

*Section of Environment, Energy, and Resources
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Environment, Energy, and Resources Law: The Year in Review 2019

Chapter BB • Science and Technology

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Chapter BB: SCIENCE AND TECHNOLOGY 2019 Annual Report¹

I. POLICY DEVELOPMENTS: EPA’S POLICY REVISION OF ITS COST-BENEFIT ANALYSIS

In June 2018, then EPA Administrator Pruitt launched a [rulemaking](#) that proposed wide-ranging changes to the Agency’s calculations of costs and benefits in rulemaking.² Less than a year later, current Administrator Wheeler jettisoned that formal rulemaking process in a [May 2019 memorandum](#).³ Instead, Administrator Wheeler directed that EPA Assistant Administrators make a series of policy changes to implement what he termed a new “media-specific” approach to cost-benefit calculations.⁴ He specifically directed the Assistant Administrator for the Office of Air and Radiation Safety to announce an unspecified “regulatory proposal” to implement a more transparent and consistent cost-benefit analysis.⁵

Despite the now renewed promise by EPA of a regulatory world that promises “consistency and transparency,” the problem is a Gordian knot which resists an easy solution. The process of evaluating the costs of new pollution-reducing technology compared with the putative benefits of implementing such reductions is one fraught with uncertainty. Indeed, EPA’s newly announced policy may end up resembling the dystopian brave new world of Huxley, rather than bringing a breath of fresh air to a regulatory puzzle.

As Professor Amy Sinden observed, while some costs can be quantified with some degree of precision, there is an inherent difficulty in quantifying potential environmental benefits:

While regulatory costs tend to involve values that are relatively easy to measure and express in monetary terms—the cost of installing a scrubber on a smokestack, for example—regulatory benefits tend to involve things that are hard to quantify, and even harder to monetize. They include things like effects on human health, premature death, degradation of ecosystems, extinction of species, and so on.⁶

Professor Sinden’s observation of this intractable problem is not new. In 2003, the Office of Management and Budget (OMB) issued Circular A-4 to various executive agencies; the circular discussed cost-benefit analysis and noted: “It will not always be possible to express in monetary units all of the important benefits and costs.”⁷

¹This chapter was edited by [Sarah N. Munger](#), an associate at Beveridge & Diamond, PC. [Norm Dupont](#), a partner at Ring Bender, authored this year’s policy developments concerning EPA’s proposed revision of its cost-benefit analysis. [Sarah Kettenmann](#), an associate at Beveridge & Diamond P.C., and [Mark Duvall](#), a principal at Beveridge & Diamond P.C., authored this year’s regulatory developments concerning TSCA updates.

²Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process, 83 Fed. Reg. 27,524 (June 13, 2018) (to be codified at 40 C.F.R. ch. I).

³Memorandum from Andrew R. Wheeler, EPA, to Assistant Administrators, EPA (May 13, 2019).

⁴*Id.*

⁵*Id.*

⁶Amy Sinden, [The Problem of Unquantified Benefits](#), 49 ENVTL. L. 73, 75 (2019).

⁷[Circular A-4](#), OFF. OF MGMT. AND BUDGET (Sept. 17, 2003).

A. *Where we are Today—EPA’s Current Cost-Benefit Guidance and the Supreme Court Case on Cost-Benefit Analysis*

EPA’s efforts to solve the fundamental problem of evaluating costs versus benefits of proposed regulatory actions are not new. In 1983, EPA issued its first comprehensive guidance, [Guidelines for Performing Regulatory Impact Analysis](#), in response to a 1981 Executive Order by President Reagan requiring that all agencies evaluate the “regulatory impact” of proposed regulations.⁸

EPA’s initial effort in 1981 was followed by a series of revisions and updates that culminated in a 2010 Guidance entitled [Guidelines for Preparing Economic Analysis](#).⁹ The Agency described the 2010 Guidance as “incorporate[ing] new literature published since the last revision of the Guidelines. It describes new Executive Orders (EOs) and recent guidance documents that impose new requirements on analysts, and fills information gaps by providing more expansive information on selected topics.”¹⁰ EPA’s 2010 Guidance was in turn revised in 2014 and 2016 to update specific chapters of the 2010 Guidance.¹¹ Given multiple iterations in an effort to solve the Gordian knot of balancing hard economic costs with benefits that might be enjoyed by the “commons,” it is not surprising that after a new administration arrived in early 2017 EPA thereafter announced plans to revise prior cost-benefit analysis.

