
EPA's Fuzzy Bright Line Approach to Residual Risk

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*Since its passage in 1970, section 112 of the Clean Air Act (CAA) has regulated the health risks associated with exposure to hazardous air pollutants (HAPs). Risk managers at the Environmental Protection Agency (EPA) entrusted with implementing section 112, however, often know little about the relationship between exposure to HAPs and the incidence of disease. Partly because of this uncertainty, EPA struggled to implement section 112, prompting Congress to revamp the regulatory approach in 1990. Technology-based controls now provide the first line of defense, but health-based controls similar to those in the 1970 CAA continue to govern any leftover, or residual, risk. The “residual risk” provision is found in section 112(f)(2)(A), which affords EPA discretion to set standards so long as they leave “an ample margin of safety to protect public health.” But that section also directs EPA to promulgate standards whenever lifetime excess cancer risks from exposure to a HAP exceed one-in-one million (“the trigger”). The issue of EPA’s obligations under section 112(f) recently came before the D.C. Circuit in *Natural Resources Defense Council v. EPA*—the agency contended the trigger only required that it evaluate risk in a rulemaking, while environmental groups argued the trigger required EPA to eliminate all risks above the one-in-one-million mark. The court sided with EPA, holding that the agency had reasonably interpreted its obligations under the statute. This Note explores the impact of the court’s decision on future EPA residual risk rulemaking. It contends that EPA’s reading of section 112(f)(2)(A), while not confidence-inspiring, does provide a workable framework for addressing the core concerns posed by the scientific uncertainty underscoring HAP regulation. However, to safeguard against EPA defaulting to a risk-management approach that ignores source-specific variation, this Note concludes that courts must take a particularly hard look at EPA residual risk standards.*

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INTRODUCTION

The relationship between exposure to hazardous air pollutants (HAPs) and the incidence of disease is plagued by uncertainty. This poses several problems from a regulatory perspective. If health effects are uncertain, how much cancer risk from a particular HAP is acceptable? Modeling techniques such as

quantitative risk assessment can provide some guidance, but setting tolerable risk levels is ultimately a value-laden process. Who then should set these values, and what should that process look like? Although proposals may differ, any answer to these questions must acknowledge the limitations that uncertainty places on regulatory solutions.

What is certain is that exposure to HAPs must be limited, one way or another, in order to protect public health adequately. In an effort to meet this challenge, Congress made HAP regulation a centerpiece of the landmark Clean Air Act (CAA or the Act) of 1970.¹ Congress entrusted the task of achieving the Act's ambitious targets primarily to the newly created Environmental Protection Agency (EPA). EPA struggled to implement the obscure HAP provisions, though, prompting Congress to amend the CAA in 1990.² In those amendments, Congress opted for a technology-based approach to reducing HAP emissions at the outset, followed by health-based standards designed to eliminate any leftover, or residual, risk that the technology controls did not adequately address.³ The "residual risk" provision is found in section 112(f) of the Act, which directs EPA to reduce any remaining risks associated with HAP emissions within an "ample margin of safety to protect public health."⁴

But what does "an ample margin of safety" mean? EPA, as the agency entrusted with implementing the CAA, has considerable discretion in making this determination. The statute, however, suggests Congress did not intend to leave this discretion entirely uncabined: the last sentence of section 112(f)(2)(A) provides a procedural trigger for EPA to promulgate standards under this section when lifetime excess cancer risks for carcinogens exceed one-in-one million.⁵ This clue from Congress, while not definitive in setting a substantive health-based standard EPA must arrive at, does provide some indication that, at minimum, Congress considered risks above one-in-one million worthy of particular attention.

Yet, a directive simply to "promulgate standards" does not address what those standards must entail. If EPA has already determined what the "ample margin of safety" is for a particular HAP, must it still abide by Congress's procedural command? This issue came to a head in the recent D.C. Circuit Court of Appeals decision, *Natural Resources Defense Council v. Environmental Protection Agency (NRDC v. EPA)*.⁶ There, the procedural trigger was met—cancer risks from synthetic organic chemicals exceeded one-in-one million—but EPA did not promulgate any standards. Instead, EPA

1. Clean Air Act Amendments of 1970, Pub. L. No. 91-604, § 112, 84 Stat. 1676, 1685 (amended 1990).

2. 42 U.S.C. § 7412 (1990).

3. *Id.*

4. *Id.* § 7412(f)(2)(A).

5. *Id.*

6. 529 F.3d 1077 (D.C. Cir. 2008).

construed its procedural obligation under the Act as requiring only that it further evaluate risk in a rulemaking, and ultimately decided that its preexisting technology-based standards already provided an “ample margin of safety.”⁷ The court agreed, holding that EPA’s interpretation of its obligations under section 112(f)(2)(A), “although not an inevitable one, certainly is, at least, a reasonable construction of the statute.”⁸

This Note explores the impact of the court’s decision on future EPA residual risk standards for carcinogens. It argues that EPA’s interpretation of section 112(f)(2)(A) provides a workable framework for addressing the core concerns posed by the scientific uncertainty underscoring HAP regulation, but, at least in the form endorsed by the court, does not adequately ensure that EPA will consider health risks on a case-by-case basis. To safeguard against EPA’s defaulting to a risk-management approach that produces regulations clustered at the statutory minimum, this Note contends that courts should take a particularly hard look at EPA residual risk standards.

While this may nonetheless leave EPA with significant discretion, this Note further examines why the alternative advanced by NRDC—that section 112(f)(2)(A) requires EPA to eliminate all risks above one-in-one million—may do little in constraining the range of EPA’s regulatory outcomes. Rather, because the uncertainty surrounding HAPs affords EPA significant discretion in calculating risk levels, setting a one-size-fits-all standard may simply shift EPA policy making on risk tolerance into EPA’s assessment of risk.

I. REGULATING HAZARDOUS AIR POLLUTANTS

A. Overview

Section 112 of the CAA requires EPA to establish national emission standards for hazardous air pollutants (NESHAPs).⁹ Currently, the CAA defines “hazardous air pollutants,” for which EPA must issue standards, as air pollutants that “present, or may present . . . a threat of adverse human health effects . . . or adverse environmental effects.”¹⁰ Section 112 refers to two types of HAPs: carcinogens, which cause various types of cancer, and non-carcinogens, which cause other serious neurological, reproductive, or acute

7. *Id.* at 1080.

8. *Id.* at 1083.

9. 42 U.S.C. § 7412 (2006).

10. *See id.* § 7412(b)(2). Under the 1970 CAA, EPA had to issue standards for any air pollutant “to which no ambient air quality standard is applicable and which in the judgment of the [EPA] causes, or contributes to . . . an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness.” Clean Air Act Amendments of 1970, Pub. L. No. 91-604, § 112(a)(1), 84 Stat. 1676, 1685 (amended 1990).

diseases.¹¹ Studies indicate carcinogenic HAPs, such as benzene and vinyl chloride, cause an estimated three thousand cases of fatal cancer each year and non-carcinogenic HAPs, such as mercury and cadmium, can result in reproductive harms, birth defects, and lung disease.¹² The detrimental health effects of human exposure to HAPs are uncontested and, as the data indicate, present a serious risk to public health.

Less clear, however, is the relationship between exposure to any particular HAP and the incidence of cancer or other detrimental health effect.¹³ To account for these uncertainties, EPA employs risk assessments to predict the probability of developing a particular health condition as a result of exposure to a particular HAP.¹⁴

B. Risk Assessment

Risk assessment provides qualitative and quantitative indications of the human health risks attributable to exposure to an environmental agent.¹⁵ Risk management is the process of determining how to respond to the information collected in a risk assessment.¹⁶ EPA's risk assessments of carcinogens consist of four steps: hazard identification, dose-response evaluation, exposure assessment, and risk characterization.¹⁷

1. Hazard Identification

Hazard identification, the first step, examines whether a particular agent is capable of increasing an individual's risk of developing cancer.¹⁸ EPA considers whether an agent is likely a human carcinogen by evaluating all available data concerning the potential carcinogenicity of the substance.¹⁹ Based on this assessment, EPA classifies the agent in one of five categories²⁰ and undertakes additional risk evaluation only for compounds that fall into the

11. 42 U.S.C. § 7412; see also Bradford C. Mank, *A Scrivener's Error or Greater Protection of the Public: Does the EPA Have the Authority to Delist "Low-Risk" Sources of Carcinogens from Section 112's Maximum Achievable Control Technology Requirements?*, 24 VA. ENVTL. L.J. 75, 82–83 (2005).

12. Mank, *A Scrivener's Error*, *supra* note 11, at 83.

13. See Alan Rosenthal, George M. Gray & John D. Graham, *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 ECOLOGY L.Q. 269, 277–78 (1992).

14. *Id.*

15. *Id.* at 270.

16. *Id.*

17. See Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992 (Sept. 24, 1986).

18. Rosenthal et al., *supra* note 13, at 279.

19. Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. at 33,992.

