in the CWA regulatory process. Because the CWA statutory objective and goals were considerably broader than the scope of existing WQS, EPA and the scientific community had a strong incentive to develop new scientific methods. Because the science of biocriteria essentially did not exist when Congress enacted the CWA, its later development demonstrated the need for the law to adapt to new science. Successive regulatory functions to which biocriteria were applied would demand increasing scientific rigor. As the science developed further, it made possible a fundamental rethinking of the statutory focus. This has increased, and will continue to increase, the tools available to EPA and the states to work toward the broad statutory mission Congress articulated in the CWA.

This Part will explain the multiple ways in which law and science have coevolved in the specific context of the biocriteria program. First, however, it is useful to explain the distinction between

120. The text of section 319 is somewhat confusing and internally inconsistent, however, regarding the distinction between "pollutants" and "pollution." Although the provision consistently uses the broader term "pollution," suggesting authority to address sources of impairment other than pollutants, other parts of the provision refer confusingly to "sources which add significant pollution," *id.* § 1329(a)(1)(B), or to "reduce pollutant loadings resulting from" categories of nonpoint sources, *id.* § 1329(b)(2)(A). It is difficult to understand how a nonpoint source can "add" a "man-made or man-induced alteration" of the integrity of water.

"scientific knowledge" and "regulatory knowledge," and describe the importance of that distinction to democratic governance and the separation of powers in the regulatory arena.

A. Preface: Scientific Knowledge and Regulatory Knowledge

Scientific knowledge is knowledge that expands or improves our understanding of the world around us. It may have utilitarian value, for example, to promote new engineering that improves our physical welfare. It also has intrinsic value because it improves the human intellectual condition by satisfying our natural curiosity. It might support or inform specific decisions, or it may simply improve our understanding of some portion of the universe. Scientific knowledge is not bounded or constrained by preconceived ideas, except for those inherent in the scientific process. Lawyers might call those procedural, rather than substantive, constraints, and they include testable hypotheses, accepted methodology in data collection and analysis, insistence on replicable results, peer review, and proper attention to prior knowledge in the field.[121] The lack of substantive constraints allows innovation and creativity, while procedural constraints help ensure consistency in approach, a common understanding of the degree of reliability that can (or cannot) be attributed to particular sets of data, and a shared analytical and intellectual lexicon scientists can use to report and debate their theories and proposed findings.

"Regulatory knowledge," by contrast, is a special form of knowledge that helps to inform regulatory decisions. One could view regulatory knowledge as one subset of scientific knowledge, *i.e.*, scientific knowledge with the particular function of generating or supporting a regulatory decision. In legal terms, regulatory knowledge could be viewed as knowledge or information that is *material* to a particular regulatory decision, just as material facts comprise the subset of factual information pertinent to a constitutional, statutory, or common law legal standard.[122] A specific set of scientific knowledge may or may not be material to a decision under a particular regulatory standard.

121. *See generally* ROBERT NOLA & HOWARD SANKEY, THEORIES OF SCIENTIFIC METHOD: AN INTRODUCTION 12–31 (Routledge 2014) (2007).

122. Information relevant to intent, for example, is material to a fraud claim, see 26 SAMUEL WILLISTON & RICHARD A. LORD, WILLISTON ON CONTRACTS § 69:2 (4th ed. 2018), but not to a simple breach of contract claim. *See id.* § 63:1.

For example, scientific evidence that a species of fish is more sensitive to lower levels of a particular contaminant than reflected in the applicable numeric WQC for that contaminant is material to a regulatory decision to strengthen the standard, making that evidence regulatory knowledge.[123] New scientific information about an anatomical characteristic of those fish unrelated to pollution sensitivity may improve our understanding of the species, but it would not constitute regulatory knowledge because it is immaterial in setting an appropriate WQC. Thus, in the context of biocriteria, scientific knowledge is also regulatory knowledge when it is material to the establishment of a WQC; to listing a water body due to a violation of the WQC; in establishing TMDLs, permit limits, or other regulatory controls to redress a WQC violation; or in taking an enforcement action against a source that causes or contributes to that violation.

Viewing regulatory knowledge only as a subset of all scientific knowledge, however, oversimplifies the full spectrum of "knowledge" material to most regulatory decisions. Except when a statutory or other legal standard specifies that a decision must be made on scientific grounds alone,[124] scientific knowledge is usually only one of several kinds of knowledge material to a regulatory decision. Other material factors may include economics, technical feasibility, societal values, or other policy considerations. As a fundamental tenet of administrative law, courts may rescind or remand agency decisions that fail to consider all relevant factors, as established in the statute, regulations, or otherwise.[125]

This distinction is important in determining *who* is best suited or legally authorized to draw conclusions and make decisions from a particular body of regulatory knowledge, and with input from what sources. Those choices are important to ensure accountability and democratic governance, and to guard against bias. If the knowledge is largely or entirely scientific, it may be most

123. *See* 40 C.F.R. § 131.11(a)(1) (2018) (requiring WQC sufficient to protect designated uses); WQS HANDBOOK CHAPTER 3, *supra* note 71, § 3.5.

124. *See, e.g.*, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 462–63, 471 (2001) (holding that sections 108 and 109 of the Clean Air Act require EPA to set ambient air quality standards based entirely on adverse effects to human health and welfare, and not on economic or other grounds). Even here, however, EPA often must determine the appropriate degree of safety to incorporate into a regulatory standard otherwise informed by scientific knowledge.

125. *See* Motor Vehicles Mfrs. Ass'n. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42–43 (1983).

appropriate to defer to the expert judgment of agency or other scientists, perhaps with input from a science advisory board or committee.[126] Even in the face of disagreements within the scientific community, courts routinely defer to agency scientific judgments, so long as they are supported by credible information and reflect reasonable conclusions drawn from that information.[127]

If regulatory knowledge includes information beyond scientific knowledge, however, agency officials then have the discretion to reach decisions based on a wider range of scientific and non-scientific factors, including more subjective considerations of public policy and values. The public is entitled to comment on all aspects of regulatory decisions (science, law, policy, facts, and values) through the usual notice and comment process prescribed by the Administrative Procedure Act ("APA").[128] Judicial review ensures that the agency considers all of the relevant factors, acts within the scope of its statutory authority, and makes rational decisions supported by the applicable science and other regulatory knowledge,[129] but courts still show deference to agency judgments within areas of law and policy delegated to them by the legislature.[130]

Although more challenging examples will be addressed later, an unsurprising but illustrative example of a decision involving both scientific knowledge and additional regulatory factors involved a challenge to a revised NPDES permit issued by the Ohio Environmental Protection Agency ("OEPA") to a municipal sewage treatment plant. The permit included water quality-based effluent limitations for phosphorus and total dissolved solids ("TDS") based on aquatic ecosystem impairment downstream of the discharge as evidenced by biocriteria violations and other scientific observations.[131] OEPA argued that limits stricter than those in the

126. *See, e.g.*, 42 U.S.C. § 7409(d)(2) (2018) (requiring EPA to convene scientific review committee to assist in review of National Ambient Air Quality Standards). EPA has made extensive use of external advisors to help in the development of biocriteria. *See, e.g.*, PRIMER ON USING BIOLOGICAL ASSESSMENTS, *supra* note 86, at ii–iii; PRACTITIONER'S GUIDE TO THE BIOLOGICAL CONDITION GRADIENT, *supra* note 86, at iii–iv.

127. *See, e.g.*, Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc., 435 U.S. 519 (1978).

128. 5 U.S.C. § 553(c) (2018).

129. *Id.* § 706.

130. *See* Chem. Mfrs. Ass'n v. Nat. Res. Def. Council, Inc., 470 U.S. 116 (1985); Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984).

131. City of Salem v. Koncelik, 843 N.E.2d 799, 800–01 (Ohio Ct. App. 2005).

original permit were mandatory once biocriteria violations were detected,[132] meaning that biocriteria science was the only material factor in the decision. The Ohio Supreme Court remanded the permit to the agency, but not based on the appellant's challenges to the scientific merits of the decision. Rather, the Court faulted OEPA for not taking into account other considerations mandated by the applicable agency regulation.[133] Once the agency properly considered those factors on remand, both the administrative appeals tribunal[134] and the Ohio Court of Appeals[135] rejected a subsequent legal challenge by the city.

Although OEPA may have been correct in the initial appeal that the CWA requires stricter permit limits based on WQS violations irrespective of other considerations,[136] that is not what the applicable state regulation provided.[137] OEPA was obligated to justify the permit revision based on applicable state statutory and regulatory considerations. In the end, science properly informed the agency decision, along with other elements of regulatory knowledge, and the courts deferred to both agency science and policy decisions based on each set of knowledge. The judicial remand, however, ensured that the agency included all relevant factors in its decision, including the scientific knowledge, and was accountable for that decision on the record.

B. Coevolution of Scientific Knowledge and Regulatory Knowledge in the Biocriteria Program

Although the manner in which law and science have coevolved in the biocriteria program could be organized in several ways, the following five examples illustrate the dynamic. The organization tracks generic issues in complex regulatory programs, and therefore could be used to evaluate the coevolution of law and

132. *Id.* at 803.

133. *Id.* at 803–04 (holding that the agency failed to consider, as required by the applicable state regulation, whether attainment of the biocriteria was possible, whether regulation of the target source alone would redress the problem, and other factors).

134. City of Salem v. Koncelik, 2009 WL 1504198 (Ohio Envtl. Rev. App. Comm'n May 27, 2009).

135. City of Salem v. Korleski, 934 N.E.2d 360, 365 (Ohio Ct. App. 2010).

136. *See* 33 U.S.C §§ 1311(b)(1)(c), 1313(e)(3)(A) (2018).

137. The appropriate forum to conform Ohio law to the CWA would have been a new rulemaking proceeding. Alternatively, if EPA believed that the Ohio requirements contravened the CWA by requiring impermissible factors to be considered, it could have required the state to amend its rules as part of the WQS review process. *See id.* § 1313(c).

science in other environmental statutes, or other statutes involving scientific knowledge.

1. Deciding Whether to Authorize or Require Regulatory Action

Science often identifies previously unknown or poorly understood problems for which a regulatory response might be appropriate. Although properly tailored regulations can result in net societal benefits, they often entail economic costs to the targets of the regulation, and may restrict individual liberty to varying degrees. Thus, a decision to regulate, how to do so, and to what degree, should not be taken lightly. Scientific information can help to document the severity of a problem, thus providing the necessary factual underpinning for regulatory action.

