RISK ASSESSMENT & COST CONTAMINATION

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Cost has become a central issue of administrative law. Courts, policymakers, and scholars have weighed in on the extent to which agencies should consider cost when creating regulations. The foremost solution that has gained bipartisan support is a two-step process involving a purely science-based risk assessment stage followed by a cost-conscious risk management stage. Congress has found this approach so compelling that some statutes now mandate the process. This Article examines two such statutes—the Toxic Substances Control Act and the Endangered Species Act—and conducts the first forensic analysis of whether this two-step structure actually binds agencies. The investigation reveals that agencies likely "cheat," and cost considerations contaminate their risk assessments. Consequently, agencies misrepresent risk to the public and undermine their own democratic accountability. The Article next looks to the reasons why an agency might cheat and proposes a triage "step zero" that allows agencies to prioritize risk assessments, conserving resources without deceiving the public.

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Introduction

Something odd is happening in Johnson County, Indiana. The illnesses of old men are afflicting young girls.

In 2012, Karley Brennan was diagnosed with Cutaneous T-Cell Lymphoma.[1] Pocking the body with red rashes, T-cell lymphoma is a cancer that enlarges lymph nodes,[2] typically in men over age fifty-five.[3] Karley's doctors were shocked to make the diagnosis: Their patient was only eight years old.[4]

But Karley's diagnosis was part of a trend. A wave of rare blood, bone, and brain cancers was washing over Johnson County's small community.[5] In the past decade, at least sixty-eight area children—boys and girls—have been diagnosed,[6] outstripping the rate of pediatric cancer in eighty percent of the nation's counties.[7] And although Karley is now in remission, not all children have been as fortunate. A fourteen-year-old who previously inhabited the same apartment as Karley died of cancer in 2015 after her tumor spread in an aggressive manner more common in adult men.[8]

An organized group of local parents has determined that the culprit is something in the air.[9] At least one old, industrial site[10] is leaking a poisonous plume of trichloroethylene ("TCE"), a carcinogen that spreads underground and eventually infiltrates homes.[11] TCE is a colorless fluid often used in dry cleaning[12] and is one of roughly 86,000 commercial chemicals in a list main-

1. Sandra Chapman, *Franklin Families Discover Girls Diagnosed with Cancer Lived in Same Apartment*, 13 WTHR Indianapolis (Dec. 3, 2015), https://perma.cc/P8S6-23NR.
2. *Cutaneous T-Cell Lymphoma*, Lymphoma Res. Found., https://perma.cc/VAG4-WFP4.
3. Chapman, *supra* note 1.
4. *Id.*
5. *See id.*
6. Susan Cosier, *With Dozens of Sick Children, Parents Took a Hard Look at Their Town's Toxic Legacy*, Earth Island J. (June 11, 2019), https://perma.cc/DDV7-BCB2 ("Emma is one of 68 children in Johnson County, Indiana, diagnosed with cancer over the past decade . . . .").
7. Hiroko Tabuchi, *A Trump County Confronts the Administration Amid a Rash of Child Cancers*, N.Y. Times (Jan. 2, 2019), https://perma.cc/3VMK-3LZM.
8. *Id.*
9. *Id.*
10. *See* Sarah Bowman, *Everything You Need to Know About Contamination and Childhood Cancer in Franklin, Indiana*, IndyStar (Jan. 22, 2019), https://perma.cc/RLL8-PGF6 (discussing how cancer-causing chemicals are coming "from at least one former industrial site," and identifying TCE as one of the "the main contaminants in question").
11. *See* Tabuchi, *supra* note 7. The Indiana State Department has determined that the cases do not constitute a cluster of cases meriting further investigation, but passing this step is notoriously difficult, and advocates believe that the link may be made down the road. *See also* Cosier, *supra* note 6 (discussing the current state of investigation and the difficulty of proving clusters).
12. *See* Tabuchi, *supra* note 7.

tained by EPA.[13] The agency recently chose TCE as one of ten chemicals to investigate under the Toxic Substances Control Act ("TSCA"), a federal law requiring EPA to evaluate and manage the risk posed by chemicals.[14] Yet after initially proposing a broad scope for evaluating chemical risk,[15] EPA announced it would not consider how chemicals are disposed or how the disposed chemicals can leak into the environment when evaluating the threat posed by TCE.[16] In short, EPA's newly narrowed focus will ignore communities like Johnson County.

The decision to exclude clear risks from a risk assessment seems to defy logic if the agency is basing its determination on science alone. But there is a likely explanation: The agency is not only considering risk when defining the scope of its assessment, but also the potential cost of regulation. Rather than finding that TCE is dangerous and then facing the political decision of how to regulate, the agency is manipulating its risk analysis to downplay the potential risk, deescalating any subsequent regulatory decisions.

Evaluating risk and determining what to do about it are central jobs of the agencies tasked with keeping us safe. For decades, policymakers have emphasized the importance of separating scientific risk assessments from decisions about how to manage risk.[17]

The first step, risk assessment, is supposed to be governed solely by science to ensure that government officials and the public understand the true risks posed to health or the environment.[18] After determining the risk—of a given chemical, for example—the second step is determining what to do. If no risk is found, then no action is needed. But if the chemical poses a risk, then officials must decide whether and how to manage it, a decision that calls for considerations of cost, politics, and other non-risk factors.[19] For example, an agency might decide to issue labeling requirements, impose additional safety precau-

13. *About the TSCA Chemical Substance Inventory*, EPA, https://perma.cc/46TU-H5TT.

14. Pub. L. No. 94-469, 90 Stat. 2003 (1976) (15 U.S.C. §§ 2601–2697 (2018)).

15. *See* EPA, EPA-740-R1-7004, Scope of the Risk Evaluation for Trichloroethylene 12 (2017) ("EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle.").

16. *See* EPA, EPA-740-R1-7014, Scope of the Risk Evaluation for Trichloroethylene 54–56 (2018) (explaining that ambient air, soil disposal, and exposures will not be part of the risk analysis).

17. *See, e.g.*, William D. Ruckelshaus, *Risk, Science, and Democracy*, 1 Issues in Sci. & Tech. 19 (1985).

18. *See* Nat'l Research Council, Risk Assessment in the Federal Government: Managing the Process 3 (1983) (contrasting risk assessment, defined as the "use of the factual base to define health effects of exposure of individuals or populations to hazardous materials and situations," with "risk management," which considers "social, economic, and political concerns").

19. *See* Ruckelshaus, *supra* note 17, at 28.

tions, or ban the chemical altogether. This second step is called "risk management."

Despite this separation, agencies may be tempted to let non-risk considerations that belong in the risk management phase bleed into the risk assessment stage. If an agency claims no risk exists in a risk assessment or downplays the risk, then the agency can avoid controversial management decisions. This temptation is probably especially potent when the agency suspects that the cost of mitigating the risk fully will be untenable—either because the costs of regulation would be excessively high or because the costs have distributive effects the agency disfavors. This Article terms this phenomenon "cost contamination." Such cost contamination might occur through the unconscious or conscious biases of career employees, but seems especially likely to occur through the conscious orchestrations of political appointees.

Congress has recognized these temptations, and in some cases has expressly legislated a two-step process, requiring agencies to engage in a risk assessment phase based solely on science without considering cost and a risk management phase taking cost into account. But it is not clear such legislative prescriptions work. For example, EPA is pursuing a narrow risk assessment of TCE even though TSCA was amended in 2016 to require just such a two-step process.[20]

The danger of cost contamination is that agencies can covertly favor certain entities, like regulated industries, by doctoring risk assessments. In doing so, agencies can decrease the perceived need to mitigate a risk and minimize or avoid regulation. This approach involves less political blowback than releasing an accurate risk assessment and declining to manage risk out of solicitude for regulated industries. If cost contaminates risk assessments, then Congress and the public may not fully understand the health and environmental risks to which they are exposed. This lack of information hampers their ability to accurately assess agency management decisions. If the public cannot accurately evaluate these decisions, constituents and legislators cannot hold agency decisionmakers responsible when they pursue management decisions with which the public disagrees.

By focusing on cost, this Article connects to a broader discussion about the role of cost in regulation. Since as early as 1979,[21] there has been debate about whether agencies faithfully follow congressional instruction not to consider

20. Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448, 460–61 (2016) (codified as amended at 15 U.S.C. § 2605 (2018)).

21. George C. Eads, *The Confusion of Goals and Instruments: The Explicit Consideration of Cost in Setting National Ambient Air Quality Standards*, *in* TO BREATHE FREELY: RISK, CONSENT, AND AIR 227–31 (Mary Gibson ed., 1985) (discussing how cost considerations feature in setting National Ambient Air Quality Standards, notwithstanding a statutory injunction against cost consideration in the Clean Air Act); Richard L. Revesz & Michael Livermore, *Rethinking Health-Based Environmental Standards*, 89 N.Y.U. L. REV. 1184, 1232 (2014)

cost. In recent years, the Supreme Court has upheld and struck down federal regulations based on the Court's understanding of whether,[22] how,[23] and when[24] agencies can consider cost. These outcomes raise the already high stakes for how agencies profess to consider cost and what they do in practice.

This Article examines whether the two-step framework delivers on its promise to bind agencies in how they consider cost. What follows is an investigation into agencies' tendency to consider cost inappropriately, Congress's attempts to constrain agencies, and agencies' surreptitious efforts to circumvent Congress's rules. Unsurprisingly, these agency efforts do not announce themselves. So this Article undertakes a forensic investigation of agency actions to unearth clues of illegal cost consideration, the first of its kind.

For subjects of investigation, this Article analyzes two laws separated by several decades. The first example is EPA's ongoing implementation of the 2016 TSCA amendments, the only piece of major environmental legislation in the past twenty years. After years of agency inaction, Congress feared EPA was failing to conduct chemical risk assessments because of the anticipated cost of regulation.[25] Congress therefore mandated a two-step process, requiring an initial science-based, cost-blind risk assessment phase, and a second management phase taking cost into account. Nonetheless, this Article will argue that EPA is still considering cost during risk assessment.

The second example predates TSCA but requires slightly more nuance to map onto the two-step process, and thus comes second in this Article. The focus is the response of the U.S. Fish and Wildlife Service ("FWS") and the National Marine Fisheries Service ("NMFS") to the Endangered Species Act ("ESA") amendments of 1978 and 1982.[26] After years in which both agencies listed species as endangered without regard for cost, Congress amended the ESA in 1978, introducing a step that mandated cost consideration.[27] To Con-

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(describing Eads' testimony before Congress after serving on Carter's Council of Economic Advisors).

22. *See generally* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (prohibiting EPA from considering cost when setting National Ambient Air Quality Standards).

23. *See generally* EPA v. EME Homer City Generation, 572 U.S. 489 (2014) (upholding EPA's method of cost consideration in implementing the "Good Neighbor Provision" of the Clean Air Act).

24. *See generally* Michigan v. EPA, 135 S. Ct. 2699 (2015) (striking down EPA regulation because the agency considered cost too late in decision-making process).

25. 162 CONG. REC. H2977 (daily ed. May 24, 2016) (statement of Rep. Polis arguing that the cost-benefit analysis had set too high a bar for the agency to reach, leading to an impotent law).

26. Endangered Species Act Amendments of 1982, Pub. L. No. 97-304, 96 Stat. 1411 (codified as amended at 16 U.S.C. § 1531 (2018)); Endangered Species Act Amendments of 1978, Pub. L. No. 95-632, 92 Stat. 3751 (same).

27. *See* Pub. L. No. 95-632, §§ 2–3, 92 Stat. 3751, 3751–52 (1978) (defining "critical habitat" and requiring the Secretary to investigate federal projects' effects on critical habitat).

gress's dismay, the agencies stopped listing species altogether. Congress determined that the agencies were illegally allowing cost to influence not only risk management decisions, but also listing determinations in the risk assessment phase.[28] In 1982, Congress amended the act again to more explicitly separate the science-based listing determination from the cost-conscious consideration of defining critical habitat.[29] Although Congress' efforts have partly succeeded in constraining how the agencies make decisions, evidence suggests that the FWS and NMFS have still found ways to illegally take cost into account at certain junctures in the listing decision.

These two examples are chosen because in both cases, it is evident that a mandated two-part process was central, rather than incidental, to the laws' amendments and critical for getting bipartisan support. Both laws therefore illustrate the strong perceived need for a two-step approach to cost consideration. The statutes also reveal Congress's concerted effort to rectify the identified problem, and continued shortcomings despite those efforts. Finally, the examples complement each other because of their temporal separation. TSCA demonstrates that these concerns and approaches are pressing today. Meanwhile, the ESA offers decades of data to examine. Furthermore, regulations promulgated in August 2019 propose to significantly shift the way cost factors into species listing and critical habitat decisions.[30] Thus, the past effects of cost on the law have immediate bearing on the present. Although both examples involve environmental regulations, they demonstrate that the same problems occur across different types of environmental harm and different agencies. Moreover, both examples offer generalizable insights likely to apply any time agencies are called on to evaluate and manage risk, environmental or otherwise.

This Article proceeds in three parts. Part I discusses the benefits of a two-step process, the temptation agencies face to ignore that two-step process, and the cost contamination in TSCA and the ESA that Congress sought to address. Part II examines the congressional remedies in each case and then determines whether those attempted remedies have been successful. Part III then organizes the reasons agencies cheat into two primary categories: the desire to escape public scrutiny and the desire to conserve agency resources. The former harms democracy and should be discouraged, but the latter has policy merits.

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28. *See infra* Part II.A.

29. *See* Pub. L. No. 97-304, § 2, 96 Stat. 1411, 1411–12 (1982) (requiring listing determinations to be made "solely on the basis of the best scientific and commercial data available" but requiring critical habitat designation to be made "taking into consideration the economic impact" of the designated habitat).

30. *See* Darryl Fears, *The Trump Administration Weakened the Endangered Species Act Rules—17 Attorneys General Have Sued Over It*, WASH. POST (Sept. 25, 2019), https://perma.cc/TLJ4-YVAV ("The administration would also be allowed to reveal, for the first time in the 45 years since the act was signed into law by the Nixon administration, the financial burden of protecting wildlife.").

Part III next proposes a solution that serves to preserve agency resources while preventing agencies from lying to the public, recommending that agencies openly engage in a "step zero" that prioritizes risk assessments based on a loose, but explicit, consideration of cost before engaging in a science-based, cost-blind risk assessment and cost-based management decision.

Most agency actions ultimately involve accepting some level of risk to avoid untenable economic burdens upon society. This Article does not seek to achieve a world in which agencies can keep everyone completely safe. The goal is to prevent agencies from lying to us about it—from telling us that we are safe when we are not.

I. Goals and Incentives in Agency Rulemaking

To determine what forces influence agency decisions at different points in the decision-making process, it is helpful to understand why a two-step process is desirable and why agencies might be inclined to meld the two steps. The following Section outlines the necessity of considering risk and cost in regulation as well as the virtues of separating the two phases. The second Section then discusses why agencies might be motivated not to follow this paradigm. The third Section analyzes Congress's attempt to remedy EPA's implementation of TSCA prior to 2016. The fourth Section explores how Congress aimed to help agencies consider cost appropriately in the ESA Amendments of 1978. Both examples illustrate the problems Congress sought to fix through amendments.

A. The Importance of a Two-Step Process

The history of EPA elucidates why the two-step process developed. This Section traces that history from burning rivers to invisible agents of disease.

The need for risk assessment arises from situations of uncertainty.[31] If everyone can immediately appreciate the nature of a given risk, it follows that a risk assessment is unnecessary. "[M]ost people [do] not need a scientific panel to tell them that air is not supposed to be brown, that streams are not supposed to ignite and stink, [and] that beaches are not supposed to be covered with raw sewage,"[32] observed William Ruckelshaus, the first EPA Administrator, who served under President Nixon and later under President Reagan.[33] Conceived in 1970,[34] the early EPA was primarily tasked with quelling the sort of obvious

31. *See* Ruckelshaus, *supra* note 17, at 26–27.

32. *See id.* at 25.

33. *See id.* at 19.

34. *See EPA History*, EPA, https://perma.cc/GT7E-NASK.

dangers Ruckelshaus describes.[35] Thus, risk analyses were not central to EPA's mission.

However, once an agency faces uncertain risks, the agency must engage in risk assessment to determine just how dangerous a given threat is at different levels of exposure. Over the course of the 1970s, EPA began to focus increasingly on identifying and regulating carcinogens.[36] EPA had already determined how to address more visible forms of pollution like smog and sewage,[37] and postwar Americans were increasingly anxious about evolving technology and resultant new chemicals in the environment.[38] But identifying carcinogens was a tricky business. On the one hand, it would take significant time and resources on the part of scientists and public officials to determine with certainty that a chemical was carcinogenic.[39] On the other hand, if the agency waited for conclusive proof before regulating a suspected carcinogen, many people might develop preventable cancer in the interim.[40] EPA needed a way to evaluate and regulate uncertain risk.[41]

One theoretical solution to this dilemma was to "play it safe" and eliminate public exposure to any suspected carcinogen. Indeed, in its earliest years, EPA had aimed to fully eliminate some types of health and environmental risks, a vision seemingly shared by Congress.[42] But that approach would call for banning thousands of commercially important possible carcinogens[43]—and likely

35. *See* Sheila Jasanoff, *Science, Politics, and the Renegotiation of Expertise at EPA*, 7 OSIRIS 194, 197–98 (1992); *see also* Ruckelshaus, *supra* note 17, at 25.

36. *See* Jasanoff, *supra* note 35, at 201 (outlining the shift to focusing on carcinogens); *see also* Ruckelshaus, *supra* note 17, at 25 (discussing the shift to debating carcinogenic risk after controlling "the grosser sorts of pollution").

