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Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals

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INTRODUCTION

Scientific information about the human health risks of exposure to toxic chemicals is critical to making sound regulatory decisions. The rapidly expanding information base about chemicals has complicated the task of regulators and has spawned a growing professional discipline called, alternately, risk assessment or quantitative risk assessment (QRA).¹ A risk assessment is an analytical report that provides qualitative and quantitative indications of the human health risks attributable to exposure to an environmental agent.

The results of risk assessments now guide regulators of toxic substances in making screening, priority-setting, and standard-setting decisions. Screening decisions, which may be based on a very simple assessment, determine whether a particular chemical exposure may pose enough risk to justify a more detailed risk assessment. Priority-setting decisions identify those chemical exposures which are serious enough to justify regulation. Standard-setting decisions involve setting specific limitations on discharges to adequately protect the public from chemical exposures. The process of making priority-setting and standard-setting decisions is often called "risk management."² In this article, we examine

^{1.} Quantitative risk assessment, sometimes called probabilistic risk assessment (PRA), was developed by engineers to study safety, failure rates, and integrity of structures and processes. The 1975 Rasmussen Report was one of the first serious attempts to examine the health consequences of large scale application of nuclear power in the United States. It applied QRA to accident scenarios and estimated the consequences of the calculated exposures by using epidemiological studies of the survivors of the atomic bombings of Hiroshima and Nagasaki. See U.S. NUCLEAR REGULATORY COMM'N, WASH-1400, NUREG-75/014, REACTOR SAFETY STUDY: AN ASSESSMENT OF ACCIDENT RISKS IN THE U.S. COMMERCIAL NUCLEAR POWER PLANTS app. VI (1975) (calculation of reactor accident consequences) (popularly known as the Rasmussen Report).

^{2.} Former EPA Administrator William Ruckelshaus popularized the distinction between risk assessment and risk management. See U.S. ENVTL. PROTECTION AGENCY, RISK ASSESSMENT AND MANAGEMENT: FRAMEWORK FOR DECISION MAKING 3 (1984). For further explanation of the distinction, see COMMITTEE ON THE INSTITUTIONAL MEANS FOR As-SESSMENT OF RISKS TO PUB. HEALTH, NATIONAL ACADEMY OF SCIENCES, RISK

the role legislation should play in deciding both how risk assessments are conducted and how they are used in administrative decisionmaking.

We have limited our discussion in this article to risk assessments of environmental exposures that may lead to human cancer. Our focus reflects the special interest which Congress and the agencies have placed on cancer risk, in response to the widespread public concern about this frightening disease which accounts for roughly one in four fatalities in the United States each year.³ While the causal connections between certain occupational chemical exposures and human cancers are well documented.⁴ the overall fraction of human cancer attributable to occupational and environmental exposures is uncertain and may be quite modest.⁵ Increasingly, federal agencies are beginning to use QRA to assess various noncancer health effects such as kidney damage, neurobehavioral deficits, and developmental and reproductive effects. However, risk assessors still calculate and report cancer risks more frequently than noncancer risks.⁶ Moreover, agencies typically impose more stringent standards in response to indications of cancer risk than they do in response to indications of other risks.⁷ Although cancer risks currently tend to dominate scientific, regulatory, and legislative discussions, concern for other health risks probably will increase in the decades ahead.⁸ While methods of noncancer risk assessment generally differ from methods of cancer risk assessment, many of the legislative issues raised in this article are also applicable to assessment of these other risks.

Assessment in the Federal Government: Managing the Process 3, 18-19 (1983); National Research Council, National Academy of Sciences, Risk and Decision Making: Perspectives and Research (1982).

4. The causal association between benzene exposure and leukemia is one of the classic findings in the epidemiology of occupational disease. For a discussion of the epidemiology of benzene and cancer, see *id.* at 123-32. The scientific literature on environmental exposures and human cancer, however, is scanty, and "[t]here are no known cases of cancer (or birth defects) caused by exposure to trace quantities of any environmental chemical, natural or synthetic." M. ALICE OTTOBONI, THE DOSE MAKES THE POISON: A PLAIN-LANGUAGE GUIDE TO TOX-ICOLOGY 178 (2d ed. 1991).

5. See Richard Doll & Richard Peto, The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today, 66 J. NAT'L CANCER INST. 1191 (1981); Michael Gough, How Much Cancer Can EPA Regulate Anyway?, 10 RISK ANALYSIS 1 (1990).

6. John D. Graham et al., The Potential Health Benefits of Controlling Hazardous Air Pollutants, in CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS: HEALTH BENE-FITS OF AIR POLLUTION CONTROL 145, 161 (John Blodgett ed., 1989).

7. See U.S. GEN. ACCOUNTING OFFICE, REPRODUCTIVE AND DEVELOPMENTAL TOXI-CANTS: REGULATORY ACTIONS PROVIDE UNCERTAIN PROTECTION 16 (1991).

8. For a summary of reasons to support the development of noncancer risk assessment, see John S. Evans et al., Summary of Workshop to Review an OMB Report on Regulatory Risk Assessment and Management, 3 RISK: ISSUES IN HEALTH & SAFETY 71, 82 (1992).

^{3.} JOHN D. GRAHAM ET AL., IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK 1 (1988).

The U.S. Environmental Protection Agency (EPA)⁹ and the Food and Drug Administration (the FDA)¹⁰ have led the development of formal approaches to cancer and toxics risk assessment in regulatory decisionmaking.¹¹ EPA initially used risk assessment only as a screening and priority-setting tool to identify potential regulatory targets (i.e., suspect chemicals, products, facilities, and industries),¹² but more recently, it has incorporated risk assessment into most of its standard-setting programs as well.¹³ Thus, the findings of EPA risk assessments influence how the agency allocates its resources and how stringently it regulates particular environmental exposures.

Although risk assessments are now commonplace at many federal and state agencies, there are no uniform guidelines that specify how regulatory officials should calculate chemical risks.¹⁴ Nor are there any uni-

10. For a discussion of the history of the FDA's risk assessment process, see Richard Merrill, FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?, 5 YALE J. ON REG. 1 (1988); see also Peter B. Hutt, Use of Quantitative Risk Assessment in Regulatory Decisionmaking under Federal Health and Safety Statutes, in RISK QUANTITATION AND REGULATORY POLICY 15, 20-21 (David G. Hoel et al. eds., 1985).

11. See, e.g., Health Risk and Economic Impact Assessments of Suspected Carcinogens: Interim Procedures and Guidelines, 41 Fed. Reg. 21,402 (1976); Proposed Guidelines for Carcinogen Risk Assessment, 49 Fed. Reg. 46,294, 46,298 (1984); Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992 (1986) [hereinafter EPA Guidelines]; Guidelines for Mutagenicity Risk Assessment, 51 Fed. Reg. 34,006 (1986); Guidelines for the Health Risk Assessment of Chemical Mixtures, 51 Fed. Reg. 34,004 (1986); Guidelines for Estimating Exposures, 51 Fed. Reg. 34,042 (1986). Although the Occupational Safety and Health Administration (OSHA) also uses risk assessment, it has done so reluctantly and only after significant judicial pressure. See Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 654 (1980). For a regulatory history of OSHA's resistance to risk assessment, see GRAHAM ET AL., supra note 3, at 80-91.

12. See Roy E. Albert et al., Rationale Developed by the Environmental Protection Agency for the Assessment of Carcinogenic Risks, 58 J. NAT'L CANCER INST. 1537 (1977) (reviewing EPA's early approach to risk assessment, as outlined in Health Risk and Economic Impact Assessments of Suspected Carcinogens: Interim Procedures and Guidelines, 41 Fed. Reg. 21,402 (1976)).

13. U.S. ENVTL. PROTECTION AGENCY, supra note 2, at 30-35.

14. The Carter Administration made several unsuccessful attempts to establish uniform risk assessment guidelines. See, e.g., Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks, 44 Fed. Reg. 39,858 (1979); see also infra part V.E. Although a 1983 Committee of the National Academy of Sciences recommended uniform risk assessment guidelines, see COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, supra note 2, at 80, such guidelines have never been developed for the entire federal government. In 1985, the U.S. Office of Science and Technology Policy (the OSTP) made a step in this direction by publishing a statement of the relevant scientific principles. See U.S. Interagency Staff Group on Carcinogens, Chemical Carcinogens: A Review of the Science and Its Associated Principles, 67 ENVIL. HEALTH PERSP. 201 (1986). Under the Bush Administration, the OSTP has established an Interagency Committee on Risk Assessment under the auspices of the Federal Coordinating Council on Science, Engineering, and Technology (FCC-SET). See infra part V.E. However, not all students of the risk assessment process are con-

^{9.} For a concise summary of the conventional methodologies used at EPA to conduct risk assessments, see Peter W. Preuss & Alan M. Ehrlich, *The Environmental Protection Agency's Risk Assessment Guidelines*, 37 J. AIR POLLUTION CONTROL ASS'N 784 (1987).

form criteria that indicate how the findings of risk assessments should influence regulatory decisions. In particular, there is no guideline which sets a universally acceptable or unacceptable numerical level of risk for use in regulatory decisions.¹⁵ While this suggests a potential for inconsistency in agency action, as we argue in Part V below, it is not clear that a universally acceptable level of risk should be established in regulation or legislation.

The existing environmental statutes covering chemical carcinogens¹⁶ contain primarily narrative rather than numerical tests for priority setting and standard setting. A typical narrative statute might direct an agency to protect the public health with an "ample margin of safety" or to reduce "unreasonable" risks to public health. While narrative statutes do not use hard numbers to specify the desired level of protection, they generally are intended to compel regulatory agencies to target potential chemical hazards and to set highly stringent standards to protect public health and the environment. However, existing statutory directives have not fully achieved these objectives.¹⁷

Federal agencies have adopted risk assessment not in response to a specific legislative mandate, but in the spirit of using good science to inform administrative decisions.¹⁸ Indeed, most environmental statutes were written before risk assessment emerged as a professional discipline. However, federal courts have supported agency use of risk assessment, in some cases overturning rulemaking decisions because they lacked an ade-

16. For a summary of statutes that cover chemical carcinogens, see U.S. OFFICE OF TECH. ASSESSMENT, ASSESSMENT OF TECHNOLOGIES FOR DETERMINING CANCER RISKS FROM THE ENVIRONMENT 178-79 (1981).

17. For example, under the Toxic Substances Control Act's "unreasonable risk" standard, only 22 actions have been taken to control five substances since its passage in 1976. See U.S. GEN. ACCOUNTING OFFICE, GAO-RCED-90-189, TOXIC SUBSTANCES: EFFECTIVENESS OF UNREASONABLE RISK STANDARDS UNCLEAR 1-2 (1990); infra text accompanying notes 218-38. The regulation of airborne carcinogens (air toxics) under section 112 of the Clean Air Act has also been spotty: "Under Section 112 of the Act, EPA has set highly compromised emission standards for just a fraction of the industrial sources of just seven cancer-causing air pollutants. Under section 202, EPA has issued modest standards for only one motor vehicle pollutant beyond the three Congress controls itself-diesel particulate emissions." Clean Air Act Amendments of 1989—Part 1, Air Toxics and Incineration: Hearings on S. 816 and S. 196 Before the Subcomm. on Environmental Protection of the Senate Comm. on Environment and Public Works, 101st Cong., 1st Sess. 181, 182 (1989) (statement of David D. Doniger, Senior Attorney, Natural Resources Defense Council, on behalf of the National Clean Air Coalition); see also infra parts II.B, III.A. On the slow pace of progress under the Clean Water Act, see U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-91-154, WATER POLLUTION: STRONGER EF-FORTS NEEDED BY EPA TO CONTROL TOXIC WATER POLLUTION (1991).

vinced that uniform guidelines would be a step in the right direction. See, e.g., GRAHAM ET AL., supra note 3, at 208-11.

^{15.} Kathryn E. Kelly, The Myth of 10^{-6} as a Definition of Acceptable Risk (June 1991) (unpublished paper presented at the 84th Annual Meeting of the Air and Waste Management Association, on file with author).

quate foundation in risk assessment.¹⁹ In light of the growing influence of risk assessment in decisions made at EPA and other administrative agencies,²⁰ legislators have become increasingly interested in how risks are calculated and in how the findings of risk assessment reports are used by administrative agencies charged with protecting public health, public safety, and the environment.²¹

Former EPA Administrator William Ruckelshaus has described the emergence of risk assessment in the agencies, in response to pressure from the courts (for example, the Supreme Court's 1980 benzene decision²²), as a shotgun wedding between science and the law.²³ However, in the case of risk management, a more appropriate metaphor might be a "casual courtship," since both science and law, as we shall describe, have only sporadic influence on risk management.

While not unfettered, agency discretion in risk management remains extremely broad. In particular, agencies have considerable discretion in translating narrative statutes into specific risk management decisions, since narrative standards are not self-defining, and since courts generally will defer to agency efforts to translate such standards into specific actions. Legislators have responded to this situation with proposals which they hope will constrain agency risk management decisions to a narrower range of outcomes which would more closely approximate legislative aims.²⁴ Since agencies make extensive use of quantitative risk assess-

22. 448 U.S. at 607.

^{19.} The landmark case in favor of QRA is Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980). The Supreme Court invalidated OSHA's attempt to tighten the benzene standard under the Occupational Safety and Health Act of 1970, due to the agency's failure to quantify risk. *Id.* at 653. The Fifth Circuit used similar reasoning in a decision involving the regulation of urea-formaldehyde foam insulation under the Consumer Product Safety Act. *See* Gulf South Insulation v. U.S. Consumer Prod. Safety Comm'n, 701 F.2d 1137, 1148 (5th Cir. 1983). This line of cases has been criticized by commentators who see QRA as a barrier to regulation. *See, e.g.*, Nicholas A. Ashford et al., *Law and Science Policy in Federal Regulation of Formaldehyde*, 222 SCIENCE 894 (1983).

^{20.} Risk assessment is also playing an increasingly significant role in environmental tort law. See Donald W. Stever, The Use of Risk Assessment in Environmental Law, 14 COLUM. J. ENVTL. L. 329, 336-37 (1989); W.F. Pederson, What Judges Should Know About Risk, 2 NAT. RESOURCES & ENV'T 35, 37-38 (1986). For a comprehensive review of the role risk assessment plays in administrative and judicial decisions, see FRANK B. CROSS, ENVIRONMEN-TALLY INDUCED CANCER AND THE LAW (1989).