It may well be that EPA’s plans are more than “just another attempt” to adjust prior versions of a policy initially published more than two decades ago. Even before Administrator Pruitt proposed a rulemaking on cost-benefit analysis, commentators warned that partisan politics were sullyng cost-benefit risks.¹² Some commentators warned that the new initiative of Administrator Wheeler might exclude scientists from EPA’s Science Advisory Board from evaluating some of the proposed reforms, particularly those in evaluating benefits from new proposed air regulations.¹³ Other commentators noted that Administrator Wheeler’s initiative mirrored prior industry requests made by the National Association of Manufacturers and the American Petroleum Institute, and noted that some NGO observers saw the new initiative as an effort to “muddy” the science of risk assessment by posing alternative values and then implying that there was no certainty at all.¹⁴ Some conservative policy think-tanks applauded the arrival of what it termed “common sense” in Administrator Wheeler’s new cost-benefit initiative, although it noted that the details remained to be worked out.¹⁵

Much of the current debate over the proper application of cost-benefit analysis was invigorated, if not sparked by the U.S. Supreme Court in its 5-4 decision rebuking EPA for

⁸ENVTL. PROT. AGENCY, GUIDELINES FOR PREPARING REGULATORY IMPACT ANALYSIS (1983).

⁹ENVTL. PROT. AGENCY, GUIDELINES FOR PREPARING ECONOMIC ANALYSIS (2010).

¹⁰*Id.* at p. 1-1.

¹¹See [Guidelines for Preparing Economic Analysis](#), ENVTL. PROT. AGENCY (last updated Jan. 31, 2018) (providing chapter outlines and dates that each chapter was updated).

¹²See, e.g., Camille Harmer & Josh T. Smith, [Politics Sully Cost-Benefit Analysis of Regulations](#), S FLA. SUN SENTINEL (Oct. 12, 2017, 8:15 AM) (advocating that regulations be insulated from political pressures).

¹³Amena H. Saiyid, [EPA May Sideline Scientists in Changes to Cost-Benefit Analysis](#), BLOOMBERG ENV’T (June 4, 2019).

¹⁴Ninna H. Farah, [Planned Changes to EPA Pollution Analyses Align with Industry Requests](#), SCI. AM. (May 31, 2019).

¹⁵Darren Bakst, [Common Sense Finally Coming to EPA With Cost-Benefit Analysis](#), THE HERITAGE FOUND. (June 12, 2019).

not properly accounting for costs when regulating mercury emissions from power plants. In [Michigan v. EPA](#), the Court considered whether EPA’s regulation of mercury and other toxic substances (MATS) was permissible under the Clean Air Act.¹⁶ The Court explained that section 112 of the Clean Air Act authorized EPA to impose certain additional requirements on stationary source power plants but “only if the Agency ‘finds such regulation is appropriate and necessary after considering the results of the [public health] study.’”¹⁷ EPA did conduct a “Regulatory Impact Analysis,” as required by an existing Presidential Executive Order, to estimate the potential benefits of a new regulation of mercury and other air emissions from power plants and concluded that the benefits, particularly the indirect (co-benefits) benefits of regulating MATS, far outweighed the costs.¹⁸ But, the Agency conceded that that analysis was not used in arriving at its ultimate statutory conclusion that the regulation was “appropriate and necessary.”¹⁹ The Supreme Court reversed EPA’s determination, concluding that the statutory language, “appropriate and necessary” mandated at least some consideration of the “costs” or a proposed regulation, and therefore, EPA must revisit its decision which violated this key statutory limitation.²⁰