20. Group A: carcinogenic to humans; group B: probably carcinogenic to humans; group C: possibly carcinogenic to humans; group D: not classifiable as to human carcinogenicity; and group E: evidence of noncarcinogenicity for humans. *Id.* at 33,996–34,000.

top two categories (“carcinogenic to humans” and “probably carcinogenic to humans”) and sometimes the third (“possibly carcinogenic to humans”).²¹

2. *Dose Response Evaluation*

Next, dose-response evaluation examines the relationship between the dose of an agent identified as a known, probable, or possible carcinogen and the probability of developing cancer.²² Often, little is known about how a substance causes cancer. Characterizing the relationship between the agent and the effect can therefore be difficult.²³ In particular, the risk assessor must determine whether the likelihood of developing cancer can be assumed to follow a linear trajectory as dosage increases, or if there is a “threshold” dosage below which the agent is not carcinogenic.²⁴ On this issue, EPA has taken a conservative position and requires the use of a linear model in all risk assessments unless persuasive evidence supports the choice of another model.²⁵

3. *Exposure Assessment*

The third step, exposure assessment, evaluates the extent to which the relevant population is likely to be exposed to the carcinogen.²⁶ Predicting population behavior and assessing which populations are most sensitive to carcinogens, however, is a complicated process.²⁷ To avoid making these estimates, EPA usually assumes exposure rates based on the maximally exposed individual (MEI).²⁸ EPA’s use of the MEI has come under attack as facilitating over-regulation; critics argue the MEI produces regulations that may exceed by orders of magnitude the actual exposure to any real person.²⁹ Supporters point out that highly exposed persons have an equal right to protection, and that conservatism is appropriate given other uncertainties in risk assessment.³⁰

21. *Id.*

22. Rosenthal et al., *supra* note 13, at 285.

23. *Id.* For example, questions arise as to whether humans respond to the same dose-response mechanisms as lab animals and whether different populations, such as children, respond differently than the baseline population. *Id.* at 287.

24. *Id.* at 285.

25. Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992, 33,992 (Sept. 24, 1986). The EPA guidelines do not indicate, however, what sort of evidence would be persuasive. *See id.*

26. Rosenthal et al., *supra* note 13, at 290.

27. *Id.* at 290.

28. *Id.* at 291.

29. *Id.*

30. *Id.*

4. Risk Characterization

Finally, in risk characterization, the risk assessor combines the estimates of toxicity and exposure to produce a description of the nature and extent of the risk posed by the particular agent.³¹ This description typically is expressed numerically as the incremental lifetime risk of cancer due to the agent at a particular level of exposure.³² Due to the conservative assumptions built into its risk assessment process, such as its use of linear models and the MEI, EPA considers that a risk estimate produced in line with its procedures should be regarded as a plausible upper bound of risk.³³ As a result, EPA encourages risk assessors to include additional information, including a discussion of the weight of evidence for classifying the agent as a carcinogen and a summary of the various sources of uncertainty in the risk estimate.³⁴

Congress significantly altered EPA's regulatory approach to HAPs under section 112 in the 1990 CAA Amendments. Congress did not disturb, however, EPA's methodology—risk assessment—for addressing scientific uncertainty with respect to HAPs.³⁵ As this Note will reveal, EPA's oversight of risk assessment significantly handicaps any effort to restrict the agency's discretion in setting substantive risk levels.³⁶ Accordingly, to assess the effectiveness of EPA's interpretation of section 112(f), one must take into account the impact of delegating risk assessment authority to EPA. Likewise, EPA's current interpretation of section 112(f) must be evaluated against the backdrop of EPA's struggles under the 1970 version of the CAA.

C. The Clean Air Act Amendments

1. The 1970 Clean Air Act

Section 112 of the 1970 CAA required EPA to establish health-based emissions standards for HAPs that provided an "ample margin of safety" to protect public health from that air pollutant.³⁷ EPA managed to identify and list only eight HAPs, and promulgated standards for only some sources of seven types of HAPs, before Congress amended the CAA again in 1990.³⁸ Even that

31. *Id.*

32. Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992, 33,998–33,999 (Sept. 24, 1986).

33. Rosenthal et al., *supra* note 13, at 294.

34. Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. at 33,998–33,999.

35. *Id.*

36. *See infra* Part III.B.

37. Clean Air Act Amendments of 1970, Pub. L. No. 91-604, § 112(b)(1)(B)(ii), 84 Stat. 1676, 1685 (amended 1990).

38. *See* CRAIG N. JOHNSTON, WILLIAM F. FUNK & VICTOR B. FLATT, LEGAL PROTECTION OF THE ENVIRONMENT 367–68 (2005) (EPA listed asbestos, benzene, beryllium, inorganic arsenic, mercury, radionuclides, coke oven emissions, and vinyl chloride).

accomplishment is misleading, however, as five of the seven regulations that EPA listed resulted from court orders.³⁹ In contrast, state agencies listed hundreds of HAPs during the twenty years that EPA remained bogged down in delays.⁴⁰

What accounts for the discrepancy? Commentators point to several factors, but two considerations stand out. First, EPA faced heavy burdens if it chose to list a pollutant as a HAP.⁴¹ Since EPA could avoid, in its judgment, unduly costly regulations only by exercising discretion not to list pollutants as HAPs in the first place, in most cases it took no action at all.⁴² Similarly, EPA employed a strategy of delaying listing pollutants as HAPs for as long as possible, often until prompted by litigation.⁴³

Compounding the problem, until the late 1990s, EPA assumed that all carcinogens were non-threshold chemicals which posed risks to human health at all concentrations.⁴⁴ EPA therefore had to assume that there was no completely safe level other than zero exposure. As a result, EPA suggested early on that the “ample margin of safety test,” if interpreted literally, might be construed to require zero emissions for carcinogens.⁴⁵ Under this reading, the “ample margin of safety” standard would effectively shut down large sectors of industry.⁴⁶ Even after EPA rejected this literal construction of the Act, agency officials continued to view the costly NESHAPs as too expensive to justify in light of the uncertain reductions in cancer risk.⁴⁷

Second, the only directive Congress provided EPA with to set standards for HAPs—the “ample margin of safety”—left EPA with too little guidance and too much discretion. This ambiguity factored into EPA’s reluctance to

39. See Mank, *A Scrivener’s Error*, *supra* note 11, at 86–87.

40. See Victor B. Flatt, *Gasping for Breath: The Administrative Flaws of Federal Hazardous Air Pollution Regulation and What We Can Learn From the States*, 34 *ECOLOGY L.Q.* 107, 114 (2007).

41. See John S. Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 *YALE J. ON REG.* 277, 309 (1992); Bradford C. Mank, *What Comes After Technology: Using an “Exceptions Process” To Improve Residual Risk Regulation of Hazardous Air Pollutants*, 13 *STAN. ENVTL. L.J.* 263, 268 (1994); Rosenthal et al., *supra* note 13, at 302.

42. See Applegate, *supra* note 41, at 309.

43. See Mank, *What Comes After Technology*, *supra* note 41, at 269.

44. See Proposed Guidelines for Carcinogen Risk Assessment, 61 *Fed. Reg.* 17,960, 17,968 (April 23, 1996); Mank, *A Scrivener’s Error*, *supra* note 11, at 83. EPA generally assumed most non-carcinogens were “threshold” chemicals posing risk to human health only above threshold concentrations. See National Emission Standards for Hazardous Air Pollutants; Policy and Procedures for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer, 44 *Fed. Reg.* 58,642, 58,659–60 (October 10, 1979); Mank, *A Scrivener’s Error*, *supra* note 11, at 83–84.

45. See Mank, *What Comes After Technology*, *supra* note 41, at 268.

46. *Id.*

47. See Rosenthal et al., *supra* note 13, at 302 (explaining “since listing [a HAP] could trigger extremely costly NESHAPs, EPA was reluctant to list substances without compelling evidence of widespread population risk.”); see also Mank, *What Comes After Technology*, *supra* note 41, at 268 (noting “the ‘ample margin of safety’ language proved counterproductive because the EPA was reluctant to effectively shut down entire industries by listing pollutants, where such listing would require zero emission standards”).

issue standards, as section 112's legislative history did not clearly address how the EPA should balance issues such as health, cost, and feasibility.⁴⁸ Hence, EPA often deliberately delayed issuing NESHAPs for fear of judicial reversal.⁴⁹ Even after courts stepped in to clarify EPA's obligations under section 112,⁵⁰ however, the standard left EPA with considerable discretion to avoid listing HAPs. Professor Dwyer has argued this ambiguity was largely by design, as Congress wanted to create a program that was "more symbolic than functional."⁵¹ Whatever the motivation, Congress did not provide EPA sufficient parameters within which to administer the HAP provisions under the 1970 CAA Amendments.