^{21.} A recent published forum presents positions forwarded by Sen. Daniel Patrick Moynihan (D-New York), Rep. J. Roy Rowland (D-Georgia), Sen. Joseph Lieberman (D-Connecticut), Rep. Bob Traxler (D-Michigan), Sen. Steve Symms (R-Idaho), and Rep. Dan Ritter (R-Pennsylvania). See Should We Set Priorities Based on Risk Analysis?, 17 EPA J., Mar.-Apr. 1991, at 13, 18, 20, 22, 24, 26, 29. As Sen. Lieberman writes, "If Congress and the public are to have confidence in decisions based on risk, we must be convinced that those experts entrusted with the responsibility to guard human health and the environment are actually making the decisions." *Id.* at 22.

^{23.} See William D. Ruckelshaus, Science, Risk, and Public Policy, 221 SCIENCE 1026 (1983).

^{24.} See infra parts III.A-.B; infra notes 26-27.

ments in risk management, a number of the newer legislative proposals would establish numerical "bright lines" to control the risk management process. The term "bright line," which is commonly used to indicate a clear distinction, has become firmly entrenched in environmental policy

jargon, and refers to quantitative risk levels which are written into environmental laws.²⁵

Legislators see mandated numerical risk levels, or bright lines, as a means to reduce executive branch discretion and gain greater congressional control over risk management. For example, Congress might mandate that the amount of dioxin permitted in freshwater fish be reduced until the excess lifetime cancer risk to the average sport fisherman is less than one chance in a million. The idea is that by specifying the numerical level of risk for the agency, legislators could better guarantee that an appropriate degree of protection is provided to the public.

While at least one state instituted bright-line environmental legislation during the 1980's,²⁶ the U.S. Congress has just begun to consider the idea. In 1989 the major Senate and House proposals on clean air used the bright line approach in prescribing the desired stringency of emission standards for toxic air pollutants at factories.²⁷

However, the final Clean Air Act Amendments of 1990 incorporated a bright line only as a screening and priority-setting device (that is, as a threshold for triggering further regulatory consideration).²⁸ Other recent legislative proposals would utilize bright lines for standard setting under several other major federal environmental statutes. In particular, proposed amendments would establish maximum permissible risk levels for pesticide residues under the Federal Food Drug and Cosmetic Act²⁹ and for permissible amounts of dioxin in surface water under the Clean Water Act.³⁰ At this writing, the fate of these more recent proposals in Congress is not apparent.

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^{25.} In fact, the term predates the practice of risk assessment altogether, and was previously used by EPA personnel in numerous contexts to refer to statutory attempts to maximize congressional control over agency discretion. Telephone Interview with Jimmie Powell, Minority Counsel, Senate Committee on Environment and Public Works (Aug. 17, 1990).

^{26.} See Act of Jan. 9, 1984, ch. 443, 1983 N.J. Laws 1801, 1802 (codified at N.J. STAT. ANN. § 58:12A-13(b) (West Supp. 1990)).

^{27.} See S. 816, 101st Cong., 1st Sess. § 2 (1989); H.R. 2585, 101st Cong., 1st Sess. § 2 (1989).

^{28.} See Pub. L. No. 101-549, sec. 301, § 112(f)(2)(A), 104 Stat. 2399, 2543-44 (1990). For an extensive description of the political history of the amendments, see Julie L. Edelson, A Win for Clean Air, ENVTL. FORUM, Jan.-Feb. 1991, at 10. For a more complete discussion of the approach used in the Clean Air Act Amendments, see *infra* part III.A.

^{29.} See S. 1074, 102d Cong., 1st Sess. (1991) (proposed by Sen. Edward Kennedy); H.R. 2342, 102d Cong., 1st Sess. (1991) (proposed by California Rep. Henry A. Waxman).

^{30.} See H.R. 2084, 102d Cong., 1st Sess. (1991) (proposed by South Carolina Rep. Robin Tallon).

In this article, we examine the case for and the case against the use of bright lines in regulatory statutes. Our major thesis is that legislating bright lines would do little to constrain agency discretion in risk management, since agencies would retain enormous discretion in the risk assessment process. In the face of profound scientific uncertainty about cancer risk, agency risk assessors can make numerous quasi-policy judgments³¹ in deciding how chemical risks are calculated. Although Congress could constrain the discretion of risk assessors by mandating specific analytic methods and data sources, there is a real danger that such detailed legislative prescriptions would undermine scientific progress in risk assessment.

If Congress is determined to mandate bright lines, it should undertake more policy analysis to determine how to construct bright lines to achieve its public policy goals. While the most popular variant of bright line legislation would compel the reduction of lifetime cancer risks from each source of chemical exposure to less than one chance in a million lifetimes,³² it is by no means clear that this single approach would be appropriate in all circumstances.

Taking into account the scientific limitations of current risk assessment methods, we argue that legislators should consider bright lines as a device to guide agency priority setting, as they did in drafting the 1990 Clean Air Act, Amendments rather than as a tool to control the precise level of stringency that final standards must satisfy. Legislators should also consider "fuzzy bright lines," which establish a numerical range of acceptable risk rather than a single number.³³

The article begins in part I with a review of the scientific underpinnings of risk assessment, emphasizing the application of QRA to chemical carcinogens. As we note, risk assessors face tremendous uncertainties in their choice of biological assumptions, statistical models, and sources of data, all of which can affect the outcome of the risk assessment greatly. In part II, we describe how EPA currently performs risk assessments and how the agency uses these assessments to make risk management decisions under the existing narrative statutes.³⁴ In part III, we briefly describe recent legislative proposals which attempt to use bright lines to control agency discretion. In part IV, we discuss how bright lines might be constructed to achieve particular legislative goals. In part V, we discuss the advantages and disadvantages of bright lines in light of recent

^{31.} Other writers have called these judgments science-policy assumptions, default positions, or inferences in the absence of hard data. See, e.g., Thomas O. McGarity, Substantive and Procedural Discretion in Administrative Resolutions of Science Policy Questions: Regulating Carcinogens in EPA and OSHA, 67 GEO. L.J. 729, 754-59 (1979).

^{32.} See Kelly, supra note 15.

^{33.} See infra part IV.E.

^{34.} For a broad overview of EPA's implementation of risk assessment, see Stever, supra note 20, at 332-36.

legislative proposals. In particular, we address the impact of bright line legislation on the furtherance of democratic values, public health and economic efficiency, good regulatory science, civic education, and administrative consistency. We conclude with a plea to legislators and their staffs to look carefully at the principles of risk assessment and management before incorporating specific risk numbers into legislation.

I

QUANTITATIVE RISK ASSESSMENT

In order to understand the complexities of any statutory scheme of risk assessment and management, one needs a basic understanding of quantitative risk assessment (QRA). In this section, we describe how the federal government conducts risk assessments of chemical exposures that may cause cancer. Cancer risk assessment is complicated by an immature technical basis that is rapidly changing in response to advances in scientific knowledge. It is crucial for legislators to consider how responsive agency risk assessments will be to scientific progress when drafting environmental legislation.

We focus in this section on the particular method of risk assessment which EPA uses to support its risk management decisions under existing environmental legislation.³⁵ Within EPA, the responsibility to perform risk assessments is divided among the Office of Research and Development and the program offices that make regulatory decisions. We focus on EPA because it is responsible for implementation of a large proportion of risk management statutes. In addition, EPA's methods of conducting risk assessments have been very influential in the many other federal and state agencies which also perform risk assessments. Although EPA's QRA procedures may seem rigorous and the results of risk assessments very precise, they are not. In the first place, the state of the art of risk assessment, as well as the scientific knowledge on which it is based, is rapidly evolving.³⁶ In the second place, while EPA's risk assessment guidelines are important, they are not uniformly used by other federal and state agencies, by academics and private consultants, or

^{35.} To trace the evolution of EPA's approach to carcinogen risk assessment, see Albert et al., *supra* note 12; Proposed Guidelines for Carcinogen Risk Assessment, 49 Fed. Reg. 46,294 (1984); EPA Guidelines, *supra* note 11, at 33,992.

^{36.} See, e.g., Dennis J. Panstenbach, Important Recent Advances in the Practice of Health Risk Assessment: Implications for the 1990's, 10 REG. TOXICOLOGY & PHARMACOLOGY 204 (1989); CARCINOGEN RISK ASSESSMENT: NEW DIRECTIONS IN THE QUALITATIVE AND QUANTITATIVE ASPECTS (Ronald W. Hart & Fred D. Hoerger eds., 1988). EPA has indicated its intent to review its 1986 guidelines in light of recent experience and the evolving science. See Intent to Review the 1986 Guidelines for Carcinogen Risk Assessment, 53 Fed. Reg. 32,656 (1988).

even by all program offices within EPA.³⁷ The following discussion will highlight sources of uncertainty and controversy in the process.

EPA uses risk assessment to predict the probability of developing cancer as a result of exposure to a particular agent.³⁸ As currently practiced, risk assessment of a carcinogen takes place in four steps: hazard identification, dose-response evaluation, exposure assessment, and risk characterization.³⁹

The first step, hazard identification, is the process of determining whether an "agent" (for example, an industrial chemical, a natural product in the environment, or a particular lifestyle) increases a person's risk of developing cancer.⁴⁰ The second step, dose-response evaluation, reveals how the likelihood of cancer changes with the level of exposure.⁴¹ A risk assessor might estimate, for example, how the probability of lung cancer changes with the number of cigarettes smoked. The third step, exposure assessment, quantifies the amount, or dose, of the carcinogen to which people may be exposed. This may be the amount of a chemical in the air near a factory, the concentration of radon in the basement of a home, or the amounts of various foods and beverages which an individual consumes each day.⁴²

After these quantitative inputs to a risk assessment have been determined, the numbers are combined to yield an overall estimate of risk, the basic component of the final step, risk characterization. A risk characterization is usually expressed numerically as the incremental lifetime risk of cancer due to a particular agent at a particular level of exposure (also referred to as an incremental risk).⁴³ This is the number that a risk manager might compare to a legislated bright line. Good risk characterizations contain not only a final risk number but also a discussion of the uncertainties in and the assumptions behind the assessment,⁴⁴ but unfortunately this step is rarely taken.

39. COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, supra note 2, at 3; EPA Guidelines, supra note 11, at 33,993-94.

40. EPA Guidelines, supra note 11, at 33,994.

41. Id. at 33,996-98. See generally Lauren Zeise et al., Dose-Response Relationships for Carcinogens: A Review, 73 ENVTL. HEALTH PERSP. 259 (1987) (reviewing the experimental evidence for various shapes of dose-response relationships for carcinogens).

42. EPA Guidelines, supra note 11, at 33,998.

43. Id. at 33,998-99.

44. Id. at 33,999; see also ADAM M. FINKEL, CONFRONTING UNCERTAINTY IN RISK MANAGEMENT: A GUIDE FOR DECISION-MAKERS (1990) (proposing a number of quantitative methods for showing the uncertainty in risk assessment values).

^{37.} GRAHAM ET AL., supra note 3 (examples of benzene and formaldehyde in chapters six and seven).

^{38.} Although quantitative risk assessment was originally applied only to radiation, the same concepts and tools were later expanded to encompass cancer induced by agents other than radiation. For an early example of this expansion, see Roy E. Albert & Bernard Altshuler, Assessment of Environmental Carcinogen Risks in Terms of Life Shortening, 13 ENVTL. HEALTH PERSP. 91 (1976).

Cancer risk estimates are predictions of an unknown future, rather than estimates of the future behavior of a known phenomenon. For this reason, they can be quite difficult to quantify with precision. A comparison of the prediction of car accident rates to that of cancer rates illustrates the difficulty. An estimate of the number of persons who will be killed in car accidents can be based on frequency data—actual counts of automobile fatalities over a number of years. A prediction can thus be based on the past behavior of the system. In contrast, cancer risk predictions are based on extrapolated probabilities, not on past frequencies. There are a number of reasons for this. For example, the causes of cancer are much more complex, because cancer does not develop immediately after exposure to a carcinogen, and because regulators want to know the potential risk of substances to which the public has not yet been exposed in great numbers. As a consequence, predictions of cancer risk cannot be known with similar degrees of precision.

In evaluating the seriousness of incremental cancer risks, it is useful to have a sense of perspective about the frequency of cancer. At current U.S. mortality rates, a baby born today has about a one-in-four, or 0.25, chance of contracting fatal cancer in his or her lifetime. This is the average American's baseline cancer risk from all causes. An incremental risk of one in a million, or 10^{-6} , the most frequently proposed bright line risk standard, is equivalent to a change in lifetime cancer risk from 0.25 to 0.250001.

A. Hazard Identification

The most definitive way to determine whether a compound can cause human cancer is through the science of epidemiology. Cancer epidemiology attempts to establish associations between human exposure to a suspected cancer causing agent and the frequency of cancer in the human population.⁴⁵ The major drawback of epidemiological studies is that they cannot measure risks before those who are exposed develop cancer, but merely identify effects which have already occurred. Risk managers want to identify human carcinogens before cancer develops, before they can be discovered by epidemiology.

Furthermore, cancer epidemiology is fraught with interpretive difficulty.⁴⁶ Cancer is a disease with a long latency period that arises from many causes, only some of which are known. Human exposures to potential carcinogens are often complex, uncertain, and poorly documented. If exposures are mismeasured, the epidemiologist will have a

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^{45.} For an excellent introduction to epidemiology, see Norton Nelson, *Toxicology and Epidemiology: Strengths and Limitations, in* EPIDEMIOLOGY AND HEALTH RISK ASSESSMENT (L. Gordis ed., 1988).

^{46.} Eliot Marshall, *Experts Clash Over Cancer Data*, 250 SCIENCE 900 (1990) (describing in detail the controversy surrounding interpretation of national cancer epidemiology data).

difficult time detecting any association between exposure and disease, even if one exists. Moreover, epidemiological studies are often plagued by confounding factors, such as smoking, by a lack of suitable control groups, and by alternative interpretations of data. Due to practical limitations on the size of studies and the large background risk of cancer, epidemiologists usually cannot detect modest cancer risks that would still be of concern to risk managers. While some epidemiological studies of animal carcinogens have been "negative," this may simply reflect the inadequate sample sizes in these studies.⁴⁷ When epidemiologists do detect human cancer risks, they usually do so in occupational settings where historical levels of exposure have been quite high.⁴⁸ If findings from the workplace are to be extrapolated to environmental settings, epidemiologists must resolve uncertainties about how to extrapolate tumors observed at relatively high doses to the tumors that might occur at low levels of environmental exposure.