At the very end of 2018, EPA announced that it had now supplemented its prior cost benefit analysis, and surprise, it had a dramatically different result. Based upon a narrower definition of “benefits” that excluded the indirect or co-benefits from the MATS regulation, [EPA concluded](#) that the costs now significantly outweighed the projected benefits of the regulation.²¹ EPA’s new view of calculating cost versus benefits drew a rapid review from the Congressional Research Service, which summarized the new approach in context of EPA’s prior cost-benefit calculations and presented certain issues for Congress to consider.²²

B. *Where Do We Go Tomorrow?*

Many parts of EPA’s statutory framework, whether under the Clean Air Act, the Clean Water Act, or other statutes require some cost-benefit analysis prior to regulation. If the proverb ‘the devil is in the details’ is correct, then it is likely that Administrator Wheeler’s new initiative to revise the exact nature of the Agency’s cost-benefit calculus will face scrutiny on all sides. Given the Supreme Court battle in *Michigan v. EPA*, it is not surprising that the Administrator directed that EPA’s Office of Air and Radiation be the first EPA Office to complete its review by the end of 2019. But, progress may be delayed given the resignation of Assistant Administrator Wehrum of that Office earlier this year.²³

¹⁶135 S. Ct. 2699, 2705 (2015).

¹⁷*Id.* at 2716 (quoting 42 U.S.C. § 7412n(1)(A)).

¹⁸*Id.* at 2705.

¹⁹*Id.* at 2706.

²⁰*Id.* at 2707 (“Read naturally in the present context, the phrase ‘appropriate and necessary’ requires at least some attention to cost. One would not say that it is even rational, never mind ‘appropriate,’ to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits.”).

²¹Memorandum from EPA to Docket for Rulemaking: Compliance Cost, HAP Benefits, and Ancillary Co-Pollutant Benefits for “National Emission Standards for Hazardous Air Pollutants: Coal-and Oil-Fired Electric Utility Steam Generating Units -- Reconsideration of Supplemental Finding and Residual Risk and Technology Review” (Dec. 14, 2018).

²²*Id.*

²³Marianne Lavell, [Wehrum Resigns from EPA, Leaving Climate Rule Rollbacks in His Wake](#), INSIDE CLIMATE NEWS (June 26, 2019).

The Office currently has only an acting Assistant Administrator, and she has not made a formal announcement of an exact date for issuance of a new cost-benefit analysis. Whenever the new policy is promulgated one can anticipate substantial review of this first new wave of regulatory revisions, and likely, a new spate of litigation in 2020.

II. REGULATORY UPDATE: AN UPDATE ON THE TOXIC SUBSTANCES CONTROL ACT

Pursuant to the Toxic Substances Control Act (TSCA), as amended by the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), EPA must develop a framework rule to evaluate risks of existing and new chemical substances.²⁴ This article provides an update on the status of EPA’s risk evaluations under TSCA section 6 (15 U.S.C. section 2605).²⁵ It requires that EPA conduct risk evaluations to determine whether a chemical presents an unreasonable risk of harm to human health or the environment, including vulnerable subpopulations, considering conditions of use. This determination is made without consideration of costs or other non-risk factors.²⁶ If EPA determines that the chemical presents an unreasonable risk, it must promulgate a rule to impose restrictions to eliminate the unreasonable risk.

Risk evaluations must use best available science,²⁷ considering and describing the weight of the evidence that is available.²⁸ However, EPA is only obligated to account for reasonably available information—information that EPA possesses or “can reasonably generate, obtain, and synthesize.”²⁹ For each risk evaluation to be conducted, EPA must further publish the evaluation’s scope in the Federal Register.³⁰

A. EPA’s Risk Evaluations

TSCA section 6(b) requires EPA to conduct risk evaluations for ten initial chemical substances, to be followed by additional risk evaluations on other substances.³¹ EPA published a list of the ten chemicals that would undergo risk evaluations on December 19, 2016.³² The list’s publication triggered a statutory deadline for EPA to have completed risk

²⁴[Pub. L. No. 114-182](#), 130 Stat. 488, § 4.