37. Ruckelshaus, *supra* note 17, at 25 ("When I left EPA in 1973, the means for ending the worst forms of pollution were fairly well in hand.").

38. *See* Jasanoff, *supra* note 35, at 201 (summarizing postwar Americans' concerns about health and cancer as motivating this shift).

39. *See id.* at 202 ("EPA had to identify and regulate suspected carcinogens before there was conclusive proof that they did indeed cause cancer in humans."); Ruckelshaus *supra* note 17, at 25 (noting that "only the slow mills of science can grind out the truth" but public officials "do not have that kind of time").

40. *See* Jasanoff, *supra* note 35, at 202 (discussing this tension regarding carcinogen identification); *see also* Ruckelshaus, *supra* note 17, at 29 (critiquing the position that regulations should be based solely on demonstrated connections between substances and human health effects).

41. *See* Ruckelshaus, *supra* note 17, at 26 (discussing the new centrality of uncertainty and the necessity for risk assessment).

42. *See* Elizabeth L. Anderson, *The Red Book in Context: Science at the Center*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT 1197, 1198 (2003) (referencing EPA's early goal of achieving zero risk); *see also* Ruckelshaus, *supra* note 17, at 21–22, 25 (referring to early EPA and congressional goals to achieve zero risk).

43. *About the TSCA Chemical Substance Inventory*, EPA, https://perma.cc/M45F-V3RT (stating that the inventory of chemicals eligible for assessment and regulation is at 85,000).

force the United States into a pre-industrial state of existence.[44] In the pollution context, Professors Richard Revesz and Michael Livermore call this the "stopping-point problem": Because many pollutants could harm health at any level, the risks associated with the pollutants could not be completely eradicated without banning emissions altogether.[45] Thus, EPA had to come up with a method to differentiate among possible risks to determine which were worth regulating.

In 1976, EPA announced a new two-step regulating process.[46] EPA Administrator Russell Train explained that two decisions must be made with respect to each suspected carcinogen: "The first decision is whether a particular substance constitutes a cancer risk. The second decision is what regulatory action, if any, should be taken to reduce that risk."[47] In the first step, the goal was to identify substances tied to a "statistically significant excess incidence" of cancerous tumors.[48] The agency would rely on statistically significant correlation rather than "proof" of causation because the latter would be an unusable standard. It was virtually impossible to establish causation with certainty, EPA explained, in part because studies tended to be done with non-human animals, rather than people.[49]

While the first step would focus on scientific analyses to identify the carcinogenic risk of a substance, the second step would require consideration of additional factors like "the benefits conferred by the substance, the availability of substitutes, and the costs of control of the substance."[50] If the carcinogenic risk was small relative to the costs associated with regulation,[51] then EPA would either not regulate the chemical at all or do so in a limited fashion.[52]

This two-step approach emphasized the importance of considering cost in regulation while also recognizing that regulatory cost was analytically unrelated to whether a substance caused cancer. The same announcement separated over-

44. *See* Ruckelshaus, *supra* note 17, at 27 (calling such a goal "impossible . . . for an industrial society").

45. *See* Revesz & Livermore, *supra* note 21, at 1186–87 (2014) (defining the "stopping-point problem").

46. *See* Health Risk and Economic Impact Assessments of Suspected Carcinogens, 41 Fed. Reg. 21,402, 21,403 (May 25, 1976) [hereinafter EPA Two Step]; *see also* Anderson, *supra* note 42, at 1198.

47. EPA Two Step, *supra* note 46, at 21,403.

48. *Id.*

49. *Id.* at 21,404.

50. *Id.* at 21,403.

51. In the context of this Article, "cost" of regulation refers not only to the costs directly borne by the agency in devising and enforcing a regulation, but also the cost to the public, which would include foregoing the benefits of a carcinogenic substance. The fact that Administrator Train listed benefits of the substance separately from the "cost of control" suggests that at least in this context, he thought of them distinctly. *See id.*

52. EPA Two Step, *supra* note 46, at 21,403.

sight of the risk assessment phase by introducing a "Cancer Assessment Group," an advisory board of senior EPA scientists who, together with outside consultants, would evaluate available data related to possible carcinogenic substances and make recommendations about risk.[53] "These analyses," the announcement stated, "will be directed toward risk assessment and will be conducted independently of economic impact analyses."[54]

Early attempts to systematize the first step, risk analysis, emphasized usability over sophistication. An early prototype of risk assessment drafted by EPA in 1972 was used a few years later to justify banning DDT,[55] the carcinogenic pesticide made notorious by Rachel Carson's *Silent Spring*.[56] This prototype was composed of seven "cancer principles," or guidelines for identifying carcinogens, which included standards for how the agency would evaluate available scientific studies of a potential carcinogen.[57] For example, "negative results" suggesting a substance did not cause cancer "should be considered superseded by positive results" suggesting a substance did cause cancer,[58] and animal studies should include "two species of animals of both sexes."[59]

Unsurprisingly, pesticide manufacturers were displeased by EPA's risk assessments, and lawsuits challenging agency findings ensued.[60] The agency quickly realized it would need more than a list of seven rules of thumb for its risk assessments to reliably survive legal challenges.[61]

At the same time, EPA was facing challenges from within its own walls. Anne Gorsuch, President Reagan's first appointee to head EPA (and Justice Neil Gorsuch's mother), oversaw a deregulatory agenda at the agency that included a twenty-five percent budget cut and an unexplained delay cleaning up a toxic waste dump and Superfund site in Southern California.[62] Leaked documents to Congress revealed that Gorsuch likely hoped the delay would weaken the Superfund regulation, protect polluting companies, and hobble California

53. *Id.*

54. *Id.*

55. *See* Jasanoff, *supra* note 35, at 203 (calling EPA's "seven cancer principles" for DDT the agency's first approach at identifying carcinogens).

56. *See generally* RACHEL L. CARSON, SILENT SPRING (1962); *see also The Story of Silent Spring,* NRDC (Aug. 13, 2015), https://perma.cc/C6AC-L3S2 (describing *Silent Spring*'s exposure of DDT).

57. Nathan R. Karch, *Explicit Criteria and Principles for Identifying Carcinogens: A Focus of Controversy at the Environmental Protection Agency*, *in* 2 NAT'L RESEARCH COUNCIL, DECISION MAKING IN THE ENVIRONMENTAL PROTECTION AGENCY 131 (1977).

58. *Id.* at 132.

59. *Id.*

60. *See* Jasanoff, *supra* note 35, at 203–04 (referring to EPA's increasingly detailed risk assessments in response to litigation from pesticide manufacturers).

61. *Id.*

62. Scott Tong, *What Happened When an Industry-Friendly EPA Leader in the '80s Went Too Far*, MARKETPLACE (May 2, 2017), https://perma.cc/A984-35KG.

Governor Jerry Brown, a Democratic candidate for the U.S. Senate.[63] Gorsuch resigned amid scandal in 1983, and her deputy went to jail for lying to Congress.[64] Ruckelshaus was reappointed EPA Administrator and wrote an article championing a two-step regulatory approach shortly thereafter.[65]

EPA was not the only agency facing pushback over its handling of carcinogenic risk. The Occupational Safety and Health Administration ("OSHA"), established the year after EPA, was chided by the Supreme Court in 1980 for promulgating a costly regulation to protect workers against a carcinogenic risk from low benzene concentrations.[66] The Court overturned the regulation,[67] inspiring *The New York Times* editorial board to publish an op-ed titled *So, It's a Carcinogen, But How Bad?*[68] In the op-ed, editors expressed concern that regulators were treating all carcinogens equally, regardless of potency or rarity of the carcinogen or the cost of regulation.[69] "No amount of a carcinogen is good," concluded the editorial, "[b]ut before society decides how to allocate scarce billions for health, it is proper—indeed, essential—to ask: How much is how bad?"[70]

By 1983, OSHA, the Food and Drug Administration, and the Consumer Product Safety Commission were all facing challenges similar to EPA's with respect to risk regulation.[71] The National Academy of Sciences convened a committee at the behest of Congress to separate risk assessment from regulatory policy decisions and develop guidelines for risk assessment that could be used across agencies.[72]

The result was the National Research Council's influential "Red Book," named for its color, an influential document that essentially formalized and endorsed the two-step process, laying out the separate phases of risk assessment and risk management.[73] The Red Book defined "risk assessment" as "the char-

63. *Id.*

64. *Id.*

65. *Id.; see also* Ruckelshaus, *supra* note 17 (explaining Ruckelshaus' two-step regulatory process).

66. Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst., 448 U.S. 607 (1980); Editorial, *So It's a Carcinogen, But How Bad?*, N.Y. Times, July 9, 1980, at A18.

67. *Indus. Union Dep't*, 448 U.S. at 640.

68. Editorial, *supra* note 66.

69. *See id.* (beginning by noting the differences among carcinogens' risk and regulators' failure to recognize these differences).

70. *Id.*

71. *See* Anderson, *supra* note 42, at 1198–99 (listing these agencies and discussing an effort to bring "continuity to the risk assessment process" across the four agencies).

72. *Id.* at 1197–98.

73. *See id.* at 1200 (referring to the book as a "landmark document that has enduring impacts on the process and practice of risk assessment and risk management"); Thomas A. Burke, *The Red Book and the Practice of Environmental Public Health: Promise, Pitfalls, and Progress*, 9 Hum. & Ecological Risk Assessment 1203, 1203 (2003) (describing the Red Book as an "essential reading[ ]" that has had a "profound impact on . . . regulatory decision-mak-

acterization of the potential adverse health effects of human exposures to environmental hazards."[74] Relying on reviews of current research to extrapolate the extent of health risks to humans at different levels of exposure, risk assessment should produce a summary judgment on "the existence and overall magnitude of [a] public health problem" and note any uncertainties associated with the final judgment.[75]

The Red Book broke down risk assessment into steps that are still widely used today.[76] This model can work across multiple organizational forms[77] and can be modified to accommodate different statutes.[78] When faced with a potential risk, agency scientists conduct a literature review and reach a conclusion of the seriousness of the risk based on that review.[79] In the case of health risks such as carcinogens—a topic on which the Red Book focused heavily but not exclusively[80]—the committee identified four typical steps that are still commonly used today: hazard identification (identifying a causal link to a particular health effect), dose-response assessment (the magnitude of exposure needed to cause the health effect), exposure assessment (the determination of exposure before or after applying regulatory controls), and risk characterization (a summary of the risk, including the degree of uncertainty).[81]

In the Red Book, agencies had a new gold standard for regulating in the face of uncertainty, carcinogenic or otherwise. Risk assessment was to be based solely on scientific studies about a potential threat's dangers to health or the environment. The cost to industry of mitigating a risk, the availability and cost of safer alternatives, the costs to the agency of enforcement—none of these considerations were relevant to answering the question of whether a substance

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ing"); Michael Dourson & Jacqueline Patterson, *A 20-Year Perspective on the Development of Non-Cancer Risk Assessment Methods*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT 1239, 1239 (2003) ("Separation of the science of risk assessment from the policy of risk management is one of the most oft-cited recommendations.").

74. NAT'L RESEARCH COUNCIL, *supra* note 18.

75. *Id.*

76. *See, e.g.*, *Human Health Risk Assessment*, EPA, https://perma.cc/L6M3-8Y79 (listing the same stages of risk assessment as outlined in the Red Book); Joseph V. Rodricks, *Chemical Risk Assessments and Their Uses in Decision-Making,* ILSI NORTH AMERICA (July 2017), https://perma.cc/3H66-AVQD (referring both to EPA and to the Food and Drug Administration ("FDA") and presenting the four steps of risk assessment as a "standardized four-step framework"). Rodricks worked for fifteen years as a scientist at the FDA. *Joseph V. Rodricks*, RAMBOLL, https://perma.cc/K8JP-5JKD.

77. *See* NAT'L RESEARCH COUNCIL, *supra* note 18, at 89–93 (laying out different potential organizational structures for separated risk assessment and management).

78. *See id.* at 42–43 (describing the different statutes governing decision-making across the agencies) .

79. *See id.* at 107 (describing the job as conducting literature reviews).

80. *See id.* at 17–18 (stating that while the report is directed primarily at carcinogenic risk, it could apply to other types of risk).

81. *Id.* at 3.

was dangerous in the first place. A carcinogen causes cancer regardless of whether a marketable alternative exists; small toys are choking hazards regardless of whether regulating the toys would cost manufacturers dearly.

Ultimate management decisions, however, must inevitably incorporate politics, cost, and other policy values. If a rare, weak carcinogen only causes death in one in one billion people, few would argue it merits the same regulatory investment as a common, potent carcinogen that causes the death of one in one thousand people. Depending on the cost of regulation and the values of the policymakers, the former may merit no regulation at all, given that statistically the substance would fell only seven people worldwide. Relatedly, if two carcinogens cause cancer with the same frequency, but only one has readily affordable alternatives, the regulatory management decisions for each carcinogen will likely be different. The former is more easily banned than the latter, the benefits of which need to be weighed against the costs associated with cancer.[82]

The virtue of separating risk assessment from risk management is its assurance that the public will be provided with accurate information by which to judge the ultimate management decision. This is not to say that risk assessment can ever be *completely* divorced from policy judgments. Scientists assessing risk must review many studies, some provided by biased parties, and emerge with a single determination of how dangerous a substance, product, or scenario is. To accomplish this task, scientists must make all kinds of choices about how to synthesize available information. For example, the decision that studies with positive results—those linking a substance to poor health outcomes—should outweigh studies with negative results finding no such link is a policy determination.[83] Valuing the former more than the latter is a conservative approach from a health perspective because it errs on the side of finding a borderline substance dangerous. Similarly, policy tradeoffs are also implicated in determining the level of statistical significance necessary to deem positive results reliable.[84] The higher the level of statistical significance needed, the likelier studies will be excluded from consideration, and the less likely substances are to be found risky. A normative framework that values minimizing regulation would argue in favor of requiring a very high degree of statistical certainty while a framework that values minimizing health risks would argue the opposite. Agen-

82. Although cost-benefit analysis is one way of considering cost in risk management, it is not specifically prescribed by the two-step approach. Rather, cost must be taken into account in some form. *See* John Wood, *Can We Teach Old Laws a New Risk? Federal Environmental Law, Risk Management, and Contamination of U.S. Water Supplies with Pharmaceutical and Personal Care Products*, 21 N.Y.U. ENVTL. L.J. 193, 209–28 (2014) (discussing multiple economic means of carrying out risk management, including cost-benefit analysis, cost-effectiveness analysis, risk-risk tradeoff, and regulatory budget).

83. *See id.* at 29–33 (listing policy judgments made in risk assessments).

84. *See id.* at 29.

cies face a slew of such decisions, and they have accordingly published standardized guidelines for addressing these questions across risk assessments.[85]

But the fact that some policy determinations are inevitable does not mean that the levees should be lowered to allow all non-science considerations, or that it is not worthwhile to separate risk assessment and risk management. We accept that sports have standardized rules that might benefit one side over the other—the person who serves first in tennis has an advantage[86]—but that does not mean a referee can consider any factors, like the popularity of a player or the outcome of a game, when calling a serve. The fact that scientists must follow value-laden guidelines when weighing the relative importance of scientific studies does not mean it is appropriate for them to consider the potential cost of regulation when determining whether a substance causes cancer. Risk assessment and risk management still have fundamentally different goals and call upon different kinds of expertise.[87]

Thus, even critics who question the ability of agencies to fully divorce risk assessment from policy endorse the separation between risk assessment and risk management.[88] Although the process and institutional organizations vary across federal agencies, separating risk assessment from risk management has become administrative canon. The first stage, risk assessment, is a scientific inquiry with the goal to provide the agency and the public with an accurate understanding of the risks posed by a given phenomenon. The second stage, risk management, incorporates cost and politics to decide whether a risk is worth regulating, and if so, how. Numerous agency guidelines reinforce this division.[89] Additionally,

85. *See* INST. OF MED., ENVIRONMENTAL DECISIONS IN THE FACE OF UNCERTAINTY 109–11 (2013) (listing several examples of agencies publishing guidance on how to conduct risk assessments); *see also* EPA, *Risk Assessment Guidelines*, https://perma.cc/49SH-LMCC (listing the many guidelines for different types of risk assessment within EPA).

86. *See* Franc Klaassen & Jan R. Magnus, *Does the "Serving-First Advantage" Actually Exist?*, OUPBLOG (July 1, 2014), https://perma.cc/8XGR-Q8NW ("[I]t is wise to elect to serve after winning the toss.").

87. *See* NAT'L RESEARCH COUNCIL, *supra* note 18, at 151–52 (recommending separation of the two stages, despite the inevitability of some policy considerations in defining the parameters in risk assessment).

88. *See* Jasanoff, *supra* note 35, at 215–16 (citing a "blending of the norms of scientific and administrative practice" but then endorsing the "creation of a credible scientific forum" for conducting risk assessments separately); NAT'L RESEARCH COUNCIL, *supra* note 18, at 151–52.

89. *See, e.g.*, FDA, GUIDANCE FOR INDUSTRY: Q9 QUALITY RISK MANAGEMENT 4–5 (2006), https://perma.cc/T264-G8KV (separating risk assessments from "risk control," which FDA evidently uses as a stand-in term for risk management decisions, using risk management to refer to the culmination of phases in decision-making); *Hazard Identification and Assessment*, OSHA, https://perma.cc/K7EW-MWCX (outlining best practices for risk assessments as distinct from hazard prevention and control); *Hazard Prevention and Control*, OSHA, https://perma.cc/UEC7-D3TF; *Risk Assessment Guidelines*, EPA, https://perma.cc/ARM2-K79Y (describing risk assessments as "based on sound science" and cataloguing the multiple guide-

many agencies publish risk assessments separately from risk management decisions.[90]

This tidy approach works only if agencies follow their own rules. The next Section will discuss what would motivate an agency to "cheat."