Credible epidemiological studies, especially several showing the same positive result, are considered adequate evidence of human carcinogenicity. Such results are difficult to obtain except when studying very potent carcinogens or carcinogens which cause an unusual type of tumor. For example, epidemiological studies identified vinyl chloride as a human carcinogen because it causes liver angiosarcoma, an extremely rare type of tumor.⁴⁹ By contrast, there is little consensus within the scientific community on how much weight to give negative epidemiological reports, or on how to resolve controversies when there are both positive and negative epidemiological studies of a compound.⁵⁰ As a result, fewer than sixty chemicals and mixtures have been identified as known human carcinogens.⁵¹

In light of the limits of epidemiology and the need to identify hazards before they cause serious harm, scientists have resorted to animal experiments in an effort to identify agents that are potential human carcinogens.⁵² The key laboratory test used in hazard identifica-

^{47.} Gay Goodman & Richard Wilson, Quantitative Prediction of Human Cancer Risk from Rodent Carcinogenic Potencies: A Closer Look at the Epidemiologic Evidence for Some Chemicals Not Definitively Carcinogenic in Humans, 14 REG. TOXICOLOGY & PHARMACOL-OGY 118, 119-20 (1991).

^{48.} See GRAHAM ET AL., supra note 3, at 180-81.

^{49.} See Laszlo Makk et al., Clinical and Morphological Features of Hepatic Angiosarcoma in Vinyl Chloride Workers, 37 CANCER 149 (1976).

^{50.} See, e.g., Patricia A. Buffler, The Evaluation of Negative Epidemiologic Studies: The Importance of All Available Evidence in Risk Characterization, 9 REG. TOXICOLOGY & PHAR-MACOLOGY 34 (1989); Ralph R. Cook, The Role of "Negative" Epidemiology Data in the Evaluation of Risk, 9 REG. TOXICOLOGY & PHARMACOLOGY 44 (1989).

^{51.} LORENZO TOMATIS ET Al., Human Carcinogens So Far Identified, 80 JAPANESE J. CANCER RES. 795, 800 (1989).

^{52.} For a recent analysis of the use of animal tests to predict human carcinogenicity, see Bruce C. Allen et al., *Correlation Between Carcinogenic Potency of Chemicals in Animals and Humans*, 8 RISK ANALYSIS 531 (1988), as well as the comments from various viewpoints

tion is the long-term rodent bioassay, which is conducted on the assumption that a rodent carcinogen may also be a human carcinogen. In addition, laboratory tests of the biological properties of chemicals provide information which can help scientists assess a chemical's potential for human carcinogenicity.⁵³

The National Toxicology Program (the NTP) of the U.S. Department of Health and Human Services has established rigorous guidelines for the conduct of rodent carcinogen bioassays.⁵⁴ Under the NTP's guidelines, a researcher must expose fifty animals of each sex of two species (usually rats and mice) to several dose levels of the suspected carcinogen for virtually their entire lives.⁵⁵ The dose levels selected are the maximum tolerated dose (the MTD) and fractions thereof, usually MTD/2 or MTD/4. The MTD is the highest dose that the animals can tolerate without becoming so sick that the test will not be useful in detecting tumors. High dose levels are chosen to compensate for the small number of rodents, which are expensive to house and feed. Since most bioassays are performed with only fifty animals at each dose level, the animals must be given the highest dose that they can tolerate if the researchers are to maximize their chances of seeing a statistically significant response.⁵⁶ However, the small number of animals used greatly limits the sensitivity of the assay. For example, if a dose of a carcinogen causes an increased cancer risk of one in 100 in a rodent's lifetime, it is unlikely to be detected in a cohort of fifty rodents.

Tumors observed at the MTD are considered relevant on the theory that cancer is a disease that can be caused by a single molecule of a carcinogen interacting with the DNA in a single cell, and therefore, the response of a carcinogen at the MTD can be extrapolated to the much lower levels of exposure that humans experience.⁵⁷ However, there is controversy within the scientific community about whether results from rodent bioassays performed at or near the MTD are applicable to the much lower levels of exposure typically faced by humans.⁵⁸

54. EPA Guidelines, supra note 11, at 33,994.

55. James Huff & Joseph Haseman, Long-term Chemical Carcinogenesis Experiments for Identifying Potential Human Cancer Hazards: Collective Database of the National Cancer Institutes and National Toxicology Program (1976-1991), 96 ENVTL. HEALTH PERSP. 23 (1991). 56. Id.

57. OTTOBONI, supra note 4, at 96-99.

58. For two recent critiques of the ability of animal tests at the MTD to predict human carcinogenicity, see Bruce N. Ames & Lois Swirsky Gold, *Too Many Rodent Carcinogens: Mitogenesis Increases Mutagenesis*, 249 SCIENCE 970 (1990); C. Jelleff Carr & Albert C.

which follow the article.

^{53.} Tests that measure the mutagenicity (i.e., an agent's ability to alter DNA) of chemicals are believed to give information concerning possible carcinogenicity. For a seminal paper in this area, see Bruce N. Ames, *Identifying Environmental Chemicals Causing Mutations and Cancer*, 204 SCIENCE 587 (1979). For an analysis of the use of such short-term tests to understand human carcinogenic potential, see Raymond W. Tennant et al., *Prediction of Chemical Carcinogenicity in Rodents from In Vitro Genetic Toxicity Assays*, 236 SCIENCE 933 (1987).

Several hundred compounds have been shown to cause cancer in animal tests.⁵⁹ The usefulness of these studies in predicting human carcinogenicity depends on the accuracy of certain assumptions. These include the assumption that humans respond in a similar manner to rodents;⁶⁰ the assumption that results of exposure to high doses over the relatively short lifetimes of animals are functionally equivalent to the results of exposure to low doses over human lifetimes;⁶¹ and the assumption that cross-species scaling methods accurately extrapolate doses given to small test animals to reflect comparable human doses.⁶² These assumptions are hotly contested within the scientific and regulatory communities, but a frequently stated rationale is that, while they may not be accurate, they are conservative-reliance upon them will minimize the chance that a carcinogen will be falsely exonerated.⁶³ On the other hand, carcinogens are unlikely to be classified as carcinogens until enough high-quality, large-sample testing has been done in a variety of rodent strains and species to reveal their carcinogenic activity.

When making a judgment about whether a particular agent is likely to be a human carcinogen, EPA states that all available data concerning the potential carcinogenicity of the compound should be reviewed and considered by evaluating the weight of the evidence.⁶⁴ EPA scientists place each compound into one of the following five categories, which

59. NATIONAL INSTS. OF HEALTH and NATIONAL CANCER INST., U.S. DEP'T OF HEALTH AND HUMAN SERVS., NIH PUB. NO. 87-2947, SURVEY OF COMPOUNDS WHICH HAVE BEEN TESTED FOR CARCINOGENIC ACTIVITY CUMULATIVE INDEXES (1987); Lois Swirsky Gold et al., Ranking the Potential Carcinogenic Hazards to Workers from Exposures to Chemicals That Are Tumorigenic in Rodents, 76 ENVTL. HEALTH PERSP. 211, 211 (1987). For air pollutants, see Joellen Lewtas, Experimental Evidence for the Carcinogenicity of Air Pollutants, in AIR POLLUTION AND HUMAN CANCER 49-61 (Lorenzo Tomatis ed., 1990).

60. Allen et al., supra note 52, at 531.

61. Ames & Gold, supra note 58, at 970-71.

62. EPA's surface-area method for scaling doses across species "is considered to be appropriate because certain pharmacological effects commonly scale according to surface area." EPA Guidelines, *supra* note 11, at 33,998. However, there is a great deal of work currently being conducted to find better methods of cross-species extrapolation. For an overview, see Curtis C. Travis, *Pharmacokinetics, in* CARCINOGEN RISK ASSESSMENT 87 (Curtis C. Travis ed., 1988). In addition, government agencies concerned with risk assessments have been working on standardizing cross-species scaling factors, since agencies such as EPA and the FDA currently use different factors, which can lead to as much as a sevenfold difference in risk estimates. *See* Federal Coordinating Comm. on Science, Engineering, and Technology, A Cross-Species Scaling Factor for Carcinogen Risk Assessment Based on Equivalence of mg/kg^{3/4}/day (1991) (draft document on file with author).

63. Whether in fact these assumptions are always conservative is an open question. See, e.g., Adam M. Finkel, Is Risk Assessment Really Too Conservative?: Revising the Revisionists, 14 COLUM. J. ENVTL. L. 427, 441-47 (1989).

64. EPA Guidelines, *supra* note 11, at 33,994. For example, EPA suggests evaluation of the results of epidemiological studies, long-term animal bioassays, short-term laboratory tests of the biological properties of chemicals, and mechanistic studies, along with consideration of the physical and chemical properties of the compound. *Id.* at 33,994-96.

Kolbye, Jr., A Critique of the Use of the Maximum Tolerated Dose in Bioassays to Assess Cancer Risks from Chemicals, 14 REG. TOXICOLOGY & PHARMACOLOGY 78 (1991).

have official verbal descriptions used in communicating carcinogenic hazard to the public.⁶⁵

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 Group E: Evidence of noncarcinogenicity for humans

Group B is further subdivided into categories B1 and B2, depending on the availability of positive epidemiological data. B1 chemicals have limited human evidence supporting, although not establishing, a finding of carcinogenic hazard to humans, while B2 chemicals (as well as C and D chemicals) are classified solely on the basis of animal data.

EPA performs quantitative cancer risk assessments for compounds that fall into categories A, B1, B2, and sometimes for compounds that fall into category C.⁶⁶ An EPA panel of scientists called the Carcinogen Risk Assessment Verification Endeavor (CRAVE), located in the Office of Research and Development, periodically reviews the scientific evidence for these classifications. Classifications officially approved by EPA's CRAVE are released to the public in several formats, including the computerized on-line service known as the Integrated Risk Information System (IRIS).⁶⁷ However, the CRAVE review process is slow, and EPA program offices sometimes perform risk assessments before the CRAVE review process is complete.⁶⁸

According to EPA guidelines, the evidence of carcinogenicity in humans and animals, both positive and negative, should be considered separately.⁶⁹ The judgments from these two assessments are then combined and the agent is preliminarily assigned an EPA carcinogen classification.⁷⁰ The preliminary classification can then be changed to reflect a higher or lower likelihood of human carcinogenicity on the basis of the results of short-term,⁷¹ in vitro,⁷² metabolic,⁷³ or toxicokinetic⁷⁴ studies.

69. In the absence of human data, the weight of the evidence that an animal carcinogen will be a human carcinogen increases (a) with the number of animal studies showing a positive response; (b) with the number of different strains or species showing a positive response; (c) with the number of different tissues in the body which develop tumors following exposure to the compound; (d) in the presence of a clear cut dose-response relationship for all tumors, but especially for malignant tumors; (e) with a shortening of life due to tumors induced by the agent. EPA Guidelines, *supra* note 11, at 33,994.

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^{65.} Id. at 33,996-34,000.

^{66.} EPA Guidelines, supra note 11, at 33,996, 34,003.

^{67.} IRIS is an electronic data base built and maintained by EPA to aid practitioners in performing risk assessments. It contains hazard identification and dose-response data on chemicals officially reviewed by CRAVE.

^{68.} See, e.g., OFFICE OF AIR QUALITY PLANNING AND STANDARDS, U.S. ENVTL. PRO-TECTION AGENCY, EPA-450/89, CANCER RISK FROM OUTDOOR EXPOSURE TO AIR TOXICS ES-4 (1989) (noting that only 18 out of 83 pollutants have CRAVE verified potency factors).

^{70.} Id.

^{71.} See Raymond W. Tennant, The Genetic Toxicity Database of the National Toxicology

In reality, such changes are rarely made.⁷⁵ Some critics of EPA argue that agency scientists give undue emphasis to positive evidence of carcinogenicity from long-term animal bioassays and do not incorporate other types of scientific information, and hence that EPA's method does not truly consider the weight of the full evidence.⁷⁶

The ability of EPA's hazard identification process to incorporate new scientific findings is a topic of active concern.⁷⁷ The EPA guidelines on hazard identification require that a finding of animal carcinogenicity be taken as possible or probable evidence of human carcinogenic potential.⁷⁸ As a result, EPA has difficulty responding to new scientific data which suggest that some animal carcinogens in fact do not pose risks to humans.

EPA currently is facing just such a question in a case involving new information about the biological mechanisms of certain rat cancers. A number of hydrocarbon compounds, including unleaded gasoline, have been found to cause tumors in the kidneys of male rats.⁷⁹ Recent scientific research suggests that the biological mechanism responsible for the

Program: Evaluation of the Relationships Between Genetic Toxicity and Carcinogenicity, 96 ENVTL. HEALTH PERSP. 47-51 (1991). A great deal of scientific effort has been directed at finding short-term tests to identify potential human carcinogens. See, e.g., Tennant et al., supra note 53; Larry D. Claxton et al., An Analysis by Chemical Class of Salmonella Mutagenicity Tests as Predictors of Animal Carcinogenicity, 205 MUTATION RES. 197 (1988).

72. The term in vitro simply refers to experiments of biological properties done outside the body. For example, studies of the metabolism of a chemical can be studied either by administering the chemical to an animal and monitoring metabolism (in vivo experiment) or by testing the metabolic reaction with purified enzyme in a test tube (in vitro experiment).

73. Differences in metabolism occasionally have had a large effect on hazard identification. See, e.g., RISK ASSESSMENT FORUM, U.S. ENVTL. PROTECTION AGENCY, EPA/625/3-91/019F, ALPHA_{2µ}-GLOBULIN: ASSOCIATION WITH CHEMICALLY INDUCED RENAL TOXIC-ITY AND NEOPLASIA IN THE MALE RAT (1991) (detailing a carcinogenic process that only seems to occur in male rats).

74. Toxicokinetics (also called pharmacokinetics) is concerned with the absorption, distribution within the body, metabolism, and excretion of toxic chemicals. For examples of the use of pharmacokinetic information in risk assessment, see Daniel Krewski et al., *The Application of Pharmacokinetic Data in Carcinogenic Risk Assessment, in 8 PHARMACOKINETICS IN RISK ASSESSMENT, DRINKING WATER AND HEALTH 441 (1987); Kenneth T. Bogen, Pharmacokinetics for Regulatory Risk Analysis: The Case of Trichloroethylene, 8 REG. TOXI-COLOGY & PHARMACOLOGY 447 (1988).*

75. For mention of one such rare change in classification, for para-dichlorobenzene, see J. Ashby et al., A Scheme for Classifying Carcinogens, 12 REG. TOXICOLOGY & PHARMACOLOGY 270, 293 (1990). The classification of this carcinogen was changed from B2 to C on the basis of new mechanistic data suggesting that the tumors in animals were not relevant to humans. See John D. Graham, Resolving the Regulatory Science Dilemma, in HARNESSING SCIENCE FOR ENVIRONMENTAL REGULATION 211, 216 (John D. Graham ed., 1991) [hereinafter HARNESSING SCIENCE].