The initial phase in this decision process may be legislative. Congress or a state legislature may decide as a matter of policy whether the problem is serious enough to warrant government intervention, or whether other remedies such as market solutions or public education are more appropriate. So long as those legislative policy choices have a rational basis, and do not contravene constitutional provisions, courts are properly reluctant to interfere.[138] In enacting solutions, however, the legislature can either mandate a regulatory response or authorize it at the discretion of an administrative agency such as EPA. In between those extremes, the legislature might adopt a two-part process requiring the agency to regulate only if it makes a certain discretionary determination, sometimes known as a regulatory "trigger."[139] These legislative decisions involve a complex interaction between law and science, and evolve as scientific capacity and understanding grow.

The CWA mandates that either individual states or EPA promulgate WQS for all surface waters in each state.[140] Moreover, in somewhat general terms, the statute establishes minimum requirements for WQS. WQS must "protect the public health or welfare, enhance the quality of water and serve the purposes of" the

138. *See* W. Coast Hotel Co. v. Parrish, 300 U.S. 379 (1937) (upholding minimum wage law for women); United States v. Ashland Oil & Transp. Co., 504 F.2d 1317 (6th Cir. 1974) (upholding constitutionality of Clean Water Act).

139. *See, e.g.*, Ethyl Corp. v. U.S. EPA, 541 F.2d 1, 11–17 (D.C. Cir. 1976) (en banc) (discussing "trigger" provision of Clean Air Act authorizing EPA to regulate motor vehicle fuel additives upon a finding that emissions "will endanger the public health or welfare").

140. *See* 33 U.S.C. § 1313 (2018).

CWA.[141] By incorporating the objective and goals of the statute by reference, the term "serve the purposes of" requires designated uses that comply, at a minimum, with the "fishable and swimmable" uses specified in CWA section 101(a)(2),[142] as well as WQS that match the objective of the Act to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[143] The Act does not require adoption of biocriteria *per se*, or any other specific form of WQC. Rather, it left to EPA and states the discretion to "fill in the gaps" of the statute as the relevant science and statutory implementation evolved,[144] under the EPA Administrator's general authority to "prescribe such regulations as are necessary to carry out his [or her] functions under [the CWA]."[145]

Of course, at the time the CWA was enacted, EPA and some states had already developed WQS under the 1965 Water Quality Act, which Congress undoubtedly assumed would constitute the baseline from which a more extensive WQS program would evolve.[146] In the 1987 amendments to the CWA, for example, Congress endorsed EPA's development of biological monitoring and assessment methods to control the adverse impacts of toxic pollutants for which numeric WQC were not feasible.[147] Likewise, as discussed above,[148] EPA understood that existing WQS did not adequately define biological integrity or ensure attainment of the full statutory goals and objectives. The science of biocriteria evolved to fill this gap, and it continues to evolve to do so more comprehensively and effectively. Unfortunately, however, the legal regime has failed to coevolve in ways that ensure its complete and adequate implementation by all states.

In the first major biocriteria guidance document issued in 1990, EPA acknowledged that chemical-specific WQC "alone cannot

141. *Id.* § 1313(c)(2)(A).

142. *Id.* § 1251(a)(2).

143. *Id.* § 1251(a).

144. *See* Am. Paper Inst., Inc. v. U.S. EPA, 996 F.2d 346, 351–56 (D.C. Cir. 1993) (upholding EPA's adoption of WET criteria as an example of statutory "gap-filling").

145. 33 U.S.C. § 1361(a) (2018).

146. *See* S. REP. NO. 92-414, at 3–4, 6–7 (1971), as *reprinted in* 1972 U.S.C.C.A.N. 3668, 3670–72, 3675–76.

147. *See* Pub. L. No. 100-4, § 308(d), 101 Stat. 7, 39 (1987), *adding* 33 U.S.C. § 1313(c)(2)(B).

148. *See supra* Part II.B.

identify or address all surface water pollution problems."[149] However, at the time, only a limited number of states had adopted or were working to develop biocriteria.[150] Therefore, the document identified biocriteria development as a priority. Even though it was a guidance document rather than a binding regulation, it purported to *direct* all states to adopt biocriteria during the 1991–1993 triennial review of WQS to "achieve the objectives of the Clean Water Act set forth in Section 101 and comply with statutory requirements under Sections 303 and 304."[151] The 1990 Program Guidance indicated that adoption of narrative criteria alone could be accomplished with little or no data collection, meaning there was no real reason why all states could not adopt some form of narrative biocriteria expeditiously; but that full implementation would require adoption of numeric applications of biocriteria, which would require more data and analysis by individual states.[152] In later documents, EPA similarly acknowledged that biocriteria were the only kinds of WQC developed to date which were able to fully implement the goals and objectives of the CWA, and to comply specifically with the requirements of section CWA section 303.[153]

EPA elected to urge states to adopt biocriteria through guidance, however, and not to require them via enforceable regulations. In later biocriteria guidance documents, EPA simply *suggests* that states adopt biocriteria as an effective way to fully implement the CWA, or

149. 1990 BIOCRITERIA PROGRAM GUIDANCE, *supra* note 85, at vii. *See also id.* at 4 (referring to biocriteria as an "essential third element" of WQS to implement the CWA fully).

150. *See id.* at ix (indicating that, as of 1990, only 1 state had instituted numeric biocriteria, 5 more states were using biocriteria to define aquatic life uses and to enforce WQS, another 15 states were developing biological assessments for future criteria development, and 20 states were using biological assessments to ascertain the status of biota in their waters).

151. *Id.* at vii. *See also id.* at 3 (admonishing states to adopt biological WQC to meet the statutory objectives and to comply with the WQS provisions of the statute).

152. *See id.* at 6–7. The 1990 Program Guidance was followed by specific procedures for states to adopt narrative biocriteria. *See* OFFICE OF WATER, U.S. ENVTL. PROT. AGENCY, EPA-822-B-92-002, PROCEDURES FOR INITIATING NARRATIVE BIOLOGICAL CRITERIA (1992).

153. *See, e.g.*, OFFICE OF POLICY, PLANNING & EVALUATION, U.S ENVTL. PROT. AGENCY, EPA-230-R-96-007, SUMMARY OF STATE BIOLOGICAL ASSESSMENT PROGRAMS FOR STREAMS AND RIVERS 1-1 (1996) (finding biocriteria "unique" in focus on overall aquatic ecosystem health); PRIMER ON USING BIOLOGICAL ASSESSMENTS, *supra* note 86, at ix (reiterating "EPA's long-standing policy that biological assessments should be fully integrated in state and tribal water quality programs and used together with [other methods] to assess attainment of designated aquatic life uses . . . ").

advises states about the potential utility of biocriteria in meeting the statutory objective and goals.[154] To this day, no provision in EPA's WQS regulations requires states to adopt biocriteria. Indeed, EPA has not amended its regulation governing state WQS adoption in any *significant* way since 1983,[155] despite extensive evolution of the relevant science.

Because EPA has not amended its enforceable WQS regulations to require states to adopt biocriteria, states have adopted a patchwork of methods that have developed slowly over time, but remain incomplete. To be sure, significant progress has been made. Many states have adopted bioassessment methods to measure the health of water bodies using the same methods as would apply to biocriteria (comparing the biotic populations of the water body with those of a healthy reference water). An increasing number of states have adopted either narrative biocriteria, translator methods to implement narrative biocriteria in individual circumstances, or numeric biocriteria.[156] Based on a review of EPA's national biocriteria state-by-state website and other available state documents,[157] it appears that twelve states have adopted no biocriteria at all, while another fifteen have adopted only narrative biocriteria with no quantitative means of implementing them. Thus, roughly three decades after EPA provided guidance on

154. This change appears to have occurred as early as 1994. In its official guidelines for the 1994 WQS assessment cycle, EPA "strongly recommend[ed]," but no longer indicated it was requiring, that states adopt numeric or narrative biocriteria. *See* Adler, *Legal Perspectives on Biocriteria, supra* note 20, at 354.

155. EPA adopted 40 C.F.R. pt. 131 substantially in its current form in 1983. *See* 48 Fed. Reg. 51,400, 51,405 (Nov. 8, 1983). Relatively minor amendments were promulgated in 1991, see 56 Fed. Reg. 64,876, 64,893 (Dec. 12, 1991); 1994, see 59 Fed. Reg. 64,339, 64,344 (Dec. 14, 1994); and 1995, see 60 Fed. Reg. 15,366, 15,386 (Mar. 23, 1995), but none of those amendments addressed the development of biocriteria.

156. Although relatively few states had made significant use of biocriteria by 1991, when EPA conducted its first comprehensive survey in 1995, 41 states had used bioassessments for some purposes, 29 states had narrative biocriteria, but still only 1 had numeric criteria. By 2001, 57 of 65 jurisdictions (including states, tribes, and interstate pollution control entities) used some form of bioassessment, but still only 29 had some form of narrative criteria, with 11 more in development, and 4 had numeric criteria, with an additional 9 reportedly under development. *See* Adler, *The Two Lost Books in the Water Quality Trilogy, supra* note 20, at 72.

157. *See Information on Bioassessment and Biocriteria Programs for Streams and Wadeable Rivers*, U.S. ENVTL. PROTECTION AGENCY (Dec. 13, 2016), https://www.epa.gov/wqc/information-bioassessment-and-biocriteria-programs-streams-and-wadeable-rivers [https://perma.cc/3ZJ4-FDUE]. Several uncertainties complicate this analysis, and a more definitive analysis would require a state-by-state survey of knowledgeable program officials, either in writing, by telephone, or otherwise. Nevertheless, this level of survey suffices to confirm that state adoption of biocriteria remains significantly incomplete.

methodologies for quantitative approaches to fulfill the CWA biological integrity objective, more than half of the states have failed to do so.

EPA also has not exercised its authority to adopt biocriteria for states that have failed to do so entirely, or have failed to do so in a sufficient manner. EPA clearly has the legal authority—and arguably a mandate—to adopt federal biocriteria for states. Section 303(c)(3) requires EPA to inform states when their WQS are "not consistent with the applicable requirements of [the CWA]" to provide the state the opportunity to adopt any necessary revisions.[158] If the state fails to do so, section 303(c)(4) requires EPA to "promptly prepare and publish proposed regulations," and within 90 days thereafter to promulgate regulations, if a state fails to do so. Given EPA's position that no other form of WQC suffices to address the biological integrity components of the CWA, it appears that EPA has a legal duty to enforce adoption of effective biocriteria for every state.