B. The Seduction of Cost Consideration

Given the benefits of the two-step process and agencies' apparent embrace of the approach, one might expect agencies to adhere to the framework. But there are incentives for an agency to depart from protocol. In particular, there are reasons an agency might allow considerations that belong in Step Two to contaminate Step One.

To begin, it is useful to define what the term "cost" encompasses for the purposes of this Article. The term is intended to cover the same kinds of cost that would be covered by a cost-benefit analysis of the type agencies commonly conduct when promulgating regulations.[91] Not all regulations require a formal cost-benefit analysis,[92] and some agencies are more inclined than others to use these analyses.[93] Nevertheless, these costs are likely to be considered in some fashion by an agency when deciding how to manage a risk.[94] The "cost" of a regulation includes governmental costs of implementing and enforcing a regulation, such as hiring new employees or investing in a communications campaign. But "cost" also refers to the anticipated costs incurred by the regulated industry, such as investments in new equipment or opportunity costs. And, costs to other members of the public are included.

These sorts of costs underlie the resistance to agency actions discussed in the previous Section. Dampening such resistance to agency action no doubt appeals to agency officials.

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lines EPA has devised to govern risk assessments, as distinct from risk management, which EPA discusses separately at *Risk Management*, EPA, https://perma.cc/2LFE-SW2C).

90. *See, e.g.*, INST. OF MED., *supra* note 85, at 118–19 (discussing the separate 2003 publication of an underlying risk assessment of listeriosis by health agencies and 2008 compliance policy guide, determining how to manage the risk).

91. *See, e.g.*, EPA, GUIDELINES FOR PREPARING ECONOMIC ANALYSES 8-1 (2010) (defining costs in cost-benefit analysis as "social cost" or "the total burden that a regulation will impose on the economy").

92. *See id.* at 2-1 to 2-5 (discussing the various executive orders and statutes that determine the requirements for economic assessments of regulations).

93. *See generally* Michael A. Livermore, *Cost Benefit Analysis and Agency Independence*, 81 U. CHI. L. REV. 609 (2014) (chronicling how EPA's frequent use of cost-benefit analysis enabled it to set many of the standards governing the methodology that other agencies would eventually adopt).

94. For example, Executive Order 12,866 requires cost-benefit analyses for any "significant regulatory action," usually triggered by having an effect on the economy of $100 million or more. *See* EPA, *supra* note 91, at 2-2; Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (1993).

Considering cost during risk assessment offers a potential way for an agency to decrease the controversy surrounding a given regulation. Imagine for example, that an agency is assessing a commercial substance used to make durable plastics, Substance X, to determine if it is carcinogenic. Agency scientists conduct a risk assessment and determine that Substance X does cause cancer, and that one in one million children between ages zero and four will die annually from exposure. But suppose also that there are no affordable industry alternatives to Substance X, and Substance X is currently considered critical to making cars. The agency considers banning Substance X, but the costs of such a regulation—billions of dollars in costs to car manufactures and loss of welfare to millions of people who want cars but can no longer afford them—outweigh the benefits of the regulation, saving the lives of roughly twenty children nationwide.[95] The agency therefore decides not to regulate Substance X.[96]

Under the two-step approach, the agency ought to release (1) a risk assessment showing the true risk of Substance X as well as (2) a cost assessment explaining the agency's decision not to regulate. But this rule might meet with considerable public resistance. After all, the agency would have to acknowledge that its regulation tolerates the death of twenty children per year. Even if the majority of Americans believe preserving the auto-industry is worth that price, some may not, and it is likely car drivers everywhere will feel a little worse knowing that they are exposing their young children to a carcinogen, even if the risk of death is small.

But what if the agency has a hunch from the beginning that banning Substance X would be infeasible? Everyone at the agency, scientists and policymakers alike, know that Substance X is critical to cars and not easily replaceable. In other words, everyone knows that the costs of regulation would be so high that it is incredibly unlikely any ban will ever come to pass. The agency has a strong incentive to skew its risk assessment to find that Substance X is less dangerous or even safe. If no risk is found, the agency is spared the investment of further resources required to complete the risk management phase. Scarce employee time can instead be spent investigating other substances with a better chance of being regulated. Moreover, the agency does not have to worry as much about public blowback for its decision. If the public believes that Substance X is safe, then there is no controversy over not regulating it.

The above situation might seem harmless; if the regulation is not worth making, why not tell a white lie to make the public feel better about the unregulated risk? One reply is that lies, even those justified in the eyes of agency officials, tend to erode public trust in agencies over the long term and under-

95. *See* Kids Count Data Center, Annie E. Casey Found., https://perma.cc/J3PN-LV2H (finding that, as of 2017, there were roughly twenty million children between ages zero and four in the United States).

96. For the sake of simplicity, we can assume that there are two regulatory alternatives in this case: banning or no regulation at all.

mine agency legitimacy.[97] This would pose a real threat to the way agencies operate in American democracy.

In any event, one need only tweak the example slightly to make cost contamination seem more nefarious. Imagine now that in fact the costs of regulating Substance X were not particularly large relative to the benefits to society as a whole. Imagine instead that the agency's concerns were not with the *magnitude*, but with the *distribution* of cost: The rule's benefits would go to children, who have little political power, while the rule's costs would fall on the auto industry. Imagine that for whatever reason, the agency head is especially chummy with automakers. In such a case, the regulation is unlikely to occur, just as in the first scenario, again because of cost considerations. But here, the regulation is cost-justified. The only reason the rule will not be promulgated is that its costs fall on politically powerful parties. Rather than openly acknowledge in the risk management phase that the agency wants to protect the auto industry and thus does not wish to regulate, the agency can disguise its decision in a risk assessment.

When an agency allows cost to contaminate its risk assessment, the agency issues an inaccurate finding that misleads the public. If the public has no idea of the risk it is facing because the agency has affirmatively lied about the risk, the public cannot effectively evaluate agency management decisions. Accordingly, the public cannot hold agencies—nor the presidential administrations overseeing them—responsible, undermining democratic accountability.[98]

Enter Congress. Positive political theorists have argued that by prescribing procedures for agency decision-making, Congress restrains rogue agencies that would otherwise deviate from statutory mandates.[99] According to this concep-

97. *See* Craig W. Thomas, *Maintaining and Restoring Public Trust in Government Agencies and Their Employees*, 30 ADMIN. & SOC'Y 166, 185–86 (1998) (describing how agency lies erode public trust, even when those lies seem justified to officials).

98. A popular theory of agency legitimacy relies on the fact that agencies answer to the President, and that voters may remove the President if they do not like agency policy. *See* Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461, 466 (2003) (explaining that this model is "flourish[ing] today").

99. *See, e.g.*, Michael Asimow, *On Pressing McNollgast to the Limits: The Problem of Regulatory Costs*, 57 L. & CONTEMPORARY PROBS. 127, 129 (1994) (summing up the supposed importance of procedures as "[t]he procedure energizes constituents who will alert legislators to instances in which agencies stray from the path of righteousness."); Mathew D. McCubbins et al., *Administrative Procedures as Instruments of Political Control*, 3 J. L. ECON. & ORG. 243, 244 (1987) (explaining how procedures are a means of controlling agencies that limit the range of feasible policy options); McNollgast, *The Political Origins of the Administrative Procedure Act*, 15 J. L. ECON. & ORG. 180, 181 (1999) ("By reducing administrative discretion, formal procedures create transaction costs that increase the time and resources needed to change policy."); Roger Noll, *The Political Foundations of Regulatory Policy*, 3 J. INST. & THEORETICAL ECON. 377, 403 (1983) ("[T]he regulatory process provides some opportu-

tion, administrative agencies present a so-called "principal-agent problem."[100] Congress, the principal, must delegate significant decision-making to agencies because legislators lack the time and expertise to make all administrative decisions.[101] Congress also may want to dodge tough political choices.[102] But agencies, the "agents," may have different incentives from the authorizing Congress due to political agency heads or other reasons, and may ultimately choose either to shirk responsibility or exceed their statutory mandates.[103] Congress and the public are at a disadvantage in overseeing rogue agencies because of information asymmetry; only the agency knows the basis for its decisions.[104] By statutorily prescribing agency procedures for decision-making and building disclosure into the process, these theorists argue, Congress can force agencies to honor the values underlying their statutory authority and share information with the public.[105]

But traditional solutions involving procedural remedies assume that agencies will be truthful when summarizing the decision-making process for the public.[106] If agencies claim not to consider cost during one step of the process while covertly taking cost into account, statutory procedures do little to alleviate informational disadvantages on the part of Congress or the public. Nevertheless, Congress has attempted to rein in agency discretion through procedural requirements. The rest of this Part explores specific instances where Congress has attempted to prescribe a two-step procedure.

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nity for checking the particularistic pressures that are missing in public expenditure programs or administrative methods lacking procedural safeguards.").

100. *See* McCubbins et al., *supra* note 99, at 247 ("The problem of bureaucratic compliance has long been recognized as a principal-agent problem."). Work in this area tends to simplify dynamics by treating Congress as a single entity and the agency as another single entity, though both in fact comprise many individuals with diverse incentives. *See id.* at 248 (noting that in Congress there are many principals, but that the analysis ignores this complexity). For simplicity, this Article continues the approach of treating Congress as one entity and the agency as the other.

101. *See* McNollgast, *supra* note 99, at 187–88 ("Presumably if elected officials delegate policy to agencies at some procedural cost, the reason is that the costs of procedures are not so great as the alternative costs of specifying policies in detail on their own . . . .").

102. *See* Colton C. Campbell, *Creating an Angel: Congressional Delegation to Ad Hoc Commissions*, *in* 25 CONGRESS & THE PRESIDENCY 161, 163 (1998) (discussing how legislators can "shift blame" through delegation).

103. *See* McNollgast, *supra* note 99, at 184 (describing "agency drift").

104. *See* McCubbins et al., *supra* note 99, at 244 (discussing how procedures can "mitigate informational disadvantages faced by politicians in dealing with agencies").

105. *Id.*

106. At least one paper has advocated for increased penalties to disincentivize lying, even with increased procedures, seemingly acknowledging that procedures alone do not protect against dishonest agencies. *See* Asimow, *supra* note 99, at 131–32 (discussing penalties proposed by Arthur Lupia and Mathew D. McCubbins, *Designing Bureaucratic Accountability*, 57 L. & CONTEMP. PROBS. 91 (1994)).

C. The Toxic Substances Control Act

In 1976, a proliferating number of untested chemicals were seeping into American life and causing public concern. Congress responded with TSCA.[107]

Five years earlier, the President's Council on Environmental Quality had released a report that tens of thousands of unregulated chemicals were entering the American marketplace through various commercial uses.[108] Although recently enacted laws like the Clean Air Act and the Clean Water Act targeted the emission of dangerous chemicals, no existing law aimed to curb the use of these chemicals to begin with.[109] Not only did the federal government lack a mechanism for regulating these chemicals, but it also lacked a means of tracking which harmful chemicals were circulating.[110] Evidence suggested that in some cases, chemical manufacturers and processors who knew substances caused cancer hid the information from the government and the public.[111] In one case, dangerous chemicals led to a rash of severe neurological disorders in workers involved with pesticide manufacturing.[112] A sense of urgency therefore imbued the passing of TSCA.

TSCA aimed both to produce information about commercial chemicals and to regulate dangerous ones. The Act required companies to notify EPA before manufacturing a new chemical or using an existing chemical in a new way.[113] TSCA further enabled EPA to require industries to test chemicals for safety if the substance possibly presented an "unreasonable risk of injury to health or the environment"[114] or if the environment or humans would be exposed to the chemical "in substantial quantities."[115] If, in light of these studies provided by industry and other sources, EPA found "a reasonable basis to conclude . . . a chemical substance . . . presents or will present an unreasonable risk of injury to health or the environment," the agency could regulate the substance.[116] Such regulation could entail banning the chemical, limiting the

107. Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended 15 U.S.C. §§ 2601–2697 (2018)).

108. *See* Colin P. Eichenberger, *Improving the Toxic Substances Control Act: A Precautionary Approach to Toxic Chemical Regulation*, 72 A.F. L. REV. 123, 125 (2015) (citing 55,000 such chemicals); Sanne H. Knudsen, *Regulating Cumulative Risk*, 101 MINN. L. REV. 2313, 2367 (2017) (citing over 61,000 such chemicals at the time of TSCA's adoption).

109. Knudsen, *supra* note 108, at 2367.

110. *See* Eichenberger, *supra* note 108, at 125–26 (discussing the lack of information the government had about chemicals in use).

111. *Id.* at 126.

112. *Id.* at 127.

113. 15 U.S.C. § 2604(a)(1)(A), (B) (2018).

114. *Id.* § 2603(a)(1)(A)(i).

115. *Id.*

116. *Id.* § 2605(a).

amount of the chemical produced, labeling requirements, or other types of safeguards.[117]

Although the statute repeatedly referenced "unreasonable risk," it never answered the critical question of what exactly an unreasonable risk was.[118] Surely the harm a substance was likely to cause constituted part of the equation, but the phrase "unreasonable risk" suggested that some risks must exist that were reasonable. If all risks were not automatically unreasonable, lawmakers were clearly intending some other factor to be considered in addition to the risk of harm. EPA interpreted the phrase by weighing "the severity and the probability that harm will occur against the effect of the final regulatory action on the availability to society of the benefits of the chemical."[119]

Thus, TSCA required EPA to consider cost at every step of the process, as underlined by language in the conference report accompanying the law. Before requiring a company to test a chemical, EPA had to "consider reasonably ascertainable costs and other burdens associated with conducting tests and publish[ing] such considerations in the Federal Register."[120] The agency had to engage in the same analysis before determining if it was appropriate to regulate.[121] This hindered the ability of the agency not only to regulate but also to gather information. For example, EPA might suspect a substance to be toxic, but if it also determined that it would be costly to require the chemical manufacturer to do testing, the agency would be prohibited from requiring the company to produce further information. The agency could require testing if it deemed the benefits of testing would outweigh the costs to industry, but this was difficult to prove; after all, the reason the agency was requiring testing in the first place was that it lacked sufficient information about the chemical in question.[122]

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117. *Id.* § 2605(a)(1)(A), (B).

118. *See* Eichenberger, *supra* note 108, at 129.

119. Premanufacture Notification Exemptions, 60 Fed. Reg. 16,316, 16,328 (Mar. 29, 1995) (to be codified at 40 C.F.R. pt. 723) (citing H.R. REP. NO. 94-1341 at 14 (1976)).

120. *See* H.R. REP. No. 94-1679 at 59, 61 (1976) (Conf. Rep.). This "unreasonable risk" analysis applied unless the agency could prove a given substance about which insufficient information was available would be released and cause "substantial environmental or significant or substantial human exposure." What constituted "significant or substantial" exposure was also undefined. *Id.*

121. *See id.* at 62 (discussing how even if the agency has a basis to conclude a substance presents "a significant risk of serious or widespread harm to human beings," the agency may nonetheless publish a finding that the risk is not unreasonable).

122. *See* Kristen Ekey, Note, *Tick Toxic: The Failure to Clean Up TSCA Poisons Public Health and Threatens Chemical Innovation*, 38 WM. & MARY ENVTL. L. & POL'Y REV. 169, 183 (2013) (discussing how under the 1976 text, TSCA placed the burden of proving an "unreasonable risk" on EPA, how in practice EPA seldom exercised its limited authority to force chemical testing, and how manufacturers were not required to submit extra information until EPA had proven a chemical posed an "unreasonable risk").

These cost-related hurdles to regulation meant that between 1976 and 2015, EPA used TSCA to regulate only five of 84,000 listed chemicals.[123] For the last twenty years of that time period, the agency issued zero TSCA regulations.[124]

The death knell for TSCA came from a Fifth Circuit ruling in 1991 that compounded the burdensome cost analyses already ascribed to the statute.[125] At stake was EPA's regulation banning most uses of asbestos, an act the agency took pursuant to its authority under TSCA.[126] Asbestos was the quintessential toxic substance—a carcinogen known to be dangerous since 1964[127] with a dizzying omnipresence in everything from roof shingles to home insulation.[128] But the court struck the regulation down, claiming that EPA failed to muster substantial evidence to support its rule.[129]

Because TSCA seemingly required cost consideration at every step of the process, the court decided that EPA had a burden to justify not only the costs of regulation in general, but the costs of the agency's specific regulatory approach. Focusing on the "unreasonable risk" language of the statute, the court determined that EPA's ten years of work and thousands of pages of documenting the dangers of asbestos could not satisfy the statute's standard.[130] The statute, the court noted, did not allow EPA to reduce all risks, but only to reduce *unreasonable* risks.[131] To identify such risks, the court determined the agency had to engage in a cost-benefit analysis not only to prove a given regulation's environmental and health benefits outweighed the economic effects of the regulation, but also to determine the regulation was the "least burdensome" of regulatory options.[132] The ban was enjoined, despite the fact that 12,000 to 15,000 Americans died annually from asbestos exposure.[133]

The failure to regulate a poster child for toxicity like asbestos weighed heavily on legislators, who eventually amended TSCA in 2016 through the

123. *See* Eichenberger, *supra* note 108, at 133, 137 (giving the current number of chemicals in the TSCA inventory and the number regulated, respectively).

124. *See id.* at 137.

125. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1207 (5th Cir. 1991); *see* Eichenberger, *supra* note 108, at 137.

126. *See Corrosion Proof Fittings*, 947 F.2d at 1207.

127. *See* Sonya Lunder, *Asbestos Kills 12,000-15,000 People Per Year in the U.S.*, Asbestos Nation, https://perma.cc/HR3Z-3VP7.