76. See Ashby et al., supra note 75.

77. See id. at 273.

78. EPA Guidelines, supra note 11, at 33,996.

79. W. Gary Flamm & Lois D. Lehman-McKeeman, The Human Relevance of the Renal Tumor-Inducing Potential of d-Limonene in Male Rats: Implications for Risk Assessment, 13 REG. TOXICOLOGY & PHARMACOLOGY 70, 72 (1991).

male rat kidney tumors may be unique to male rats and have no relevance to humans.⁸⁰ The use of these tumors as a basis for human risk assessment is a source of ongoing controversy in the risk assessment community,⁸¹ and EPA must decide how to incorporate this information into its classification decisions.

B. Dose-Response Evaluation

Once a carcinogenic hazard has been identified, the second step in assessing cancer risks is the determination of the relationship between the dose of the agent and the probability of developing cancer.⁸² We will discuss dose-response analysis of both carcinogens and noncarcinogens, since some scientists believe that, contrary to current agency practice, a similar method should be used to assess both types of toxic responses.

Toxicologists have for many years engaged in efforts to determine what dose of a chemical is safe and what is harmful. The data they have discovered describing these dose-response relationships have been used in occupational health, environmental protection, and medicine to protect people from the toxic effects of chemicals. Central to these efforts to determine a safe level of exposure is the concept of a response threshold.⁸³

The threshold is the dose of the toxicant below which no adverse effects will occur. Above the threshold, adverse effects do occur. There are two types of thresholds: population and individual. A population threshold is the dose of a compound below which absolutely no one in the population will show a response. An individual threshold is the dose below which an individual will not have a response. Individual thresholds vary from person to person and from toxin to toxin. The population threshold can be thought of as the threshold for the most sensitive individual in the population.

The dose-response relationship for a chemical is usually determined by tests on rodents, exposing them to a variety of doses of the compound and observing any toxic responses. The lowest dose producing an adverse effect on the animals is called the lowest observable adverse effect

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^{80.} Id. at 75-77.

^{81.} See James A. Swenberg, Risk Assessment of Chemicals Causing α_{2u} -Globulin Nephropathy, 13 REG. TOXICOLOGY & PHARMACOLOGY 1 (1991); Flamm & Lehman-McKeeman, supra note 79, at 70.

^{82.} The very idea that dose determines response is the fundamental tenet of toxicology, exemplified by the oft-quoted phrase from Paracelsus: "All substances are poisons; there is none which is not a poison. The right dose differentiates a poison and a remedy." John Doull & Margaret C. Bruce, *Origin and Scope of Toxicology, in* CASARETT AND DOULL'S TOXICOL-OGY: THE BASIC SCIENCE OF POISONS 3 (Curtis D. Klaassen et al. eds., 3d ed. 1986) (quoting Paracelsus).

^{83.} For a discussion of thresholds, see Arthur C. Upton, Are There Thresholds for Carcinogenesis? The Thorny Problem of Low-Level Exposure, 534 ANNALS N.Y. ACAD. SCI. 863 (1988).

level (LOAEL), and the next tested dose below the LOAEL is called the no observable adverse effect level (NOAEL).⁸⁴ The threshold dose in the experiments, then, is assumed to be somewhere between the LOAEL and the NOAEL, although its actual value is unknown.⁸⁵

When the rodent dose-response relationship is used to establish safe human doses, the NOAEL is divided by a safety factor. This safety factor accounts for potential differences in human and rodent response, protects potentially sensitive segments of the human population, and accounts for lack of knowledge of human response when there is little or no human data. The safety factor is usually 100 or 1000, which means that toxicologists set the safe level of exposure for humans at 1/100 or 1/1000 of the animal NOAEL.⁸⁶

Dose-response evaluation for carcinogens differs from that used in traditional toxicology. With suspected carcinogens, the threshold concept is essentially discarded—the threshold dose below which no risk may be seen is assumed to be zero. The no-threshold model, which is prominently used in cancer risk assessment, postulates that cancer can arise from a single change to the DNA of a single cell.⁸⁷ In other words, theoretically, a single molecule of a carcinogen has some nonzero probability of causing cancer. For this reason, assessors of cancer risk assume that any dose of a carcinogen, however small, increases the probability of tumor formation.⁸⁸

Further complications arise in collecting and interpreting data from rodent tests of carcinogenicity. Chemicals may exhibit carcinogenic activity in some rodent species but not in others. The same chemical may even test positive in one strain of rats while testing negative in another strain of rats. Pathologists may disagree about the classification of tumors, especially when hyperplasia (a pretumor condition), benign tumors, and malignant tumors must be distinguished. Chemicals may cause tumors in one or more sites in the rodent's body which have no obvious human counterpart.⁸⁹

^{84.} Curtis D. Klaassen, Principles of Toxicology, in CASARETT AND DOULL'S TOXICOL-OGY: THE BASIC SCIENCE OF POISONS, supra note 82, at 28, 28-29.

^{85.} OTTOBONI, supra note 4, at 112-15.

^{86.} Klaassen, supra note 84, at 29.

^{87.} For an early paper discussing this theory, see K.S. Crump et al., Fundamental Carcinogenic Processes and Their Implications for Low Dose Risk Assessment, 36 CANCER RES. 2973 (1976).

^{88.} Klaassen, supra note 84, at 30; see also JOHN J. COHRSSEN & VINCENT T. COVELLO, U.S. COUNCIL ON ENVTL. QUALITY, EXECUTIVE OFFICE OF THE PRESIDENT, RISK ANALY-SIS: A GUIDE TO PRINCIPLES AND METHODS FOR ANALYZING HEALTH AND ENVIRONMEN-TAL RISKS 95 (1989) ("There is a strong ongoing debate over whether chemical carcinogens in small doses can be detoxified, or whether even a minute amount leads to the development of cancer.").

^{89.} See supra note 81 and accompanying text.

Scientists must make judgment calls to complete a dose-response evaluation of any particular animal carcinogen. The important judgments include (a) which set of animal data (e.g. which animal species response from which bioassay) to use in the modeling process;⁹⁰ (b) which tumor types (e.g., benign and/or malignant) and tumor sites (e.g., liver and/or Zymbal gland) in the animal to count;⁹¹ (c) how to extrapolate the high-dose findings from animal bioassays or occupational epidemiology to the low doses humans encounter in daily life;⁹² and (d) how to scale the doses between species, adjust for different routes of exposure (e.g., ingestion in animals versus inhalation in humans), and account for variable durations or patterns of exposure.⁹³ None of these judgments can currently be resolved solely on the basis of science. In the face of this uncertainty, agency scientists make quasi-policy judgments that reflect values about how protective or conservative they should be.⁹⁴

Perhaps the most contentious judgment in carcinogen risk assessment is how to extend the dose-response curve from the high doses to which animals are exposed in the laboratory to the lower doses to which humans are exposed in the environment.⁹⁵ There are several well-known statistical models for fitting the animal data and extrapolating the doseresponse curve to low doses.⁹⁶ Often each model will fit the experimental animal data quite well and have at least some plausible basis in biology. The models nonetheless may yield low-dose risk estimates for the same chemical, or even from the same data set, that vary enormously, by factors of hundreds or even of thousands.⁹⁷

^{90.} The official decision rule is in the EPA Guidelines, *supra* note 11, at 33,997. For a discussion of EPA methods for estimating dose-response, see Elizabeth L. Anderson et al., *Quantitative Approaches in Use to Assess Cancer Risk*, 3 RISK ANALYSIS 277, 289-93 (1983).

^{91.} EPA Guidelines, supra note 11, at 33,997. Many scientists believe that some tumor sites may be less relevant to human responses than others, including the livers of mice, the testes of male rats, and rodent organs with no human equivalent such as Zymbal or preputial glands. See, e.g., J. Doull, The Mouse in Safety Evaluation, in 10 ARCHIVES OF TOXICOLOGY 3 (Philip L. Chambers et al. eds., 1986); R.R. Maronpot et al., Liver Lesions in B6C3F1 Mice: The National Toxicology Program Experience and Position, in 10 ARCHIVES OF TOXICOLOGY, supra, at 10; Ashby et al., supra note 75, at 281-82. For an alternative method of choosing the proper data, see S.K. Wolff et al., Selecting Experimental Data For Use In Quantitative Risk Assessment: An Expert-Judgment Approach, 6 TOXICOLOGY & INDUS. HEALTH 275 (1990).

^{92.} See Dennis J. Panstenbach, Health Risk Assessments: Opportunities and Pitfalls, 14 COLUM. J. ENVTL. L. 379, 389-90 (1989); COHRSSEN & COVELLO, supra note 88, at 80-82.

^{93.} See COHRSSEN & COVELLO, supra note 88, at 75-79.

^{94.} See supra note 31 and accompanying text.

^{95.} For an extensive discussion on the subject, including arguments for and against the use of conservative assumptions in extrapolating, see Finkel, *supra* note 63, at 435-38. For a thorough discussion of low-dose extrapolation procedures, including the wide range of potency estimates that can be derived from the same data set using different extrapolation procedures, see Robert L. Sielken, Jr., *The Capabilities, Sensitivity, Pitfalls, and Future of Quantitative Risk* Assessment, in ENVIRONMENTAL HEALTH RISKS: ASSESSMENT AND MANAGEMENT 94 (R. Stephen McColl ed., 1987).

^{96.} Klaassen, supra note 84, at 30-32.

^{97.} Panstenbach, supra note 92, at 389-96; see, e.g., Sielken, supra note 95.

As a default position based primarily on policy considerations,98 EPA requires use of the linearized multistage (LMS) model in all risk assessments. Agency risk assessors can choose another model only if there is persuasive evidence to support their choice; EPA guidelines do not indicate what sort of evidence would be persuasive.⁹⁹ EPA favors the LMS model because it is generally considered to be a conservative method of estimating low-dose risks. Among biologically plausible models, few produce higher estimates of risks than does the LMS model.¹⁰⁰ Scientists derive the critical low-dose potency parameter, the so-called q_1^* , by applying LMS to the tumor incidence data in rodents. The q_1^* is the upper ninety-five percent confidence limit on the linear term of the dose-response function.¹⁰¹ This linear term is produced by the LMS model's linearization of the data: the model assumes that the dose-response relationship is linear at low doses, regardless of the shape of the dose-response curve within the range of tested doses. The q_1^* , which EPA calls the "cancer potency factor" (the CPF), is an estimate of the carcinogenic strength of a compound based on the LMS model.¹⁰² The cancer potency factor reflects the fact that not all carcinogenic agents are equal; CPF's differ by factors of as much as a million.¹⁰³

While the choice of a conservative method of low-dose extrapolation is not strictly defensible on scientific grounds, EPA defends its choice of the conservative LMS method on several grounds. Conservatism can compensate for unknown differences in sensitivity between inbred, genet-

^{98.} The terms "default position" or "default assumption" are used to refer to arbitrary choices made by agency risk assessors in the face of uncertainty. These assumptions are usually defended on the grounds that they are scientifically plausible and are likely to lead to a risk estimate that is larger than the actual risk. The latter rationale is often referred to as a quasipolicy position, since it reflects a policy maker's desire to err on the side of safety when relying on a risk estimate in the face of uncertainty. See McGarity, supra note 31.

^{99.} EPA Guidelines, supra note 11, at 33,997-98.

^{100.} Id. But see John C. Bailar III et al., One Hit Models of Carcinogenesis: Conservative or Not?, 8 RISK ANALYSIS 485 (1988) (challenging general view that LMS is a conservative method of estimating low-dose risks).

^{101.} The potency parameters are usually generated by computer programs. For an explanation of one of the most widely used low dose extrapolation programs as well as a technical discussion of the LMS, see R.B. HOWE & K.S. CRUMP, GLOBAL 82: A COMPUTER PROGRAM TO EXTRAPOLATE QUANTAL ANIMAL TOXICITY DATA TO LOW DOSES (1982) (prepared for the Office of Carcinogen Standards, Occupational Safety and Health Administration, on file with author).

^{102.} However, some scientists believe it is only a surrogate for a compound's toxicity or MTD. See, e.g., Ames & Gold, supra note 58, at 970. See also supra text accompanying notes 90-94.

^{103.} For example, the CPF's for the two EPA class B2 carcinogens hydrazine and folpet, both based on LMS estimates from animal data, differ by a factor of about 850. This indicates that it would take about 850 times more folpet than hydrazine to produce the same carcinogenic response. The difference between the CPF for dioxin, another B2 carcinogen, and the CPF for folpet is a factor of over 40 million! However, the potency factor for dioxin is under intense scrutiny. See infra notes 109-11 and accompanying text.

ically identical rodents and genetically heterogeneous humans.¹⁰⁴ Conservatism can also protect potentially sensitive human subpopulations, such as the ill, the elderly, and children. Conservatism also corrects for the possibility that the observed tumor frequency underestimates the true

frequency, due to sampling variability.¹⁰⁵

EPA has established guidelines for resolving the various judgment calls in dose-response evaluation.¹⁰⁶ These include the preferred procedure for calculating low-dose potency using the LMS model. The EPA guidelines are often criticized, and the agency has indicated that it intends to review the appropriateness of these guidelines and implement any necessary revisions.¹⁰⁷

As in the other areas of risk assessment, significant effort is being directed toward improving dose-response modelling. Some scientists are promoting new models based on cancer biology as better methods for estimating carcinogenic risks.¹⁰⁸ However, it is not yet certain that these models will be accepted in the regulatory arena.

104. The rodents used in long-term bioassays, from which the dose-response relationship is derived, have been bred to be genetically identical. Therefore, for example, if an agent must be metabolized to the active carcinogenic compound, all of the animals will metabolize it at about the same rate and to the same extent. Within the human population, however, genetic diversity may mean that some people will not metabolize the agent at all, some will metabolize it to a great extent, and others will metabolize it to some degree within this range. The problem is that scientists do not know where in the human range of metabolizing ability the rat falls. For examples of possible human genetic differences in cancer susceptibility, see Neil E. Caporaso et al., *Lung Cancer and the Debrisoquine Metabolic Phenotype*, 82 J. NAT'L CANCER INST. 1264 (1990); Thomas A. Sellers et al., *Evidence for Mendelian Inheritance in the Pathogenesis of Lung Cancer*, 82 J. NAT'L CANCER INST. 1272 (1990).

105. Finkel, supra note 63, at 439-40.

106. See EPA Guidelines, supra note 11, at 33,997-98. For purposes of dose-response evaluation, epidemiological studies with well characterized exposures would be the best option, but these are virtually never available. In using animal tests to estimate human dose-response, then, it is generally assumed, in the absence of evidence to the contrary, that human beings are as sensitive to the effects of the carcinogen as the most sensitive species tested. There is often a rather large difference in experimentally determined carcinogenic potency between different species of experimental animals. EPA's guidelines mandate the use of data from the most sensitive species unless there are compelling reasons not to, such as demonstrated differences in carcinogen metabolism. Id.