With both strong incentive and sufficient discretion to avoid acknowledging that a potential HAP warranted regulation, it is perhaps understandable why EPA promulgated only seven standards in twenty years. Congress partially addressed this recipe for under-regulation by significantly curtailing EPA's discretion to list HAPs in the 1990 CAA Amendments. Nonetheless, the relationship between EPA's incentives and discretion to regulate, which combined to paralytic effect under the 1970 Act, remains a vital consideration in assessing EPA's current approach to hazardous air pollutants.

2. *The 1990 Amendments*

Given EPA's shortcomings under the 1970 CAA, Congress revamped the federal regulatory approach to HAPs in 1990.⁵² Rather than require EPA to list chemicals as hazardous one-by-one, Congress directly listed 191 substances.⁵³ And, in place of a singular health-based approach, Congress implemented both technology-based controls (Phase I) and health-based controls (Phase II) under the new section 112.⁵⁴

In Phase I, EPA must issue technology-based standards set at the maximum achievable control technology (MACT) for all new and existing major sources⁵⁵ that emit one or more of the listed HAPs.⁵⁶ The Act defines

48. See Mank, *What Comes After Technology*, *supra* note 41, at 268.

49. See Mank, *A Scrivener's Error*, *supra* note 11, at 86.

50. See discussion of *Vinyl Chloride*, *infra* Part I.D.1.

51. See John P. Dwyer, *The Pathology of Symbolic Legislation*, 17 *ECOLOGICAL L.Q.* 233, 233 (1990).

52. See S. COMM. REP. NO. 101-228, at 128 (Report on S. 1630, Clean Air Act Amendments of 1989) (noting "the law has worked poorly. In 18 years, the EPA has regulated only some sources of only seven chemicals. One reason the law has worked poorly is the standard of protection required . . . the EPA has not been willing to write standards so stringent because they would shutdown major segments of American industry"). See also Mank, *A Scrivener's Error*, *supra* note 11, at 89.

53. 42 U.S.C. § 7412(b)(1) (2006). However, EPA maintains responsibility for identifying future HAPs. *Id.* § 7412(b)(2).

54. See *Sierra Club v. EPA*, 353 F.3d 976, 979 (D.C. Cir. 2004) (outlining new scheme under section 112).

55. The CAA defines "major source" as "any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit

MACT as the technology that provides the “maximum degree of reduction in emissions of the hazardous air pollutant[.]”⁵⁷ The MACT for any source depends on whether the source is new or already exists: standards for new sources may not be less stringent than “the emission control that is achieved in practice by the best controlled similar source”; standards for existing sources may not be less stringent than “the average emission limitation achieved by the best performing 12 percent of the existing sources.”⁵⁸ After this “floor” is set, EPA may require a greater reduction in emissions, taking into account costs and non-air quality related health, environmental, or energy impacts or requirements.⁵⁹ EPA must revise its MACT standards every eight years to reflect recent technological developments.⁶⁰

In Phase II, the Act requires EPA to perform a health-based review of any residual health risks left over from the initial technology-based regulations.⁶¹ EPA must submit a report to Congress containing its finding within six years of promulgating a MACT standard.⁶² If Congress does not act on the report, section 112(f)(2) instructs EPA to conduct residual risk analysis within eight years of promulgating a MACT standard.⁶³ As under the pre-1990 approach, EPA must determine whether such standards are required “in order to provide an ample margin of safety to protect public health . . . or to prevent . . . an adverse environmental effect.”⁶⁴

The revised framework in section 112 addressed some of the key problems that hampered HAP regulation under the 1970 CAA. By directly listing substances, Congress eliminated the administrative delay involved in EPA listing pollutants as hazardous. By imposing technology-based standards as the initial step, Congress also alleviated part of the problem presented by scientific uncertainty; the substance of Phase I standards are determined by reference to the technology controls industry has already achieved, not through the highly contentious risk characterization process. The 1990 Amendments thus eliminate EPA’s ability to refuse to issue standards for hazardous pollutants because of uncertain health effects.⁶⁵

considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants.” 42 U.S.C. § 7412(a)(1).

56. *Id.* § 7412(d)(6).

57. *Id.*

58. *See* *Natural Res. Def. Council v. EPA*, 529 F.3d 1077, 1079 (D.C. Cir. 2008); 42 U.S.C. § 7412(d)(3).

59. 42 U.S.C. § 7412(d)(2); *see also* Flatt, *supra* note 40, at 115–16.

60. 42 U.S.C. § 7412(d)(6).

61. *Id.* § 7412(f)(1)(A).

62. *Id.*

63. *Id.* § 7412(f)(2)(A).

64. *Id.*

65. This is true at least for the 191 substances Congress has identified as hazardous. 42 U.S.C. § 7412(b)(1) (2006). EPA retains discretion to refuse listing—and therefore avoid issuing technology-based standards for—other potential HAPs. *Id.* § 7412(b)(2).

Nonetheless, issues that plagued the old section 112 scheme remain. Notably, Phase II continues to direct EPA to account for residual health risks by reference to the “ample margin of safety,”⁶⁶ a standard that EPA has struggled to implement. Because the 1990 Amendments still define that standard in light of the statute’s pre-1990 history, the next Part explores the meaning of the “ample margin of safety.”

D. The “Ample Margin of Safety”

I. Vinyl Chloride

Congress did not specify whether EPA could consider the cost and technological feasibility of regulating HAPs in setting health standards under the 1970 CAA. EPA began to consider such factors in issuing regulations during the 1970s and 1980s,⁶⁷ including the standard it issued for vinyl chloride, a carcinogenic chemical used in the manufacture of plastics.⁶⁸ NRDC challenged the regulation, claiming that section 112 did not permit EPA to consider non-health factors in establishing emission standards for HAPs.⁶⁹

In *Natural Resources Defense Council v. Environmental Protection Agency (Vinyl Chloride)*, in a unanimous en banc decision, the D.C. Circuit struck down EPA’s regulation; but the court disagreed with NRDC’s contention—that EPA must focus entirely on health considerations when setting HAP standards.⁷⁰ Rather, the court concluded that the “ample margin of safety” standard in section 112 requires EPA to set HAP regulations under a two-step process.⁷¹ First, the agency must determine at what level of concentration a chemical poses an “acceptable risk to health.”⁷² At this stage, EPA may not consider cost or technological feasibility in determining the “safe” or “acceptable” level of risk, but the court emphasized that “safe” does not mean risk free.⁷³ Second, EPA has the discretion to set emission standards stricter than the “safe” emission level in order to provide an “ample margin of safety” to the public.⁷⁴ EPA may consider technological or cost factors, however, in assessing what constitutes an “ample margin of safety.”⁷⁵ *Vinyl*

66. 42 U.S.C. § 7412(f)(2)(A) (2006).

67. Mank, *A Scrivener’s Error*, *supra* note 11, at 87.

68. See *Natural Res. Def. Council v. EPA (Vinyl Chloride)*, 824 F.2d 1146, 1148 (D.C. Cir. 1987) (en banc).

69. *Id.* at 1147–48. NRDC also argued that section 112 required EPA to adopt zero emission standards for any non-threshold carcinogens, which the court rejected. *Id.* at 1152, 1154–63.

70. *Id.* at 1147–48.

71. *Id.*

72. *Id.* at 1165.

73. *Id.* at 1164–65.

74. *Id.* at 1165.

75. *Id.*

Chloride remains the only major case that analyzes section 112's "ample margin of safety" standard. Since the 1990 Amendments did not alter this framework, the case continues to govern how EPA must comply with the standard.

2. *The Benzene NESHAP*

EPA applied the D.C. Circuit's framework in *Vinyl Chloride* to issue residual risk standards in the 1989 Benzene rulemaking.⁷⁶ In so doing, EPA set out its current approach to addressing residual risk from HAPs.⁷⁷ In line with *Vinyl Chloride*, EPA first identifies a "safe" risk level for a particular HAP considering only health criteria.⁷⁸ In the Benzene NESHAP, EPA determined that lifetime excess cancer risks for carcinogenic HAPs such as benzene that are at or below one hundred-in-one million are "presumptively safe."⁷⁹ In the second step, EPA considers whether providing the public with "an ample margin of safety" requires risks to be reduced further than this "safe" level, based on EPA's consideration of health information and other factors such as cost, economic impact, and technological feasibility.⁸⁰

However, EPA's approach to residual risk in the Benzene NESHAP went beyond the minimum requirements laid out in *Vinyl Chloride*. In the preamble, for instance, EPA stated that despite the one hundred-in-one million "floor," it would strive to protect "the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million."⁸¹ Moreover, EPA acknowledged that in a particular case, risk lower than the presumptively acceptable level (one hundred-in-one million) might be unacceptable in light of other health risk factors.⁸² At least with respect to carcinogens, EPA thus embraced a more contextual approach to residual risk in the Benzene NESHAP than *Vinyl Chloride*'s two steps required.