128. *See* World Health Org., Chrysotile Asbestos 3 (2014), https://perma.cc/AC6D-TCVE.

129. *Corrosion Proof Fittings*, 947 F.2d at 1207.

130. *See* Knudsen, *supra* note 108, at 2373.

131. *Corrosion Proof Fittings*, 947 F.2d at 1215.

132. *Id.* at 1216–17, 1222.

133. *See* Lunder, *supra* note 127.

Frank R. Lautenberg Chemical Safety for the 21st Century Act.[134] Members of Congress blamed the TSCA fiasco on cost contamination. The Senate report noted that "EPA's application of the 'unreasonable risk' standard for regulatory action has been hampered by the statutory language itself, which suggests that cost and benefit considerations must be applied to the agency's decisions on the health and environmental risks posed by a chemical substance."[135]

Lawmakers agreed that the role of cost in TSCA needed to be scaled back, but not eliminated entirely. Over the course of two congressional sessions, legislators from both parties worked to produce a bill that would enable EPA to make purely science-based findings about the dangers of a substance without wreaking widescale economic havoc.[136] The solution at which Congress arrived was to designate an explicitly science-based risk assessment phase[137] during which EPA could evaluate chemicals for safety, without proving such analysis was cost-justified, and a separate risk management phase that explicitly instructed EPA to take cost into account.[138]

Congress also prescribed a science-based prioritization step before risk assessment, a kind of "step zero." An agency is facing tens of thousands of candidate chemicals to sift through has to start somewhere. This step assures that the agency's prioritization of which risk assessments to do first is based on science, rather than cost. The amended statute requires EPA to establish a "risk-based screening process" for prioritizing chemicals through notice-and-comment rulemaking.[139] Congress listed the factors the agency was to consider, none of which included cost. Instead, EPA must analyze "the hazard and exposure potential of a chemical substance or a category of chemical substances, . . . the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical

134. Pub. L. No. 114-182, 130 Stat. 448 (2016); *see also Toxic Substances Control Act and the Chemicals Management Program at EPA: Hearing Before the S. Comm. on Env't & Pub. Works*, 109th Cong. 9 (2006) (statement of Senator James M. Jefford, paraphrasing prior testimony by former EPA general counsel Donald Elliott) ("Mr. Elliott stated, if after thousands of deaths from asbestos exposure EPA could not regulate asbestos under Section 6, it is virtually impossible for EPA to regulate any chemical under Section 6."); S. Rep. No. 114-67, at 4 (2015) (discussing the failure to regulate asbestos and the attention paid in redrafting to the "unreasonable risk" language) .

135. S. Rep. No. 114-67, at 4.

136. *See The TSCA Modernization Act of 2015: Hearing Before the H. Subcomm. on Envt. & the Econ. of the H. Comm. on Energy and Commerce*, 114th Cong. 1–2 (2015) (opening statement of Rep. John Shimkus (R-IL)) (referring to "a lot of hours" put in "over the past couple of years," emphasizing the compromises made, and emphasizing the desire for EPA to do objective scientific evaluations while expressing concern for business interests).

137. 15 U.S.C. § 2605(b) (2018).

138. *Id.* § 2605(c).

139. *Id.* § 2605(b)(1)(A).

substance manufactured or processed."[140] The prioritization process ends with EPA designating chemicals as "high priority" or "low priority" based on whether the agency decides "without consideration of cost or other nonrisk factors" that the chemicals pose "an unreasonable risk of injury to health or the environment."[141]

After the science-based prioritization process, the agency conducts a risk assessment of high-priority chemicals.[142] In this new risk assessment phase, the law requires EPA to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors."[143] The agency must publish the findings of this risk assessment through notice-and-comment rulemaking.[144]

If EPA determines a chemical poses an unreasonable risk, the agency must publish a final rule on risk management within two years of the publication of the risk assessment in the Federal Register.[145] In this step, EPA is required to consider "the reasonably ascertainable economic consequences of the rule"[146] through a number of different lenses:

> i. the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
> ii. the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and
> iii. the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.[147]

The congressional drafters emphasized these changes as critical to attaining sound policy that balanced safety against economic health. Congress did not prescribe a methodology for cost consideration, nor did legislators claim cost had to be the decisive factor in regulation. But the amendments do clarify whether and when EPA must consider cost.

Moreover, the drafters suggested that this approach was necessary to achieve bipartisan compromise. Representative John Shimkus (R-IL), who headed the subcommittee drafting the amendments, introduced the bill to the

140. *Id.*
141. *Id.* § 2605(b)(1)(B).
142. *Id.* § 2605(b)(2)(B) (instructing EPA to begin assessment on twenty high-priority chemicals within three and a half years).
143. *Id.* § 2605(b)(4)(A).
144. *Id.* § 2605(b)(4)(H).
145. *Id.* § 2605(c)(1)(B).
146. *Id.* § 2605(c)(2)(A)(iv).
147. *Id.*

House floor as follows: "We want our constituents to be safe, and we want markets to work. This bill delivers both."[148] A Democratic member of the subcommittee added, "What brought us together is the failure of the current statute to keep the American public safe. . . . For the first time, the decision of whether a chemical needs to be regulated will be based purely on the risk it poses."[149] The Senate report accompanying the amendments further underlined that consideration of cost had been central to debate: "Substantial stakeholder attention has been focused on the shortcomings in" the statutory section covering risk assessment and risk management.[150]

Here was a bipartisan compromise that attempted to incorporate both science and cost into different parts of the regulating process. It was not the first time Congress had attempted such a fix. The next Section turns to another, earlier congressional effort to require a two-step regulatory approach—the ESA.

D. The Endangered Species Act

Decades before the TSCA amendments, Congress grappled with how to force agencies to separate science and cost while drafting the ESA. In the ESA, Congress was less explicit about establishing a two-step process, and the resulting regulatory framework's mapping onto the two-step process involves a bit more nuance. Nevertheless, after controversy and debate, it is clear Congress effectively arrived at a two-step process for its solution.

Passed in 1973,[151] the ESA looms so large in wildlife law that it is often referred to as the "backbone" of American conservation.[152] The law was the final note in a crescendo of increasing public awareness of mass species extinction that began with the disappearance of the passenger pigeon in 1914 and

148. 161 CONG. REC. H4556 (daily ed. June 23, 2015).

149. 161 CONG. REC. H4556–57 (daily ed. June 23, 2015) (statement of Rep. Frank Pallone, Jr. (D-NJ)).

150. S. REP. No. 114-67, at 4 (2015).

151. *See* Origins of Federal Wildlife Laws and Enforcement, FWS: NAT'L CONSERVATION TRAINING CTR., https://perma.cc/JDL4-Z8G7 (listing conservation statutes of the United States by date).

152. *See, e.g.*, Joel T. Heinen, *Thoughts and Theory on Incentive-Based Endangered Species Conservation in the United States*, 23 WILDLIFE SOC'Y BULLETIN (1973–2006) 338, 338 (1995) (calling the ESA "the backbone of conservation in the United States"); Letter from Lisa Faust, Vice President of Conservation and Sci., Megan Ross, Zoo Director, and Kevin Bell, President and CEO, Lincoln Park Zoo, to Nat'l Fish & Wildlife Serv., A Letter on Behalf of the Endangered Species Act (Sept. 20, 2018), https://perma.cc/CK55-637C (calling the ESA the "backbone of America's conservation strategy"); Press Release, FWS, Improvements to Petitioning Process Under Endangered Species Act Promotes Coordination, Transparency; Ensures Robust Scientific Review (Sept. 26, 2016), https://perma.cc/R2FE-RJC8 (calling the ESA the "backbone of conservation efforts" in the U.S.).

grew stronger under the influence of thinkers like John Muir, Aldo Leopold, and Rachel Carson.[153]

For all that, the original Act itself was relatively simple. The ESA required two agencies—the FWS and NMFS—to identify and protect species of plants and animals that were endangered or threatened.[154] Endangered species were defined as "any species which is in danger of extinction throughout all or a significant portion of its range," excluding insect pests.[155] Threatened species were defined as "any species which is likely to become an endangered species within the foreseeable future."[156]

To determine which species were endangered or threatened, the agencies had to determine the extent to which different species were at risk. In other words, agency scientists had to conduct risk assessments.[157]

These listing decisions were to be made "on the basis of the best scientific and commercial data available."[158] Importantly, the term "commercial data" referred to scientific studies from industry—typically on the effect of commerce on a given species—not data about the economic value of the species or the cost to commerce of potential regulation.[159] The Secretary was also to consult "as appropriate" relevant interested groups, including "the affected states" and "interested parties and organizations."[160] The opinions of the consulted groups, however, do not seem to have been binding on the Secretary.[161] Once animals were listed, they received a number of automatic protections. Federal agencies had to consult the FWS or NMFS to ensure governmental projects would not

153. *See* Shannon Petersen, *Congress and Charismatic Megafauna: A Legislative History of the Endangered Species Act*, 20 ENVTL. L. 463, 469–73 (1999) (discussing the increasing public anxiety that led to the ESA).

154. *See* Endangered Species Act of 1973, Pub. L. No. 93-205, 87 Stat. 884, 885–86 (current version at 16 U.S.C. § 1531 (2012)) (describing the purpose of the Act and defining "Secretary" as Secretary of the Interior or the Secretary of Commerce). Within each department, the FWS and NMFS respectively implement the ESA. *See* Endangered Species, FWS, https://perma.cc/LG42-FFQN (discussing how the agency administers the ESA); Endangered Species Act Guidance, Policies, and Regulations, NOAA FISHERIES, https://perma.cc/5NN5-K2VT.

155. *See* 87 Stat. at 885.

156. *See id.* at 886.

157. *See* Boyd et al., *Consistent Extinction Risk Assessment Under the U.S. Endangered Species Act*, 10 CONSERVATION LETTERS 328, 328 (2016) ("Listing decisions depend on science-based risk assessment . . . .").

158. *See* 87 Stat. at 887 (prescribing considerations for listing decisions).

159. *See* Holly Doremus, *Listing Decisions Under the Endangered Species Act: Why Better Science Isn't Always Better Policy*, 75 WASH. U. L. REV. 1029, 1043 (1997) (discussing this language and its role in listing).

160. *See* 87 Stat. at 887 (outlining procedure in "Basis for Determinations").

161. This interpretation is based both on the text of 87 Stat. 887, which seems to lay this out as a procedure more than an exercise with substantive decisive force, and on how the ESA unfurled, as discussed in the rest of this Part.

further endanger listed species.[162] In addition, neither the government nor private actors could "take" the species,[163] a term of art which covers everything from selling to trapping to harming the species in any way.[164]

In its salad days, the ESA enjoyed a level of bipartisan support virtually unimaginable today. The Senate passed the bill unanimously, and the House approved the bill 390-12.[165] The law's scientific approach gratified the public as well. One editorial pronounced, "the . . . bill may well mean the difference between survival and extinction of animals whose existence should not in the first place have had to depend on the whim or the greed of man."[166] The implementing agencies listed species quickly and in great numbers. In the following five years, 658 species were listed, with an additional 112 animal species and 1,800 plant species proposed for listing.[167]

Evidently, the Act was even more effective than some members of Congress had anticipated. In 1978, the Supreme Court ruled that under the ESA, the Tellico dam begun by the Tennessee Valley Authority ("TVA") could not be completed because it would harm a local, three-inches long fish: the snail darter.[168] Congressional hearings reveal that some members of Congress were not only irked that the law had managed to stop such an expensive project, but also that it had done so to protect what in the eyes of many was a pretty lame fish. An exchange between TVA representative John J. Duncan and Representative Robert L. Leggett (R-CA), drives this sentiment home:

> Duncan [referring to a visual aid]: I have a picture of the snail darter. You cannot eat it. It is not much to look at. It is a slimy color.
> Leggett: Is that the actual size?
> Duncan: Yes. This is the actual size.[169]

The snail darter's forestallment of the dam received the most attention, but other members of Congress also aired grievances. Representative Trent Lott of Mississippi lamented that endangered cranes—not even particularly attractive ones, in his view—had slowed the building of a highway in his state.[170] Walter Flowers, a congressman from Alabama, expressed concerns about the

162. *See* 87 Stat. at 892 (requiring interagency cooperation).

163. *Id.* at 893–94 (listing "[p]rohibited [a]cts").

164. *Id.* at 886 (defining "take").

165. *History of the Endangered Species Act*, BALLOTPEDIA, https://perma.cc/B792-MM7B.

166. Editorial, *Survival or Extinction*, N.Y. TIMES (Sept. 23, 1973), https://perma.cc/47MR-BWUX.

167. *Endangered Species: Hearings Before the H. Subcomm. on Fisheries and Wildlife Conservation and the Envt. of the H. Comm. on Merchant Marine and Fisheries*, 95th Cong. 1 (1978) [hereinafter *1978 House Hearings*].

168. *See* Tenn. Valley Auth. v. Hill, 437 U.S. 153, 172 (1978).

169. *See 1978 House Hearings, supra* note 167, at 54.

170. *See id.* at 59–60.

ability to develop along the state's Caheba River.[171] Robin L. Beard, a Tennessee representative, summarized the concern of many as follows: "There appears to be no leeway whatsoever to allow valuable public projects to go forward if there is a risk that any endangered specie might be adversely affected."[172]

A clear contingent of lawmakers believed that ESA regulations should bend to economic factors. But other legislators nonetheless thought it crucial to protect the scientific integrity of listing decisions.[173] John Dingell, the primary sponsor of the original ESA,[174] sought to distinguish between the listing of a species—the factual finding that the species was endangered—and subsequent management decisions.[175] According to Dingell, the problem was not the factual finding that the snail darter was endangered, but the management decisions surrounding the finding, including the TVA's failure to consult earlier with the FWS.[176]

Environmentalists also urged proceeding with caution, for fear that cost-conscious amendments to the law would replace the scientific basis of listing. True, they allowed, the snail darter was not the Robert Redford of fishes, but protecting uncharismatic animals preserved the ecosystems in which they lived.[177] As one environmentalist testified, automatically exempting expensive federal projects ran the risk of taking "a deplorable step backward to the days when this country focused only on the immediately apparent financial benefits" of public projects, with no concern for long-term environmental impacts.[178]

Compromise was therefore necessary to satisfy both the lawmakers who wanted to ensure the ESA yielded to cost at some point and those who wanted to ensure biological listing decisions remained scientifically sound. To strike a compromise, Congress amended the ESA.

Legislators did not change the requirements for listing, but they added a new provision requiring the FWS and NMFS to designate "critical habitat" at

171. *See id.* at 181–82.

172. *Id.* at 65.

173. *See, e.g.*, H.R. Rep. No. 95-1625, at 69 (1978) (expressing the concerns of a group of representatives that considering economic impact in critical habitat designation would open loopholes for agencies to abuse under political pressure).

174. Jonathan Wood, The Road to Recovery 10 (2018), https://perma.cc/CS37-53ZJ.

175. *See 1978 House Hearings*, *supra* note 167, at 183–84 (recording Dingell's inquiry into exactly which part of the process critics quarreled with, and whether they disputed the snail darter's listing or rather the consequences of listing).

176. *Id.* at 56–57, 72–73.

177. *See, e.g.*, *id.* at 28 ("The end of the snail darter would mean the end of any large, free-flowing stretch of river in the region, the end of any association that humans might have with such free flowing rivers . . . ."); *id.* at 31 ("When a species is endangered . . . [i]t means most often that a special ecosystem is about to be destroyed . . . .").

178. *Id.* at 31.

the same time.[179] In the original ESA, habitat was mentioned as a vague factor that could be part of an agency's conservation plan for a species,[180] a reason to list a species,[181] or a consideration for the Secretary to evaluate when reviewing projects planned by other federal agencies.[182] The statute required no formal designation of critical habitat by the Secretary, and the law laid out no instructions for how the Secretary was to define the habitat worth protecting.

The new amendment, by contrast, required the Secretary to formally designate critical habitat through notice-and-comment rulemaking and announce the regulation at the same time as the listing decision.[183] More importantly, the statute made cost a central factor to define the bounds of the critical habitat. The amendment required the Secretary to consider the "economic impact, and any other relevant impacts, of specifying any particular area as critical habitat."[184] Furthermore, the Secretary could exclude any area if "the benefits of such exclusion outweigh the benefits of specifying the area as part of critical habitat," unless the exclusion would result in species extinction.[185] As with TSCA, the amendment did not prescribe a specific means of considering cost, such as a cost-benefit analysis, and it did not claim that cost must be the decisive factor in critical habitat designations. Nevertheless, the FWS and NMFS would have to make it clear they had considered cost in these regulatory decisions.

Although Congress did not use the terminology, legislators were, in essence, setting up a two-step approach to protecting species. The first step was a science-based risk assessment designed to answer a factual question: whether or not a species was endangered.[186] The Secretary had to publish this decision for the public to see.[187] The second step was a risk management one: The agency

179. Endangered Species Act Amendments of 1978, Pub. L. No. 95-632, 92 Stat. 3751, 3764 ("[T]he Secretary shall also by regulation, to the maximum extent prudent, specify any habitat of such species which is then considered to be critical habitat.").

180. *See* Endangered Species Act of 1973, Pub. L. No. 93-205, 87 Stat. 884, 885 (describing "habitat acquisition" as a measure covered by the term "conserve").

181. *See* 87 Stat. at 886 (listing "curtailment of [a species's] habitat or range" as a reason for designation).

182. 92 Stat. at 3752 (describing the bases for the "Secretary's Opinion").

183. *Id.* at 3764–65 (ordering critical habitat to be declared at the same time as listing and outlining requirements for notice "with respect to the determination of listing [and] critical habitats").

184. *Id.* at 3766.