107. Intent to Review Guidelines for Carcinogen Risk Assessment, 53 Fed. Reg. 32,656 (1988). Although no further official action has been taken, EPA is currently reviewing these guidelines.

108. See, e.g., James D. Wilson, Assessment of Low-Exposure Risk from Carcinogens: Implications of the Knudson-Moolgavkar Two-Critical Mutation Theory, in BIOLOGICALLY-BASED METHODS FOR CANCER RISK ASSESSMENT 275 (Curtis C. Travis ed., 1989). For an excellent discussion of biologically based carcinogen dose-response models, see Suresh H. Moolgavkar & George Luebeck, Two-Event Model for Carcinogenesis: Biological, Mathematical, and Statistical Considerations, 10 RISK ANALYSIS 323 (1990). For an example with actual data, see Samuel M. Cohen & Leon B. Ellwein, Cell Proliferation in Carcinogenesis, 249 SCI-ENCE 1007-11 (1990). The notorious pollutant dioxin¹⁰⁹ may offer federal agencies their first opportunity to replace the LMS with such a biologically based doseresponse model. In light of mounting scientific evidence that the LMS model is not appropriate for dioxin,¹¹⁰ EPA Administrator William Reilly has ordered the agency to reconsider how it assesses the cancer risks posed by dioxin.¹¹¹ This will be an extremely important case for the use of science in risk assessment, both because of the notoriety of dioxin and because of the precedent-setting implications of allowing use of a dose-response model other than the LMS.

C. Exposure Assessment

Exposure assessment is the phase of a risk assessment that determines just how much exposure to a carcinogen people actually confront. Exposure can occur through a variety of routes, including inhalation,¹¹² dermal absorption,¹¹³ and ingestion of contaminated food or water.¹¹⁴ While some sources of pollution cause human exposure through more than one such pathway, EPA risk assessments do not always consider this possibility. More recent risk assessments, however, indicate a trend to account for as many sources and routes of exposure as possible.¹¹⁵

Exposure assessment permits evaluation of two risk parameters: population risk (incidence) and maximum individual risk (MIR). Population risk is the traditional public health measure that reports the number of cases of disease in the population attributable to a specific source or contaminant. The person at maximum individual risk is the individual who suffers the largest incremental risk due to a particular source or contaminant. In theory, the MIR should reflect scientific information about variability in human exposure and sensitivity to chemical carcinogens.

Since little is known about which people are most sensitive to chemical carcinogens, EPA usually assumes that the person at MIR is the

^{109.} Dioxin is 2,3,7,8-Tetrachlorodibenzodioxin (Chemical Abstract Service Registry Number 1746-01-6).

^{110.} See Leslie Roberts, *Dioxin Risks Revisited*, 251 SCIENCE 624 (1991), for a discussion of a symposium convened to address the scientific basis of dioxin risks, especially as related to dose-response determination.

^{111.} Leslie Roberts, EPA Moves to Reassess the Risk of Dioxin, 252 SCIENCE 911 (1991).

^{112.} U.S. ENVTL. PROTECTION AGENCY, EPA/600/8-89/043, EXPOSURE FACTORS HANDBOOK 3-1 to 3-14 (1989) [hereinafter EPA EXPOSURE FACTORS HANDBOOK].

^{113.} Id. at 4-1 to 4-17; see also Thomas E. McKone, Dermal Uptake of Organic Chemicals from a Soil Matrix, 10 RISK ANALYSIS 407 (1990) (presenting a two-layer model for estimating dermal uptake).

^{114.} EPA EXPOSURE FACTORS HANDBOOK, supra note 112, at 2-1 to 2-67.

^{115.} For a discussion of advances in exposure assessment, see Wayne R. Ott, Total Human Exposure, 19 ENVTL. SCI. & TECH. 880 (1985); Paul J. Lioy, Assessing Total Human Exposure to Contaminants, 24 ENVTL. SCI. & TECH. 938 (1990); and Thomas E. McKone, Human Exposure to Chemicals from Multiple Media and Through Multiple Pathways: Research Overview and Comments, 11 RISK ANALYSIS 5 (1991).

maximally exposed individual (the MEI). The MEI is the (usually hypothetical) person expected to receive the greatest lifetime exposure from a particular source. The MEI may be the resident living closest to a factory that emits the suspected carcinogen, or the resident who draws his or her drinking water from the well closest to a Superfund site that is leaking a suspected carcinogen.¹¹⁶

EPA generally uses predictive models, rather than direct measurements, to calculate the exposure of the MEI.¹¹⁷ In the case of a resident at a factory fenceline, a mathematical dispersion model might estimate the air concentration of the carcinogen 200 meters from the source (EPA typically assumes in such scenarios that the fenceline, and the residence of the MEI, are 200 meters from the source).¹¹⁸ In addition, the models often assume that the MEI is outdoors breathing air at this predicted concentration twenty-four hours a day for seventy years.¹¹⁹ Although no one spends his or her entire life outdoors at the fenceline of the factory, and although few factories produce the same products, or even exist, for seventy years, the MEI calculation is designed to be conservative. By overstating probable actual exposure, it provides a safety margin, giving an upper bound on the true lifetime exposure.

Use of the hypothetical MEI to set standards is extremely controversial. Critics of MEI-based standards argue that it is unsound to regulate, often at very great cost, on the basis of an inflated exposure scenario that never occurs.¹²⁰ Supporters argue that highly exposed people, even if they are few in number, have a right to protection, and that the conservatism in MEI scenarios may be appropriate given the other uncertainties in risk assessment.¹²¹

The population risk estimate tells the risk manager how many cases of disease are expected to occur in the exposed population. It is a more difficult quantity to calculate than the MIR because the assessor needs to know how many people are exposed to the contaminant, at what levels of concentration, and for what periods of time. If humans were known to

118. See Hawkins, supra note 117, at 109.

121. For a spirited defense of both the methodology and rationale behind an MEI approach to QRA, see Katherine Kaufman, In Defense of the Maximally Exposed Individual, ENVTL. FORUM, Mar.-Apr. 1990, at 50.

^{116.} For a discussion of why the MEI assumptions might result in allocation of greater resources to address less important risks, at the expense of more significant risks, see Finkel, *supra* note 63, at 430.

^{117.} For a discussion of MEI calculations and their associated uncertainties, see Neil C. Hawkins, Conservatism in Maximally Exposed Individual (MEI) Predictive Exposure Assessments: A First-Cut Analysis, 14 REG. TOXICOLOGY & PHARMACOLOGY 107 (1991).

^{119.} Id.

^{120.} See Bernard Goldstein, The Maximally Exposed Individual: An Inappropriate Basis for Public Health Decisionmaking, ENVTL. FORUM, NOV.-Dec. 1989, at 13.; cf. Hawkins, supra note 117, at 107, 116 (recognizing criticism of the MEI model as a public health risk assessment measure, but advocating use of a modified MEI model to identify sources which require a complete population risk assessment).

differ in their susceptibility to carcinogens, the calculation of population risk would be even more complex. In the absence of such data, however, assessors typically assume that at a given level of exposure each person will incur the incremental cancer risk predicted by the LMS procedure.¹²²

In the example of a carcinogenic air pollutant, the quantity of concern is the concentration of a suspected carcinogen in the ambient air, which is inhaled by all members of the population. Assessors can either measure ambient levels of a compound directly or, if sources and emission rates are known, they can model the ambient levels. In real world situations, assessors usually employ a combination of the two methods.

While researchers often prefer detailed monitoring of a carcinogenic pollutant to uncertain modelling, monitoring is expensive and cumbersome.¹²³ Furthermore, exposure to a compound cannot be monitored unless the compound has already been released into the environment, and even then, the researcher cannot be certain that the compound will behave similarly in other environments. Still, both methods can prove useful. For example, to perform a QRA for exposure to perchloroethylene, a common drycleaning solvent, a researcher could either monitor exposure in a particular neighborhood with special measuring devices or devise a model of exposure. The model might take into account the number of drycleaners in the neighborhood, the amount of perchloroethylene each emits, the behavior of perchloroethylene in the atmosphere, and meteorological data. In either case, the researcher would use the data to estimate the exposure to the general population and to determine the population risk.

In the absence of hard data, the exposure assessment process proceeds with common default assumptions. For example, for pollutants found in drinking water, EPA recommends that risk assessors assume that all people in the population consume two liters of water per day.¹²⁴ Another frequent assumption is that everyone in the population breathes air at a rate of twenty cubic meters per day (m³/day).¹²⁵ Food intake

^{122.} If, for example, it is estimated that the level of some air pollutant causes 300 cancers per year in the United States, then the average population risk, or the increase in probability of cancer over background for each person in the U.S., would be 300/240,000,000 or 0.0000125 (also expressed as 12.5×10^{-6}). Due to differences in exposure to the agent, some people's risk would be higher, some lower, but the average across the whole population would be 12.5×10^{-6} .

^{123.} See generally NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, HUMAN EXPOSURE ASSESSMENT FOR AIRBORNE POLLUTANTS: ADVANCES AND OPPORTU-NITIES (1991).

^{124.} EPA EXPOSURE FACTORS HANDBOOK, *supra* note 112, at 2-10. The value of two liters per day is given as a reasonable worst case consumption value for adults, again with an eye to not underestimating the exposure. *See infra* text accompanying notes 252-54, 259-71.

^{125.} EPA EXPOSURE FACTORS HANDBOOK, supra note 112, at 3-6. Here the value of 20 m^3 air/day is recommended as an average value; 30 m^3 air/day is assumed to be a worst-case

generally is derived from market basket surveys or from national consumption surveys which measure the quantity of all types of groceries purchased or consumed.¹²⁶ The assumptions used in exposure assessment usually do not take into account the heterogeneity of the population, including differences between the sexes, between adults and children, between different age groups, between different ethnic and socioeconomic groups, and between those with different levels of activity.¹²⁷ Hence, exposure assessment is yet another source of uncertainty in the risk assessment process. Sometimes it produces large overestimates of exposure, as in the MEI;¹²⁸ in other cases, it may lead to serious

Variability in human exposure, even if known with certainty, presents a delicate challenge for risk managers, who must decide, at least implicitly, what fraction of the exposed population should be protected. Alternatively, differing levels of protection must be offered to different segments of the exposed population.

D. Risk Characterization

When a risk assessor has the three important pieces of information—an identified hazard, an estimate of the dose-response relationship (q_1^*) , and estimates of exposure (or dose)—he or she can make a numerical estimate of risk. Essentially all the assessor does is multiply the q_1^* , the cancer potency factor derived from the LMS procedure, by the measured or predicted exposure. The q_1^* is usually expressed in units of increased lifetime probability of cancer per milligram of carcinogen per kilogram of body weight per day of exposure, and the exposure is expressed in units of milligrams of carcinogen per kilogram of body weight per day. The calculation therefore leads to an estimate of the increase in the lifetime probability of cancer from the particular level of exposure.

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underestimates, 129

value. Id.

^{126.} See, e.g., id. at 2-10 to 2-38. These estimates are quite inclusive. They contain average consumption estimates (as well as other percentiles of the distribution) for garden grown produce, purchased produce, meat and poultry, dairy products, and even recreationally caught fish. Other assumptions are often layered on top of these. For instance, in calculating risk from pesticide residues on produce, EPA assumed that all produce consumed contained the maximum allowable level of all types of pesticides registered for use on that crop. NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX 56 (1987). In fact, pesticide residue levels are rarely near the maximum allowed and few if any crops are treated with all available pesticides. Again, these assumptions are intended to be conservative, to make it unlikely that the risk is underestimated. See, e.g., OFFICE OF PESTICIDE PROGRAMS, U.S. ENVTL. PROTECTION AGENCY, PO-SITION DOC. 2/3, EBDC SPECIAL REVIEW TECHNICAL SUPPORT DOCUMENT (1989).

^{127.} EPA is aware of, and attempts to account for, some variation in individual consumption patterns. See, e.g., EPA EXPOSURE FACTORS HANDBOOK, supra note 112, at 2-1 to 2-10.

^{128.} Hawkins, supra note 117, at 116.

^{129.} Finkel, supra note 63, at 430.

For a properly performed risk characterization, this number is only the beginning.

The meaning of EPA's risk estimates cannot be accurately conveved except in light of the numerous assumptions that have been made.¹³⁰ As two commentators have stated, risk estimates from analyses done according to EPA procedures "do not give certainty in the scientific sense, nor can they be used to establish precise numbers of persons who will be stricken with some disease."¹³¹ However, the number that comes from the risk characterization step is often reported and used without qualification.¹³² Advocates of risk assessment constantly call for analysts to quantify and report the full range of uncertainty in a risk assessment.¹³³ In fact, because of the numerous conservative assumptions built into the EPA risk assessment process (so-called "compounded conservatism"),¹³⁴ EPA has stated that a risk estimate produced in accord with its procedures should be regarded as a plausible upper bound on risk.¹³⁵ That is, the actual risk will almost certainly lie somewhere between the EPA risk estimate and zero. The actual risk is very unlikely to be greater than the EPA risk estimate, is probably lower than the EPA estimate, and may even be zero.136

Therefore, EPA states that, in addition to the risk number, a risk characterization should contain: (a) a discussion of the "weight of the evidence" for human carcinogenicity (e.g., the EPA carcinogen classification);¹³⁷ (b) a summary of the various sources of uncertainty in the risk estimate, including those arising from hazard identification, dose-response evaluation, and exposure assessment; and (c) a report of the range of risks, using EPA's risk estimate as the upper limit and zero as the lower limit.¹³⁸

There is no currently established method for generating a central estimate of risk between zero and the upper limit,¹³⁹ although there have

133. See, e.g., FINKEL, supra note 44, at ix-xvii.

134. For discussion of the pitfalls of regulating on the basis of conservative risk estimates, see Richard J. Zeckhauser & W. Kip Viscusi, Risk Within Reason, 248 SCIENCE 559 (1990); Albert L. Nichols & Richard J. Zeckhauser, The Perils of Prudence: How Conservative Risk Assessments Distort Regulation, 8 REG. TOXICOLOGY & PHARMACOLOGY 61 (1988).

135. See EPA Guidelines, supra note 11, at 33,997-98. However, some disagree with this characterization of the EPA estimate as an upper bound. See, e.g., Finkel, supra note 63, at 447-53.

136. EPA Guidelines, supra note 11, at 33,998.

137. See supra note 65 and accompanying text.

138. See EPA Guidelines, supra note 11, at 33,998-99.

139. Id. at 33,998. EPA, however, would make use of such a procedure if it became avail-

^{130.} See Milton Russel & Michael Gruber, Risk Assessment in Environmental Policy-Making, 236 SCIENCE 286, 287 (1987).