²⁵[15 U.S.C. § 2605 \(2018\)](#).

²⁶*Id.* § 2605(b)(4)(A).

²⁷Best available science includes the consistent application, if possible, of relevant “scientific information, technical procedures, measures, methods, protocols, methodologies, or models.” It also may include an assessment of the clarity or completeness of the methods and data that were used to generate the information, and may also include independent verification or peer review of the information. 15 U.S.C. § 2625(h) (2018).

²⁸[15 U.S.C. § 2625\(i\) \(2018\)](#); *see also* [40 C.F.R. § 702.33](#) (defining weight of the evidence as a systematic review method to “comprehensively, objectively, transparently, and consistently” evaluate information).

²⁹15 U.S.C. § 2625(k) (2018); 40 C.F.R. §§ [702.41](#), 702.33.

³⁰The scope of the risk evaluation includes the chemical substance’s hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations to the chemical substance. 40 C.F.R. § 702.41.

³¹15 U.S.C. § 2605(b); *see also* Ryan Carra and Mark Duvall, [EPA’s Risk Evaluation Framework Rule Incorporates Key Industry Suggestions](#), BEVERIDGE & DIAMOND (July 20, 2017) (summarizing EPA’s risk evaluation framework under TSCA).

³²Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act, [81 Fed. Reg. 91,927](#) (Dec. 19, 2016).

evaluations within three years, or by December 19, 2019, with the option to extend up to six months. In 2019, EPA completed draft risk evaluations for five of the substances 1-bromopropane, 1,4-dioxane, methylene chloride, hexabromocyclododecane (HBCD), Pigment Violet 29.³³ Final risk determinations for all ten are due by June 19, 2020.

B. Critiques of EPA's Draft Risk Evaluations

1. Public Comments and Peer Review

The draft risk evaluations received criticism in public comments. Some commenters questioned the scope of the risk evaluation, and others asserted that EPA had underestimated risks to human health or failed to use the best available science.

The Science Advisory Committee on Chemicals (SACC) identified issues with each of the draft risk evaluations as well.³⁴ SACC encouraged EPA to proceed with having the National Academy of Sciences conduct a peer review of EPA's systematic review protocol, used for all the draft risk evaluations. A particular concern was with data gaps. For Pigment Violet 29, for example, SACC requested an improved discussion on why available study data are adequate to reach the conclusion of no unreasonable risk, and for EPA to justify why additional testing is not necessary to confirm that conclusion. It recommended that EPA more aggressively pursue information from manufacturers. Such comments reflect the challenges that EPA faces to collect exposure and toxicity data, some of which may not be publicly available. In some cases, robust summaries may be available in connection with dossiers submitted under the European Union's REACH [regulation](#), but the full studies may only be available from the data owners.³⁵

2. Legal Proceedings Regarding Risk Evaluations

That issue arose in connection with the risk evaluation for Pigment Violet 29, where a European data owner provided complete studies to EPA but claimed portions of some studies as confidential. Environmental organizations submitted a request under the Freedom of Information Act (FOIA) for complete copies of the studies. EPA granted the confidentiality claim and denied the FOIA request on the basis that the studies were not submitted by a person subject to TSCA, and thus were submitted voluntarily.³⁶

Several advocacy groups³⁷ and 14 state Attorneys General³⁸ separately petitioned EPA under TSCA section 21 to initiate a rulemaking under TSCA section 8(a)³⁹ for the reporting of the manufacture and processing of asbestos, so as to help EPA with its risk

³³[Assessing and Managing Chemicals under TSCA](#), ENVTL. PROT AGENCY (last updated Dec. 2, 2019) (providing links to the risk evaluation for each of the priority chemicals).

³⁴[Science Advisory Committee on Chemicals Meetings](#), ENVTL. PROT AGENCY (last updated Feb. 20, 2020).

³⁵*Regulation (EC) No 1907/2006 of the European Parliament and of the Council*, EUR-LEX.EUROPA.EU (Dec. 18, 2006).