185. *Id.*

186. Professor Holly Doremus has noted that even listing determinations include some policy judgments—for example, just how imperiled a species has to be before it is considered threatened or endangered. *See generally* Doremus, *supra* note 159. These considerations are analogous to the policy tradeoffs discussed in Section I.A above and, for the same reasons, do not suggest that there is no distinction between risk assessment and risk management.

187. *See* Endangered Species Act of 1973, Pub. L. No. 93-205 § 4, 87 Stat. 884, 887 (current version at 16 U.S.C. § 1533 (2018)) (describing the Federal Register publication require-

was to designate critical habitat based on whether protecting a given area was "worth" the cost. The agency now had an obligation to consider whether increasing a species' chances by ten percent, for example, was worth halting the construction of a dam.

Admittedly, the two-step process agreed upon in the ESA does not rise to the platonic ideal endorsed by the Red Book. Although the listing decision must be based solely on science, the decision to list itself bestows some protections on endangered species automatically. Private parties may not "take" the species, or import the species, or sell the species, for example.[188] Thus, the listing decision is not purely a risk assessment step because it precipitates some management outcomes.

Nonetheless, many important management decisions did not automatically attach to listed species and instead depended on the critical habitat designation. First, species listed as threatened did not receive the same automatic protections as species listed as endangered.[189] Listing a species as threatened rather than endangered, therefore, is theoretically much closer to a pure risk assessment decision. Second, the amendment highlighted "critical habitat" as a key metric that implementing agencies should use in evaluating other federal agencies' projects[190] and as an area that might require other "special management considerations or protection" by the Secretary.[191] The scope of a species' critical habitat thus had significant implications for whether federal projects could go forward and what areas might be subject to additional protective management. Accordingly, the critical habitat designation step was a true, cost-conscious risk management step with considerable management implications.

Lawmakers who redrafted the ESA and TSCA evidently believed that if they told agencies when to consider cost and when not to, the agencies would follow orders. Part II looks at the regulations that followed these amendments for clues about whether the agencies followed Congress' instructions.

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ments the Secretary must follow). These requirements continue today. *See id.* § 4(b)(3)(B) (codified at 16 U.S.C. § 1533(b)(3)(B) (2018)) (instructing the Secretary to publish the agency's reaction to listing petitions, regardless of outcome, in the Federal Register). The Secretary is also required to publish any regulations proposed by the Secretary, rather than petition, for comment. *See id.* § 4(b)(5)–(6) (describing publication requirements in the Federal Register "if a determination as to whether a species is an endangered species or a threatened species . . . is involved").

188. *See* 87 Stat. at 893 (current version at 16 U.S.C. § 1538 (2018)) (listing prohibited acts like importing or taking "with respect to any endangered species").

189. *See id.* (referring only to "endangered species").

190. *See* Endangered Species Act Amendments of 1978, Pub. L. No. 95-632 § 3, 92 Stat. 3751, 3752–3753 (referring to critical habitat multiple times as a consideration the Secretary must make in "interagency cooperation").

191. *Id.* at 3751.

II. Evidence of Cost Contamination

Part I explained the theoretical benefits of a two-step approach to regulation and chronicled efforts by Congress to control when regulating agencies must and must not take cost into account. Alarmed by one agency fetishizing cost under TSCA and another agency ignoring cost under the ESA, Congress attempted to embed instructions into the statutes themselves. In both cases, legislators mandated an initial risk assessment step, where economic factors were verboten. Second, lawmakers required a subsequent risk management step where costs must be accounted for.

It is hardly surprising that legislators would turn to legislation to fix a problem. But the fact that a solution comes naturally does not mean it works. This Part analyzes the aftermath of both amendments to determine whether the agencies followed their new sets of marching orders.

A. The Toxic Substances Control Act

The 2016 amendments to TSCA are relatively recent, but there is already evidence that cost considerations are contaminating the risk assessment process despite statutory mandates that EPA not consider "costs or other nonrisk factors" in prioritizing chemicals or in assessing their risk.[192] In some cases, scenarios of cost contamination are smudged with the fingerprints of political appointees aiming to avoid controversial cost-based policy decisions. But in other cases, different dynamics seem to be driving agencies to "cheat."

The agency's interpretation of statutory text, principles for risk prioritization, and scope documents for the first ten risk assessments provide evidence that the agency is considering cost illegally in these initial parts of the decision-making process. This Section discusses each of the above in turn.

1. Interpreting "Unreasonable Risk"

The text of the TSCA amendments itself sends conflicting messages about the role of cost. Although the amendments purportedly removed cost from prioritization and risk assessments and relegated economic factors to the risk management stage,[193] the text presents a confusing picture.

The seeds of confusion lie in the troublesome phrase "unreasonable risk." Despite explicitly banning cost consideration in the prioritization and risk assessment of substances, Congress nevertheless retained the standard of "unreasonable risk" in both steps. In the prioritization step, the law states that "[t]he Administrator shall designate as a high-priority substance a chemical substance

192. *See* 15 U.S.C. §§ 2605(b)(1)(B), 2605(b)(4)(A) (prohibiting cost in chemical prioritization and risk assessments, respectively).

193. *See supra* section I.C.

that the Administrator concludes, without consideration of costs or other nonrisk factors, may present *an unreasonable risk* of injury to health or the environment."[194] During risk assessment, "[t]he Administrator shall conduct risk evaluations . . . to determine whether a chemical substance presents *an unreasonable risk* of injury to health or the environment, without consideration of costs or other nonrisk factors."[195]

Consequently, despite being forbidden to analyze cost during these early stages, the agency is still tasked with differentiating between risks that are reasonable and risks that are unreasonable. This renders the term "unreasonable" quite a cipher. If not all risks are unreasonable, then the agency must consider some additional factor beyond scientific risk to identify chemicals worth testing and regulating—but that factor must not be cost or another non-risk consideration.

One potential path out of these interpretive woods might lie in reading "unreasonable risks" as meaning "significant risks." If this were the case, the agency would only have to set some threshold at which a risk becomes serious enough to qualify as significant. Admittedly, this might be a thorny policy question. Nonetheless, a threshold could theoretically be chosen without reference to regulatory costs.[196]

The problem is that Congress clearly knew how to use the word "significant," and indeed did so in one of the same sections where the phrase "unreasonable risk" appears. During the prioritization process, EPA is to consider among other things, "storage near significant sources of drinking water,"[197] "significant changes in the conditions of use of the chemical substance,"[198] and "significant changes in the volume of a chemical substance."[199] The fact that the statute immediately follows this list with a standard that uses a different word—"unreasonable"[200]—suggests that something beyond significance is at play, even if risk magnitude is a factor. It is difficult to dismiss these textual differences as meaningless, because Congress was quite attentive to the fact that this particular statutory language had caused problems historically, and focused on fixing it. As discussed in Part I, the Senate Report accompanying the

194. 15 U.S.C. § 2605(b)(1)(B)(i) (2018) (emphasis added).

195. *Id.* § 2605(b)(4)(A) (emphasis added).

196. For example, an agency could make a normative argument that a worker's facing a one in ten chance of developing cancer each day is violative of human dignity, while a chance of 1 in 10,000 is not. Alternatively, and perhaps more plausibly, an agency might rely on market preferences or surveys to determine the risk tolerance of average Americans. *See* Lewis A. Kornhauser, *On Justifying Cost-Benefit Analysis*, 29 J. LEGAL STUD. 1037, 1039 (2000) (describing how risk preferences are generally determined for regulatory purposes).

197. 15 U.S.C. § 2605(b)(1)(A).

198. *Id.*

199. *Id.*

200. *Id.* § 2605(b)(1)(B).

amendments acknowledged as much: "EPA's application of the 'unreasonable risk' standard for regulatory action has been hampered by the statutory language itself, which suggests that cost and benefit considerations must be applied to the agency's decisions on the health and environmental risks posed by a chemical substance."[201]

Interpreting "unreasonable risks" as "significant risks" is therefore not a textualist slam-dunk. But if "unreasonable" refers to more than just the magnitude of the risk and suggests some kind of balancing of factors, it is difficult to know what to balance, given the statute's prohibition against considering "nonrisk factors."[202]

EPA evidently possesses no ready solutions to the puzzle, because the agency has declined to define "unreasonable risk" despite public requests to do so in light of the term's ambiguity and seeming relation to cost.[203] In the agency's 2017 final rules articulating a process for prioritization and a process for risk evaluation, EPA said it would not define "unreasonable risk" because "each risk evaluation will be unique."[204] Instead, the agency offers a list of factors it will consider in making the determination, all of which seem to be associated with ascertaining the nature and magnitude of risk—for example, "the effects of the chemical substance on the environment and environmental exposure under the conditions of use" and "the severity of hazard"[205]—but the agency explicitly reserves the right to consider other factors as well.[206]

TSCA's textual ambiguity and EPA's regulatory ambiguity about what constitutes an "unreasonable risk" does not prove that that the agency is considering cost at this stage, but it does reveal a statutory deficiency that makes it easier for EPA to stumble into considering cost informally. The question is whether EPA is, in fact, falling into the trap of cost consideration.

2. Establishing the Prioritization Process and Stumbling into Cost

Evidence suggests EPA has already faltered because of cost in the context of prioritizing chemicals for risk assessment under TSCA. The amendments required the agency to promulgate rules about how it would prioritize chemicals for risk assessment, as well as how the risk assessments themselves would be

201. S. Rep. No. 114-67 at 4 (2015).

202. 15 U.S.C. § 2605(b)(4)(F).

203. *See* Humane Soc'y, Comment Letter on EPA-HQ-OPPT-2016-0654 (March 20, 2017), https://perma.cc/Q9GN-QC96 ("Because the meaning of 'unreasonable risk' in other settings does include consideration of costs, alternatives, and benefits . . . the meaning of 'unreasonable risk' is unclear. . . . EPA should describe their approach.").

204. EPA, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,734 (July 20, 2017).

205. *Id.* at 33,735.

206. *See id.* (discussing "relevant factors, including but not limited to" those listed).

conducted.[207] In the last days of the Obama Administration, EPA published a proposal explaining the agency's approach to prioritization.[208] The agency emphasized that scientific factors like a chemical's carcinogenic nature, toxicity, and ability to accumulate in the body or nature would play central roles in designating a chemical "high priority" or "low priority."[209]

In addition to considering scientific factors, the agency announced it would consider the availability of alternatives in determining which chemicals to pursue for risk assessments.[210] This proved to be a sticking point. Multiple comments filed in response to the proposal pointed out that determining whether substitutes were available for a substance was unrelated to the immediate question of determining whether that substance might be hazardous to health and the environment.[211]

Prioritizing chemicals based on the availability of substitutes inherently meant taking cost into account at the prioritization stage. Consider two chemicals, A and B, both of which are candidates for risk assessment and, if necessary, risk management. Based on an initial review of available studies, chemical A seems to pose a greater risk of a health hazard than chemical B. But there are also no known safe substitutes for A, while there are known substitutes for B. Therefore, regulating chemical A is likely to cost industry more than regulating chemical B. Banning chemical A might either shutter the industries using the chemical or force industry to invest in research for alternatives; banning chemical B merely involves switching to a known substitute. Thus, an inquiry into the availability of alternatives for a particular chemical is implicitly an inquiry into the costs of regulating that chemical.

Investigating chemical substitutes is cost consideration by another name and therefore, under TSCA's amendments, illegal to consider in prioritization or risk assessment. Just like other types of cost consideration, an investigation into substitutes can point in the opposite direction of science-based risk con-

207. 15 U.S.C. § 2605(b)(1)(A), (4)(B).

208. *See generally* EPA, Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4825 (Jan. 17, 2017) [hereinafter Proposed Prioritization Rule].

209. *See id.* at 4827 (discussing how EPA will prioritize among chemicals in the 2014 TSCA Work Plan).

210. *Id.* at 4828.

211. *See* Humane Soc'y, *supra* note 203 (discussing how "costs, alternatives, and benefits" are usually implicated by the phrase "unreasonable risk," but how the considerations are prohibited by TSCA); Nat'l Res. Def. Council, Comments Under the Amended Toxic Substances Control Act (March 20, 2017) https://perma.cc/DT2L-LBB7, ("[T]he consideration of potential alternatives [sic] substitute chemicals during the risk evaluation process is premature, contrary to law, and may be counterproductive in some ways."); Nat'l Wildlife Fed., Comment on EPA-HQ-OPPT-2016-0636 (Mar. 20, 2017), https://perma.cc/HA3E-B4XL ("[A]vailability of alternatives . . . would be appropriately considered during the risk management phase.").

cerns. In fact, the case above illustrates this point. The existence of available substitutes supports prioritizing chemical B for risk assessment, but potential hazard factors support prioritizing chemical A for risk assessment.

Responding to concerns around this issue was one of EPA's early tasks under the Trump Administration.[212] The agency had no rebuttal to critical comments and instead acknowledged in a rule finalizing the prioritization process that substitute considerations were factors of the sort "expressly excluded from consideration" by the statute.[213] The agency was thus forced to renege, agreeing that "the consideration of alternatives is most appropriately considered as part of any risk management rule."[214] The finalized prioritization process emphasized only risk-related factors.[215]

This episode illustrates the seduction of forbidden cost consideration, particularly in the presence of muddled statutory guidance. Although it is difficult to know with certainty, the circumstances suggest that this flirtation with economic impact was unintentional. First, the agency blatantly published its intention to consider alternatives during a science-based phase of decision-making, a strange step if the agency realized it was proposing something illegal. Second, the agency had no ready response to the commenters' criticism, and indeed fully acknowledged and adopted the position that considering alternatives would be illegal. Finally, this series of events is not easily explained by the political valences of the two administrations that proposed and finalized the rule. If the Obama Administration was viewed as being relatively open to stringent environmental regulation,[216] and the Trump Administration is relatively hostile to regulation costly to industry,[217] then one would not expect the former EPA to push considering regulatory costs and the latter to abandon the effort.

EPA's brush with alternatives likely exemplifies how under-resourced agencies forced to prioritize can naturally gravitate toward considering cost or proxies of cost. Considering what alternatives already exist as a proxy for regulatory cost might seem like a simple way to prioritize low-hanging fruit for risk assessment and regulation. But, in the case of TSCA, this approach is likely illegal.

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212. *See* EPA, Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753, 33,759 (July 20, 2017) [hereinafter Final Prioritization Rule] (published during the first summer of the Trump presidency and addressing comments filed about the availability of substitutes).

213. *Id.*

214. *Id.*

215. *See id.* (listing scientific criteria under "Screening Review").

216. *See* Eric Lipton et al., *The Real-Life Effects of Trump's Environmental Rollbacks: 5 Takeaways from Our Investigation*, N.Y. TIMES (Dec. 26, 2018), https://perma.cc/G8PU-52R3 (referring to "Obama expansion of [environmental] rules").

217. *See id.* (referring to "Trump rollbacks" of environmental rules).

There is other evidence, however, that EPA is also considering cost more covertly in a fashion driven by political leadership. Political motivations seem the most likely explanation for the agency's approach to scoping risk assessments.

3. Scoping Risk Assessment and Covert Cost Consideration

Over the course of 2017 and 2018, EPA announced the first ten chemical substances the agency intended to assess for risk and published the scope of the intended risk assessments for each.[218] Among the substances are TCE, the toxin ravaging Johnson County, and, at long last, asbestos.[219] So far, so good—the agency has followed its statutory mandate, which requires speedily selecting ten substances for risk assessment.[220]

But if the goal of a risk assessment is to evaluate the risk of a substance accurately, then EPA's definition of the scope of its risk assessments is surprisingly narrow. Take, for example, the conditions of use the agency elects to analyze for risk. TSCA instructs the agency to look for unreasonable risk associated with "the conditions of use" of a substance, which the statute defines as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[221] Such a comprehensive definition seemingly mandates a broad consideration of uses in risk assessments. Yet in the scoping documents for each of the ten chemicals, EPA suggested it would exclude many kinds of uses, even seemingly significant ones.[222]

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218. *Risk Evaluations for Existing Chemicals Under TSCA*, EPA, https://perma.cc/WB74-BQCN.

219. *Id.*

220. *See* 15 U.S.C. § 2605(b)(2)(A) (2018) (requiring ten chemicals be evaluated for risk within 180 days of the amendments' publication).

221. *Id.* § 2605(b)(4)(A), 2602(4).

222. *See* EPA, EPA-740-R1-7019, Problem Formulation of the Risk Evaluation for 1-Bromopropane 12–13 (2018) (removing uses previously included because they were not "intended, known or reasonably foreseen"); EPA, EPA-740-R1-7012, Problem Formulation of the Risk Evaluation for 1,4-Dioxane 11 (2018) (same); EPA, EPA-740-R1-7018, Problem Formulation of the Risk Evaluation for Asbestos 10–11 (2018) (same); EPA, EPA-740-R1-7020, Problem Formulation of the Risk Evaluation for Carbon Tetrachloride 13 (2018) (same); EPA, EPA-740-R1-7012, Problem Formulation of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster 13 (2018) (same); EPA, EPA 740-R1-7016, Problem Formulation of the Risk Evaluation for Methylene Chloride 14 (2018) (same); EPA, EPA-740-R1-7017, Problem Formulation of the Risk Evaluation for Perchloroethylene 15 (2018) (same); EPA, EPA-740-R1-7014, Problem Formulation of the Risk Evaluation for Trichloroethylene 12–13 (2018) (same); EPA, EPA-740-R1-7015, Problem Formulation of the Risk Evaluation for N-Methylpyrrolidone 11

For example, instances of contamination by one substance, suspected carcinogen 1,4-dioxane, would not be part of the risk assessment because they did not occur as a result of an *intended* use of the substance.[223] But such contamination is known to be common. Specifically, sudsy cosmetics like shampoo and bubble bath tend to have chemicals added to make the products less harsh on the skin.[224] 1,4-dioxane results as a byproduct, remaining in the cosmetics to which consumers are exposed.[225] As a result, the suspected carcinogen 1,4-dioxane occurs in ninety-seven percent of hair relaxers and fifty-seven percent of baby soaps, as well as many other products.[226] Yet none of these channels of exposure, along with a myriad of other unintended instances of contamination, would be included in assessing the risk the chemical poses to society.