Thus, with respect to this first manifestation of the coevolution of law and science, the decision whether to allow or require regulation, the science of biocriteria appears to have leapt ahead of the law. Biocriteria science evolved almost immediately in response to the new challenges presented by the biological integrity mandates of the CWA. Biocriteria concepts evolved quickly enough to support the adoption of narrative biocriteria early in the history of CWA implementation, and then to support more rigorous numeric criteria not long after. The applicable "law," in the form of EPA's enforceable WQS regulations and EPA's decisions on whether to exercise its authority under section 303(c)(3) and (4), however, has not co-evolved in response to the scientific advances.

2. Defining Regulatory Goals

Although legislative policy judgments ordinarily dictate or guide regulatory policy goals, scientific knowledge can also play an important role. In the context of biocriteria, the CWA invokes the concept of "chemical, physical, and biological integrity" in both its opening statutory objective, and in its definition of "pollution."[159]

158. 33 U.S.C. § 1313(c)(3) (2018).
159. *Id.* §§ 1251(a), 1362(19).

Yet despite the centrality of this concept to the statutory scheme, the term "integrity" is not defined in the statute. Biocriteria science has shed considerable light on the appropriate meaning of the term, but again, the regulatory process has not co-evolved to provide either a statutory or regulatory definition of integrity. Rather, EPA has left the concept to regulatory guidance documents that lack the force and effect of law.

Both the Senate Report and the House Report leading to the 1972 CWA shed some light on the term "integrity." Both committee reports support the basic premise of biocriteria by focusing on ecosystem structure and function. Unhelpfully, however, each depicts the idea in a slightly different hue. The Senate Report suggests that "integrity requires that any changes in the environment resulting in a physical, chemical or biological change in a pristine water body be of a temporary nature, such that by natural processes . . . the aquatic ecosystem will return to a state functionally identical to the original."[160] The House Report appears to have taken a somewhat less absolutist view, indicating that integrity is "a concept that refers to a condition in which the natural structure and function of ecosystems is maintained,"[161] without suggesting that no long-term change in an aquatic ecosystem is acceptable. Under either formulation, the legislative history suggests a focus on overall aquatic ecosystem health rather than simply water quality.

Biocriteria science evolved to provide a new methodology through which the integrity of aquatic ecosystems could be assessed. However, the ability to assess changes in aquatic ecosystem composition and structure is different from defining what integrity means, as well as when it is being preserved or attained. Given inevitable anthropogenic change in a modern economy, those decisions involve value judgments and other factors in addition to scientific knowledge. In an earlier article, I noted " . . . the problem of how to reach societal—as opposed to scientific—judgments about what level of deviation from entirely unimpaired ecosystems is the appropriate target for restoration. These judgments . . . involve questions that cannot be answered by science alone, questions that nuclear physicist Alvin Weinberg

160. S. REP. NO. 92-414, at 76 (1971), as *reprinted in* 1972 U.S.C.C.A.N. 3668, 3742.
161. H.R. REP. No. 92-911, at 76–77 (1972).

termed 'trans-scientific.'"[162] Defining "acceptable" levels of deviation from reference conditions is the most challenging in highly disturbed ecosystems. As noted in EPA's recent Science Plan for biocriteria:

> One of the most vexing problems facing water resource managers is how to establish meaningful biological criteria and restoration targets for severely degraded water bodies in heavily modified landscapes. The problem centers on how to estimate the biological potential of degraded water bodies, which requires that we understand (1) the biological and environmental factors that currently limit each water body's biological condition, and (2) the feasibility of removing these limitations to improve a water body's biological condition.[163]

Science is extremely helpful in informing such decisions. Increasingly sophisticated applications of biocriteria, for example, can measure ever finer tuned gradations in the degree to which aquatic ecosystem structure and function has been altered.[164] Likewise, remediation can be facilitated through scientific efforts to identify stressors and the kinds of harm they cause, and to predict what levels of ecosystem function will likely be restored as those stresses diminish.[165] Decisions about restoration feasibility and desirability, however, may also involve other aspects of aquatic biology and landscape ecology, economics, engineering, social values, and other factors.

The question of how the legal and regulatory process should evolve in explicating the meaning of "biological integrity" is not an easy one, from either a legal or a political perspective. EPA has statutory authority to promulgate regulations defining the meaning of the term "integrity" more clearly.[166] In the past, courts have given EPA wide latitude to fill gaps in the WQS regulatory program.[167] Thus, EPA could promulgate regulations defining

162. *See* Adler, *Resilience, Restoration, and Sustainability, supra* note 20, at 147.

163. EPA BIOCRITERIA SCIENCE PLAN, *supra* note 93, at 26. *See also* BIOLOGICAL ASSESSMENT PROGRAM REVIEW, *supra* note 86, at 37 (noting that "the CWA does not provide an explicit description of biological integrity nor specify ecological assessment endpoints and scientific methods to measure integrity").

164. *See generally* PRACTITIONER'S GUIDE TO THE BIOLOGICAL CONDITION GRADIENT, *supra* note 86.

165. *See* STRESSOR IDENTIFICATION GUIDANCE, *supra* note 91.

166. 33 U.S.C. §§ 1314(a), 1361(a) (2018).

167. *See* Am. Paper Inst. v. U.S. EPA, 996 F.2d 346, 348 (D.C. Cir. 1993) (approving WET methodology as "necessary gap-filling in CWA statutory scheme").

biological integrity as a measure against which the sufficiency of state biocriteria can be assessed.

Several issues, however, complicate EPA's regulatory authority to define biological integrity, and also complicate the desirability and feasibility of greater unity in the process. First, even in their undisturbed conditions, aquatic ecosystems vary dramatically around the country, across a wide range of characteristics. Those include water body type (large rivers, smaller streams, lakes, wetlands, estuaries, bays, coastal waters, etc.), hydrology (perennial, ephemeral, or intermittent), species composition, geographic and topographic setting, climate, the nature of associated terrestrial ecosystems, etc. Thus, any effort to define what level of deviation from undisturbed conditions constitutes "acceptable" biological integrity, and how that deviation should be measured, requires considerable variation to account for that complexity.

Second, as part of the cooperative federalism philosophy of the CWA and many other federal environmental statutes, Congress divided responsibility for the WQS program between EPA and the states.[168] EPA develops guidance for state programs and minimum requirements for WQS by regulation,[169] but states have some degree of latitude in determining appropriate levels of protection for their particular environmental, economic, and other circumstances. Although few courts have ruled directly on the issue, it appears that states have somewhat more latitude in deciding on the appropriate uses for which water bodies should be protected than it does in establishing the levels of protection appropriate for those uses.[170] Thus, for the purpose of establishing biocriteria to define what levels of deviation from unimpaired reference waters are acceptable, states might make different choices about which aquatic ecosystem functions and values to protect for different water bodies, such as urban streams relative to wilderness areas.

It is clear, however, that Congress intended that EPA establish, and have the authority to enforce, minimum levels of protection for WQS in order to prevent a "race to the bottom" phenomenon[171]

168. *See* Glicksman & Batzel, *supra* note 1, at 121–25, 134–37.

169. *See* 40 C.F.R. pts. 130, 131 (2018).

170. *See* Miss. Comm'n on Nat. Res. v. Costle, 625 F.2d 1269 (5th Cir. 1980).

171. For a critique of the "race to the bottom" theory, see Richard L. Revesz, *Rehabilitating Interstate Competition: Rethinking the "Race-to-the-Bottom" Rationale for Federal Environmental*

in which states might compete with one another for economic growth at the expense of water quality. EPA has the authority to review state WQS for adequacy and consistency with the statutory requirements, and to adopt federal WQS for a state not only when it fails to do so entirely, but also when the state standards are "determined by the Administrator [of EPA] not to be consistent with the applicable requirements of [the CWA],"[172] or "in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of [the CWA]."[173]

The Act requires that WQS be stringent enough to serve the goals and purposes of the CWA.[174] EPA has properly interpreted this provision as demanding that WQS must, at a minimum, meet the goal of section 101(a)(2) of the Act to "provide[] for the protection and propagation of fish, shellfish, and wildlife . . . ."[175] EPA has further indicated that the term "propagation" requires that fish, shellfish, and wildlife be protected at all stages of their life cycle.[176] Curiously, however, EPA omits from this requirement the more fundamental statutory objective in section 101(a) to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[177] As one aspect of regulatory coevolution in response to the ability of biocriteria to measure biological integrity, EPA should amend its regulations to require that state WQS attain the more holistic statutory objective.

Moreover, whether measured against the narrower "protection and propagation" goal or the broader "chemical, physical, and biological integrity" objective, it would also seem appropriate for EPA to define, by regulation, the manner in which states must meet those legal targets. That would include a determination of the

Regulation, 67 N.Y.U. L. REV. 1210 (1992). See *id.* n.1 for a collection of early law review articles explaining the theory.

172. 33 U.S.C. § 1313(c)(4)(A) (2018).

173. *Id.* § 1313(c)(4)(B).

174. *Id.* § 1313(c)(2)(A).

175. *Id.* § 1251(a)(2); 40 C.F.R. §§ 130.3, 131.2 (2018). In its NPDES permitting regulations, EPA interprets this to mean a "balanced, indigenous population of shellfish, fish, and wildlife . . . ." 40 C.F.R. § 125.62(c) (2018).

176. *See* CHARLES E. STEPHEN ET AL., U.S. ENVTL. PROT. AGENCY, PB85-227049, GUIDELINES FOR DERIVING NUMERICAL NATIONAL WATER QUALITY CRITERIA FOR THE PROTECTION OF AQUATIC ORGANISMS AND THEIR USES 1–9, 19–20 (1985), https://www.epa.gov/sites/production/files/2016-02/documents/guidelines-water-quality-criteria.pdf [https://perma.cc/7DYF-XM2Z].

177. 33 U.S.C. § 1251(a) (2018).

kinds and levels of stringency in biocriteria necessary to ascertain whether a balanced, indigenous population of biota is adequately protected, as well as a regulatory definition of biological integrity.