EPA promulgated the Benzene NESHAP in 1989, one year before Congress amended the Clean Air Act in 1990. Both EPA and Congress have subsequently pointed to the Benzene NESHAP as a reasonable approach to determine the "ample margin of safety" under the 1990 CAA Amendment's

76. National Emission Standards for Hazardous Air Pollutants; Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants (Benzene NESHAP), 54 Fed. Reg. 38,044 (Sept. 14, 1989) (to be codified at 40 C.F.R. pt.1) (noting the Benzene standards would follow the "policy approach for setting NESHAP that is consistent with the requirements of *Vinyl Chloride*").

77. *Id.*

78. *Id.*

79. *Id.* at 38,044–38,046.

80. *Id.* at 38,046.

81. *Id.*

82. *Id.*

section 112(f).⁸³ Yet Congress also amended section 112(f) to require EPA to promulgate standards for sources emitting carcinogens when MACT standards did not reduce cancer risks to less than one-in-one million (the “trigger”).⁸⁴ This appears at odds with EPA’s conclusion in the Benzene NESHAP that cancer risks below one hundred-in-one million are “presumptively safe.”⁸⁵ Did Congress therefore alter EPA’s approach to residual risk set forth in the Benzene NESHAP, establishing one-in-one million as the “ample margin of safety” for carcinogens? Must EPA then eliminate all risk above this threshold? If not, what does Congress’ mandate to “promulgate standards” entail?

These questions were the subject of *NRDC v. EPA*, in which the D.C. Circuit upheld one of EPA’s first efforts at residual risk rulemaking under the revised section 112.⁸⁶ Petitioners NRDC and the Louisiana Environmental Action Network (LEAN)⁸⁷ challenged EPA’s decision to not impose any health-based restrictions under its Hazardous Organic NESHAP (HON).⁸⁸ In a decision by Judge Silberman, the D.C. Circuit denied the petition, holding that EPA reasonably interpreted its obligations to issue residual risk standards under section 112(f)(2)(A).⁸⁹

II. NRDC V. EPA: THE “NEW” SECTION 112 GOES TO COURT

A. Background

In 1994, EPA promulgated MACT standards for the synthetic organic chemical manufacturing industry (SOCMI) as the first phase of technology-based regulation under the HON.⁹⁰ SOCMI sources produce hundreds of high-volume organic chemicals as either final products or feedstock used to produce

83. EPA has directly championed its Benzene approach. See Residual Risk Report to Congress, EPA-453/R-99-001 (1999), available at http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf (noting for public health risk management decision making in the residual risk program, EPA considers the two-step process culminating with an “ample margin of safety” determination, as established in the 1989 benzene NESHAP, and endorsed by Congress in the 1990 CAA Amendments as a reasonable approach). The endorsement by Congress to which EPA refers is more subtle. See 42 U.S.C. § 7412(f)(2)(B) (2006) (noting “[n]othing . . . shall be construed as affecting, or applying to the Administrator’s interpretation of this section, as in effect before November 15, 1990, and set forth in the Federal Register of September 14, 1989 (Federal Register 38044)”). The cited item in the Federal Register is to EPA’s Benzene rulemaking. See also *infra* Part II.B.

84. 42 U.S.C. § 7412(f)(2)(A).

85. See Benzene NESHAP, *supra* note 76, at 38,044–38,046.

86. *Natural Res. Def. Council v. EPA*, 529 F.3d 1077, 1087 (D.C. Cir. 2008).

87. This Note refers to NRDC’s and LEAN’s positions simply as NRDC’s.

88. *Natural Res. Def. Council*, 529 F.3d at 1080.

89. *Id.* at 1087.

90. See National Emission Standards for Organic Hazardous Air Pollutants, 59 Fed. Reg. 19,402 (April 22, 1994) (to be codified at 40 C.F.R. pt. 63). The SOCMI in the United States is comprised of 238 facilities. *Natural Res. Def. Council*, 529 F.3d at 1080.

other chemicals.⁹¹ Synthetic organic chemicals have few uses, but “often serve as raw materials in the production of plastic, rubbers, fibers, protective coatings and detergents.”⁹² Prior to implementing the HON, EPA estimated that total HAP emissions from SOCOMI facilities were 570,000 tons per year.⁹³ After implementing the HON, EPA estimated that the total HAP emissions fell to 66,000 tons per year,⁹⁴ and HAP emissions from regulated emission points at SOCOMI facilities fell by 95 to 98 percent.⁹⁵

In 2006, EPA undertook the second, risk-based phase of HAP regulation to evaluate the remaining risk from HON-regulated sources. After conducting a risk assessment for the SOCOMI,⁹⁶ EPA concluded that no source presented a maximum individual lifetime cancer risk greater than one hundred-in-one million and that only two sources were likely to present a risk of one hundred-in-one million.⁹⁷ Based on these results, EPA proposed two regulatory options. In Option 1, EPA proposed to re-adopt, rather than revise, the HON, as EPA proposed to find that the level of control called for by the HON already protected public health within an “ample margin of safety.”⁹⁸ In Option 2, EPA proposed requiring further reductions of HAP emissions by applying additional controls for equipment leaks and by controlling some additional emission points.⁹⁹ EPA estimated that Option 2 would (1) reduce cancer incidence by preventing one cancer case every one hundred years; (2) reduce lifetime cancer risk from one hundred-in-one million to sixty-in-one million; and (3) reduce by 450,000 the number of individuals exposed to cancer risks in excess of one-in-one million.¹⁰⁰ Initially, EPA estimated that these reductions would come at a total annualized cost of \$13 million, but later revised this figure to \$6 million in response to comments.¹⁰¹

EPA selected Option 1 in its final rule, concluding that based on the SOCOMI risk assessment (which found that no individual faced cancer risks

91. *Id.*

92. *Id.* at 1078–79.

93. National Emission Standards for Hazardous Air Pollutants for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry (SOCMI NESHAP Proposed Rule), 71 Fed. Reg. 34,422, 34,425 (June 14, 2006).

94. *Id.*

95. EPA estimates the reductions resulted primarily through the application of control technologies such as thermal oxidizers, carbon absorbers, and steam strippers. *Id.* at 34,433.

96. EPA used the Human Exposure Model as its primary tool of risk assessment, which computes cancer risks for populations near industrial emission sources by incorporating air dispersion data, census data, meteorological information, and HAP dose-response data, including risk factors and reference values. *Id.* at 34,430.

97. *Id.* at 34,430–34,432 (summarizing RRA results).

98. *Id.* at 34,422, 34,436.

99. *Id.* at 34,422.

100. *Id.* at 34,436.

101. National Emission Standards for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry (SOCMI NESHAP Final Rule), 71 Fed. Reg. 76,603, 76,605 (Dec. 21, 2006).

greater than one hundred-in-one million), and applying the Benzene NESHAP approach (under which cancer risks at or below one hundred-in-one million are “presumptively acceptable”), it had complied with its obligations under CAA section 112(f).¹⁰² Notably, EPA determined that Option 2, with its estimated annual costs of \$6 million, “would be unreasonable given the minor associated improvements in health risks.”¹⁰³

B. Summary of NRDC's Arguments

NRDC challenged EPA's rulemaking on three grounds: (1) that the standards EPA promulgated did not reduce the lifetime excess cancer risk to exposed persons to under one-in-one million, as required by section 112(f); (2) that EPA impermissibly considered costs in reviewing the MACT standard applicable to the industry under section 112(d)(6); and (3) that EPA's reliance on industry-supplied data in setting the “ample margin of safety” under section 112(f) violated the Administrative Procedure Act (APA) as arbitrary and capricious.¹⁰⁴ To understand the implications of EPA's interpretation of its authority and responsibilities under section 112(f) presented by the *NRDC v. EPA* decision, several aspects of the controversy warrant a closer look.

1. NRDC's Argument Under Section 112(f)

Section 112(f)(2)(A) contains three sentences. The controversy surrounding each sentence's independent significance, their relationship to each other, and their relationship to other provisions of section 112 proved to be the central battleground in NRDC's challenge to EPA's rulemaking.¹⁰⁵ Section 112(f)(2)(A) states in full:

If Congress does not act on any recommendation submitted under paragraph (1) [directing the EPA to prepare a report evaluating residual risks within 6 years of the 1990 CAA Amendments], the Administrator shall, within 8 years after promulgation of standards for each category or subcategory of sources pursuant to subsection (d) of this section [MACT standards], promulgate standards for such category or subcategory if promulgation of such standards is required in order to provide an ample margin of safety to protect public health in accordance with this section (as in effect before November 15, 1990) or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

102. *Id.*

103. *Id.*

104. *Natural Res. Def. Council v. EPA*, 529 F.3d 1077, 1081 (D.C. Cir. 2008).

105. Indeed, both the petitioner's and the respondents' voluminous briefing on this matter would give pause to the most dutiful legislative draftsman.