Similarly, all of the scope documents exclude "legacy uses" of a substance—uses for which the product is no longer intentionally produced in the United States.[227] This means the agency will be unable to use TSCA to assess the risk for any products or conditions in which hazardous substances are present—even if such products or conditions are widespread—so long as those substances are no longer produced in the United States for that purpose.[228]

(2017) (excluding uses, including intentional misuses); EPA, EPA-740-R1-7021, Problem Formulation of the Risk Evaluation for Pigment Violet 29 11 (2017) (same).

223. *See* 1,4-Dioxane 2018, *supra* note 222, at 18 (explaining instances of contamination will not be considered because it is not an intended use).

224. *See 1,4-Dioxane*, Campaign for Safe Cosmetics, https://perma.cc/967J-87UV.

225. *Id.*; *see also* Envtl. Defense Fund, Comment Letter on Ten Scopes Under the Toxic Substances Control Act (Sept. 19, 2017) ("[T]he decision to exclude 1,4-dioxane's presence in numerous consumer, commercial, and industrial products as a byproduct of ethoxylation is entirely inappropriate, and will result in deficient and erroneous evaluation.").

226. *1,4-Dioxane*, *supra* note 224.

227. *See* Problem Formulation of the Risk Evaluation for 1-Bromopropane, *supra* note 222, at 12 (excluding legacy use and associated disposal); Problem Formulation of the Risk Evaluation for 1,4-Dioxane, *supra* note 222, at 12 (same); Problem Formulation of the Risk Evaluation for Asbestos, *supra* note 222, at 12 (same); Problem Formulation of the Risk Evaluation for Carbon Tetrachloride, *supra* note 222, at 12 (same); Problem Formulation of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster, *supra* note 222, at 12 (same); Problem Formulation of the Risk Evaluation for Methylene Chloride, *supra* note 222, at 12 (same); Problem Formulation of the Risk Evaluation for N-Methylpyrrolidone, *supra* note 222, at 12 (same); Problem Formulation of the Risk Evaluation for Perchloroethylene, *supra* note 222, at 12 (same); Problem Formulation of the Risk Evaluation for Pigment Violet 29, *supra* note 222, at 12 (same); Problem Formulation of the Risk Evaluation for Trichloroethylene, *supra* note 222, at 12 (same).

228. *See* Envtl. Defense Fund, *supra* note 225. *See also* Annie Sneed, *Trump's EPA May Be Weakening Chemical Safety Laws*, Sci. Am. (Aug. 16, 2017), https://perma.cc/N7M2-KH62 (citing fire retardants as an example of a class of chemicals that would escape regulation).

After receiving comments[229] that these exclusions seemed to contravene TSCA's mandate to consider all conditions of use, EPA justified its exclusions as a means of conserving agency resources: "To use agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other agency programs, [and] to maximize scientific and analytical efforts," EPA announced in its final rule, the agency would exclude conditions "that fall under the jurisdiction of other EPA-administered statutes."[230] Accordingly, the agency plans to ignore significant risks if the risk could be regulated by, for example, the Clean Air Act or Clean Water Act.[231]

This exclusion poses problems for a couple of reasons. For one thing, TSCA does not allow the agency to exclude major risk factors for the sake of agency efficiency.[232] The statute expressly instructs EPA to evaluate the chemical's dangers as a whole and consider whether different conditions of use, when considered together, constitute a risk.[233] Furthermore, the agency's decision to exclude known risks will prevent the agency from accurately assessing the cumulative risk of a chemical. Relatedly, narrowed scopes could result in EPA making misleading findings that a chemical known to pose significant risks does not pose an unreasonable risk.

The evidence suggests cost is contaminating the agency's risk assessments. EPA explicitly cites a shortage of agency resources as the reason it is taking a controversially narrow approach to its risk assessments. As with the agency's announcement of considering substitutes during prioritization, this is an express—perhaps inadvertent—admission that the agency is allowing administrative cost to influence the scope of risk assessment in a dramatic way. But the agency is probably not only considering costs to itself. The anticipated costs to regulated industry, and a desire to reduce those costs, almost certainly drove the agency's narrow risk assessments. After the Obama EPA initially announced a plan to evaluate the danger of chemicals "as a whole" under TSCA, Utilities Solid Waste Activities Group ("USWAG"), an industry group, wrote comments objecting and claiming that EPA had discretion to ignore uses poten-

229. *See, e.g.*, Envtl. Defense Fund, *supra* note 225.

230. This justification can be found in PROBLEM FORMULATION OF THE RISK EVALUATION FOR TRICHLOROETHYLENE, *supra* note 222, at 13, but it is boilerplate language found in all of the problem formulations except for that of Pigment Violet 29, for which the agency says it decided to exclude no uses, PROBLEM FORMULATION OF THE RISK EVALUATION FOR PIGMENT VIOLET 29, *supra* note 222, at 15.

231. *See id.* (listing these statutes as excusing exclusion of conditions of use from risk assessment).

232. *See, e.g.*, Att'ys Gen. of Mass., Cal., Haw., Me., Md., N.J., N.Y., Or., Vt., & D.C., Comment Letter on Problem Formulations for Risk Evaluations (Aug. 3, 2018) (referring to EPA's proposal to evaluate only some conditions as an "unlawfully restrictive application of TSCA").

233. *See* 15 U.S.C. § 2605(a) (2018) (stating that if "any combination of such activities, presents an unreasonable risk of injury to health or the environment," a risk management rule is required).

tially covered by other statutes to conserve agency resources.[234] EPA subsequently adopted that position and argument. Nancy Beck, a Trump political appointee overseeing the toxic chemical unit at the time, was previously employed by the American Chemistry Council, another industry interest group.[235] An increased desire to minimize costs to industry seems almost inevitable with such a leader. But skewing risk assessments to avoid regulation likely entails fewer political hazards than openly allowing such sympathies to prevail in risk management.

EPA has released several draft risk evaluations related to its ten priority chemicals.[236] Its first risk assessment, for Pigment Violet 29,[237] does little to allay concerns about cost contamination. The agency concluded Pigment Violet 29 posed no unreasonable risk,[238] departing from European authorities that have flagged the chemical as a likely persistent, bioaccumulative, toxin and worthy of further investigation.[239] EPA repeatedly acknowledged its lack of information about a number of relevant factors related to the chemical,[240] but nonetheless claimed it had enough information to evaluate the substance.[241] In the process, the agency chose to rely on a single, private discussion with a chemical manufacturer to determine workers' exposure to air toxicity,[242] twenty-four scientific studies the agency claimed could not be shared with the public because they contained "confidential business information,"[243] and at least two studies that were considered "not reliable" by the manufacturer who produced

234. *See* USWAG, Comment Letter on Procedures for Prioritization of Chemicals for Risk Evaluation (Mar. 20, 2017) (on file with author).

235. *See* Sneed, *supra* note 228. Nancy Beck has since left EPA to join a detail with the White House National Economic Council. *EPA Toxics Deputy Leaving for White House Detail*, InsideEPA.com (June 19, 2019), https://perma.cc/T6XU-K4JL.

236. *See, e.g.*, EPA, Draft Risk Evaluation for 1,4-Dioxane (2019); EPA, Draft Risk Evaluation for C.I. Pigment Violet 29 (2018) [hereinafter Violet 29 Risk Evaluation]; EPA, Draft Risk Evaluation for Cyclic Aliphatic Bromide Cluster (2019).

237. Violet 29 Risk Evaluation, *supra* note 238.

238. *Id.* at 5.

239. *See* ECHA, Draft Community Rolling Action Plan (CoRAP) Update for Years 2019-2021 1 n.2, 22 (2018) (first defining "PBT" and then listing the pigment under its CAS number 81-33-4 as a "suspected PBT" scheduled for further assessment in 2021).

240. *See, e.g.*, Violet 29 Risk Evaluation, *supra* note 236, at 30–31 (acknowledging lack of data on absorption potential and carcinogenity).

241. *See id.* at 32 (declaring Pigment Violet 29 presents no unreasonable risk).

242. *See id.* at 22 (citing a private email to the agency). The email is archived with EPA. [Email Between Dr. Robert C. Mott (Sun Chemical Corporation) and Alie Muneer (EPA) Regarding Exposure Questions], EPA, Health & Environmental Research Online, https://perma.cc/VX3L-89M6.

243. Violet 29 Risk Evaluation, *supra* note 236, at 5.

them.[244] Relying on this information to deem the chemical safe enough for workers manufacturing Pigment Violet 29, EPA declined to conduct any analyses related to consumers or "downstream" processors, claiming that such exposures would be lower than those experienced by manufacturing workers.[245] Former Assistant Secretary of Labor for OSHA, David Michaels, challenged this claim in comments. "At OSHA," said Michaels, "there were many, many instances where exposures in downstream users of a chemical or product were substantially higher than exposures in manufacturing facilities."[246] Responding to comment letters by academics and environmental groups criticizing the lack of transparency in EPA's process—and arguments that TSCA's text prohibits reliance on health studies not disclosed to the public[247]—in March 2019, EPA made public the twenty-four studies it previously refused to release.[248]

EPA's assessment of Pigment Violet 29 also received a scathing review from the TSCA Science Advisory Committee on Chemicals,[249] an expert group established by TSCA to provide independent advice to EPA in implementing the statute.[250] The Committee's report catalogued shortcomings in the agency's assessment, including inconsistent and inaccurate descriptions of Pigment Violet 29,[251] failure to use common methodologies to fill informational gaps,[252] and the tendency to make "sweeping generalizations" based on limited information.[253]

The sum of evidence suggests that cost is contaminating EPA's risk assessments under TSCA. Further research should continue to monitor the agency's implementation, as the amendments to TSCA are still young. For a statute with a longer history and data, the discussion turns to the ESA.

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244. Envtl. Def. Fund, Comments on Draft Risk Evaluation for C.I. Pigment Violet 29, at 3 (Jan. 14, 2019), https://perma.cc/NWU5-FVT5.

245. Violet 29 Risk Evaluation, *supra* note 236, at 23.

246. David Michaels, Comment Letter Re: Draft Toxic Substances Control Act Risk Evaluations: Colour Index Pigment Violet 29 at 4 (Jan. 14, 2019), https://perma.cc/VA5B-5MVD.

247. *See, e.g.*, *id.* at 1 (noting the studies could not be evaluated because they were not made public); EarthJustice, Comment Letter Re Draft Risk Evaluation for Pigment Violet 29, at 15 (Jan. 14, 2019) (claiming the studies' confidentiality was contrary to TSCA) (on file with author); Envtl. Def. Fund, *supra* note 244, at 11 (arguing non-disclosure of the 24 studies violates TSCA § 14); Comments from Academics, Scientists and Clinicians on the Draft Risk Evaluation for C.I. Pigment Violet 29, at 5 (Jan. 14, 2019) (on file with author) (urging EPA to release the studies to comply with TSCA).

248. Press Release, EPA, EPA Makes Studies on PV29 Publicly Available (Mar. 22, 2019), https://perma.cc/G3ES-LNL3.

249. TSCA Science Advisory Comm. on Chems., Peer Review for EPA Draft Risk Evaluation of C.I. Pigment Violet 29 (2019), https://perma.cc/YX65-YBKA.

250. 15 U.S.C. § 2625(o) (2018).

251. TSCA Science Advisory Comm. on Chems., *supra* note 249, at 15–16.

252. *See id.* at 15 n.1 (describing the "read-across" approach of using analogous chemicals to make inferences about the target chemical).

253. *Id.* at 16.

B. The Endangered Species Act

Just as amendments to TSCA have failed to constrain agency consideration of cost, so too have amendments to the ESA failed to control when and how cost is considered. This Section discusses the results of the 1978 amendments, the subsequent correction to those amendments, and current observations of the ESA's implementation.

The 1978 amendments to the ESA dramatically changed the Act's implementation. The new decision-making process was supposed to consist of two steps: a listing decision—made on the scientific determination of whether a species was endangered or threatened, without any regard to cost—and a critical habitat designation made only after considering the economic impacts of protecting the area of habitat in question.

The FWS and NMFS did in fact change the way they implemented the ESA. Both agencies virtually stopped listing species as threatened or endangered altogether. The brisk clip of listings that had typified the ESA since its passage screeched to a halt following the 1978 amendments. In the four years between 1978 and 1982, fewer than five percent of these proposals led to listings, and only one animal species passed through the entire proposal and listing process,[254] the Hay's Spring amphipod.[255] A five millimeter-long crustacean, the Hay's Spring amphipod was believed at the time to occur in only one place in the United States, the National Zoo.[256]

Circumstances suggest the listing downturn resulted from the ESA amendments, not a single administration's political aims. This downturn spanned the administrations of both a Democratic and Republican president, so the decreased rate in listing could not have been the result of a single White House's agenda. Moreover, the fact that the most successful animal listing during this period involved an animal with no wild habitat strongly suggests that the new critical habitat provision has thrown a wrench in the regulatory gears.

Why the sudden decrease in listings if the criteria for listing did not change? Once agencies were forced to engage in a separate analysis that mandated caring about cost—a consideration previously forbidden under the former ESA—it is likely that consideration began to contaminate their listing decisions. If agencies declined to list species, they could avoid making critical habitat designations. Avoiding critical habitat designations had two clear virtues for agencies. First, eschewing critical habitat designations allowed the agencies to avoid difficult, public decisions about whether to designate critical habitat that might stop lucrative federal projects. Instead, the agencies could

254. Oliver A. Houck, *The Endangered Species Act and Its Implementation by the U.S. Departments of Interior and Commerce*, 64 U. COLO. L. REV. 277, 283 (1993).

255. H.R. REP. NO. 97-567, at 11 (1982).

256. *Id.*

clothe their decisions in scientific certainty by claiming the species did not merit listing at all. Second, dodging the critical habitat designation saved the agencies resources. If a species was arguably threatened, for example, but the agency did not want to spend time promulgating a detailed critical habitat rule, especially if habitat would ultimately be too costly to protect effectively, the agency could conserve agency resources by simply declining to list the species. The agency did not have the option to list the species but decline to designate critical habitat, because the statute required that both be announced together.

The broad trends of listing that occurred after the 1978 amendments suggest that cost considerations were interfering with risk assessment. Individual instances of failures to list also support this contention, as illustrated by the case of the unfortunate Illinois mud turtle.

1. Amendment Fallout and the Case of the Illinois Mud Turtle

To see an example of cost contamination up close, consider the Illinois mud turtle. About the size and shape of a dark brown bocce ball,[257] the Illinois mud turtle splits its time between midwestern sandy shrubland and ponds, where it eats insects, crustaceans, and fish.[258] Because of habitat destruction, scientists began to worry about conserving the turtle as early as 1971.[259] Several scientific studies later,[260] the FWS proposed that the Illinois mud turtle be listed as endangered in 1978.[261] Shortly after this proposed listing, Congress enacted the 1978 amendments.[262]

The amendments' requirement that critical habitat designation take cost into account led the Service to withdraw the Illinois mud turtle's listing proposal.[263] In late 1979, the FWS re-proposed listing the turtle, but with a smaller designated critical habitat than previously planned, resulting from the agency's cost consideration.[264] Thus far, these actions seemed to track the approach Congress had laid out: a science-based risk assessment followed by a cost-conscious critical habitat designation.

But the agency encountered resistance from a powerful entity that had a twenty-percent ownership in the proposed critical habitat area: Monsanto Ag-

257. *See* Ralph Loos, *Rare Find: Illinois Mud Turtle Slowly*, STATE J. REG., June 28, 1998.

258. *See* C. KENNETH DODD JR., A CONTROVERSY SURROUNDING AN ENDANGERED SPECIES LISTING: THE CASE OF THE ILLINOIS MUD TURTLE 1–3 (1982) (discussing the different habitats required by the turtle and its diet).

259. *See id.* at 1, 6–7 (referencing initial concerns about the turtle in 1971 and the proposed reasons for listing, respectively).

260. *See id.* at 1 (citing various studies prior to 1978).

261. *Id.* at 7.

262. *See id.* at 6–7 (discussing the 1978 amendments and the subsequent withdrawal of the listing).

263. *Id.*

264. *Id.* at 7.

ricultural Products Company.[265] Monsanto did not want the turtle listed as endangered at all. Perhaps the company wanted to avoid navigating the automatic protections that came with listing, like prohibitions against "taking" the species,[266] or perhaps the company understood that listing was a prerequisite to designating critical habitat, and that attacking the former could stop the latter. Regardless of its motivation, the company hired a consulting firm to conduct its own scientific analysis of the turtle and attack the scientific findings of the FWS.[267] In congressional oversight hearings, the company claimed that its own scientific analyses were being ignored by the FWS, even though agency officials had met with the company and explained why Monsanto's scientific findings—such as the fact that the turtle was likely a subspecies rather than a species—were irrelevant to listing (because the ESA protects subspecies as well as species).[268]

Lobbying continued, however, and the Office of Management and Budget decided to make a case study of the Illinois mud turtle to determine if the agency was appropriately taking cost into account.[269] This was the first study of its kind for the FWS.[270] Around the same time, seemingly inspired by a letter from Monsanto, Senator Orrin Hatch (R-UT) filed a Freedom of Information Act Request with the agency.[271]

To bolster its scientific risk assessment, the agency asked scientists inside and outside the agency to review the listing decision for the Illinois mud turtle.[272] The scientists criticized the scientific report produced by Monsanto's consultants and reaffirmed the need for the turtle to be listed.[273] In addition, presumably in an effort to move proceedings along, the FWS expressed willingness to further alter the critical habitat designation at the request of industry.[274]

But the Illinois mud turtle could not catch a break. Unbeknownst to the biologists at the FWS, in 1980, the agency's director—Lynn Greenwalt, a political appointee—followed the recommendation of Monsanto and assembled a new panel of experts to analyze the plight of the turtle.[275] None of the scientists involved in the original listing decision were invited or allowed to present their

265. *See id.* at 8 (referring to Monsanto's twenty-percent ownership of Big Sand Mound).