It may not be possible to make those determinations solely on scientific grounds. Is there a minimum level of deviation from reference conditions at which aquatic ecologists can conclude *objectively* that "integrity" is restored or at which all life cycles of indigenous aquatic populations have been protected? Or do those choices depend, in part, on economic factors, public preferences, and other considerations? In analogous situations in which the appropriate line between acceptable and unacceptable water quality degradation involves value judgments in addition to scientific knowledge, EPA has provided a range of permissible state choices.[178]

Moreover, to the extent that it is desirable and feasible to define biological integrity with some uniformity, balanced against desirable flexibility between states, it is also challenging to ensure that states assess and report attainment with those standards consistently. Bioassessment results can change based on reference water selection, sampling methodology, species identification, and other steps in the bioassessment process.[179] The law can evolve in response to this variability if EPA establishes regulatory criteria to ensure consistency in application of state biocriteria. Likewise, consistency among states will increase as biocriteria science develops methods that reduce variability and uncertainty in the assessment and reporting process.

3. Determining Regulatory Means

Scientific advances can also support new means of implementing or attaining regulatory goals once they are set. Once EPA and states developed biocriteria, they needed to develop the means to implement them through the CWA's regulatory provisions. Even for relatively mature regulatory programs, the applicable legal and

178. For example, in establishing WQC for non-threshold toxicants—pollutants for which no zero risk level can be identified but for which the incremental risk of harm is extremely low as the dose diminishes—EPA identified a permissible incremental risk range of one in a million exposed individuals (10^{-6}) to one in ten thousand (10^{-5}). *See* WQS HANDBOOK CHAPTER 3, *supra* note 71, § 3.3. EPA also recommends other assumptions for human health-based WQC, such as water and fish consumption rates, bioaccumulation, and other factors, but accepts some flexibility in application of those factors. *See id.*

179. *See* BIOLOGICAL ASSESSMENT PROGRAM REVIEW, *supra* note 86, at 11–47.

regulatory framework should continue to evolve in parallel with the science.

The regulatory uses to which biocriteria have been put, as dictated by the statutory scheme set forth in Part II, include (1) general water body assessment for the purposes of identifying water quality problems, program planning, and program evaluation;[180] (2) more targeted water quality monitoring to comply with specific listing provisions, such as sections 303(d) and 319(a);[181] (3) development of TMDLs and associated regulatory requirements, such as stricter provisions in NPDES permits or nonpoint source management measures;[182] and (4) enforcement actions.[183]

There are three distinct but related reasons why the level of scientific detail and support needed to bolster regulatory uses of biocriteria might differ, and therefore, why those regulatory uses coevolved as biocriteria science improved. First, as the stakes associated with agency action increase, affected parties are increasingly likely to mount legal challenges. As noted above, biocriteria were not subject to significant legal scrutiny at the outset, because they were not used initially for regulatory purposes.[184] Specific individuals or entities are not likely to be adversely affected in a sufficiently particularized or immediate way to have an incentive to challenge general water body assessments, and if they did, the issue might not be justiciable on grounds of standing[185] or finality.[186] A section 303(d) water body listing, however, has potential regulatory implications. Once states develop pollutant load allocations ("pollution budgets") for a water body, they need to incorporate stricter effluent limits on individual dischargers through NPDES permits. Therefore, citizen groups are more likely to challenge agency failure to list impaired waters based on biocriteria violations.[187] A party whose NPDES permit might be

180. 33 U.S.C. §§ 1313(e), 1315(b) (2018).

181. *Id.* §§ 1313(d), 1329(a).

182. *Id.* §§ 1311(b)(1)(C), 1312, 1313(d).

183. *See id.* §§ 1319, 1365. Violations of biocriteria can also be used to support nuisance lawsuits for either damages or injunctive relief. *See* Buchholtz v. Dayton Int'l Airport, 1995 WL 811897 (S.D. Ohio, Oct. 30, 1995).

184. *See supra* notes 21–24 and accompanying text.

185. *See* 5 U.S.C. § 702 (2018) (affording judicial review of agency action only to those "suffering legal wrong . . . or adversely affected or aggrieved by agency action).

186. *See id.* § 704 (allowing review only for "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court").

187. *See* Ohio Valley Envtl. Coal., Inc. v. Pruitt, 893 F.3d 225 (4th Cir. 2018).

strengthened due to a TMDL might have an incentive to challenge that TMDL,[188] any enforceable permit revisions adopted to implement the TMDL,[189] or enforcement actions for violations of the revised permit.[190]

Second, different regulatory tools are subject to different burdens of proof or standards of review. Listing decisions, TMDL development, and NPDES permit decisions are all subject to deferential standards of judicial review under the "arbitrary and capricious" standard of the Administrative Procedure Act[191] or a state equivalent. For fact-based decisions, the agency action might be subject to the "substantial evidence" standard of review.[192] CWA civil enforcement actions require the government, or a private party in the case of a citizen suit or common law nuisance case, to prove their case by a preponderance of the evidence.[193] Criminal enforcement actions require proof beyond a reasonable doubt.[194] Different levels of scientific proof—or certainty—may be needed to meet these differing legal standards of review.

Third, some decisions require relatively more or less regulatory knowledge as opposed to scientific knowledge. A report characterizing the degree to which water bodies deviate from reference conditions may reflect some judgment about the choice of reference water bodies or the appropriate statistical methodology to determine when the deviation reaches a particular

188. EPA or a state agency might seek to dismiss such a case on finality grounds, arguing that the TMDL itself imposes no regulatory requirements until translated into an enforceable permit or other regulatory requirement. *See id.*

189. *See* Las Virgenes Mun. Water Dist.–Triunfo Sanitary Dist. v. McCarthy, 2016 WL 393166 (N.D. Cal. Feb. 1, 2016); Bd. of Comm'rs. of Fairfield Cty. v. Dir. Koncelik, 2013 WL 2422905 (Ohio Ct. App. May 23, 2013); *In re* Sheffield Wind Project, 2010 WL 3455113 (Vt. Super. Ct. Aug. 26, 2010).

190. *See* Ohio *ex rel.* DeWine v. Osborne Co., 2018 WL 3740501 (Ohio Ct. App. Aug. 6, 2018); Ohio Valley Envtl. Coal., Inc. v. Fola Coal Co., 82 F. Supp. 3d 673 (S.D.W. Va. 2015), *aff'd*, 845 F.3d 133 (4th Cir. 2017); Ohio Valley Envtl. Coal. v. Elk Run Coal Co., 24 F. Supp. 3d 532 (S.D.W. Va. 2014); City of Salem v. Koncelik, 843 N.E.2d 799 (Ohio Ct. App. 2005).

191. 5 U.S.C. § 706(2)(A) (2018).

192. *Id.* § 706(2)(E).

193. *See* 36 ROBERT W. VINAL, AM. JUR. PROOF OF FACTS § 533 (3d ed. 2018) (discussing the proof of wrongful discharge of pollutants into waterways under the CWA). Private parties also are not entitled to the kind of deference to which courts typically accord government experts, making their burden greater in practice. *Elk Run Coal Co.*, 24 F. Supp. 3d at 562–63.

194. *See* David A. Brose, *Interpreting the Criminal Sentencing Provisions of the Clean Water Act: Lessening the Government's Burden of Proof at the Cost of Constitutional Rights*, 10 MO. ENVTL. L. & POL'Y REV. 47 (2003).

level of statistical significance or suggests a particular ecological effect.[195] Those judgments are largely scientific in nature and likely to be given considerable judicial deference.

Other agency decisions, however, may require more regulatory knowledge. For example, a decision to list a water body and to develop a TMDL requires a finding not only that a WQC has been violated, but also that applicable technology-based limitations "are not stringent enough to implement any water quality standard applicable to such waters."[196] A state or EPA then must adopt a TMDL "at a level necessary to implement the applicable water quality standards with seasonal variations and a margin of safety which takes into account any lack of knowledge concerning the relationship between effluent limitations and water quality."[197] The first step in this process may involve uncertainties about the relationship between effluent limitations on point sources, efforts to reduce or eliminate nonpoint source pollution or other aquatic ecosystem stressors, and attainment of biocriteria. Adopting and incorporating a TMDL into enforceable NPDES permits may require additional considerations of feasibility and efficacy. An even more sophisticated mixture of scientific and legal judgment is needed to determine whether available information is sufficiently strong to prove a cause-and-effect relationship between a pollution source and a biocriteria violation under either the civil or criminal burden of proof.

The dynamic relationship between law and science belies a simple or mechanical approach to implementation. Statutory mandates often remain static (such as CWA section 303(d) and the related requirement of section 303(b)(1)(C) to require "any more stringent limitations . . . necessary to meet water quality standards").[198] Citizen advocates, impatient with our collective failure to meet the statutory goals and objectives many decades after the initial deadlines, will use the mandamus remedy in the CWA citizen suit provision[199] to insist on strict compliance with

195. *See Elk Run Coal Co.*, 24 F. Supp. 3d at 541–42, 554–56.

196. 33 U.S.C. § 1313(d)(1)(A) (2018).

197. *Id.* § 1313(d)(1)(C).

198. *Id.* §§ 1313(d), 1311(b)(1)(C).

199. *Id.* § 1365(a)(2) (authorizing suits "against the Administrator [of EPA] wherever there is alleged a failure . . . to perform any act or duty under [the CWA] which is not discretionary . . .").

EPA's statutory duties wherever the scientific basis exists to do so.[200] Regulated parties whose permits may become stricter, or who may be the subject of enforcement actions due to biocriteria, will raise legal challenges or defenses asserting the need for greater scientific knowledge to justify additional regulatory measures.[201] Facing pressure from both sides, but also balancing the need for expeditious statutory implementation and enforcement against the desire to ensure that regulatory actions are defensible against legal challenge, agency officials need to make judgment calls about when the relevant science supports the next regulatory step in the process of coevolution. Those decisions depend to some extent on the degree of legal risk agency officials deem acceptable.

Thus far, biocriteria science has fared well under the light of judicial scrutiny. Courts have upheld biocriteria against challenges to stricter NPDES permits[202] and upheld permits in citizen challenges based on potential biocriteria violations.[203] Courts have similarly accepted the validity of biocriteria to support enforcement actions brought by government agencies,[204] citizen groups,[205] and private landowners.[206]

Despite the fact that biocriteria have been in use for more than three decades, however, they have been tested in very few reported judicial decisions, and most of those decisions have been recent. This suggests that EPA and state agencies have been conservative in moving biocriteria from the realm of monitoring and assessment to that of regulation. This conclusion appears to be supported by a preliminary assessment, based on a paper review of available documents, of the regulatory uses to which states put biocriteria. Although this tentative assessment was constrained by several

200. *See* Ohio Valley Envtl. Coal., Inc. v. Pruitt, 893 F.3d 225 (4th Cir. 2018); Heal the Bay, Inc. v. McCarthy, 2014 WL 12696352 (N.D. Cal. Mar. 31, 2014).