Emissions standards promulgated under this subsection shall provide an ample margin of safety to protect public health in accordance with this section (as in effect before November 15, 1990), unless the Administrator determines that a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

If standards promulgated pursuant to subsection (d) of this section and applicable to a category or subcategory of sources emitting a pollutant (or pollutants) classified as a known, probable or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million, the Administrator shall promulgate standards under this subsection for such source category.¹⁰⁶

a. *EPA's Substantive Obligation*

NRDC first contended that the third sentence obligated EPA to set health-based standards for facilities that emit synthetic organic chemicals, which are known human carcinogens, to achieve a substantive residual risk level of less than one-in-one million.¹⁰⁷ In contrast, EPA read the one-in-one million provision in the third sentence not as a substantive benchmark, but merely as a procedural “trigger” to conduct additional rulemaking.¹⁰⁸ EPA maintained that the only substantive requirement comes in the second sentence, which directs EPA to set standards to provide “an ample margin of safety to protect public health.”¹⁰⁹ Under this view, the trigger in the third sentence requiring EPA to promulgate additional standards simply directs EPA back to the second sentence; so long as the standards ensure an “ample margin of safety,” cancer risks may exceed one-in-one million.¹¹⁰

The court agreed with NRDC that the third sentence of section 112(f)(2)(A) requires EPA to “promulgate standards” whenever the lifetime risk exceeds one-in-one million; however, the court noted that the text does not specify what those standards substantively require.¹¹¹ Rather, reasoning that Congress would have clearly set a “bright line” standard if that was its intention, the court concluded the subsection was drafted as a “deliberately ambiguous compromise.”¹¹²

106. 42 U.S.C. § 7412(f)(2)(A) (2006).

107. *Natural Res. Def. Council*, 529 F.3d at 1081.

108. *Id.* at 1083.

109. *Id.* at 1081–82; Final Brief for Respondent U.S. Environmental Protection Agency at 23–24, *Natural Res. Def. Council v. EPA*, No.07-1053 (D.C. Cir. 2008).

110. *Natural Res. Def. Council*, 529 F.3d at 1082.

111. *Id.* at 1081.

112. *Id.* Rep. Henry Waxman did not concur in the court’s assessment of the legislative history of the 1990 Amendment. See Rep. Henry A. Waxman, *An Overview of the Clean Air Act Amendments of 1990*, 21 ENVTL. L. 1721, 1779 (1991) (noting “[w]ith regard to carcinogens, section 112(f)(2)(A)

To resolve the ambiguity, the court relied primarily on section 112(f)(2)(B), which contains a reference to EPA's prior interpretation of what constitutes an "ample margin of safety"—one hundred-in-one million—in the benzene rulemaking.¹¹³ Since subsection (B) instructs that nothing in subsection (A) shall affect EPA's Benzene NESHAP, the court reasoned that residual risk standards are pegged not at the one-in-one million limit argued by NRDC, but at the one hundred-in-one million standard established in the Benzene NESHAP.¹¹⁴ The court recognized that EPA's view left the third sentence of section 112(f)(2)(A) "relatively anodyne," but because the HON was within this upper-bound risk, the court found that EPA's decision not to impose additional requirements was reasonable under *Chevron*¹¹⁵ and therefore merited judicial deference.¹¹⁶

b. EPA's Procedural Obligation

NRDC also contended that even if the third sentence is simply a procedural trigger for EPA to promulgate additional standards, EPA did not comply with this obligation.¹¹⁷ EPA interpreted its obligation to "promulgate additional standards" to require only that it undertake a rulemaking (in which it decided not to change existing standards).¹¹⁸ NRDC argued that by merely reaffirming its technology-based standards, EPA contravened its obligation to "promulgate additional standards" in two respects. First, the technology-based standards EPA set for the industry were promulgated under section 112(d), which governs MACT requirements, not 112(f), which governs residual risk.¹¹⁹ Accordingly, NRDC alleged that EPA had not complied with section 112(f)'s requirement to "promulgate additional standards *under this subsection*," not 112(d).¹²⁰ Second, NRDC asserted that "EPA's interpretation ignores the entire purpose of the CAA's residual risk provision: to strengthen the original 112(d) standards to address risks that remain 8 years later."¹²¹ With this purpose in mind, NRDC argued that the plain meaning of "promulgate standards" in this

specifically defines the crucial phrase 'an ample margin of safety' . . . [I]f a [MACT] standard does not reduce lifetime cancer risk to the individual most exposed . . . to less than one in one million, the 'ample margin of safety' standard is not met"). Waxman was recently elected chair of the influential House Energy and Commerce Committee; it will be interesting to see whether he uses this leverage to attempt to correct the D.C. Circuit's reading of section 112(f)(2)(A)..

113. *Natural Res. Def. Council*, 529 F.3d at 1082–83.

114. *Id.*

115. *Chevron U.S.A, Inc. v. Natural Res Def. Council*, 467 U.S. 837 (1984) (instructing courts to defer to reasonable agency interpretations of ambiguous statutes that the agency administers).

116. *Natural Res. Def. Council*, 529 F.3d at 1083.

117. *Id.*

118. *Id.*

119. See Final Reply Brief of Petitioners Natural Resource Defense Council & Louisiana Environmental Action Network at 5, *Natural Res. Def. Council v. EPA*, No.07-1053 (D.C. Cir. 2008).

120. *Id.* (emphasis added).

121. *Id.*

context directs EPA to set emission standards sufficient to reduce remaining risks, and that by re-adopting the original standards, EPA had not met this obligation.¹²² The court rejected NRDC's procedural argument, however, finding that "this position finds no support in the text of the statute."¹²³

2. *NRDC's Cost Argument Under Section 112(d)*

Second, the court considered NRDC's argument that EPA's technological update inappropriately considered costs, because the initial MACT standard directed that "leakless components" should not be considered due to the high cost of replacing existing components.¹²⁴ Although the court agreed that EPA may not consider costs in setting the MACT "floor," and observed that EPA "may have done just that," the court noted that the time period for challenging those standards had expired.¹²⁵ The court therefore framed the issue as whether EPA's reaffirmation of its cost-based technology review gave rise to a new opportunity to challenge the MACT standards.¹²⁶ The court did not decide the question, however, reasoning instead that because EPA concluded there were no significant technological developments, "it is irrelevant whether EPA considered costs in arriving at the initial MACT floor and reaffirming that standard in the residual risk rulemaking."¹²⁷ NRDC provided no evidence to the contrary, and the court upheld EPA's decision that no new controls were necessary.¹²⁸

3. *NRDC's APA Argument*

Finally, the court examined whether EPA's analysis of the residual health risks from facilities that use or produce synthetic organic chemicals was arbitrary and capricious and therefore violated the APA. NRDC argued that EPA's residual risk assessment was fundamentally flawed because it was based on industry-supplied data, which was both incomplete and unreliable.¹²⁹

122. *Id.* at 6. Notably, NRDC's procedural argument merited only one paragraph of discussion by the court. *Natural Res. Def. Council*, 529 F.3d at 1083. After invoking several canons of statutory interpretation—i.e., the legislative history of section 112(f)(2)(A) and related provisions of section 112(f)—in dismissing NRDC's first argument (that the third sentence provides a substantive residual risk limit of one-in-one million), the court rejected NRDC's procedural argument solely upon finding no textual support in the statute. *Id.* Arguably, as NRDC asserts, allowing EPA to re-adopt its original MACT standards in its Phase II residual risk regulations seems at odds with both the spirit and structure of section 112. Final Reply Brief of Petitioners Natural Resource Defense Council & Louisiana Environmental Action Network at 5–6, *Natural Res. Def. Council v. EPA*, No.07-1053 (D.C. Cir. 2008).

123. *Natural Res. Def. Council*, 529 F.3d at 1083.

124. *Id.* at 1084.

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.* at 1084–85.

However, the court found that NRDC was essentially arguing that “EPA could have used *better* data,” which it noted misstates the inquiry under the arbitrary and capricious standard.¹³⁰ Having found that EPA provided a reasonable basis for relying on industry-provided data, the court determined that EPA’s decision did not violate the APA.¹³¹

Each of NRDC’s arguments touches on critical issues surrounding how HAPs should be regulated in the United States: what is an acceptable amount of risk—or the “ample margin or safety”—that society can bear? How is that determination made, and by whom? And what factors should be considered in arriving at this determination? NRDC’s petition also revealed EPA’s interpretation of the process Congress installed under section 112(f) to guide HAP regulation. The merits of EPA’s approach to section 112(f), and the need for judicial oversight of this risk determination process, are the subject of Part III.