266. *See* James Salzman, *Evolution and Application of Critical Habitat Under the Endangered Species Act*, 14 HARV. ENVTL. L. REV. 311, 314 (1990) (describing the automatic protections that apply to both public and private actors).

267. *See* DODD, *supra* note 258, at 4–5, 9 (referring to hiring LGL and to its attacks on the agency's findings).

268. *Id.* at 9.

269. *See id.* at 13 (referencing the OMB study).

270. *Id.*

271. *See id.* (referencing the filing and letter from Monsanto).

272. *See id.*

273. *See id.* at 11–12 (discussing the scientists' severe criticism of the LGL report).

274. *See id.* at 13.

275. *Id.* at 13–14.

findings, despite one panel member's request that the scientists be contacted.[276] This new panel found that there was inadequate scientific basis to list the turtle, and Director Greenwalt withdrew the listing.[277]

The FWS biologists sent a point-by-point refutation of the panel's finding to Greenwalt, but Greenwalt withdrew the proposal all the same.[278] There was some resistance from scientists and conservationists to the decision not to list, but this ultimately subsided, and the Illinois mud turtle was never listed.[279]

2. Congress Corrects the Correction

Such tribulations were not confined to the Illinois mud turtle, and Congress began to hear complaints that the Act was not achieving an appropriate balance between scientific and economic considerations.[280] "As the Endangered Species Act stands today," the wildlife chairman of the Environmental Defense Fund testified in a 1982 congressional hearing, "the species that are most likely to be added to the threatened or endangered lists are those least likely to benefit from the fact of listing . . . the listing of which will have little or no impact upon any economic or commercial interest."[281]

Critics identified more than one reason for the ESA's failures. According to the chief of the FWS Office of Endangered Species Scientific Authority[282]—the group circumvented in the case of the ill-fated Illinois mud turtle[283]—the agency's administration was purposefully frustrating the listing process.[284] But environmental groups took issue with the statute itself. They argued that the listing decision ought to depend on scientific determinations while the decision of how to protect listed species ought to require economic considerations, but that the Act as written blurred these two steps.[285] Requiring the agency to publish an economically justified critical habitat at the same time as publishing the listing decision invited cost considerations to influence both decisions.[286]

This problem was compounded by President Reagan's Executive Order 12,291, which required agencies to conduct detailed cost analyses of any eco-

276. *Id.* at 14.
277. *Id.* at 15.
278. *Id.*
279. *Id.* at 16.
280. *See Endangered Species Act: Hearing Before the H. Subcomm. on Fisheries and Wildlife Conservation and the Envt. of the H. Comm. on Merchant Marine and Fisheries*, 97th Cong. 1 (1982) [hereinafter *1982 House Hearing*] (describing various criticisms leveled at the Act).
281. *Id.* at 156.
282. *See id.* at 153 (identifying the role of John Spinks).
283. *See* DODD, *supra* note 258, at 10, 15 (identifying OES and later discussing its refusal to sign onto the other panel's findings).
284. *1982 House Hearing*, *supra* note 280, at 156.
285. *See id.* at 156, 175, 388 (all emphasizing the necessary two-step distinction).
286. *Id.* at 156–57.

nomically "major rule," and thus encouraged the FWS to avoid promulgating costly rules that demanded extra time and resources.[287] An FWS director in charge of species listing admitted to Congress that the agency felt compelled to do economic analyses of both the listing decision and critical habitat designation under the executive order, even though the statute only called for economic consideration in the latter stage, because the agency had to ensure the listing decision was not so costly as to constitute a major rule.[288]

Congress therefore decided to amend the ESA again to further clarify and encourage the two-step process. Legislators changed the statute's language to ensure that listing decisions were made "*solely* on the basis of the best scientific and commercial data available" and eliminated the suggestion that the Secretary first consult "as appropriate" with affected states and "interested persons and organizations."[289] Additionally, the statute no longer required the critical habitat designation to be published at the same time as the listing decision, but rather allowed for an extra year to "prevent its designation from influencing the decision on the listing of a species."[290] In hearings, the goal to separate these determinations took the unlikely form of a hypothetical endangered male and female toad abiding in downtown Houston.[291] The toad couple ought to be listed as endangered, one anxious representative suggested, but subsequent critical habitat designations, limited by cost considerations, ought not to shutter Houston's entire metropolitan area.[292]

The first attempt to legislate a two-step process had failed, so Congress was trying again. Legislators bet that the greater precision in their language would prevent the agency from wriggling out of a strictly scientific risk assessment.

3. Clues About the Effectiveness of the 1982 Amendments

The rate of listing accelerated after the 1982 amendments. By 1988, about fifty species were listed per year.[293] This might seem surprising given that the 1982 amendments did not eliminate a critical habitat designation but only clarified the separation between the risk assessment listing decision and the critical

287. *See id.* at 157; Exec. Order No. 12,291, 3 C.F.R. 127 (1981). If the decision did qualify as a major rule, then more detailed cost analyses were required. *Id.*

288. *1982 House Hearing*, *supra* note 280, at 336–38.

289. *See* S. 90-9, 98th Cong. § 4(b) (1983) (bracketing the deletions and italicizing the additions); H.R. REP. NO. 97-567, at 62 (1982) (italicizing the added word "solely" to the Act's "basis for determinations" section).

290. *See* H.R. REP. NO. 97-567, at 12 (1982).

291. *1982 House Hearing*, *supra* note 280, at 338.

292. *See id.*

293. *See* Houck, *supra* note 254, at 284 (noting this rate as reported by Congress six years after 1982 amendments).

habitat risk management decision. As it turns out, these changes proved consequential, because subsequently the agency found a new way of avoiding critical habitat designation: "prudency." This excuse has allowed the agency to make listing decisions without making critical habitat designations.

The ESA has included the prudency escape hatch since the 1978 amendments.[294] According to the statute, the agencies must designate critical habitat for listed species, but only "to the maximum extent prudent and determinable."[295] As of the beginning of 2015, only 704 of the more than 1,500 listed species had critical habitat designations.[296] The FWS cited "prudency" concerns in ninety-nine percent of cases lacking critical habitat, one study of listings between 1980 and 1988 found.[297]

Legislative history suggests the "prudence" exception was intended only for unusual situations. The House report on the 1978 amendments emphasized that declining to define critical habitat was for "rare circumstances where the specification of critical habitat concurrently with the listing would not be beneficial to the species."[298]

Yet the agency has come to cite "prudence" frequently as a reason for not listing.[299] If the agency designates critical habitat, the reasoning goes, the designation will attract collectors, vandals, and hunters to the area, ultimately bringing more harm than good to the species.[300] In reality, however, these forces probably do not pose significant threats to listed animals. Indeed, agency officials' statements have undermined the agencies' cover. One FWS official testified to Congress that vandalism was not a serious problem.[301] Another Department of Interior employee acknowledged in an interview that "vandalism is actually not that big a problem, but it's worth it to the bureaucracy to avoid critical habitat."[302]

This trend toward avoiding critical habitat designations on prudency grounds provides a couple of insights. The oscillation in listing frequency maps onto the introduction and exclusion of critical habitat designations, and supports the theory that cost contamination was occurring. When the agencies could not consider cost, listings were frequent; when Congress mandated contemporaneous cost-conscious critical habitat designation, listings plummeted; and when the agency subsequently found a new way to avoid designation, and

294. *See 1982 House Hearing*, *supra* note 280, at 156.

295. 16 U.S.C. § 1533(a)(3)(A) (2018).

296. *Listing and Critical Habitat: Frequently Asked Questions*, FWS, https://perma.cc/YCT2-H8MK.

297. *See* Houck, *supra* note 254, at 303 (referencing a prudency reason given in 317 of 320 cases).

298. H.R. Rep. No. 95-1625, at 17 (1978).

299. Houck, *supra* note 254, at 303.

300. *See id.* (citing the reasons for not listing under "not prudent").

301. Salzman, *supra* note 266, at 335–36.

302. *Id.* at 337–38.

could thus list species without having to make costly critical habitat findings, listings bounced back.

It is worth noting, though, that even the agency's current approach of avoiding critical habitat designations could in itself be considered a kind of cost contamination. Rather than invest agency resources in a time-intensive, honest public procedure about whether to designate costly critical habitat, the agency can avoid the issue by making a dubious factual finding that designation is imprudent.[303]

Despite the resuscitated listing numbers, other evidence suggests that cost still contaminates listing decisions. Even after 1982, the FWS and NMFS remained reluctant to list certain species whose listing would likely yield negative economic impacts for certain industries. One such example is the Pacific salmon.[304] For decades, the population's decline had been documented, but listing would force NMFS to choose between protecting the salmon and allowing hydropower projects to continue.[305] Only when sued did the agency finally list the salmon.[306] And even then, NMFS only listed the species as "threatened,"[307] a classification that did not automatically require the same level of protection as an endangered finding.[308] This second-tier listing was made despite stark decline in the numbers of the salmon: in 1992, the population was found to have declined by almost ninety-nine percent over the past twenty-five years.[309] Agency neglect was not limited to fish. The FWS was equally resistant to listing the Northern Spotted Owl, which lived in forests greatly valued by the timber industry.[310]

The trajectory of the ESA suggests that statutory text can make some difference in the way agencies approach risk regulation. But text does not fully bind agencies, as recent events demonstrate. In August 2019, the FWS and NMFS promulgated new rules that will allow the agencies to disclose the cost

303. *See* Benjamin Jesup, *Endless War or End This War? The History of Deadline Litigation Under Section 4 of the Endangered Species Act and the Multi-District Litigation Settlements*, 14 VT. J. ENVTL. L. 327, 352 (2013) ("FWS had long viewed the designation of critical habitat as an expensive and controversial process that usually added little additional protection to a species once it was listed.").

304. *See* Houck, *supra* note 254, at 287 (introducing the Pacific salmon as an example of the agency confusing listing with management decisions).

305. *See id.* (discussing the conflict between hydropower and protecting the population long known to be in decline).

306. *Id.*

307. *Id.*

308. *See What Is the Difference Between Endangered and Threatened?*, FWS, https://perma.cc/6HJV-HNBU (explaining the increased discretion the Service has regarding threatened species, versus endangered ones).

309. Houck, *supra* note 254, at 287.

310. *Id.* at 290–91.

of listing a species, despite explicit statutory instruction not to consider cost.[311] The agencies contend that they will "continue to make determinations based solely on biological considerations,"[312] but suggest that in some cases, compiling and disclosing cost information might be informative to the public, and in any case, the statute does not forbid the compiling of such information.[313] When asked by commenters at what point in the process the agencies would consider cost, the agencies punted, saying they were "not creating a framework or guidelines for how or when the presentation of economic impacts of listing, reclassifying, or delisting would occur."[314] It is difficult to imagine circumstances more favorable to cost contamination.

The rule also widens the scope of cases in which the agencies may find designating critical habitat "not prudent" and thus avoid making a designation,[315] and also narrows what types of lands can be designated as critical habitat.[316] Both of these changes are almost certainly driven by a desire to decrease costly designation decisions. On the one hand, the new regulations make it easier than ever for agencies to avoid a costly critical habitat designation through the ostensibly cost-blind "not prudent" trapdoor. On the other hand, if critical habitat must be designated, limitations in scope mean that the designation will be more meager, cover less land, block fewer projects, and ultimately impose lower costs. This history illustrates the influence and limits of statutory text. Despite the law's language, political appointees may push cost consideration into the science-based stages of the regulatory process.

The sum of the evidence strongly suggests that the agencies' risk assessments under TSCA and the ESA are falling victim to cost contamination. Admittedly, a forensic investigation of the kind this Article conducts is unlikely to ever demonstrate with the precision of a geometric proof that cost contamina-

311. *See* Endangered and Threatened Wildlife and Plants; Revision of the Regulations for Listing Species and Designating Critical Habitat, 83 Fed. Reg. 35,193, 35,194 (proposed July 25, 2018) [hereinafter Proposed ESA rule] (proposing to disclose economic impacts in some cases, while acknowledging that the ESA's 1982 amendments forbid relying on such considerations for listing); Endangered and Threatened Wildlife and Plants; Revision of the Regulations for Listing Species and Designating Critical Habitat, 84 Fed. Reg. 45,020, 45,024 (Aug. 27, 2019) [hereinafter Final ESA Rule] (confirming that, despite criticism in comments, the Service is removing language from regulations prohibiting possible economic impacts).

312. Proposed ESA Rule, 83 Fed. Reg. at 35,194.

313. Final ESA Rule, 84 Fed. Reg. at 45,024.

314. *Id.* at 45,026.

315. *See* Proposed ESA Rule, 83 Fed. Reg. at 35,197 (proposing circumstances for "not prudent" finding including "circumstances that were already captured . . . and some additional circumstances"); Final ESA Rule, 84 Fed. Reg. at 45,040 (describing how the agencies changed the "not prudent" basis from a single situation in which listing is not beneficial to species to "a number of specific circumstances" leading to a "not prudent" finding).

316. *See* Final ESA Rule, 84 Fed. Reg. at 45,021 (limiting the circumstances in which unoccupied land can be designated critical habitat).

tion is the prime motivation behind certain agency actions. But the evidence certainly suggests that, more likely than not, cost contamination is occurring.

Agencies' consideration of cost is not only concerning because it is illegal. Economic encroachments into the risk assessment should also concern us for the reasons discussed in Part I. When cost colors a risk assessment, the agency is effectively lying to the public by throwing its authority behind an inaccurate factual finding. Toxic chemicals are declared safe; species facing extinction are declared to be thriving. Such misleading findings may obstruct solving the problems agencies are intended to regulate and undermine their political accountability.

But agencies' powerful attraction to considering cost despite statutory prohibitions should not be seen as reason to abandon the two-step regulatory framework. Rather, it is necessary to search for solutions that preserve the benefits of the two steps while keeping agencies' incentives and realities in mind. It is this challenge that Part III examines.

III. Step Zero: Agency Prioritization

Thus far, the examples in this Article have revealed the symptoms of cost contamination in administrative policies in different agencies, statutes, and time periods. This revelation should trouble policymakers and the public. To flout the law is bad by definition; to do so through misrepresentations to the public is worse. Correcting this dysfunction may demand changing the law, agencies' approach to the law, or both.

Cost contamination is not mutually exclusive with traditional concerns surrounding agency decision-making, like agency capture.[317] Rather, cost contamination may in some cases be a symptom of staffing agencies with officials from regulated industry. Cost contamination could also be exacerbated by a perceived judicial skepticism of costly regulation, as evidenced in the 2015 Supreme Court case *Michigan v. EPA*.[318] There, the Court struck down an EPA rule promulgated under the Clean Air Act because the agency failed to make a threshold determination about whether regulation would be "appropriate," a statutory term the Court determined implicated cost consideration.[319] An agency's desire to appease a cost-conscious Court could, ironically, drive the agency to break the law and illegally consider cost in other statutory contexts.

Thus, levers that address traditional concerns about agency capture or shift the focus of the judiciary would likely mitigate cost contamination. Rather than

317. *See, e.g.*, Abram Chayes, *The Role of the Judge in Public Law Litigation*, 89 Harv. L. Rev. 1281, 1310 (1976); Elena Kagan, *Presidential Administration*, 114 Harv. L. Rev. 2245, 2267–68 (2001); Richard B. Stewart, *The Reformation of American Administrative Law,* 88 Harv. L. Rev. 1669, 1684–88 (1975).

318. *See generally* Michigan v. EPA, 135 S. Ct. 2699 (2015).

319. *See id.* at 2707–08 (discussing how "appropriate" must refer to cost, among other factors).

re-treading such ground, this Article focuses on other solutions more narrowly directed at cost contamination, should solutions to agency capture or judicial posture prove elusive.

If TSCA and the ESA exhibit cost contamination as a common ailment in differing agency circumstances, these examples also show that the illness's causes and effects may vary. Not all of cost contamination's effects are necessarily undesirable. Thus any remedy that attempts to fix the problem of illegal cost consideration in risk assessments should try to preserve the merits of the approach while mitigating its flaws.

A. The Harms and Merits of Different Kinds of Cost Contamination

This Section examines what, if anything, is worth preserving from the current state of affairs in which agencies illegally consider cost during risk assessments. Setting aside illegality for the moment, in some cases, agencies may have good reason for covertly considering cost. Before racing to stop cost contamination, an account of the contexts in which agencies cheat may help separate illegitimate ends from meritorious ones.

Two agency motives emerge from this Article's examples of cost contamination. The first is an illegitimate agency end that ought to be snuffed out. But the second is a reasonable goal that should guide reform.

First, agencies might distort risk assessments with cost consideration to create political cover for risk management decisions. By doctoring a risk assessment, an agency can make its preferred regulatory outcome seem more reasonable, dodging public backlash and accountability. EPA's decision, led by a former industry lobbyist, to narrow the scope of TSCA risk assessments after pushback from industry probably offers an example of this type of motivation.[320] By narrowing the scope of risk assessment, the agency can downplay the magnitude of risk associated with chemicals under consideration and make lax regulatory decisions more politically palatable. Theoretically, an agency could also trump up risks to achieve the opposite effect and make regulation seem more reasonable relative to costs incurred, but this Article has not unearthed such examples.