201. *See* Ohio Valley Envtl. Coal., Inc. v. Fola Coal Co., 82 F. Supp. 3d 673 (S.D.W. Va. 2015), *aff'd*, 845 F.3d 133 (4th Cir. 2017); Ohio Valley Envtl. Coal. v. Elk Run Coal Co., 24 F. Supp. 3d 532 (S.D.W. Va. 2015); Bd. of Comm'rs of Fairfield Cty. v. Koncelik, 2013 WL 2422905 (Ohio Ct. App. May 23, 2013).

202. *See Bd. of Comm'rs of Fairfield Cty.*, 2013 WL 2422905; City of Salem v. Korleski, 934 N.E.2d 360 (Ohio Ct. App. 2010).

203. *See In re* Sheffield Wind Project, 2010 WL 3455113 (Vt. Super. Ct. Aug. 26, 2010).

204. *See* State of Ohio *ex rel.* DeWine v. Osborne Co., 100 N.E.3d 1 (Ohio Ct. App. 2017).

205. *See Fola Coal Co.*, 82 F. Supp. 3d 673; Ohio Valley Envtl. Coal. v. Elk Run Coal Co., 24 F. Supp. 3d 532 (S.D.W. Va. 2014).

206. *See* Bucholtz v. Dayton Int'l Airport, 1995 WL 811897 (S.D. Ohio, Oct. 30, 1995).

uncertainties,[207] it appears that at least 32 states use biocriteria for statewide water quality assessment, at least 29 states use biocriteria to identify and list impaired waters, at least 16 states use biocriteria for water body classification, at least 14 states use biocriteria for antidegradation program analysis, at least 13 states use biocriteria for use attainability analysis or site-specific WQC development, at least 11 states use biocriteria for NPDES permit conditions and TMDL development, at least 8 states use biocriteria to develop or require other restoration actions, and only 2 states use biocriteria for enforcement purposes.[208]

Two conclusions are apparent from these preliminary data. First, states continue to use biocriteria far more often for monitoring and assessment than for regulatory purposes. Second, by cross-referencing uses of biocriteria against the kind of biocriteria adopted by particular states, states with numeric biocriteria or narrative criteria with numeric translator procedures use those criteria for far more regulatory purposes than do states with narrative biocriteria alone.[209] The latter conclusion supports the recommendation of subsection 2, *supra*, that EPA require states to adopt biocriteria in some numeric form.

Thus, the science supporting biocriteria appears to have evolved faster than the regulatory use of that science, in some cases contrary to applicable statutory and regulatory requirements. For example, the requirement of section 303(d) to list water bodies that cannot meet applicable WQC with existing technology-based effluent limitations is mandatory, not discretionary.[210] Because TMDLs apply to all forms of WQC, the requirement applies as

207. For example, one state might have explicit regulatory authority to adopt TMDLs or NPDES permit conditions based on biocriteria, but rarely use that authority; while another state might actually be incorporating NPDES permit conditions based on biocriteria under general regulations that make no specific mention of biocriteria. As was true in attempting to enumerate which states have adopted biocriteria, see *supra* note 157, a more precise assessment would require a more detailed survey of state personnel, through written surveys, interviews, or both.

208. My Research Fellow Michael Hutchings conducted the original review of documents necessary to compile these data, and the author reviewed the initial data and reached tentative conclusions based on the available information. I am responsible for any resulting errors or uncertainties.

209. Out of 9 potential regulatory uses of biocriteria, states with narrative biocriteria appear to use them for a mean of 2.7 uses, while states with numeric biocriteria average 5 out of 9 uses, and states with narrative biocriteria and numeric translator methods average 4.1 out of 9 uses.

210. 33 U.S.C. § 1313(d) (2018); Scott v. Hammond, 741 F.2d 992 (7th Cir. 1984).

much to biocriteria as to other forms of WQC.[211] That applies to both the state obligation to list impaired waters, and to EPA's duty to list waters if a state fails to do so.[212] Similarly, state and EPA duties to adopt and enforce effluent limitations necessary to implement applicable WQC[213] applies equally to biocriteria as to other WQC.[214]

Two steps are appropriate to effectuate coevolution of the CWA regulatory program given advances in biocriteria science. First, EPA could amend its water quality standards regulations (40 C.F.R. Parts 130 and 131) to specify even more clearly that its requirements apply equally to all forms of water quality criteria. Second, EPA could more aggressively implement its statutory mandate to require states to identify impaired waters due to biocriteria violations, and to redress those violations by identifying the responsible sources of impairment where necessary through stricter NPDES permit requirements.

One potential objection to this recommendation is that states might be more reticent to adopt biocriteria if it would result in more rigorous regulatory obligations. If EPA promulgates regulations that require states to both adopt and implement biocriteria, however, this problem will be avoided. Moreover, although biocriteria have significant utility for monitoring and assessment purposes, they are far more potent in promoting the ultimate goals and objective of the CWA if paired with their associated regulatory functions.

4. Promoting Scientific and Regulatory Innovation

One key challenge in implementing the CWA is inherent in the very reason that biocriteria are needed to effectuate the full goals and objectives of the CWA. Unlike chemical-specific WQC, or even WET criteria that identify impairment from multiple chemical pollutants, biocriteria allow us to identify impairments to biological integrity from a wider range of pollution sources. Those

211. Ohio Valley Envtl. Coal., Inc. v. McCarthy, 2017 WL 600102 (S.D.W. Va. Feb. 14, 2017), *rev'd on other grounds*, Ohio Valley Envtl. Coal., Inc. v. Pruitt, 893 F.3d 225 (4th Cir. 2018).

212. *See id.*

213. 33 U.S.C. §§ 1311(b)(1)(C), 1342 (2018); Trustees for Alaska v. U.S. EPA, 749 F.2d 549 (9th Cir. 1984); Anacostia Riverkeeper, Inc. v. Jackson, 798 F. Supp. 2d 210 (D.D.C. 2011).

214. *See* 33 U.S.C. § 1342(a)(1), (b)(1) (2018); 40 C.F.R. § 122.44(d) (2018).

impairments may be difficult or impossible to remedy through the most common existing CWA tools, most notably effluent limitations or other provisions of NPDES permits. The example of coevolution of biocriteria law and science presented in this section, therefore, requires more innovative scientific and regulatory approaches.

a. Scientific Innovation

Biocriteria can be extremely resource-intensive to develop, implement, and defend against judicial challenge. To be scientifically valid, biocriteria require a large amount of data collected through intensive field research over a long period of time to account for seasonal and other variations. Although courts thus far have upheld biocriteria in various regulatory settings,[215] those cases document the level of scientific rigor—and associated agency time, effort, and resources—potentially needed to defend their actions successfully.[216] Of course, it is difficult to know whether agency effort to defend biocriteria reflected a conservative approach to ensure that early litigation defenses succeeded, and whether less effort might thus be required in later cases. That could be tested through trial and error, with some resulting legal risk. However, it would be preferable to develop methods that retain a high level of scientific rigor and defensibility, but in as efficient a way as possible.

Thus, the regulatory experience with biocriteria to date suggests an incentive to develop biocriteria that can be implemented more efficiently and cost-effectively. This coevolutionary process is already underway. For example, just as science improved the accuracy and efficiency of our criminal justice system through DNA testing,[217] scientists are developing new methods to characterize biota in a water body through DNA analysis rather than laborious and resource-intensive identifications of individual organisms.[218]

215. *See supra* note 22.

216. *See, e.g.*, Ohio Valley Envtl. Coal., Inc. v. Fola Coal Co., 82 F. Supp. 3d 673, 680–82, 687–89 (S.D.W. Va. 2015) (documenting extensive scientific support for biocriteria application).

217. *See, e.g.*, Ju-Hyun Yoo, *The Science of Identifying People by Their DNA, A Powerful Tool for Solving Crimes, Including Cold Cases from the Civil Rights Era*, 22 SYRACUSE SCI. & TECH. L. REP. 53 (2010); David DeFoore, *Postconviction DNA Testing: A Cry for Justice from the Wrongly Convicted*, 33 TEX. TECH. L. REV. 491 (2002).

218. *See* EPA BIOCRITERIA SCIENCE PLAN, *supra* note 93, at 4–5 (citing scientific literature).

That could improve both the cost-effectiveness of biocriteria implementation and its reliability relative to more subjective methods of species analysis, allowing officials to identify more taxa and more species quickly and accurately, and to deduce more information about the environmental preferences of different species.[219]

States may also be cautious about adopting and implementing biocriteria if they lack confidence in their accuracy, consistency, and ability to identify the aquatic ecosystem stressors responsible for the impairment. EPA provides significant technical assistance to states through biocriteria training and a comprehensive program to evaluate the technical rigor of state biocriteria programs (although that evaluation appears to be optional rather than mandatory).[220] Efforts are also underway to improve the consistency and efficiency of species identification.[221]

The science of biocriteria is also evolving to develop new methods to identify different forms of aquatic ecosystem impairment and different kinds of stressors, and therefore, different kinds of remedial action. The first "generation" of biocriteria compared the composition of the biotic community relative to a reference stream in terms of factors such as species diversity and relative abundance.[222] That provided insights into levels and causes of ecosystem impairment because some species are more tolerant to pollution than others. Because this methodology only measures the actual survival of individuals or entire species or taxa of species, it can only detect higher levels of pollution, that is, pollution that causes mortality or avoidance of the polluted area, rather than other adverse effects to aquatic organisms.

In response to the complexity of ecosystems that biocriteria are designed to measure and protect, scientists are developing a new generation of bioassessment tools. This can lead to new forms of

219. Lester Yuan, Richard Mitchell & Erik Pilgrim, *Use of Metagenomic Data for Bioassessment: Promises and Challenges*, Presentation at the Society for Freshwater Science, 2018 Annual Meeting, Detroit, Mich. (May 22, 2018) (on file with author).

220. *See* BIOLOGICAL ASSESSMENT PROGRAM REVIEW, *supra* note 86.