III. A FUZZY BRIGHT LINE FRAMEWORK: CONFRONTING THE REALITIES OF UNCERTAINTY

Expert discretion is the lifeblood of the administrative process, but ‘unless we make the requirements for administrative action strict and demanding, *expertise*, the strength of modern government, can become a monster which rules with no practical limits on its discretion.’¹³²

The above passage highlights a fundamental tension inherent in designing a regulatory program whose targets (HAPs) are characterized by a high degree of uncertainty. On the one hand, affording EPA significant discretion seems necessary for the agency to adequately address the varying, complex, and uncertain health risks presented by HAPs. But, in the face of uncertainty, which often provides both the incentive and the opportunity to under-regulate, this discretion must have a limit. To be effective, any regulatory approach to hazardous air pollution must be able to reconcile these competing concerns.

This Part begins by characterizing EPA’s approach to residual risk under section 112 (as advanced in the HON and approved by the D.C. Circuit in *NRDC v. EPA*) as essentially establishing a “fuzzy bright line” with respect to carcinogens, whereby EPA must eliminate risks above one hundred-in-one million, does not have to address risks below one-in-one million, and has discretion to set a residual risk standard somewhere in between. Next, this Part evaluates EPA’s interpretation of section 112 in light of the difficulties underlying any attempt to regulate uncertainty. Although EPA’s approach may appear at odds with the spirit of section 112, the framework may have relative policy advantages over the position advanced by NRDC. Finally, the Note

130. *Id.* at 1086 (emphasis in original).

131. *Id.*

132. *Motor Vehicle Mfrs. Ass’n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167 (1962)).

concludes with recommendations for how courts can ensure EPA's future residual risk rules correlate to the degree of risk presented, and do not default to the statutory minimum. In other words, courts must ensure that risk standards remain sufficiently fuzzy.

A. *The Fuzzy Bright Line in Section 112(f)*

EPA's interpretation of section 112(f)(2)(A) has effectively established a range of permissible risk levels within which it may set residual risk standards for carcinogenic HAPs (see Figure 1 below). At the low end, EPA does not need to conduct residual risk analysis for carcinogenic HAPs that the agency determines present lifetime excess cancer risks below one-in-one million. This derives from the "trigger" Congress enacted in section 112(f). At the high end, EPA must eliminate risks above one hundred-in-one million by promulgating health-based standards. This derives from EPA's interpretation of section 112's "ample margin of safety" standard in the benzene rulemaking, which established one hundred-in-one million as the presumptively safe level of cancer risk under *Vinyl Chloride's* first step.¹³³ In between, EPA retains discretion as to the ultimate risk determination, but must undertake a rulemaking to consider on a case-by-case basis the relevant factors that suggest a higher or lower level of risk is appropriate for that particular source category. EPA has committed itself to this procedural step by interpreting section 112(f)'s instruction to "promulgate standards" whenever cancer risks exceed one-in-one million to require that it undertake a rulemaking.¹³⁴

Figure 1. EPA's Residual Risk Range

risks intolerable ← (100-in-1 million) — EPA discretion — (1-in-1 million) → risks negligible

Risk ranges such as this have been termed "fuzzy bright lines," as they entail two bright lines that an agency cannot cross, but retain a range between those end points upon which agencies may locate their regulatory decisions.¹³⁵ In fact, the term may have been coined during congressional discussions on the 1990 CAA Amendments, where such a risk range became known informally as

133. Benzene NESHAP, *supra* note 76; *see also* Natural Res. Def. Council v. EPA, 529 F.3d 1077, 1082 (D.C. Cir. 2008) (noting that the benzene standard established a maximum excess risk of one hundred-in-one million). EPA did imply in its benzene standard, however, that risks could increase above the one hundred-in-one million benchmark. *See* Benzene NESHAP, *supra* note 76, at 38,045 ("[T]he Administrator believes that an MIR [maximum individual risk] of approximately 1 in 10 thousand should ordinarily be the upper-end of the range of acceptability. As risks increase above this benchmark they become presumptively less acceptable under section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability.").

134. *See* Natural Res. Def. Council, 529 F.3d at 1083.

135. *See* Rosenthal et al., *supra* note 13, at 336–37.

a “fuzzy bright line.”¹³⁶ Commentators have suggested the New Jersey Department of Environmental Protection’s Division of Environmental Quality (DEQ) has adopted an approach to risk that is strikingly similar to the position EPA has taken here.¹³⁷ They conclude, “[i]ncremental risks from a new source which are less than one in a million are considered by DEQ to be negligible. Incremental risks greater than one in 10,000 are deemed unacceptable. Risks between these two limits are judged on a case-by-case basis.”¹³⁸

This is precisely the approach EPA has taken in administering the residual risk program in section 112(f). Whether EPA in fact assesses risks within the one- to one hundred-in-one million range on a case-by-case basis is another matter. It will likely depend on how hard of a look courts give to EPA’s residual risk rules.¹³⁹

B. *The Relative Virtues of Risk Ranges*

The effectiveness of environmental programs is more a function of how likely and whether the rules are enforced . . . [an agency] will not act if there are incentives not to and no absolute requirement to do so.¹⁴⁰

The benefits of implementing a fuzzy bright line approach for EPA’s consideration of risk from HAPs have not been lost on commentators.¹⁴¹ Structurally, fuzzy bright lines can harness the strengths of the two key administrative actors involved in regulating risk—Congress and the EPA—while mitigating some of the normative concerns inherent in regulating uncertainty. Likewise, risk ranges take better account of the indirect policymaking authority bestowed upon EPA by way of the agency’s responsibility for risk assessment. As long as EPA retains considerable discretion in conducting risk assessments (which is likely a structural necessity), mandating bright line risk management standards cannot effectively decrease the level of risk reflected in EPA’s health-based standards. EPA’s

136. *Id.* (noting the idea had been advocated by a group of moderate Democrats, led by Rep. Tauzi).

137. *Id.*

138. *Id.*

139. *See infra* Part III.C.

140. *See* Flatt, *supra* note 40, at 119 (quoting Victor B. Flatt, *Spare the Rod and Spoil the Law: Why the Clean Water Act Has Never Grown Up*, 55 ALA. L. REV. 595, 597, 601 (2005)).

141. *See* Mank, *What Comes After Technology*, *supra* note 41, at 326–27; Rosenthal et al., *supra* note 13, at 336–38. Mank urged Congress in 1994 to enact a fuzzy bright line statute to address residual risk from HAPs. Mank, *What Comes After Technology*, *supra* note 41, at 326. This Note suggests, however, that the foundations for a fuzzy bright line framework are already in place, and need only be enforced by the courts to come to fruition. In other words, the key hurdle underlying Mank’s proposal—getting Congress to act to revise (again) the CAA—can be avoided so long as courts ensure EPA residual risk rules reflect case-by-case determinations of the appropriateness of cancer risk from any particular HAP source category. While this is by no means assured, it is arguably the more likely scenario, as EPA has committed to undertaking rulemakings and courts are well-versed in scrutinizing agency rules.

decision making on risk tolerance may simply bleed into its process of risk quantification.

1. *Risk Ranges Harness the Strengths of Congress and EPA*

Risk ranges provide a structural tool to reconcile competing policy goals and normative concerns involved in regulating uncertainty. Judged in terms of substantive outcomes, assigning authority over promulgating residual risk standards to an administrative agency seems practicable. Compared to Congress, EPA is better equipped to handle the complex and technical aspects of producing risk assessments.¹⁴² Even those skeptical of EPA's capacity and motivations in conducting risk analysis might agree that direct congressional participation would not create better results. For example, one version of the Senate's 1990 CAA Amendments "would have required EPA to protect the maximally exposed *actual* person near a factory rather than a *hypothetical* maximally exposed individual"—a change that, unwittingly, "could have reduced estimated exposures by a factor of 100 at some sources."¹⁴³

But handing over the regulatory store to EPA entails assigning risk management decisions to unelected administrative officials. And, as this Note has emphasized, setting risk tolerance levels involves fundamental value judgments about what level of cancer incidence we are prepared to consider acceptable. Assigning unbridled risk management control to EPA thus places these value judgments in the hands of largely unaccountable agency risk managers.¹⁴⁴ In that sense, EPA does not seem like the appropriate institution in which to vest this far-reaching authority.

Likewise, when Congress delegates broad authority to EPA in the form of ambiguous statutes which, by design, may be impossible to administer, Congress should not get political credit for sounding tough on an issue when it is in effect doing little to address the problem.¹⁴⁵ Such may have been the case with the 1970 CAA, where Congress left EPA with a vague directive and little guidance on how to implement it.¹⁴⁶ Rather, a separation-of-powers perspective dictates that Congress should have to make the tough value judgments on risk and not punt its Article I duties to an administrative agency.¹⁴⁷

142. See, e.g., Rosenthal et al., *supra* note 13, at 343–44 (observing "Congress lacks the attention span, expertise, and appreciation of the scientific process to prescribe methods of [risk assessment]").

143. *Id.* at 344.

144. Although some commentators derive legitimacy for broad EPA risk management discretion from the fact that the Administrator of the EPA is appointed by the President with the advise and consent of the Senate. See *id.* at 340.