³⁶[Letter](#) from Kevin Miller, Asst. Gen. Couns., EPA, to Dr. Ulrich Veith, Head of Prod. Stewardship and Masterdata, BASF Colors & Effects Switzerland AG, Re: [Freedom of Information Act Request EPA-HQ-2019-001853](#) (Mar. 14, 2019).

³⁷[Letter](#) from Jeffrey T. Morris, Dir., EPA, to Rebecca J. Rentz, Senior Env'tl. Couns., Occidental Petroleum Corp. (July 28, 2017).

³⁸[Letter](#) from David Hoffman, Asst. Att'y Gen for D.C., to Andrew Wheeler, Acting Admin., EPA (Jan. 31, 2019).

³⁹[15 U.S.C. § 2607\(a\)](#).

evaluation of that substance. They requested that EPA meet its obligations to use “reasonably available information” and “best available science” to evaluate the uses of asbestos and exposure pathways through which people and the environment are affected by asbestos. EPA denied both petitions, stating that it is required to use only information that is “reasonably available,” and that it believed it “already has sufficient information to conduct the risk evaluation.”⁴⁰ The advocacy groups filed a challenge of EPA’s denial in the Northern District of California. The court denied EPA’s motion to dismiss the case in November 2019.⁴¹ Ten states and the District of Columbia also sought judicial review of EPA’s denial of their petition.⁴²

The Ninth Circuit ruled⁴³ in November 2019 on several challenges to EPA’s regulations on prioritization and risk evaluation.⁴⁴ It dismissed some claims as non-justiciable or not final, but it held that EPA’s categorical exclusion of certain legacy activities was inconsistent with the statutory definition of “conditions of use.”⁴⁵

C. *Testing Authority to Develop Information for Risk Evaluations*

As amended in 2016, TSCA section 4(a)(2)⁴⁶ authorizes EPA to require manufacturers or others to develop information for purposes of prioritizing a chemical substance or performing a risk evaluation of a chemical substance. To date, EPA has not exercised that authority.

Section 4(h)⁴⁷ directs EPA to reduce the use of vertebrate animals in testing chemical substances under TSCA. EPA issued a strategic plan for this purpose in 2018.⁴⁸ In 2019, EPA updated a list of alternative test methods and strategies for new approach methodologies.⁴⁹ The Administrator issued a directive to prioritize efforts to reduce animal testing.⁵⁰

⁴⁰Asbestos; TSCA Section 21 Petition; Reasons for Agency Response, [84 Fed. Reg. 3396 \(Feb. 12, 2019\)](#) (to be codified at 40 C.F.R. ch. I); TSCA Section 21 Petition to Initiate a Reporting Rule Under TSCA Section 8(a) for Asbestos; Reasons for Agency Response, [84 Fed. Reg. 20,062 \(May 8, 2019\)](#) (to be codified at 40 C.F.R. ch. I).

⁴¹[Asbestos Disease Awareness Org. v. Wheeler](#), No. 3:19-cv-00871, 2019 WL 6050752 (N.D. Cal. Nov. 15, 2019).

⁴²[California v. EPA](#), No. 190cv-3807, 2019 WL 6877469, *1 (N.D. Cal. Dec. 17, 2019).

⁴³[Safer Chemicals, Healthy Families v. EPA](#), 943 F.3d 397, 405 (9th Cir. 2019).

⁴⁴[40 C.F.R. § 702](#) et. seq.

⁴⁵[15 U.S.C. § 2602\(4\)](#) (2018).

⁴⁶[15 U.S.C. § 2603\(a\)\(2\)](#) (2018).

⁴⁷*Id.* § 2603(h).

⁴⁸[Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA Program](#), EPA (June 22, 2019).

⁴⁹[List of Alternative Test Methods and Strategies \(or New Approach Methodologies \[NAMs\]\)](#), EPA (Dec. 5, 2019).

⁵⁰[Memorandum](#) from Andrew R. Wheeler, Admin., EPA, to Assoc. Dep’t Admin. et al., EPA (Sept. 10, 2019).