^{131.} Id. at 287.

^{132.} See George M. Gray & John D. Graham, Risk Assessment and Clean Air Policy, 10 J. POL'Y ANALYSIS & MGMT. 286 (1991), for examples of important and influential risk estimates being reported and used without qualification.

been recent attempts to generate an estimate other than the upper bound using additional scientific information in a risk assessment.¹⁴⁰

In summary, in spite of its appearance of precision, QRA is fraught with gaps in knowledge that are filled with guesses and assumptions. Risk assessors have a great deal of analytical discretion in the conduct of cancer risk assessments.¹⁴¹ As we have discussed, the choice and interpretation of data, the choice of extrapolation models, and the choice of exposure assumptions and models can make a huge difference in the outcome of a risk assessment. Quantitative risk assessment of chemical carcinogens is a relatively new practice,¹⁴² one that is still undergoing refinement and adjustment,¹⁴³ and, consequently, it is surrounded by a great deal of controversy. It is a fragile science that is being pushed, from many directions, to take on some very large responsibilities.

Π

NARRATIVE STATUTES AND RISK ASSESSMENT AT EPA

Environmental statutes guide government agencies through either narrative or numerical directives.¹⁴⁴ With the possible exception of the

able. Id.

140. See, e.g., Sielken, supra note 95, at 120-29; Gray & Graham, supra note 132, at 288, 291.

141. EPA currently has a group, under Deputy Administrator Henry Habicht, reviewing the assumptions used in agency risk assessments. *See infra* notes 491-93 and accompanying text.

142. The pathbreaking academic papers on carcinogen risk assessment were published beginning in the 1950's. See, e.g., P. Armitage & R. Doll, The Age Distribution of Cancer and a Multi-Stage Theory of Carcinogenesis, 8 BRIT. J. CANCER 1 (1954); P. Armitage & R. Doll, Stochastic Models for Carcinogenesis, 4 PROC. BERKELEY SYMP. ON MATHEMATICAL STAT. & PROBABILITY 19 (1961); Nathan Mantel & W. Ray Bryan, "Safety" Testing of Carcinogenic Agents, 27 J. NAT'L CANCER INST. 455 (1961); Crump et al., supra note 87.

143. For examples of refinements in dose-response modeling, see P.G. Watanabe et al., The Importance of Non-Linear (Dose-Dependent) Pharmacokinetics in Hazard Assessment, 1 J. ENVTL. PATHOLOGY & TOXICOLOGY 147 (1977); David G. Hoel et al., Implication of Nonlinear Kinetics on Risk Estimation in Carcinogenesis, 219 SCIENCE 1032 (1983); William H. DuMouchel & Jeffrey E. Harris, Bayes Methods for Combining the Results of Cancer Studies in Humans and Other Species, 78 J. AM. STAT. ASS'N 293 (1983). For examples of refinements in exposure assessment, see Ott, supra note 115; Thomas E. McKone, Human Exposure to Volatile Organic Compounds in Household Tap Water: The Indoor Inhalation Pathway, 21 ENVTL. SCI. & TECH. 1194 (1987); LANCE A. WALLACE, U.S. ENVTL. PROTECTION AGENCY, EPA/600/6-87/002A, THE TOTAL EXPOSURE ASSESSMENT METHODOLOGY (TEAM) STUDY (1987); P. Barry Ryan, An Overview of Human Exposure Modeling, 1 J. EXPOSURE ANALYSIS & ENVTL. EPIDEMIOLOGY 453 (1991); NATIONAL RESEARCH COUNCIL, supra note 123.

144. Narrative standards themselves are generally divided into two categories:

- 1) Technology-based standards which specify the technology that is to drive standards; and
- 2) Health-based standards which specify the public health and environmental objectives that are to drive standards.

Neither approach to setting standards explicitly incorporates risk, although the second approach may do so implicitly. Technology-based standards are perhaps most often identified with the approach in section 307 of the Clean Water Act, which sets effluent emission limitations based upon best available control technology. See CWA § 307(a)(2), 33 U.S.C.

Delaney Amendment to the Federal Food, Drug and Cosmetic Act,¹⁴⁵ which seems to compel zero risk, the existing federal environmental laws designed to reduce risks to human health due to chemical exposure use the narrative approach. These narrative statutes are generally of three types: (1) those that compel EPA to clean up the environment to the degree that is technologically achievable (often called "technology-based" statutes); (2) those that compel EPA to clean up the environment to a degree that makes sense based on a balancing of health benefits and the costs of control (so-called "balancing" statutes); and (3) those that compel EPA to clean up the environment to a degree that assures that the public health is protected, usually with some margin of safety (so-called "health-based" statutes). In some cases Congress has used more than one of these forms in a single statute.¹⁴⁶

Over the years, EPA has, through a somewhat haphazard and idiosyncratic process, translated narrative directives into decision rules for risk management based on the findings of QRA. Like the authors of several previous studies, we found some crude patterns in the numerical levels of cancer risk that affect the standard-setting process in EPA program offices.¹⁴⁷ However, we argue in this section that there is no apparent relationship between how an EPA program office uses QRA and the language of the narrative statute the program implements. In other words, narrative statutes, as currently written, do not appear to inform or constrain EPA's use of QRA in risk management decisions. Indeed, we found some rather subtle yet powerful differences in how cancer risks are calculated, reported, and regulated throughout EPA which have no obvious roots in the underlying statutory mandates.

We begin with a discussion of the Delaney Clause, the only brightline statute, and then discuss the three major categories of narrative statutes. Our intent is not to provide a comprehensive review of the relevant statutes, but rather to indicate how risk assessment and management

146. Several previous studies have compared federal environmental statutes using these or broadly similar categories of narrative language. *See, e.g.*, OFFICE OF TECHNOLOGY ASSESSMENT, UNITED STATES CONGRESS, ASSESSMENT OF TECHNOLOGIES FOR DETERMINING CANCER RISKS FROM THE ENVIRONMENT 176-81 (1981); CROSS, *supra* note 20, at 97-133.

147. See Daniel Byrd & Lester B. Lave, Narrowing the Range: A Framework for Risk Regulators, ISSUES IN SCI. & TECH., Summer 1987, at 92; Curtis C. Travis et al., Cancer Risk Management: A Review of 132 Federal Regulatory Decisions, 21 ENVTL. SCI. & TECH. 415 (1987); Curtis C. Travis & Holly A. Hattemer-Frey, Determining an Acceptable Level of Risk, 22 ENVTL. SCI. & TECH. 873 (1988); Joseph V. Rodricks et al., Significant Risk Decisions in Federal Regulatory Agencies, 7 REG. TOXICOLOGY & PHARMACOLOGY 307, 310 (1987).

^{§ 1317(}a)(2) (1988); *infra* notes 259-71 and accompanying text. Similar provisions have been incorporated into other environmental statutes. For a table presenting the statutory language establishing technology-based standards in the Clean Air Act, the Resource Conservation and Recovery Act, The Noise Control Act, the Safe Drinking Water Act, and the Clean Water Act, see Lester B. Lave & Eric H. Males, *At Risk: The Framework for Regulating Toxic Substances*, 23 ENVTL. SCI. & TECH. 386, 389 (1989).

^{145. 21} U.S.C.A. §§ 301-394 (West 1972 & Supp. 1992).

practices vary within and across the different types of narrative statutes implemented by EPA.

A. The Delaney Clause: A Bright Line of Zero Risk

The Delaney Clause, section 409 of the Federal Food Drug and Cosmetic Act (the FFDCA),¹⁴⁸ is perhaps the classic example of the zerorisk statute. While EPA and the FDA have engaged in creative legal reasoning to avoid the highly stringent regulatory implications of the Delaney Clause, there is no question that the Delaney Clause is the closest Congress has ever come to including a bright line in environmental legislation. In order to understand fully the surprising role that risk assessment has played in the implementation of the Delaney Clause, it is necessary to understand how EPA and the FDA share regulatory authority over pesticides.

The FFDCA¹⁴⁹ is one of two statutes which govern EPA's regulation of pesticides.¹⁵⁰ Under the FFDCA, EPA sets, but does not enforce, maximum allowable levels of pesticide residues (so-called tolerances) for raw agricultural commodities, animal feeds, and processed foods.¹⁵¹ Pesticide manufacturers submit applications to EPA officials, who set tolerance levels for each chemical ingredient in a pesticide and for each food commodity on which a pesticide is applied.¹⁵² Both the FDA and the U.S. Department of Agriculture monitor the food supply and enforce the legal tolerance limits set by EPA.¹⁵³

Enacted in 1958, the Delaney Clause prohibits any pesticide residue "if it is found . . . to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."¹⁵⁴ Contrary to popular perception, the FFDCA does not permit the EPA to apply the rigid approach of the Delaney Clause in setting tolerance levels for all

150. The second statute is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C.A. §§ 136-1369 (West 1980 & Supp. 1992). FIFRA authorizes EPA to register pesticide products for specific uses. *Id.* § 3, 7 U.S.C.A. § 136a (West 1980 & Supp. 1992).

151. FFDCA § 408, 21 U.S.C.A. § 436a (West 1972 & Supp. 1992).

152. NATIONAL RESEARCH COUNCIL, *supra* note 126, at 24-36. According to EPA regulations, a pesticide must have an approved tolerance level before it can be registered under FIFRA. *Id.* at 23.

153. See id. at 25; Pesticides and the Consumer, 13 EPA J., Mar.-Apr. 1987, at 14.

154. FFDCA § 409(c)(3)(A), 21 U.S.C.A. § 348(c)(3)(A) (West 1972). Identical language in other parts of the statute regulates color additives and animal drug residues. Merrill, *supra* note 10, at 3.

^{148.} FFDCA § 409, 21 U.S.C.A. § 348 (West 1972 & Supp. 1992).

^{149. 21} U.S.C.A. §§ 301-394 (West 1972 & Supp. 1992). As its name suggests, the FFDCA is the organic act of the Food and Drug Administration and regulates a variety of areas which lie outside the realm of traditional environmental protection. The sole exception is section 308 of the Act, which gives EPA the authority to regulate pesticide tolerances. FFDCA § 308, 42 U.S.C.A. § 346a (West 1972 & Supp. 1992).

foods.¹⁵⁵ Only "processed foods with concentrated pesticides" are subject to the arguably zero-risk language; raw agricultural commodities are not.¹⁵⁶ Through a fascinating combination of legal and technical maneuvers, EPA has tried to legitimize the use of QRA under the terms of the Delaney Clause.

From the beginning, implementation of the Delaney Clause was problematic.¹⁵⁷ The provision appeared to prohibit pesticide residues on the basis of a mere potential carcinogenic hazard, apparently forbidding EPA from using QRA or exempting minimal risks.¹⁵⁸ EPA responded to this predicament with a case of regulatory paralysis: since a finding of cancer risk under the Delaney Clause would trigger complete prohibition of the residues, EPA was reluctant to identify cancer risks under the clause. Only twice since its enactment has the agency invoked the clause to refuse a new food use of a carcinogenic pesticide.¹⁵⁹

In 1988, EPA faced its predicament squarely, issuing a new administrative policy entitled "Regulation of Pesticides in Food: Addressing the Delaney Paradox."¹⁶⁰ EPA divided pesticide exposures into those that pose only negligible risk, defined as "generally a quantitative risk level of 10^{-6} or less," and those that pose a greater risk and hence are worthy of heightened scrutiny.¹⁶¹ EPA also called for legislative reform of the clause. It argued that, in cases of negligible risks and of nonnegligible risks that are "nonetheless not so great as to outweigh the pesticides benefits to the food supply," the statute should be revised so that it would not require automatic prohibition.¹⁶²

^{155.} The National Academy of Science dubbed this curious contrast between the stringent standards for processed foods and the more lenient standards for raw agricultural commodities "[t]he Delaney Paradox." See NATIONAL RESEARCH COUNCIL, supra note 126, at 40-43.

^{156.} See id. at 25-27. This refers to situations in which pesticides concentrate during processing or in which they are used during postharvesting treatments. See id. at 25-27, 40-41.

^{157.} See Merrill, supra note 10; Charles H. Blank, The Delaney Clause: Technical Naivete and Scientific Advocacy in the Formulation of Public Health Policies, 62 CAL. L. REV. 1084 (1974).

^{158.} In Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987), the D.C. Circuit rejected the FDA's decision to permit the use of color additives which posed a cancer risk of less than 10^{-6} . The FDA had interpreted the Delaney Clause as allowing implicit exceptions for such "de minimis" levels of risk. The court stated that Congress had been clear in setting a rigid standard, and argued that the proper mechanism for obtaining relief from the stringency of the Delaney Clause was modification of the statute. *Id.* at 1122. The court, however, held out the possibility that a less rigid interpretation of the Delaney Clause might be appropriate for pesticides. *Id.* at 1119-20.

^{159.} NATIONAL RESEARCH COUNCIL, supra note 126, at 86-91. These cases involved the pesticides fosetylal and permethrin. EPA also limited the use of the pesticide Amitraz to pears, denying uses on apples due to excess cancer risk.

^{160.} Regulation of Pesticides in Food: Addressing the Delaney Paradox, Policy Statement, 53 Fed. Reg. 41,104, 41,104-32 (1988) [hereinafter EPA Policy Statement].

^{161.} Id. at 41,112.

^{162.} Id. at 41,108-09.

One of the reasons behind EPA's desire to consider the magnitude of the carcinogenic risks of new pesticides is its concern about the relative carcinogenicity of older and newer pesticides. Because pesticides approved in earlier decades were not adequately tested to identify their carcinogenic potential and were grandfathered in under earlier standards, EPA is concerned that strict application of the Delaney Clause to new pesticides prevents the replacement of more dangerous older chemicals with safer new ones. Because EPA does not have the administrative flexibility to approve new pesticides that are carcinogenic, older high risk pesticides are retained on the market while less toxic alternatives are discouraged because the smaller risk they pose might still trigger a registration rejection.¹⁶³

Despite the holding in *Public Citizen v. Young*¹⁶⁴ and the slim statutory authorization for EPA use of QRA under the Delaney Clause, EPA has implemented a negligible risk policy in which QRA has increasingly come to influence regulatory decisions. One area in which such judgments are made is hazard assessment. In deciding whether a pesticide is carcinogenic, EPA's Office of Pesticide Programs (the OPP), which regulates pesticides, generally uses the carcinogen classification system designed by the agency's Office of Health and Environmental Assessment within the Office of Research and Development.¹⁶⁵

EPA's increasing reliance on QRA in hazard assessment under the Delaney Clause is exemplified by its treatment of Group C carcinogens, which are classified as possibly carcinogenic to humans on the basis of animal tests. EPA notes that the Delaney Clause makes no provisions for judgments about the pertinence of animal tumors to human risk based on the weight of the evidence.¹⁶⁶ The 1988 EPA policy statement discussed above divides Group C pesticides into several categories, according to the rationale behind their classification. It then applies the Delaney Clause selectively.¹⁶⁷ If a pesticide falls into Group C on the basis of evidence of carcinogenicity in a single study, the OPP will apply the Delaney Clause unless risk assessments indicate that the risk is negligible. If a pesticide is associated with an increase in tumors in only one sex of one species, or if mechanistic information suggests that a similar

^{163.} Id. at 41,109; see also Peter Huber, The Old-New Division in Risk Regulation, 69 VA. L. REV. 1025, 1063 n.176 (1983) (discussing administrative inertia and the resulting situation where old substances are more favored than new ones).