145. See Dwyer, *supra* note 49, at 233.

146. *Id.*; see *supra* Part I.C.1.

147. Delegating vague narrative standards (like "the ample margin of safety") to EPA may raise non-delegation and bicameralism/presentment issues. Although doctrinally non-delegation subsists today largely as a canon of interpretation, *Whitman v. American Trucking Assns.*, 531 U.S. 457 (2001), normatively the concerns raised by broad and ambiguous delegations of authority still caution against

Vesting EPA with complete regulatory authority over HAPs thus presents both policy and normative concerns. In contrast, fuzzy bright lines provide a workable middle ground. By setting the risk levels between which EPA must operate, Congress is making the underlying value judgments on what levels of risk are both acceptable and unacceptable. Yet the agency retains discretion to locate particular regulations within the risk range. This provides the agency with significant flexibility to tailor risk standards on the basis of source-specific risk assessments, but not uncontained authority to make implicit cost-benefit decisions that might otherwise have produced a risk standard outside the limits that Congress provided.

As EPA has interpreted section 112(f), Congress has set the lower bound below which risks are considered negligible at one-in-one million. EPA has also read section 112(f)'s one-in-one million language to be the level of risk at which Congress requires additional risk analysis. Although the agency initially set the upper bound of acceptable risk at one hundred-in-one million (in the Benzene NESHAP), Congress indirectly approved of this limit by adding section 112(f)(2)(B) in 1990.¹⁴⁸ Thus, under EPA's approach, Congress has made explicit what risks are out of bounds and what risks require further evaluation (in a rulemaking), while leaving EPA flexibility to set source-specific standards within bounds on the basis of those results.

2. *A Bright Line Alternative Does Not Reduce EPA's Discretion*

Considering EPA's broad discretion in conducting risk assessments, a fuzzy bright line reading of section 112(f) is also preferable to the interpretation advanced by NRDC—that one-in-one million constitutes a bright line above which EPA must eliminate all risk. NRDC's dispute with EPA centered on what the third sentence of section 112(f)(2)(A) obligates EPA to do when cancer risks exceed one-in-one million. Under EPA's interpretation—risks above one-in-one million require further evaluation in a rulemaking—EPA would still prefer that risk levels remained below this threshold level, as it could avoid undertaking a formal procedural obligation. Under NRDC's interpretation, however, the consequences of EPA acknowledging that risk levels exceed one-in-one million are different in kind. EPA would no longer have to adhere to a flexible procedural step that offered a range of outcomes; EPA would have to commit to undertaking the burdensome, contentious, and costly task of promulgating substantive health-based standards.¹⁴⁹ If EPA's

such legislative abdications. Moreover, since under such mandates EPA is effectively legislating without parameters, EPA's final rules may bump up against Article I's requirements that legislation go through both houses of Congress (bicameralism) and be presented to the President for approval or veto (presentation). *See* U.S. CONST. art I, § 7.

148. *See supra* Part II.B.1.a.

149. As Professor Applegate has framed it, the problem in these situations is that the "predicate" (the set of circumstances that must exist before EPA can exert regulatory control) is the same as the

experience under the 1970 CAA is any guide, the agency will go to nearly any length to avoid this result when it believes the cost is disproportionate to the risk.¹⁵⁰

Likewise, the 1970 CAA demonstrated that armed with a vague narrative standard that afforded the agency considerable discretion, EPA could largely regulate as it saw fit.¹⁵¹ Currently, although that standard has been replaced with the section 112(f) two-phase framework, EPA retains nearly unassailable discretion in producing numerical risk standards through risk assessments.¹⁵² The *NRDC v. EPA* decision itself provides an example of this principle in practice. NRDC challenged multiple aspects of EPA's risk assessment for the SOCMI, alleging chiefly that EPA improperly relied on unverified and biased industry-supplied data from only 44 percent of the SOCMI facilities.¹⁵³ The court swept aside these arguments, however, reiterating that it "generally defer[s] to an agency's decision to proceed on the basis of imperfect scientific information."¹⁵⁴

Accordingly, even under a bright line framework, "when agency officials believe that a statutory bright line is too stringent in a particular case, they can manipulate the risk calculation to produce a numerical estimate of risk that will allow them to justify their desired level of stringency"¹⁵⁵—and courts are unwilling, and likely unable, to require anything more.¹⁵⁶ Moreover, NRDC's interpretation would have provided EPA with a strong incentive to manipulate risk calculations, since acknowledging a risk above one-in-one million would in turn require taking steps to eliminate it. EPA's history under the 1970 CAA dictates that mixing an incentive to avoid regulating with significant discretion not to regulate makes a poor recipe for regulatory success.

3. *Risk Ranges Encourage Agency Accountability and Transparency*

In contrast, under a risk range, if agency officials know that acknowledging risk does not in itself mandate additional regulations, they

"target" (the extent to which a particular risk is to be reduced). See Applegate, *supra* note 41, at 309. Thus, under the 1970 CAA, EPA struggled because "the ample margin of safety" in effect provided both the predicate and target for EPA's health standards. *Id.* Under NRDC's interpretation, risks above one-in-one million could likewise serve as both predicate and target.

150. See *supra* Part I.C.1.

151. *Id.*

152. See *Am. Iron & Steel Inst. v. EPA*, 115 F.3d 979, 1006 (D.C. Cir. 1997) (noting "a reviewing court must be 'at its most deferential'" when the challenge is to methodological study); *Columbia Falls Aluminum Co. v. EPA*, 139 F.3d 914, 923 (D.C. Cir. 1998) (concluding that a risk assessment will be upheld unless it "bears no rational relationship to the reality it purports to represent"); *Natural Res. Def. Council v. Herrington*, 768 F.2d 1355, 1391 (D.C. Cir. 1985) (rejecting challenge to modeling assumptions Department of Energy relied on to avoid issuing energy efficient standards).

153. *Natural Res. Def. Council v. EPA*, 529 F.3d 1077, 1085 (D.C. Cir. 2008).

154. *Id.* at 1086 (quoting *Sierra Club v. EPA*, 167 F.3d 658, 662 (D.C. Cir. 1999)).

155. Rosenthal et al., *supra* note 13, at 341.

156. See, e.g., *supra* note 152.

might be more forthcoming in their risk determinations. For example, EPA explicitly concluded in the HON that adding additional controls at an estimated annual cost of \$6 million “would be unreasonable given the minor associated improvements in health risks.”¹⁵⁷ Even if one disagrees with this calculation, bringing it out in the open is preferable to leaving it buried in implicit modeling assumptions made during risk assessment. For one, more transparency provides alternative routes to influence EPA policy making. Certain members of Congress or the public might consider, for instance, that decreasing the number of individuals exposed to cancer risks in excess of one-in-one million by 450,000—the “minor associated improvements in health risks”—is worth an annual \$6 million dollars.¹⁵⁸ A public outcry might also draw the attention of the President, who can alter EPA policy more easily than the courts. Providing incentives for EPA to conduct residual risk policymaking on the record ensures these non-judicial remedies remain viable.

Increased transparency can also improve the substance of EPA’s decision making by providing the agency with more information. Again, the HON provides an example. In response to comments (which would not have been solicited if EPA had adjusted its risk assessment calculation to avoid reaching a risk level of one-in-one million), EPA lowered the estimated annual cost of adding additional controls from \$13 million to \$6 million.¹⁵⁹ While this did not affect the agency’s risk standard under the HON, it may well provide the difference in future rulemakings. Finally, providing incentives to EPA to be more forthright in its risk management decisions may also influence substantive outcomes. Allowing the agency to frankly assess the full range of factors that arise in its policy considerations in a public rulemaking may produce risk standards that differ markedly from what the agency would have initially promulgated.

A bright line risk standard of one-in-one million may, on balance, require EPA to reduce more risk than a risk range would; presumably, the agency would not grossly manipulate risk assessments that clearly indicated risks above one-in-one million. This result would likely come at a significant cost, however, as the incentives of a bright line approach point away from open consideration of the policy issues involved in calculating risk. Bright lines may thus simply relocate EPA decision making on residual risk into the murkier waters of risk assessment.¹⁶⁰

157. See SOCM I NESHAP Final Rule, *supra* note 101, at 76,605.

158. *Id.*

159. See *supra* Part II.A.

160. See Rosenthal et. al. *supra* note 13, at 341–42 (observing that when EPA adjusts risk assessments “the statutory bright line would be met, but the agencies’ fundamental policy judgments would be buried in the risk assessment factors, rather than being visible in the agencies’ analysis of the acceptable risk”).

C. *Keeping Residual Risk Standards Fuzzy*

A fuzzy bright line reading of section 112(f) provides a workable framework for addressing the practical and normative concerns underlying the regulation of HAPs. But the framework is not self-executing. In particular, if future residual risk rules indicate EPA is clustering its risk standards at the high end of the spectrum (i.e., one hundred-in-one million), then the risk range will have effectively collapsed into a de facto bright line—and one which is two orders of magnitude removed from the one NRDC argued Congress enacted in section 112(f).¹⁶¹ It is incumbent upon courts to ensure EPA's residual risk rules reflect a source-by-source assessment of risk.