The appeal of pursuing a risk management decision at odds with an honest reckoning of cost likely depends on the political sympathies of a given administration and the parties upon whom a regulation's costs fall. For example, if an administration sympathizes strongly with the chemicals industry, agencies may be disinclined to promulgate regulations whose costs fall primarily on industry, even if the regulation on the whole is feasible and beneficial to the rest of society. This kind of favoritism does not pose a problem per se. Depending on

320. *See supra* Part II.A.3.

the statute under which the agency is regulating, decisions colored by an administration's political leanings may be perfectly legal.[321]

But if agency officials want to favor one group of interests over another, they should do so openly. To the extent many scholars and judges accept the broad lawmaking authority of agencies, they justify their acceptance by assuming that agencies are politically accountable.[322] If the public dislikes the solicitude a particular administration's EPA shows industry, for example, they may vote the President out of office. By hiding political cost considerations in inaccurate risk assessments, agencies undermine the democratic rationale for accepting their authority. The public cannot hold agencies and their governing administrations accountable for risk management decisions if the agencies misrepresent the factual bases underlying those decisions.

Agencies, however, probably have a second motivation for considering cost during risk assessments: efficient use of agencies resources. In such cases, agencies distort risk assessments in order to avoid expending effort on the second risk management phase.[323] For example, the FWS's current reluctance to reach the risk management decision of designating critical habitats might exemplify an agency trying to conserve agency resources.[324]

In contrast to dodging public accountability, the drive to conserve agency resources seems like a legitimate agency goal. Endowed with finite resources that fall short of colossal regulatory mandates,[325] agencies must constantly make tradeoffs about how to deploy scarce agency effort. If in the agency's estimation, regulation at the risk management phase will not be worth the trouble, tampering with risk assessments to avoid reaching risk management altogether saves the agency time.

All this is not to say that agencies help the public by distorting risk assessments for efficiency's sake. No matter which incentive primarily motivates a particular instance of cost contamination, the agency is lying to the public to achieve its desired end. Efficiency should not justify evading democratic accountability. Rather, this discussion suggests that a workable solution to cost contamination should account for agencies' limited resources.

Thus, of the two agency motivations most likely driving cost contamination, one should be discouraged—shirking public accountability—and one

321. *See* Kathryn A. Watts, *Proposing a Place for Politics in Arbitrary and Capricious Review*, 119 YALE L.J. 2, 6–7 (2009) (discussing the influence of President Clinton on agency decisions, even though the decisions were backed up by technocratic justifications).

322. *See* Bressman, *supra* note 98, at 466.

323. The proposed dichotomy of motivations does not dictate that the two incentives are mutually exclusive. Both reasons could animate an agency's cost contamination under certain circumstances.

324. *See supra* Part II.A.3.

325. *See* Jesup, *supra* note 303, at 354–55.

should be honored—conserving agency resources. The next Section proposes a solution that takes reasons for agency decisions into account.

B. Prioritizing Risk Assessments Through Cost Consideration

Three levers of change could offer potential solutions to eliminate the dishonest aspects of cost contamination while preserving some means for agencies to conserve resources: Congress could amend the statutes under which agencies regulate; agencies could change how they implement statutes; or courts could change how they review agency rulemaking.

First, Congress could try to further constrain agencies through statutory text. This Article has chronicled the effects and shortcomings of such efforts. In the case of TSCA, the 2016 amendments are likely an important step in resuscitating an impotent statute, but early signs suggest cost contamination has survived this recent bout of congressional reform. In the context of the ESA, statutory language clearly had some effect on how the FWS and NMFS operate. The amendments of 1978 essentially froze listing, and the amendments of 1982 reinvigorated listing decisions.[326] Nonetheless, the 1978 amendments demonstrated Congress's inability to force agencies to conduct two separate steps, a risk assessment and a risk management step, without the latter influencing the former, and today cost still seems to contaminate some of the agencies' listing decisions.[327]

Past legislative failures do not doom future attempts at statutory reform, however. It is possible that lawmakers should merely refocus their efforts on a different part of the decision-making process.

Thus far, this Article has focused on two steps of agency decision-making processes—risk assessment and risk management—but there is, in fact, a neglected third step that precedes these two. This is the step of prioritization. If risk assessment is step one, and risk management is step two, then prioritization is step zero.

Before conducting risk assessments, an agency must decide which risk assessments to do first. This prioritization challenge springs from the mismatch between agency resources and tasks. As the approximately 86,000 chemicals awaiting TSCA risk assessment by EPA illustrate, agencies' statutory responsibilities eclipse agencies' personnel, funds, and time.

Agencies ought to be allowed to triage risks covered by a statute and prioritize which risks deserve full risk assessments first. If an agency knows that one type of risk will likely be infeasible to regulate because of cost, while another roughly equivalent regulation will entail relatively low cost and ultimately move forward, the agency should pursue the low-hanging fruit first as a "tie-

326. *See supra* Part II.A.

327. *See id.*

breaker." This approach ensures agency resources target risks in areas that will ultimately lead to regulation and increased public safety, rather than sinking resources into examining risks that the agency will likely decline to regulate anyway. Just as emergency room doctors triage incoming patients based on initial impressions and later evaluate them more closely, agencies should be allowed to evaluate regulations based on their initial expectations about the benefits of regulation—most importantly the severity and significance of the risk averted—versus the likely costs of regulation.

Allowing agencies to prioritize risk assessments based on cost protects agency resources but avoids the evil of driving agencies to lie to the public. Instead of perverting risk assessments to avoid investing further time in risk management decisions, the agency can simply do other risk assessments first.

Similarly, cost-based prioritization allows agencies to pay homage to administrative political goals without lying to the public. If, for example, a particular administration sympathizes with a regulated industry, agencies could deprioritize risk assessments that would support costly regulation, instead of devaluing or denying the risk through a risk assessment. Agencies could save time by forgoing ersatz risk assessments but also become more politically accountable to the public. Citizens are probably better equipped to notice that an agency is failing to regulate asbestos altogether, for example, than to detect analytical moves in a risk assessment that understate asbestos's danger.[328]

In fact, one of this Article's examples in the TSCA context revealed an agency attempting to shift cost consideration into the prioritization phase. Recall that EPA initially proposed to prioritize chemicals for risk assessment based in part on whether the chemicals had known alternatives, a proxy for cost consideration.[329] Essentially, EPA was attempting—inappropriately, but understandably—to prioritize low-hanging fruit by considering alternatives. The attempt failed because the statute forbade cost consideration not only in the risk assessment stage, but in the prioritization stage. Thus, statutory language designed to protect public health instead lay the groundwork for distorting risk assessment.

Ideally, Congress would expressly permit this triage step in statutes that require agencies to regulate risk. Cost should not be the only factor driving prioritization; rather, it should serve as a tiebreaker when the agency faces a raft of potential risks to assess, and at first blush, the risks seem either equivalent or

328. *See* Holly Doremus, *Listing Decisions Under the Endangered Species Act: Why Better Science Isn't Always Better Policy*, 75 WASH. U. L.Q. 1029, 1082–83 (1997) ("Listing documents do not always contain enough information to allow others to evaluate their scientific merit."); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1656 (1995) (explaining that the "science charade" offers an opportunity to escape public scrutiny because the Administrative Procedure Act does not require the agency to explain its technical findings in a way the public could understand).

329. *See supra* Part II.A.2.

ambiguous. This scenario describes a non-negligible number of cases; agencies often must make risk assessments based on relatively thin science,[330] and in such circumstances, it seems reasonable that the agency's own anticipation of cost ought to influence priorities.

Critically, legislators should specify that in-depth analyses of cost are not required at this stage. A full cost analysis is probably impossible without a risk assessment to characterize the risk being regulated. Moreover, requirements for formal, in-depth cost analyses would eradicate the resource-saving virtues of this approach and recreate some of the evils that plagued TSCA. Rather, Congress should allow agencies to follow high-level first impressions the agencies harbor about the likely cost of regulating a risk. Because this initial prioritization would rely on high-level impressions, it would avoid duplicating the later risk management phase, just as an initial emergency-room intake exam does not render a subsequent full examination redundant.

Congress has an important part to play in discouraging cost contamination by allowing cost consideration at an earlier step in the decision-making process. But there is reason to doubt Congress's ability to execute these reforms. The federal legislature is heavily gridlocked, and statutory amendments may not be forthcoming, even for issues of bipartisan concern.[331]

Agencies, therefore, should implement this type of cost-conscious prioritization where legal. If statutes forbid cost-conscious prioritization, then agencies should not break the law. But if the statute is silent about prioritization, as is the case, for example, in the ESA, then agencies should use anticipated costs as a tie-breaker in prioritizing risk assessments.

Finally, courts should avoid unnecessarily burdening agencies in the prioritization phase. For cost-consideration at step zero to conserve agency resources, agencies must be allowed to prioritize without conducting full cost-benefit analyses, for example. If Congress loosens agencies' shackles, then the courts must not refasten them.

Thus, to decontaminate risk assessments, one may need to introduce cost consideration earlier in the regulatory decision-making process. This approach allows agencies to target low-hanging fruit and indulge political leanings without lying to the public through doctored risk assessments. These benefits are significant. But the solution is not perfect. The next Section addresses a few potential concerns about the proposed solution.

330. *See* Holly Doremus, *The Purposes, Effects, and Future of the Endangered Species Act's Best Available Science Mandate*, 34 ENVTL. L. 397, 429 (2004) ("[T]he scientific basis for many ESA actions is in fact surprisingly thin.").

331. *See* Richard L. Revesz, *Regulation and Distribution*, 93 N.Y.U. L. REV. 1489, 1520–24 (2018) (discussing trends in and reasons for gridlock in Congress).

C. Addressing a Few Concerns about Cost-Based Prioritization

If cost consideration wreaks so much havoc on risk assessment, introducing cost consideration into a preceding prioritization step might seem an odd remedy. And indeed, there are some shortcomings to the approach. Nonetheless, even if this approach fails to ensure platonically perfect rulemaking, it considerably improves upon the status quo.

First, some might worry that allowing agencies to prioritize risk assessments based on informal consideration of cost eliminates an important part of the agency decision-making record and therefore undermines the public's ability to challenge agency decisions in court. At least in the case of cost contaminated risk assessments, one might argue, the agency leaves an evidentiary trail that can be identified and condemned in litigation.

Broadly speaking, it is probably true that shifting cost consideration from risk assessment to prioritization removes some of the basis for accountability through lawsuits. But the approach should also increase democratic accountability, because agencies will have less incentive to engage in subterfuge to secretly consider cost. Rather than lying to the public about the severity of a particular risk, the agency can simply deprioritize regulating it. If the public cares enough about regulating that risk, then members of the public will exert pressure on the agency to act.[332] If the agency still fails to regulate, then citizens may vote for a new administration.[333]

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332. Several studies have measured and affirmed the ability of citizens to exert pressure on national agencies and change policy outcomes. *See, e.g.*, Dorothy M. Daley, *Citizen Groups and Scientific Decisionmaking: Does Public Participation Influence Environmental Outcomes?*, 26 J. Pol'y Analysis & Mgmt. 349, 362 (2007) ("When local citizen[s] become active at Superfund sites, the EPA is more likely to select stringent, health protective remedial actions."); Tomas M. Koontz, *Administrators and Citizens: Measuring Agency Officials' Efforts to Foster and Use Public Input in Forest Policy*, 9 J. Pub. Admin. Res. & Theory 251, 275 (1999) ("We have seen that national forest officials are more likely to use public input to shape policy decisions, while state forest officials are more likely to interact with citizens in order to gain support for agency decisions made by officials."); Tomas M. Koontz, *Citizen Participation: Conflicting Interests in State and National Agency Policy Making*, 36 Soc. Sci. J. 441, 452 (1999) (finding, in the context of forest management policy, that citizen participation representing environmental preservation interests, as opposed to economic use interests, was higher and perceived as more influential at the national agency level than at the state agency level); William M. Tabb, *Public Participation in Environmental Decisionmaking*, *in* Decision Making in Environmental Law, Elgar Encyclopedia of Environmental Law Volume II 313, 318 (Le Roy C. Paddock, Robert L. Glicksman & Nicholas S. Bryner eds., 2016) (noting that the ESA's protections "historically have fostered significant public debates between strong pro-conservation groups and" development groups, but noting that the highly technical scientific information involved in listing can make it difficult for citizens to evaluate agency decisions).

333. This view of democratic accountability of agencies reflects the view of the Supreme Court. *See* Nicholas O. Stephanopoulos, *Accountability Claims in Constitutional Law*, 112 Nw. U. L. Rev. 989, 1011–12 (2018) (discussing the Justices' views of electoral accountability of agen-

Second, one might worry that agencies' first impressions about risk and cost are wrong. Perhaps a particular risk looks as though it will be too expensive to regulate at first blush. But as the agency engages in a risk assessment and risk management decision, the agency discovers that either the risks are greater than it originally believed—thereby justifying more expensive regulation—or that the costs of regulating are lower than initially suspected, thereby making regulation more feasible. If agencies can prioritize based on cost, they will probably miss some risks worth regulating.

Although cost-based prioritization might entail some missed regulatory opportunities, this type of inaccuracy could also play out under the current regime. If an agency begins a risk assessment with the goal of downplaying the risk, then it will probably never get an accurate estimation of the risk or the costs of regulating it. Considering cost at step zero should not greatly amplify this pitfall of decision-making.

Third, this solution assumes that agencies have the ability to prioritize; in reality, some statutes may curtail this freedom. For example, some laws include statutory deadlines triggered by events outside of the agency's control, like citizen petitions for agency action.[334] If the agency fails to respond to the petition reasonably by the deadline, then citizens can sue. In such cases, agencies have reduced ability to deprioritize regulations and may be forced to conduct risk assessments. If so, agencies will likely be tempted to consider cost during the risk assessment stage.

It is true that in some cases the agency may have a limited ability to prioritize because of statutory deadlines triggered by petitions. But agencies are already routinely sued by citizen groups because they fail to meet statutory deadlines.[335] If the agency lacks the resources to meet all of its statutory deadlines, then the agency must choose which ones to meet, and again, the agency ought to consider cost in its prioritization process. This may in some cases

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cies controlled by the executive branch). Scholarly writing has also noted that oversight in the form of interest groups and media coverage constrains agency action. *See* Peter H. Schuck, *Delegation and Democracy: Comments on David Schoenbrod*, 20 CARDOZO L. REV. 775, 789–90 (1999). There is reason to be skeptical that all voters are as informed about agency actions—and the President's control over such actions—as the Supreme Court assumes, but even a skeptical account allows that some voters are thus informed, and that awareness may be especially strong with respect to agencies like EPA that receive a lot of media coverage. *See* Stephanopoulos, *supra*, at 1023–24, 1031 (discussing media coverage of agencies and the share of informed voters, respectively).

334. For example, both TSCA and the ESA allow citizens to petition for a substance or species to be listed and have statutorily mandated deadlines by which the agency must respond. *TSCA Section 21*, EPA, https://perma.cc/77TK-E47D; *Listing and Critical Habitat: Petition Process*, FWS, https://perma.cc/S5K9-DZLB.

335. *See* Ben Tyson, Note, *An Empirical Analysis of Sue-and-Settle in Environmental Litigation*, 100 VA. L. REV. 1545, 1548–49 (2014) (referring to the explosive growth of "sue-and-settle").

indirectly cause the priorities of the agency to align with those of would-be litigants, because if a risk is especially severe or widespread, the triage process is more likely to prioritize it, and such cases are also probably those whose facts would most appeal to nongovernmental groups seeking to push the agency to enforce the law. Moreover, if lawsuits did come, they would likely follow the general pattern of settling, as such suits typically do today. As part of settlement discussions, the agency could attempt to advocate for and explain the greater importance of its priorities to opposing litigants. Although it is unlikely such litigants would be sympathetic to an EPA that refused to enforce TSCA at all, they might be sympathetic to an agency that wanted in good faith to pursue a different list of high-priority chemicals.

Finally, one might wonder why agencies would choose to play along with cost-based prioritization if they can achieve the same ends through cost-contamination with less public accountability. The answer comes in two parts. First, to the extent that agencies turn to cost contamination intentionally or unintentionally as a means of conserving agency resources, prioritization would seem more efficient than cost contamination at the risk assessment stage. The former requires ex ante judgment; the latter requires a scientific charade meant to disguise cost consideration. Second, to the extent agencies turn to cost contamination because of political loyalties to regulated parties, it is likely these parties would prefer not to have risk assessments at all. Unless regulated entities are confident their product or activity poses no risk, they cannot be sure about what the outcome of a risk assessment will be, even under a friendly administration. Thus, regulated entities would likely prefer the agency deprioritize them altogether. If the regulated entities have this preference, sympathetic agencies will likely follow that preference, and consider cost at the prioritization step, not later. Even if in some cases, for some reason, agencies fall back into cost contamination, decreasing the frequency of this phenomenon will improve the state of agency decision-making relative to the status quo.

Conclusion

Risks infect every aspect of Americans' daily lives. Risks hang in the air at work and swim in the water at home. To protect against those risks, Americans look to administrative agencies. But agencies are imperfect saviors: Unable to eliminate every risk, they must make tradeoffs based on regulatory costs, ensuring that some plants, animals, and people will continue to ail, suffer, and die, even as others are saved. This responsibility may be an uncomfortable one for agencies, but agencies must not lie to the public by downplaying real risks. Instead, agencies should accept their crucial task and meet it head-on, prioritizing areas where the balance of risk and cost does not preclude regulation. Such an approach will lead to more democratic accountability. If agencies are forced to gamble with lives, the public ought to know the stakes.