^{164.} See supra note 158.

^{165.} See supra note 65 and accompanying text.

^{166.} OPP officials note that EPA cancer guidelines state that Class C carcinogens should be evaluated case by case. Interview with Dr. Richard Hill, Senior Science Advisor, Office of Pesticides and Toxic Substances, in Washington, D.C. (Aug. 4, 1991).

^{167.} EPA Policy Statement, supra note 160, at 41,112.

response in humans is unlikely, the OPP will not apply the Delaney Clause.¹⁶⁸

To determine whether a carcinogenic exposure is negligible, EPA must undertake exposure assessments, which do not appear to be authorized under the Delaney Clause. The OPP's exposure assessments include significant elements of conservatism. For example, in the absence of hard data, the OPP calculates the Theoretical Maximum Residue Concentration (the TMRC) by assuming that one hundred percent of all acres are treated with each pesticide registered for a given crop.¹⁶⁹ Furthermore, it is assumed that no degradation of the pesticide takes place through weather, time, peeling, or washing, and that the level on the dinner plate is the same as that in the field.¹⁷⁰ Carcinogenic pesticides are assumed to reach maximum allowable concentrations on all treated crops. In reality, such high and widespread residue concentrations are rare. However, not all of the OPP's assumptions are conservative. Rather than considering the exposure of the maximally exposed individual, or MEI,¹⁷¹ the office uses average food consumption values. The OPP then combines the exposure estimates it has derived from these exposure assumptions with EPA's standard cancer potency values to estimate whether lifetime risks exceed the one-in-a-million benchmark for regulation.172

While acknowledging the shaky legal ground on which its new policy rests, EPA has nonetheless sought a more liberal interpretation of the FFDCA's Delaney Clause. Under the new risk-management approach, carcinogenic pesticides found to pose only a negligible risk based on QRA can still be registered under the Delaney Clause.¹⁷³

B. Health-Based Statutes: The Clean Air Act

Perhaps the most famous narrative provisions in environmental statutes designed to protect public health are found in the Clean Air Act (CAA).¹⁷⁴ Under section 112 of the 1970 Clean Air Act, EPA was required to set emission standards for hazardous air pollutants, such as carcinogens, that would "protect the public health" with an "ample"

^{168.} Id.

^{169.} For a description of EPA assumptions in calculating the TMRC, see NATIONAL RE-SEARCH COUNCIL, *supra* note 126, at 32-33.

^{170.} OFFICE OF PESTICIDE PROGRAMS, U.S. ENVTL. PROTECTION AGENCY, GUIDELINES FOR PREPARATION OF A QUALITATIVE USE ASSESSMENT (QUA) (1988).

^{171.} See supra note 116 and accompanying text.

^{172.} OFFICE OF PESTICIDE PROGRAMS, supra note 170.

^{173. &}quot;EPA believes that current law allows this approach to be used only to the extent that the *de minimis* doctrine allows Delaney Clause considerations to be dismissed." EPA Policy Statement, *supra* note 160, at 41,110. Although this policy statement appears to conflict with the holding of *Public Citizen*, since *Public Citizen* concerned the regulation of color additives, EPA does not accept it as controlling pesticide residue decisions. See id. at 41,107-09.

^{174. 42} U.S.C.A. §§ 7401-7611q (West 1983 & Supp. 1992).

margin of safety.¹⁷⁵ EPA's efforts to implement this narrative provision using ORA between 1970 and 1990 created deep discontent in the environmental community, stimulating extensive litigation over the role of risk assessment under section 112.¹⁷⁶ In this part of the article, we examine how the air office at EPA conducts cancer risk assessments and how, prior to passage of the Clean Air Act Amendments of 1990, the office used QRA to protect public health. While EPA's assessments of cancer risks may change under the 1990 amendments,¹⁷⁷ EPA's historical use of ORA to manage air toxics illustrates the extent of agency discretion embedded in apparently health-based, narrative provisions. EPA responded cautiously or lethargically (depending on one's point of view) to the powerful regulatory authority contained in section 112.178 In 1979, EPA proposed a strategy in which it would use risk assessment in listing carcinogens for regulatory consideration, but the strategy was never finalized.¹⁷⁹ In the early years of the Reagan Administration, EPA sought to delegate the air toxics issue to the states on the grounds that only local "hot spots" were likely to justify regulatory action. Later, EPA used QRA extensively to determine the extent of cancer risks attributable to various industrial sources of air toxics. While EPA's air

175. Pub. L. No. 91-604, § 112, 84 Stat. 1676, 1685 (1970). Contrast the narrative standard governing regulation of the ubiquitous "criteria pollutants" defined in section 109 (e.g., carbon monoxide and sulfur dioxide). Under section 109, EPA must establish primary ambient air quality standards that "protect the public health" with an "adequate," rather than an "ample," margin of safety. See CAA § 109(b)(1), 42 U.S.C.A. § 7409(b)(1) (West Supp. 1992). Since criteria pollutants generally are not regulated on the basis of carcinogenicity, controversies surrounding their regulation have not focused on methods of cancer risk assessment. The key issues involving the adequacy of the margin of safety for ambient air quality standards include the definition of an adverse health effect and the identification of human health thresholds. These issues surfaced in the debate over the ambient ozone standard and in subsequent litigation. See American Petroleum Inst. v. Costle, 665 F.2d 1178 (D.C. Cir. 1981). It is not clear what Congress meant in drawing the distinction between "adequate" and "ample" margins of safety, but the example vividly illustrates the inevitable ambiguity in a narrative statute that seeks to reduce health risks.

176. John D. Graham, The Failure of Agency-Forcing: The Regulation of Airborne Carcinogens under Section 112 of the Clean Air Act, 1985 DUKE L.J. 100.

177. The 1990 Clean Air Act Amendments have replaced section 112's health-based standards with an initial phase of technology-based standards. See CAA § 112(d), 42 U.S.C.A. § 7412(d) (West Supp. 1992). Nonetheless, risk assessment remains a crucial process in setting residual emission standards for hazardous air pollutants. See CAA § 112(f), 42 U.S.C.A. § 7412(f) (West Supp. 1992). For a discussion of quantitative risk assessment under the Clean Air Act Amendments, see infra part III.A.

178. After substantial pressure and litigation from environmentalists in the early 1970's, EPA listed and regulated a grand total of four pollutants under section 112: asbestos, beryllium, mercury and vinyl chloride. See 40 C.F.R. § 61.01 (1991); Graham, supra note 176, at 104-10. To the disappointment of environmentalists, only three more National Emission Standards for Hazardous Air Pollutants (NESHAP's) were promulgated during the Carter years. 40 C.F.R. § 61.01 (1991); see also Graham, supra note 176, at 112-13.

179. See Graham, supra note 176, at 119.

office released numerous QRA's for public comment in the mid-1980's, the rulemaking process was very slow.¹⁸⁰

EPA delays in standard setting under section 112 have been attributed to several causes.¹⁸¹ EPA itself suggested that the "ample margin of safety test," if interpreted literally, might be construed to require zero emissions for carcinogens, which could produce massive dislocations given the pervasiveness of carcinogenic emissions by industry.¹⁸² If interpreted this way, section 112 would be a strict, zero-risk statute much like the Delaney Clause.

Even if section 112 did not set a zero-risk standard, some EPA officials saw the required National Emission Standard for Hazardous Air Pollutants (NESHAP)¹⁸³ as far too expensive to justify the estimated reductions in cancer risk. This produced agency paralysis almost as severe as that produced by the strict language of the Delaney Clause.¹⁸⁴ The reasons were similar: since listing could trigger extremely costly NESHAP's, EPA was reluctant to list substances without compelling evidence of widespread population risk. Some EPA officials regarded the estimated population risks from air toxics as quite small, which undercut the case for expeditious rulemaking activity.¹⁸⁵

EPA's decision to avoid section 112 listings and rulemakings sparked substantial litigation. Even when EPA did promulgate NESHAP's, it used QRA to justify emission standards that were more permissive than some desired. This also prompted environmentalists to file suit.¹⁸⁶

The most important of these cases involved EPA regulation of vinyl chloride.¹⁸⁷ In *Natural Resources Defense Council v. EPA*, ¹⁸⁸ the District of Columbia Circuit Court, sitting en banc, reversed an earlier panel decision. According to the full court, section 112 requires EPA to set NESHAP's on the basis of a two-step process. First, EPA must deter-

183. Graham, supra note 176, at 135-36.

184. See supra text accompanying notes 157-59.

185. OFFICE OF POLICY ANALYSIS, U.S. ENVTL. PROTECTION AGENCY, UNFINISHED BUSINESS: A COMPARATIVE ASSESSMENT OF ENVIRONMENTAL PROBLEMS 59 (1987).

186. See, e.g., Sierra Club v. Gorsuch, 551 F. Supp. 785 (N.D. Cal. 1982) (NESHAP for radionuclides); New York v. Gorsuch, 554 F. Supp. 1060 (S.D.N.Y. 1983) (NESHAP for arsenic).

187. See National Emission Standards for Hazardous Air Pollutants; Proposed Standard for Vinyl Chloride, 40 Fed. Reg. 59,532 (1975); National Emissions Standard for Vinyl Chloride, 40 C.F.R. §§ 61.60-.71 (1991).

188. 824 F.2d 1146 (D.C. Cir. 1987), rev'g 804 F.2d 710 (D.C. Cir. 1986).

^{180.} John P. Dwyer, The Pathology of Symbolic Legislation, 17 ECOLOGY L.Q. 233, 258-60, 268-69.

^{181.} See David D. Doniger, Federal Regulation of Vinyl Chloride, 7 ECOLOGY L.Q. 497 (1978); Graham, supra note 176, at 115-42; 3 WILLIAM H. RODGERS, ENVIRONMENTAL LAW § 5.22B (1988).

^{182.} Dwyer, supra note 180, at 254-55. For a comprehensive description of the history of EPA's position, see *id.* at 250-76.

mine "safe" levels of carcinogenic emission, without regard to cost or technological feasibility. Second, EPA may set emission standards lower than the safe emission level in order to provide an ample margin of safety to the public.¹⁸⁹ Although the agency might determine that certain nonzero risk levels are safe or acceptable, it still would be compelled in the second step to determine that the final emission standard provided an "ample margin of safety" in light of scientific uncertainties about risk and possibly other factors.¹⁹⁰

In response to the vinyl chloride decision, EPA promulgated a new policy for setting NESHAP's, which was first applied to benzene.¹⁹¹ EPA's Office of Air applies the policy to compounds listed as either Group A or Group B carcinogens under EPA's classification system.¹⁹² Risk assessments of stationary sources (e.g., oil refineries) are calculated using CRAVE potency factors¹⁹³ and a theoretical maximally exposed individual (MEI).¹⁹⁴ Since personal monitoring of exposures (or even monitoring at fixed locations) is usually considered impractical, MEI exposures are estimated by modeling.¹⁹⁵

Population risk to the general population is also considered, especially for mobile sources. EPA considers population risks in order to prevent a facility or facilities from subjecting a large population to small

Id. at 1164-65 (citation omitted).

191. See 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, 54 Fed. Reg. 38,044 (1989) (preamble explaining policy approach for setting NESHAP and applying it to certain benzene emissions); National Emission Standards For Hazardous Air Pollutants; Benzene Emissions From Chemical Manufacturing Process Vents, Industrial Solvent Use, Benzene Waste Operations, Benzene Transfer Operations, and Gasoline Marketing System, 54 Fed. Reg. 38,083 (1989) [hereinafter Proposed Benzene Emissions Rule] (preamble to proposed standard applying policy for setting NESHAP for other benzene emissions); *Benzene Rules to Heed Vinyl Chloride Decision, Though Controls May be Same, EPA Analyst Says*, 18 Env't Rep. (BNA) 2011 (Jan. 15, 1988).

193. See supra note 67 and accompanying text.

194. This calculation assumes that an individual's residence is located at the "fenceline" of a factory, which is defined to be 200 meters from the source of the pollution, and that they are outdoors for 24 hours a day over a 70-year period. See Hawkins, supra note 117, at 109; supra text accompanying note 116 (discussing the concept of the MEI).

195. See Hawkins, supra note 117, at 108. But see NATIONAL ACADEMY OF SCIENCES, HUMAN EXPOSURE ASSESSMENT FOR AIRBORNE POLLUTANTS: ADVANCES AND OPPORTU-NITIES 1-14 (1991) ("Exposure of the individual was considered key, because the committee determined that knowledge of such exposures is essential to make inferences about the general population.").

^{189. 824} F.2d at 1164.

^{190.} The court explained:

We do wish to note, however, that the Administrator's decision does not require a finding that "safe" means "risk-free," or a finding that the determination is free from uncertainty. Instead, we find only that the Administrator's decision must be based upon an expert judgement with regard to the level of emission that will result in an "acceptable" risk to health.

^{192.} See supra note 65 and accompanying text.
individual risks, thus producing a high estimated population incidence of cancer even while not greatly increasing individual cancer risk.¹⁹⁶ Under the new policy, EPA rules state that the risk to the MEI must not exceed 10^{-4} ,¹⁹⁷ and that as many people as possible must be protected from a 10^{-6} risk.¹⁹⁸ Thus, EPA has interpreted Section 112 to permit a complex balancing of both population risk and individual risk when setting emission standards for hazardous air pollutants.

C. Risk-Benefit Balancing: TSCA and FIFRA

Under some statutes, Congress wishes to provide EPA with broad discretion to weigh the risks and benefits of alternative regulatory choices. While these balancing statutes do not require risk assessment per se, in calling for EPA to eliminate "unreasonable risks," they imply that EPA should consider the magnitude of health risks, the anticipated reductions in risk from alternative standards, and the economic and social consequences of alternative standards. In striking contrast to statutes which set a bright line level of acceptable risk, these statutes invite EPA to make determinations of unreasonable risk which will vary from decision to decision based on a discretionary balancing of diverse factors.