1. *Courts Should Read the Benzene NESHAP Expansively*

Section 112(f)(2)(B) incorporates EPA's interpretation of the "ample margin of safety" as set forth in the benzene rulemaking.¹⁶² The Benzene NESHAPs substantive conclusion was that risks below one hundred-in-one million are presumptively safe within the meaning of the "ample margin of safety" standard in section 112(f).¹⁶³ EPA relied on this conclusion in selecting Option 1 over Option 2 in the HON, after determining no sources in the SOCMCI category presented cancer risks above one hundred-in-one million.¹⁶⁴ The Benzene NESHAP arguably also contained procedural elements, however, which were not at issue in NRDC's challenge to the HON. In particular, EPA committed in the Benzene NESHAP that it would strive to reduce risk to no greater than one-in-one million "for the greatest number of persons possible."¹⁶⁵

Although the D.C. Circuit considered this "an aspirational goal,"¹⁶⁶ the court reached this result in the context of dismissing NRDC's argument that one-in-one million was the substantive risk standard EPA had to achieve. NRDC did not argue that the source category at issue—SOCMI—itsself warranted a risk standard of one-in-one million, but that section 112(f) required EPA to eliminate cancer risks above one-in-one million for *all* categories of sources.¹⁶⁷ Even if it had, EPA's SOCMCI risk assessment results likely did not support a risk standard much higher than one hundred-in-one million for the entire source category.¹⁶⁸

161. See *Natural Res. Def. Council v. EPA*, 527 F.3d 1077, 1081 (D.C. Cir. 2008).

162. See *supra* Part II.B.1.a.

163. See *supra* Part I.D.2.

164. *Id.*

165. *Id.*

166. *Natural Res. Def. Council v. EPA*, 529 F.3d 1077, 1082 (D.C. Cir. 2008).

167. *Id.* at 1081.

168. See *supra* Part II.A (e.g., only two of the 238 sources in the SOCMCI category showed risk levels near the one hundred-in-one million mark).

In future residual risk rulemakings, however, that may precisely be the case. For example, if EPA's risk assessment for the SOCOMI had shown instead that only two sources indicated a risk level below one-in-one million, while the rest were closer to one hundred-in-one million, could EPA still have justified the increased risk because no source exceeded the presumptively safe benchmark? The Benzene NESHAP itself suggests otherwise, and it is up to the courts to keep EPA true to its word.

2. Courts Should Employ Hard Look Review

Hard look review of agency rulemaking under APA section 706(2)(A) is particularly appropriate for EPA's residual risk rules promulgated under CAA section 112(f).¹⁶⁹ First, courts generally make a more probing inquiry into the reasoning supporting an agency's final rule when the rule is the product of fact-intensive and policy-heavy decision making.¹⁷⁰ Residual risk rules like the HON seem to fit the bill. While many of EPA's conclusions in such rules are practically unreviewable as the product of a risk assessment,¹⁷¹ a court can require EPA to adequately explain why its risk standard is appropriate in light of its risk assessment.¹⁷² In particular, EPA stated in the Benzene NESHAP that it would examine other health and risk factors besides the one hundred-in-one million "presumptively safe level" in deciding whether to adopt more stringent emission requirements.¹⁷³ If EPA does not adequately consider these factors, which EPA itself identified as relevant, the courts should set aside the rule.¹⁷⁴

Second, courts take a harder look at agency rules that depart from previous agency positions.¹⁷⁵ Beyond the factors EPA identified in the Benzene NESHAP, it also committed in the preamble to reduce risks for "the greatest number of persons" to below one-in-one million.¹⁷⁶ Courts may seize on this commitment to justify placing the burden of proof on EPA to explain

169. In terms of policy, hard look review has proven effective in ensuring EPA undertakes reasoned decision making. See William Pedersen, *Formal Records and Informal Rulemaking*, 85 YALE L.J. 38, 60 (1975) (noting hard look review provides a lever for agency officials who believe in reasoned decision making to move others within the agency who might not).

170. See, e.g., *Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

171. See *supra* Part III.B.2.

172. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 41–57.

173. Including, the overall incidence of cancer or other serious health effects within the exposed population; the number of persons exposed within each individual lifetime range (such as a 50-km exposure radius around the emitting facilities); the science and policy assumptions and estimation uncertainties associated with the risk measures; the weight of the scientific evidence for human health effects; other quantified or unquantified health effects; and the effects resulting from co-location of facilities and co-emission of pollutants. See Benzene NESHAP, 54 Fed. Reg. 38,044, 38,045–38,046 (Sept. 14, 1989) (to be codified at 40 C.F.R. pt.1).

174. See *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971).

175. See *id.*

176. See *supra* Part I.D.2.

significant departures from this earlier position regarding section 112(f).¹⁷⁷ In fact, EPA is already familiar with this type of burden scheme. Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), EPA's Office of Drinking Water at one point established one-in-one million as the presumptive level of cancer risk permissible for a given site—known as the “point of departure.”¹⁷⁸ The agency allowed higher risk levels only if further clean-up was not reasonable and practical.¹⁷⁹ This condition in effect placed the burden on agency risk managers to justify more lenient risk levels. Although EPA established the policy in the CERCLA context internally, section 112(f) expressly references one-in-one million as the trigger for agency action. Add this to EPA's commitment in the Benzene NESHAP to reduce risks for “the greatest number of persons” to below one-in-one million and courts may feel justified in breathing a little more life into Congress' words.

Hopefully, providing EPA with greater leeway in the degree of risk it may permit will encourage the agency to conduct honest risk assessments, and EPA will narrowly tailor its standards to reflect a risk assessment's results. If not, courts should strike down the rules to ensure EPA is conducting source-specific risk analysis whenever risks exceed one-in-one million.

CONCLUSION

To be sure, the crux of EPA's interpretation in the HON—that it may re-promulgate existing technology-based MACT standards as health-based residual risk standards if it determines the former already provide an “ample margin of safety”¹⁸⁰—does not instill confidence that the agency is actively fulfilling its mandate under section 112(f) to protect the public from HAPs. Rather, it appears that EPA may be pursuing what some have identified as a persistent trend of interpreting statutes it is entrusted to administer in a manner that relieves the agency of its delegated obligations.¹⁸¹ While this is a concern, EPA must still eliminate risks above one hundred-in-one million, and has committed itself to undertake rulemakings to evaluate residual risks in excess

177. The D.C. Circuit likely did not foreclose this possibility, since EPA's risk assessment for the SOCMIs indicated that only two sources in the category showed risk levels significantly higher than one-in-one million, and the court was not entertaining a challenge to the appropriateness of EPA's standards for that particular source category.

178. See “Role of the Baseline Risk Assessment in Superfund Remedy,” Memorandum from Don R. Clay, Assistant Administrator, to the Regional Directors, at 5 (April 22, 1991).

179. *Id.*; see also Rosenthal et al., *supra* note 13, at 319.

180. See *Natural Res. Def. Council v. EPA*, 529 F.3d 1077, 1083 (D.C. Cir. 2008).

181. See Sidney A. Shapiro & Robert L. Glicksman, *Congress, the Supreme Court, and the Quiet Revolution in Administrative Law*, 1988 DUKE L.J. 819, 827 (1988) (reviewing Congressional attempts in the 1980s to combat EPA's failure to act, including the agency's “proclivity for implementing statutes in a manner contrary to congressional intent”).

of one-in-one million¹⁸²—the risk level that Congress determined warranted particular attention. This interpretation might, in the words of Judge Silberman, appear “relatively anodyne,”¹⁸³ but it must be assessed—alongside NRDC’s—in light of the realities of EPA policy making.

Either way, the import of EPA’s interpretation of section 112(f)(2)(A) will soon be realized; the rulemaking behind the *NRDC v. EPA* decision is considered a test case for how EPA intends to implement the revised residual risk provisions.¹⁸⁴ Although section 112 requires EPA to issue residual risk standards within eight years of promulgating a technology-based standard,¹⁸⁵ EPA only recently began to review standards promulgated more than a decade ago.¹⁸⁶ Time will tell whether EPA’s approach to residual risk, and courts’ response, adequately address the dangers of HAP emissions and the concerns posed by uncertainty.

182. See *Natural Res. Def. Council*, 529 F.3d at 1083.

183. *Id.*

184. See Beverage & Diamond, P.C., D.C. Circuit Upholds EPA’s Residual Risk Standard for the HON (June 11, 2008), <http://www.bdlaw.com/news-337.html>.

185. 42 U.S.C. § 7412(f)(2)(A) (2006).

186. See Beverage & Diamond, *supra* note 184, at 3.

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