221. Agency scientists must identify closely similar species through microscope examination. "Diatoms of North America," a joint project of EPA, the U.S. Geological Survey ("USGS"), and the Institute of Arctic and Alpine Research ("INSTAAR"), is one such effort to do so with respect to diatom identification. *See* DIATOMS OF NORTH AMERICA, https://diatoms.org/ [https://perma.cc/TT9L-BD43] (last visited Jan. 2, 2019).

222. *See supra* Part II.B.2.

biocriteria that measure sub-lethal impacts to aquatic species, and which examine the impacts of forms of pollution other than discharges of pollutants. For example, scientists are experimenting with methods to test the "metabolomics," or metabolic profiles of biotic samples, the differences in which can allow conclusions about sub-lethal pollution impacts on the health of aquatic organisms and the kinds of human stressors that may be responsible.[223] This evolving methodology is also potentially cost-effective because a large amount of data can be analyzed efficiently through NMR (nuclear magnetic resonance) spectroscopy. Researchers are also testing methods to compare the physiological or anatomical traits of sampled organisms with stressors that may alter those traits,[224] and drawing causal linkages between hydro-modification and water body impairment.[225]

Similarly, the first generation of biocriteria were applied in a relatively coarse way by establishing a single "cutoff" for determining whether a water body was impaired relative to a reference stream. This functioned similar to chemical-specific criteria because a fixed cutoff indicated impairment or non-impairment. A "bright line" test is useful in deciding whether additional regulatory action is mandated or desirable, for example, under sections 303(d) and 319(a).[226] However, it potentially misses more subtle gradations in impairment which scientists can now evaulate through a more flexible "biological condition gradient," and which agencies can use to identify a broader range of water body impairment and restoration strategies tailored more precisely to those conditions.[227]

Thus, experience with biocriteria in legal and regulatory settings has evolved in ways that triggered the desirability of additional scientific co-evolution. Given inherent limitations in the CWA statutory scheme, similar coevolution is needed to promote additional regulatory innovation, as discussed in the next subsection.

223. *See* Baird et al., *supra* note 94.

224. *Id.*

225. *See* Belize A Lane et al., *Revealing the Diversity of Natural Hydrologic Regimes in California with Relevance for Environmental Flows Applications*, 53 J. AMER. WATER RESOURCES ASS'N 411 (2017).

226. 33 U.S.C. §§ 1313(d), 1329(a) (2018).

227. *See* PRACTITIONER'S GUIDE TO THE BIOLOGICAL CONDITION GRADIENT, *supra* note 86.

b. Regulatory Innovation

Failure to achieve the full goals and objectives of the CWA is explained in part by a mismatch between the statutory tools Congress authorized and the broad goals it established. Regulatory innovations in biocriteria implementation can help to fill this gap.

Nearly a half-century of CWA implementation demonstrates that the statutory objective to restore and maintain chemical, physical, and biological integrity, and the subsidiary goal of the protection and propagation of balanced, indigenous populations of fish, shellfish and wildlife, are not paired with sufficiently effective statutory tools. Most notably, the largely discretionary tools Congress authorized to redress nonpoint source pollution have resulted in far less progress than has been achieved by the mandatory system of controls on point source pollutant discharges.[228]

That suggests that statutory amendments may be needed to bridge the gap between statutory aspirations and their attainment, as suggested elsewhere.[229] For example, Congress could strengthen CWA section 319 by providing EPA with the same backstop authority to adopt and enforce best management practices or other controls on nonpoint source pollution as it has for point sources. Congress could amend the statute to allow regulation of all forms of pollution;[230] and it could provide government and citizen enforcement authority against all forms of pollution.[231]

However, given the political barriers to amending the CWA over the past several decades, EPA and state agencies working to bridge the gap between the statutory aspirations and existing regulatory tools need to evolve new regulatory tools within the existing statutory flexibility. Because biocriteria can measure the impacts of water body impairment from a wide range of sources in addition to pollutant discharges, they serve as both an impetus for the

228. *See supra* note 113 and accompanying text.

229. *See generally* Adler, *Resilience, Restoration, and Sustainability, supra* note 20.

230. For example, Congress could amend section 301(a) of the Act to state: "Except as provided in [permitting and control provisions] of this title, the discharge of any pollutant *or any other pollution as defined in this Act* is hereby prohibited." 33 U.S.C. § 1311(a) (2018) (proposed new words italicized).

231. For example, Congress could amend section 505(a) of the Act to add: "(3) against any person who causes or contributes to pollution of the waters of the United States leading to a violation of any state or federal water quality standard adopted pursuant to section 303 of this Act."

coevolution of innovative tools to redress that pollution, and as a monitoring and assessment means of facilitating that innovation.

One example of this kind of regulatory innovation is the municipal separate storm sewer system ("MS4") permits that Maryland issued to Chesapeake Bay watershed counties pursuant to TMDLs designed to redress persistent impairment of the Bay and its tributaries.[232] Although the permits are designed to reduce pollutant discharge from storm sewers, those pollutants derive from dispersed municipal and suburban areas and are therefore difficult to control with the kinds of end-of-pipe effluent limitations used for more concentrated point source discharges. Instead, the Maryland MS4 permits impose controls on upstream pollution sources such as trash abatement programs and a requirement to restore 20% of a jurisdiction's impervious surfaces as a "surrogate TMDL target."[233] The permit requires chemical, physical, and biological monitoring—including benthic macroinvertebrate sampling—to assess the effectiveness of progress toward the 20% restoration requirement, and an adaptive management approach to identify and implement new control measures as needed.[234] The Court approved this iterative permitting process within the flexibility of EPA's TMDL rules, informed by biocriteria assessment and other information, as "necessary evils" given the difficulty of monitoring every stormwater control management action.[235]

Given the magnitude of the ongoing impairment of aquatic ecosystems in the United States, and the breadth of sources of that impairment, regulatory evolution will be needed to make significant progress in meeting the statutory goals and objectives. Biocriteria provide a significant scientific impetus for that innovation by providing benchmarks against which the efficacy of innovations can be measured. In the Chesapeake Bay MS4 example, biocriteria can be used to determine the efficacy of new ways to address stormwater pollution (requiring 20% restoration of impervious surfaces) by determining whether the ecological health of the affected water bodies has improved.

232. *See* Anacostia Riverkeeper v. Md. Dep't of the Env't, 134 A.3d 892 (Md. 2016).
233. *See id.* at 907–12.
234. *See id.* at 916, 922–26, 933.
235. *See id.* at 919–20, 931, 933, 936.

5. Defining (and Redefining) Regulatory Scope and Focus

The coevolution of science and law can shift the scope and focus of a regulatory statute as new scientific methods and information expand our understanding of the nature of the problem and its potential solutions. Changes in statutory interpretation, or changes in the focus of implementation due to evolving conditions or political factors, can necessitate or stimulate new scientific directions. Biocriteria have highlighted the disconnect between the statutory tools Congress incorporated into the CWA, based on its understanding of the water pollution problem in 1972, and the full scope and nature of water pollution sources we now recognize as contributing to that problem. Enhanced scientific understanding of the nature and causes of aquatic ecosystem impairment has begun to shift the scope and focus of CWA implementation in at least two important ways.

a. "Water," "Waters," or "the Nation's Waters"

Implementation of the CWA has been plagued by disputes over the scope of its regulatory jurisdiction. The most public manifestation of that uncertainty has been the scope of surface waters covered by the statute. This is particularly true given the statute's confusing definition of "navigable waters" as "the waters of the United States, including the territorial seas."[236] This terminological distinction delineates the permissible limits of point source permitting authority under CWA sections 402 and 404.[237] The scope of that jurisdiction has been disputed in the courts, and has also been the subject of recent efforts by federal agencies to clarify the issue by regulation.[238] Advances in scientific understanding of the linkages between components of aquatic ecosystems have contributed to as-yet unsuccessful efforts to resolve that dispute.[239]

It is not entirely clear whether Congress, in drafting this language, focused on the distinction between "water" and "waters," or between "the Nation's waters" and either the "navigable waters"

236. 33 U.S.C. § 1362(7) (2018).
237. *Id.* §§ 1342, 1344.
238. *See supra* notes 46–48.
239. *See, e.g.,* OFFICE OF RESEARCH & DEV., U.S. ENVTL. PROT. AGENCY, EPA/600/R-14/475F, CONNECTIVITY OF STREAMS & WETLANDS TO DOWNSTREAM WATERS: A REVIEW & SYNTHESIS OF THE SCIENTIFIC EVIDENCE, (2015).

or the "Waters of the United States." Indeed, very little in the 1972 legislative history sheds light on these distinctions.[240] Courts presume, however, that in using different words, Congress intended different meanings.[241]

For purposes of this article, the most important distinction is between "water" and "waters." The most logical, plain-meaning explanation for the distinction is that "water" refers to the liquid that comprises the most fundamental component of all aquatic ecosystems,[242] while "waters" refers to "water bodies," such as rivers, streams, lakes, estuaries, and wetlands.

This distinction between "water" and "waters" has significance for the biocriteria program in two ways. First, if the statutory objective is to restore and maintain the chemical, physical, and biological integrity of "the Nation's waters," does that mean the integrity of each individual water body, or of the Nation's waters as a whole? For example, if biocriteria rely on a small set of reference water bodies that reflect little diversity between ecosystem types, we might ensure the biological integrity of individual water bodies, but not of the Nation's waters as a whole. We might attain healthy sets of biota in each water body but experience a relative homogenization of aquatic ecosystems. That could result in the loss of diversity across aquatic ecosystems despite preserving diversity within each water body. Thus, we could be restoring and maintaining the integrity of each of the Nation's waters, but losing important aspects of the integrity of "the Nation's waters" as a diverse, inter-related complex of aquatic ecosystems.

This suggests the need for an evolution in our legal understanding of the scope of the CWA's defining opening sentence,[243] and perhaps a regulatory elucidation of that term. That regulatory evolution, in turn, will help guide the evolution of biocriteria science. Most notably, it would likely influence the

240. In a forthcoming article, I will address in more detail the implications of this confusing multiplicity of the CWA's jurisdictional terms.

241. *See supra* note 82 and accompanying text.

242. I think it fair to exclude the narrowest possible reading of the word "water" as the chemical compound H_2O, because by definition, any contaminants or other constituents in the liquid within a water body would be intermingled within the water molecules, and not part of it. As such, the "water" itself could not be polluted as defined in the CWA, but the liquid within the water body could be.

243. "The objective of this Act is to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a) (2018).

necessary diversity of reference systems used in state biocriteria development.

In a different statutory context, EPA has adopted a legal position suggesting that "waters" means waters as a whole. In its Water Transfer Rule[244] and related litigation,[245] EPA adopted the "unitary waters" concept. This legal theory suggests that, for certain CWA purposes, the "navigable waters" is a unity. In particular, it means that NPDES permits are not required when pollutants are conveyed from one portion of the navigable waters, through a point source, to another portion of those waters.[246] In that context, this interpretation narrows the scope of activities subject to the CWA's permitting requirements, and any accompanying controls.[247]

If EPA, by contrast, adopted the unitary water concept in the context of "the Nation's waters,"[248] it would support a broader application of biocriteria, and of WQS more generally. Rather than requiring only restoration and protection of individual water bodies, it would require restoration and protection of the full range of aquatic ecosystem types in the Nation's waters viewed in their entirety. Indeed, it would reflect a broader interpretation of the statutory objective. Regulatory clarification of this point would be useful in evolution of the biocriteria program. The associated science, however, would have to evolve accordingly, with attention

244. National Pollutant Discharge Elimination System (NPDES) Water Transfers Rule, 73 Fed. Reg. 33,697 (June 13, 2008) (promulgating 40 C.F.R. § 122.3(i)).

245. Catskill Mountains Chapter of Trout Unlimited, Inc. v. U.S. EPA, 846 F.3d 492 (2d Cir. 2017); Friends of the Everglades v. South Fla. Water Mgmt. Dist., 570 F.3d 1210 (11th Cir. 2009).

246. To fall within the qualified discharge prohibition of section 301(a), there must be a "discharge of any pollutant." 33 U.S.C. § 1311(a) (2018). That term, in turn, is defined as "any addition of any pollutant *to navigable waters* from any point source . . . ." *Id.* § 1362(12) (emphasis added). Thus, as EPA's argument goes, if pollutants are simply conveyed from the navigable waters *as a whole*, back into another portion of the navigable waters, there is no *addition* of pollutants to navigable waters. The navigable waters are treated as a single unit for purposes of this statutory requirement. *See Friends of the Everglades*, 570 F.3d at 1223–28.

247. It means, for example, that water from a relatively polluted water body can be conveyed through a point source into a relatively pristine water body, absent any treatment or other controls to maintain the integrity of the receiving water. For a general critique of the rule, see David Eng, Note, *Watering Down the Clean Water Act: A Critque of the NPDES Waster Transfers Rule*, 36 WASH. U. J.L. & POL'Y 179 (2011).

248. EPA could conceivably argue that the plural "waters" means one thing in the phrase "navigable waters" and another in the phrase "the Nation's waters" because it is used in a different statutory context and for a different statutory function, but that would require a very compelling rationale to be credible given the apparent inconsistency.

to the biotic integrity of large-scale aquatic ecosystems and not only individual waters.

A second manifestation of the distinction between "water" and "waters" has even broader potential effects on the scope of the CWA regulatory scheme. As noted above, Congress defined the statutory objective and the statutory definition of "pollution" by reference to "chemical, physical, and biological integrity."[249] The statutory objective is to "restore and maintain the chemical, physical, and biological integrity of the *Nation's waters*."[250] The definition of "pollution," by contrast, is the "man-made or man-induced alteration of the chemical, physical, biological, or radiological integrity of *water*."

If one focuses only on the "chemical, physical, biological, and radiological integrity of *water*," the most logical scope of WQC, including biocriteria, is on pollutants that impair the integrity of water. That might include chemicals or pathogens that harm human health through drinking water or recreational exposure, or that harm aquatic organisms directly. It may also include alteration of the physical characteristics of the water, such as temperature or pH, and impacts to microorganisms within the water column. To the extent that biocriteria measure changes in the composition or characteristics of other aquatic biota, they would serve only as one of several indicators of whether the water was polluted. The statutory objective of biological integrity, or the interim goal of protection and propagation of a balanced, indigenous population of fish, shellfish, and wildlife, by contrast, can be furthered only by focusing more broadly on the "chemical, physical, and biological integrity of the Nation's *waters*," that is, the integrity of water bodies and aquatic ecosystems.

The distinction is more than semantic, however, because of the issue discussed in the previous section regarding the gap between the statutory goals and tools of the CWA.[251] As is true for all components of WQS, biocriteria must "serve the purposes of this Act," which incorporate the objective and goals Congress articulated in section 101(a).[252] To fulfill this function fully,

249. *See supra* note 31. The definition of "pollution" adds "radiological" integrity to this triad. 33 U.S.C. § 1362(19) (2018).

250. *Id.* § 1251(a) (emphasis added).

251. *See supra* Part III.B.4.

252. *See supra* Part II.B.2.

biocriteria should define the chemical, physical, and biological integrity of the Nation's *waters*, that is, of the Nation's water bodies and aquatic ecosystems. It is difficult to understand the point of using biocriteria to define and evaluate the integrity of the Nation's waters, however, if none of the statutory tools help attain that objective.

The applicability of the term "pollution" to "water" rather than "waters," however, suggests a confusingly narrower scope of the CWA in the context of CWA section 319.[253] Section 319 is designed to require and promote state programs to address sources of nonpoint source *pollution* rather than discharges of pollutants from point sources alone. If "pollution," however, is limited to man-made or man-induced alteration of the integrity of *water*—as opposed to the integrity of *waters*—even section 319 is not broad enough to address all stressors that impair the biological integrity of aquatic ecosystems. Moreover, the control provisions in section 319 are potentially even narrower in its focus on "nonpoint sources which *add significant pollution* . . . in *amounts* which contribute to" WQS violations,[254] and in requiring "best management practices and measures which will . . . reduce pollutant loadings . . . ."[255] That focus results in an even larger mismatch between the statutory goals as defined by criteria and the tools Congress designed to attain those goals.

One possible explanation for this dichotomy is that the statutory distinction between "water" and "waters" was not intentional, despite the usual presumption to the contrary. A second possible explanation is that Congress intended WQS to serve the broader role of helping states to identify the full statutory goals, but that it intended section 319 (along with the statute's point source controls), to redress only a subset of the impairments that prevent attainment of those goals. Under that theory, other water quality problems, that is, problems resulting from all sources other than the release of pollutants or the "addition of pollution" from point or nonpoint sources, were left to state discretion, subject not even to the relatively loose scrutiny imposed under section 319.

253. 33 U.S.C. § 1329 (2018).

254. *Id.* § 1329(a)(1)(B) (emphasis added). *See also id.* §§ 1329(a)(1)(D), 1329(b)(1) (alluding to "pollution added from nonpoint sources").

255. *Id.* § 1329(b)(2)(A) (emphasis added).

A third possibility, however, is more likely to reflect the actual history and evolution of the CWA, and has greater implications for the thesis of this article. When Congress adopted the CWA in 1972, and even in 1987 when it added section 319, our understanding of the water pollution problem was still evolving. Biocriteria were still in the early phases of development. Their ability to link changes in aquatic biota with particular ecosystem stressors was limited. Thus, Congress necessarily lacked sufficient information and understanding of water pollution to fully match objectives and solutions. They apparently believed that reducing or eliminating the discharge of chemical pollutants into water would achieve the statutory objective. Now that biocriteria can more clearly define the statutory goals Congress articulated, and can help us to identify impediments to those goals, the legal system needs to evolve in response to that expanded knowledge and understanding. It can do so by allowing more innovative uses of existing statutory tools through a more expansive interpretation of statutory language that Congress wrote with a broad brush. Alternatively, Congress could amend the statute based on the lessons learned from biocriteria, and other advances in water quality science, to provide the remedial tools needed to match the statutory goals.

b. The Focus of CWA Implementation: Technology-Based Tools Versus Water Quality-Based Goals

The final example of coevolution involves renewed emphasis on the water quality approach to water pollution control relative to the technology-based focus Congress established in 1972. As discussed earlier,[256] WQS were the central focus of earlier federal water pollution control legislation.[257] A significant problem with that approach, however, was that the science to support WQS was not sufficiently evolved. The statute required water pollution control agencies not only to define water quality goals through WQS, but also to link individual pollution sources to identified WQS violations.[258] Water quality science had not yet evolved to match the legal approach Congress adopted.

To address this problem, in 1972 Congress shifted the primary focus of the CWA to a preventive strategy based relatively more on

256. *See supra* notes 28–29 and accompanying text.

257. *See* RODGERS, JR., *supra* note 29, at 253–54, 259–60.

258. *See id.*

water pollution control engineering and technology, and relatively less on water quality science.[259] Rather than assuming that pollutant discharges were permissible unless scientists could prove that those pollutants caused harm, Congress adopted a qualified ban on point source pollutant discharges unless allowed by a federal or state permit.[260] Those discharges, moreover, were subject to technology-based control requirements to reduce pollutant releases to the maximum extent possible given available technology,[261] with the ultimate goal of eliminating discharges entirely as technology improved.[262] By requiring sources to reduce, and ultimately to eliminate, pollutant discharges, Congress avoided the challenging scientific obligation of basing pollution controls on identified harm.[263] It also assumed that eliminating point source discharges would result in significant progress toward the objective of restoring and maintaining the chemical, physical, and biological integrity of the Nation's waters.[264]

The technology-based program in the CWA generated a different process of coevolution between the law and the engineering science needed to implement it. Congress directed EPA to base a first round of technology-based standards (known as "best practicable technology," or "BPT") on existing technology that met prescribed standards of practicability.[265] Congress dictated later rounds of standards to reflect technological improvements, particularly for more dangerous pollutants,[266] and for new facilities

259. *See id.*

260. 33 U.S.C. § 1311(a) (2018).

261. *See id.* §§ 1311(b), 1314(b), 1316, 1317. The precise definition of "best" technology varies with the kind of discharge, the types of pollutants released, the nature of the point source, and other factors, but those differences are not relevant here.

262. *See id.* §§ 1251(a)(1), 1311(b)(2), 1314(c).

263. Economists have critiqued this strategy for ignoring economic efficiency, because of the possibility that requiring sources to incur the costs of the best technology was decoupled from the economic benefits from reduced pollution. *See, e.g.*, Jonathan S. Masur & Eric A. Posner, *Against Feasibility Analysis*, 77 U. CHI. L. REV. 657 (2010). *But see* David M. Driesen, *Two Cheers for Feasible Regulation: A Modest Response to Masur and Posner*, 35 HARV. ENVTL. L. REV. 313 (2012).

264. Congress was not, however, under the false illusion that eliminating point source discharges alone would achieve the statutory goals. First, Congress adopted a nonpoint source pollution control program in 1972, 33 U.S.C. § 1288, and added a more aggressive program in 1987, *id.* § 1329. Moreover, Congress articulated zero discharge as an interim statutory goal, not as its ultimate objective.

265. *See* 33 U.S.C. §§ 1311(b)(1)(A), 1314(b)(1)(A) (2018).

266. *See id.* §§ 1311(b)(2), 1314(b)(2).

that were less limited by the design constraints of existing plants.[267] Congress expected this ongoing process of regulatory and technological coevolution to stimulate technological innovation that would approach, and ultimately achieve, zero discharge.[268]

This coevolution of law and engineering science prompted by the technology-based focus of the CWA reduced pollutant discharges significantly on a nationwide scale.[269] It has been deficient, however, in two respects. First, the process of legal and scientific coevolution has stagnated, leaving the zero-discharge objective unattained for most categories of discharger. The majority of EPA's categorical effluent limitations guidelines, which establish "best technology" treatment requirements for industrial categories, have not been amended for decades.[270] Either the applicable water pollution engineering has not evolved sufficiently in response to the technology-forcing pressure of the CWA, or EPA's rules have not evolved in response to engineering advances.

Second, water quality science has documented a wider range of reasons—beyond pollutant discharges—as to why aquatic ecosystems remained significantly impaired nationwide. That enhanced understanding confirmed that reducing or eliminating point source discharges alone would not achieve the statutory objective. Once again, as explained below, the law coevolved in response to those scientific advances, by shifting the relative focus of CWA implementation back toward the original water quality-based strategy in the 1965 legislation.

This shift in emphasis does not require us to abandon the technology-based approach adopted in the 1972 law, which remains in effect. Indeed, the stagnation described above suggests the need to reinvigorate the coevolutionary process in controlling point source discharges. It was also fortunate, however, that Congress choose to *augment* rather than replace the WQS program with a conditional discharge ban and technology-based treatment requirements. In the 1972 Act and later amendments, Congress retained WQS as a backup to technology-based standards, and as a way to both test their adequacy and supplement their water

267. *See id.* § 1316.

268. *See id.* §§ 1251(a)(1), 1314(b)(3), 1314(c), 1316(a)(1).

269. *See* ADLER, LANDMAN & CAMERON, *supra* note 15, at 14–18.

270. *See id.* at 137–50. Congress attempted to reinvigorate the technology-based effluent limitations program in the 1987 amendments. 33 U.S.C. § 1314(m) (2018).

pollution control requirements as necessary to meet water quality goals. That makes it easier for EPA and state agencies to shift their relative focus back and forth from technology-based to water quality-guided strategies as the science of water pollution control engineering and water quality science evolve, respectively. It makes the statutory scheme more flexible in its ability to evolve in response to changing science and technology, and to address a wider range of impairments to water quality and aquatic ecosystem health.

The renewed focus on WQS arguably began in the late 1980s and early 1990s when environmental groups filed citizen suits to press for more aggressive development and implementation of TMDLs.[271] That led to the creation of a Federal Advisory Committee Act ("FACA") Committee to address ways to improve the TMDL process.[272] For circumstances in which TMDLs indicated that stricter WQBELs for specific chemical pollutants were needed to meet numeric WQC for those pollutants, the process was conceptually straightforward,[273] even if officials developing the TMDLs and associated revised NPDES permits faced modeling and other technical challenges.[274]

Two different kinds of water quality problems, however, present other challenges for the WQS and TMDL process. First, evidence of impairment may involve something other than a violation of the WQC for an individual pollutant. Where discharges of chemical pollutants are responsible for water quality problems detected through biocriteria violations, agencies need to develop translator procedures to justify stricter effluent limitations on those chemical discharges. Second, biocriteria violations or other aquatic ecosystem harm may stem from stressors other than chemical pollutants. That raises questions about the authority of states and EPA, through TMDLs, to impose water quality management or

271. *See* Scott v. City of Hammond, 741 F.2d 992 (7th Cir. 1984), *cert. denied*, 469 U.S. 1196 (1985); Adler, *Integrated Approaches to Water Pollution*, *supra* note 20, at 205 nn.12–14 and accompanying text.

272. *See* TMDL FACA REPORT, *supra* note 109. In the interest of full disclosure, the author was a member of the TMDL FACA Committee. *See id.* at Preface/Signature Page (listing FACA Committee membership).

273. See Adler, *Integrated Approaches to Water Pollution*, *supra* note 20, at 215–21, for a description of the TMDL and pollutant allocation process.

274. *See* OFFICE OF WATER, U.S. ENVTL. PROT. AGENCY, EPA841-B-97-006, COMPENDIUM OF TOOLS FOR WATERSHED ASSESSMENT AND TMDL DEVELOPMENT (1997) (addressing modeling and other technical issues regarding TMDL development and implementation).

control requirements beyond chemical-specific effluent limitations.[275] It also challenges the scientific community to improve methods to link evidence of harm to specific stressors—exactly the kind of challenge that plagued the early WQS program under the 1965 Act.

Advances in biocriteria have clearly contributed to a renewed focus on the water quality side of the CWA. Biocriteria help us to use existing CWA provisions more creatively to address ongoing water quality problems.[276] At the same time, however, this ongoing legal evolution needs to prompt continued improvements in the degree to which biocriteria can detect impairment and the associated sources of that impairment, as well as management responses that will move us closer to attaining the statutory goals and objective.

IV. CONCLUSION: LESSONS FOR THE COEVOLUTION OF LAW AND SCIENCE

Two layers of lessons can be drawn from this case study exploring the coevolution of law and science in the CWA and its biocriteria program. First, from the narrow (but still exceedingly important) perspective of improving CWA implementation, this analysis suggests a number of ways in which either CWA law or regulatory practice can evolve in response to advances in biocriteria science, or in which it would be helpful for that science to evolve in response to legal changes. The analysis also suggests broader lessons, however, regarding the relationship between law and science in complex regulatory regimes, and how agencies can improve the nature of that interaction.

Second, from the CWA implementation perspective, Part III.B of this article suggests several ways in which additional evolution of biocriteria science would be useful in response to changes in the legal process.[277] Part III.B2 suggests the need for methods to improve reliability and consistency of biocriteria development and implementation among states; and improved methods to link stressors to impacts and to derive effective associated restoration or

275. *See* TMDL FACA REPORT, *supra* note 109, at 46–52.

276. *See supra* Part III.B.4.

277. EPA'S BIOCRITERIA SCIENCE PLAN, *supra* note 93, identifies a much more complete agenda for desirable improvements in biocriteria science, from multiple perspectives.

remediation strategies. Part II.B.3 suggests the need to improve the reliability and consistency of biocriteria to support existing and new regulatory tools. Part III.B.4.a suggests the need for new methods to detect sublethal impacts and their association with different stressors, and to further improve the biological condition gradient methodology to support more fine-tuned analysis of water body conditions. Part III.B.5.b identifies the need for improved translator mechanisms and other tools to redress non-chemical violations.

Conversely, Part III.B also suggests important ways in which the legal process should evolve in response to advances in biocriteria science. Part III.B.1 suggests that EPA should promulgate regulations requiring states to adopt biocriteria, and adopt federal biocriteria for states that fail to do so. Part III.B2 proposes that EPA should adopt a regulatory definition of biological integrity, or that Congress should do so in the statute. It also suggests that EPA amend its water quality standards regulations to define "serve the purposes of this Act" to include the overarching objective of the statute in addition to its subsidiary goals. Finally, it calls on EPA to establish more uniform requirements to ensure reliability and consistency among states in the biocriteria program. Part II.B.3 suggests that EPA amend its water quality regulations to specify explicitly that all requirements triggered by WQC violations apply equally to biocriteria, and that EPA should more aggressively require States to implement and enforce biocriteria. To the extent that regulatory innovations and flexibility within the existing statute are inadequate to address all pollution problems, Part III.B.4.a identifies the need for CWA amendments to strengthen controls on nonpoint source pollution, and to regulate and take enforcement action against all forms of pollution. Part III.B.5 identifies the need for EPA to clarify the breadth and nature of reference systems needed to ensure biological integrity across water body and ecosystem types, and the need for improved legal tools to redress non-chemical violations.

The coevolutionary model presented in this article suggests an even broader set of lessons regarding the relationship between law and science in a complex statutory regime, and regarding the relationship between scientific knowledge and regulatory knowledge. Too often, we view science as a servant of the law, providing technical tools to help us implement statutes and regulations adopted for independent reasons of law or policy. Likewise, we often view the law as the static component in the law-science relationship. Under both of those views, evolving science plays no role in the ongoing interpretation and development of the law, even in a statutory regime that involves complex scientific issues. The examples of coevolution presented in Part III demonstrate that a static model of the law-science interaction is inaccurate. Scientific advances often stimulate a legal response, and vice versa. Flexibility in the CWA provides more opportunities for that evolution by allowing innovation in regulatory tools as science progresses.

These examples of beneficial coevolution occur because agency lawyers, scientists, and policymakers routinely interact in ways that stimulate legal and scientific responses. On the other hand, the above analysis demonstrates that much of the potential for coevolution of law and science, at least in the CWA biocriteria context, remains latent or unfulfilled. At other times, that process has proceeded, but slowly or haphazardly. It would be beneficial, therefore, for EPA and other agencies dealing with complex regulatory programs to facilitate more systemic and routine interaction between law and science. This might include a structured periodic review process to develop a science agenda in response to regulatory developments, and to identify regulatory changes that are suggested or facilitated by new science. Some of the barriers to coevolution are likely to reflect factors that cannot be addressed through process innovations. Those may include the shifting policies and priorities of new administrations, or differing tolerances for legal risk as regulatory innovations approach the limits of existing statutory authority. Improved and increased communication between agency lawyers and scientists, however, may result in progress within the limits of those barriers.

Improving the process through which agency lawyers, scientists, and policy officials consider differences between scientific knowledge and regulatory knowledge also enhances accountability in the administrative process. It helps to ensure that all of the appropriate factors are considered in agency decisions, and by the appropriate decisionmakers, consistent with the statutory design. The integrity of that process can also be protected through judicial review of agency decisions. Those measures may not offset antagonism to science by those who oppose regulation generally, but it can help to safeguard democratic governance in the administration of complex statutory regimes.