For illustrative purposes, we shall examine how Congress required EPA to engage in risk-benefit balancing under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)¹⁹⁹ and under the Toxic Substances Control Act (TSCA).²⁰⁰ While the key narrative standard under both statutes is elimination of "unreasonable risk," EPA risk assessment practices under the two programs are far from identical.

New pesticides cannot be marketed in the United States unless EPA registers them under FIFRA.²⁰¹ The statute also authorizes EPA to sus-

198. See, e.g., id. at 38,091. It states:

200. 15 U.S.C. §§ 2601-2671 (1988).

^{196.} Interview with Dr. Peter Preuss, Director, Office of Technology Transfer and Regulatory Support, Office of Research and Development, U.S. Environmental Protection Agency, in Washington, D.C. (Aug. 30, 1990).

^{197.} See, e.g., Proposed Benzene Emissions Rule, supra note 191, at 38,089 ("As stated above, the baseline MIR [for certain sources of benzene emissions] is about 4×10^{-5} , which is below the presumptive acceptable risk of approximately 1×10^{-4} ."); *id.* at 38,091 ("The baseline MIR of 6×10^{-3} for benzene transfer operations is unacceptable for benzene, a known human carcinogen.").

After examining these different alternatives and their associated risk distributions, EPA has decided that Alternative 1 represents a risk that is acceptable for benzene transfer operations after considering several factors. Control to the level of Alternative 1 would reduce the MIR to about 4×10^{-5} and the annual incidence to 0.02. The majority of the people (greater than 99.9 percent) exposed to benzene emissions from this category would be exposed to risk levels lower than 1×10^{-6} .

^{199. 7} U.S.C.A. §§ 136-136y (West 1980 & Supp. 1992).

^{201.} FIFRA makes it unlawful to "distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver . . . to any person any pesticide that is not registered under this subchapter." FIFRA §§ 3(a), 7 U.S.C.A. §§ 136(gg), 136a(a) (West

pend the registrations of pesticides already on the market. EPA can withdraw a pesticide's registration only if there are labeling problems or if there are "unreasonable adverse effects on the environment," defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide."²⁰² In practical terms, EPA is not required to undertake a formal, mathematical cost-benefit analysis of each pesticide decision. Nevertheless, judicial review of the agency's registration decisions is influenced by the legislative intent that EPA should consider factors other than public health.²⁰³

In contrast to the zero-risk orientation of the Delaney Clause, which applies to processed foods, EPA's regulation of pesticide residues on raw agricultural commodities under the FFDCA also entails risk-benefit balancing.²⁰⁴ The FFDCA directs EPA to limit pesticide residues on raw agricultural commodities to the extent necessary to protect the public health, giving appropriate consideration to other "relevant factors,"²⁰⁵ including the "necessity for the production of an adequate, wholesome, and economical food supply."²⁰⁶

Under these broad statutory authorizations, EPA has used risk assessment to inform regulatory decisions about pesticides. EPA's Office of Pesticides Programs, which implements both FIFRA and the FFDCA, does not have a formal policy regarding weight-of-the-evidence classification, but scrutinizes for regulation all pesticides classified as Group A or Group B carcinogens.²⁰⁷ Group C carcinogens, which usually have only limited evidence of carcinogenicity from animal experiments, are considered on a case-by-case basis.²⁰⁸ The OPP has regulated some Group C pesticides as carcinogens, has regulated others on the basis of noncancer health effects, and has abstained from regulating others altogether.²⁰⁹

Supp. 1992).

1992]

^{202.} FIFRA § 2(bb), 7 U.S.C. § 136(bb) (1988). In a 1971 case, the D.C. Circuit noted that the law "places a heavy burden on any administrative officer to explain the basis for his decision to permit the continued use of a chemical known to produce cancer in experimental animals." Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 596 n.41 (D.C. Cir. 1971).

^{203.} Ciba-Geigy Corp. v. EPA, 874 F.2d 277 (5th Cir. 1989).

^{204.} See RODGERS, supra note 181.

^{205.} FFDCA § 408(b), 21 U.S.C. § 346a(b) (1988).

^{206.} Id. In an extended description of its strategy for risk management of pesticide residues, EPA interpreted this provision to require a "risk benefit standard" comparable to the standard setting approach under FIFRA. See EPA Policy Statement, supra note 160, at 41,104-05.

^{207.} See supra note 65 and accompanying text (discussing EPA's carcinogen classification system).

^{208.} One factor considered is the structural relationship of the "C" substance to other known carcinogens. Interview with Dr. Richard Hill, *supra* note 166.

^{209.} Telephone Interview with Dr. Michael Firestone, Office of Pesticide and Toxic Substances (Aug. 5, 1991).

In its exposure assessments, the OPP does not base its calculations on a hypothetical maximally exposed individual.²¹⁰ Instead, the office achieves a high degree of conservatism in risk assessment by calculating population risk using assumptions about population exposures that, in reality, never occur.²¹¹ For example, when determining tolerance levels for pesticide residues, the OPP assumes a maximum number of crop applications, at the maximum rate of application, with the minimum preharvest interval.²¹² It then takes average food intake values from national consumption surveys²¹³ and integrates them into its Dietary Risk Evaluation System exposure equations.²¹⁴ The office then calculates total population risk by summing the average risks posed for each crop on which the pesticide is legally applied. For occupational exposures, the office uses surrogate exposure data based on the application method.²¹⁵

Since FIFRA requires EPA to balance the risks and benefits of pesticides, no strict numerical risk levels bind OPP discretion in risk management. Indeed, OPP officials do not acknowledge operating under any formal risk range.²¹⁶ There are, however, some patterns in the risk levels which they tend to consider acceptable. The OPP tends to set acceptable risk levels for the food-consuming population within or below the range of 10^{-5} to 10^{-6} , while it tends to accept occupational risks that are less than 10^{-4} to 10^{-5} .²¹⁷

The narrative standard in the Toxic Substances Control Act (TSCA) was modeled after the one in FIFRA,²¹⁸ so it is not surprising

213. The OPP continues to assume that the one-to-three-day estimates of consumption reported in the 1977-78 USDA Nationwide Food Consumption Survey are accurate and that they reflect long-term eating patterns. It does not use data from the more recent 1987-88 Nationwide Food Consumption survey, which several critics have assailed as unreliable due to an inadequate sample size and a low response rate. See, e.g., GEN. ACCOUNTING OFFICE, GAO/RCED-91-125, PESTICIDES: FOOD CONSUMPTION DATA OF LITTLE VALUE TO ESTIMATE SOME EXPOSURES (1991).

214. Interview with Dr. Richard Hill and Dr. Michael Firestone, *supra* note 211. EPA very generally defines exposure as residue concentration multiplied by consumption. Residue concentrations are much more variable than consumption patterns. It is hard to imagine, for example, that one individual will consume 100 times more of a given crop than another individual. Moreover, those who eat more of one food tend to eat less of another. On the other hand, residue concentrations frequently vary by two to five orders of magnitude. *Id.*

215. For example, hypothetical exposures from particular application technologies (e.g., backpack sprayers) are considered. *Id.*

216. Id.

217. Id. On occasion, the office has rated as permissible occupational risks from pesticides of 10^{-4} . Id.

218. For instance, TSCA's definition of substances considered "hazardous," those which carry "unreasonable risk of injury to health or the environment," is taken from FIFRA's defi-

^{210.} Interview with Dr. Peter Preuss, supra note 196; see also supra note 116.

^{211.} Interview with Dr. Richard Hill, Senior Science Advisor, Office of Pesticide and Toxic Substances, and Dr. Michael Firestone, Office of Pesticide and Toxic Substances, in Washington, D.C. (Oct. 3, 1990).

^{212.} EPA officials acknowledge that these hypothetical levels are in fact never found in actual monitoring by the FDA. *Id.*

that EPA decisions to limit production or use of a specific chemical under TSCA²¹⁹ involve a similar balancing process.²²⁰ As under FIFRA, before EPA can determine whether a substance meets the unreasonable risk standard under TSCA,²²¹ it must consider the economic implications of regulation. In particular, EPA must weigh the economic benefits of pesticide use to farmers and consumers against the risks to human health and the environment.²²²

The meaning of unreasonable risk under TSCA has never been particularly clear,²²³ which has led some commentators to suggest that TSCA's ambiguous narrative standard reflects legislative compromise in the face of conflicting interests.²²⁴ Congress specifically refrained from requiring a formal cost-benefit analysis, but the statute itself specifies procedural steps for conducting such an analysis.²²⁵ The extensive economic analyses that EPA conducts under TSCA are taken quite seriously by courts reviewing agency actions.²²⁶

Despite EPA's enormous legal authority under TSCA, relatively few regulatory decisions have been made pursuant to the Act. Some observers attribute this inactivity to the discretionary narrative standard, surmising that agencies rarely challenge industrial interests unless they are

nition of "imminent hazard. TSCA § 6(a), 15 U.S.C. § 2605(a) (1988); FIFRA § 2(l), 7 U.S.C. § 136(l) (1988).

219. Under the Act, if the EPA administrator concludes that there is sufficient information to classify a chemical as posing an unreasonable risk, it issues a proposed order restricting manufacture, processing, and/or distribution. TSCA § 5(f)(3)(A)(i), 15 U.S.C. § 2604(f)(3)(A)(i) (1988). Of course, the agency's designation of a substance as a hazard need not trigger removal of the substance from the market. Instead, the agency can limit production, prohibit specific uses, require written warnings and labels, regulate disposal, or impose any of several other remedial measures. TSCA § 6(a), 15 U.S.C. § 2605(a) (1988).

220. See RODGERS, supra note 181. FIFRA requires industry to demonstrate safety for new pesticides while the burden of proving unreasonable risk rests with EPA for existing pesticides. FIFRA § 3(c), 7 U.S.C. § 136a(c) (1988). TSCA requires EPA to review data submitted on *new* chemicals or those with a "significant new use," but there is no requirement that such data be developed by industry. See TSCA § 5(a)(1), (d), 15 U.S.C. § 2604(a)(1), (d) (1988). The Act, however, does authorize EPA to require industry to test chemicals for safety. TSCA § 4(a), 15 U.S.C. § 2603(a) (1988).

221. TSCA § 6(a), 15 U.S.C. § 2605(a) (1988).

222. Congressional intent in this regard was clearly set forth in H.R. REP. No. 1341, 94th Cong., 2d Sess. 14 (1976).

223. For a critical analysis of the unreasonable risk framework, see John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261 (1991).

224. See, e.g., RODGERS, supra note 181, § 6.7B.

225. For example, the statute requires the EPA Administrator to publish a statement describing the magnitude of exposure and of effects on health and the environment; the benefits of the substance or mixture for various uses; the availability of other substances for such uses; and "the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health." TSCA § 6(c)(1)(D), 15 U.S.C. § 2605(c)(1)(D) (1988).

226. See, e.g., Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991), clarified, Corrosion Proof Fittings v. EPA, 1991 U.S. App. LEXIS 28,418 (5th Cir. 1991).

compelled by law to do so.²²⁷ Another explanation is that, because section 9 of TSCA states that the Act should yield to the authority of other environmental statutes,²²⁸ relatively few "unique scenarios" fall under the Act.²²⁹ Finally, fear of judicial oversight may partially explain regulatory inaction under TSCA.²³⁰

The primary responsibility of EPA's Office of Toxic Substances (the OTS) is to implement TSCA, and in doing so, the OTS has chosen to make extensive use of risk assessment. In contrast to regulators in the OPP, members of the OTS do not always consider the classification of a carcinogen in deciding whether to regulate its use.²³¹ While the OTS does not estimate the exposure of a maximally exposed individual,²³² it does consider a "reasonable worst case" scenario in its assessment of cancer risk, especially when analyzing new chemicals or new uses of existing chemicals.²³³ Such scenarios generally refer to the risk a substance poses to a worker in an occupational setting or to a consumer using a product. For example, in assessing cancer risk from chemicals used in paints, a reasonable worst-case exposure scenario might be that of a professional painter who paints six or seven hours a day in a poorly ventilated room for thirty-five years.²³⁴ While risk assessments of new chemicals are based primarily on scenarios of individual risk, without regard to the potential size of the exposed population, OTS assessments of existing chemicals typically estimate both individual and population risks.²³⁵

The OTS has not formalized its risk management criteria, in part because TSCA requires a discretionary, judgmental balancing of numerous factors. Generally, the OTS believes that situations in which lifetime individual risk is less than 10^{-6} , or in which population risk (i.e., the number of expected cases of cancer per year) is less than one, do not

231. The OTS makes little distinction between A, B, and C chemicals, but does not regulate D or E chemicals. Interview with Harry Teitlebaum, Office of Toxic Substances, U.S. Envtl. Protection Agency, in Washington, D.C. (Aug. 31, 1990); see also supra text accompanying note 65 (describing EPA's carcinogen classification system).

232. See supra text accompanying note 116 (discussing MEI).

233. While the OTS risk assessment for dioxin included maximally exposed individual calculations, this is not standard policy under the Act. See OFFICE OF TOXIC SUBSTANCES, U.S. ENVTL. PROTECTION AGENCY, EPA 560/5-90-013, ASSESSMENT OF RISKS FROM EXPO-SURE OF HUMANS, TERRESTRIAL AND AVIAN WILDLIFE, AND AQUATIC LIFE TO DIOXINS AND FURANS FROM DISPOSAL AND USE OF SLUDGE FROM BLEACHED KRAFT AND SULFITE PULP AND PAPER MILLS (1990).

234. Interview with Harry Teitlebaum, supra note 231. 235. Id.

^{227.} See U.S. GEN. ACCOUNTING OFFICE, supra note 17, at 4-5.

^{228.} TSCA § 9, 15 U.S.C. § 2608 (1988).

^{229.} Interview with Dr. Richard Hill, supra note 166.

^{230.} Under TSCA the Administrator was not granted the unlimited enforcement authority found in FIFRA. Rather, if a proposed restrictive rule is contested, in order to enforce it EPA must receive an injunction from a federal district court which considers the adequacy of its reason for intervention. TSCA § 5(e)(2)(A), 15 U.S.C. § 2604(e)(2)(A) (1988).

warrant the attention of the agency.²³⁶ While population risk dominates the OPP's decisions, the OTS considers both individual risk and population risk in deciding whether to regulate. For example, in deciding to phase out the use of asbestos in almost all products over a seven-year period,²³⁷ the OTS concluded that the rule would prevent 200 cases of cancer and would also relieve certain highly exposed individuals of a 10^{-3} lifetime excess cancer risk. It cited both of these factors as justifying the costs caused by the suspension.²³⁸

In summary, risk management decisions made by the OTS and the OPP demonstrate the manner in which EPA uses QRA in its implementation of the narrative standards in balancing statutes. The differences in the techniques used by the two offices demonstrate the flexibility which such narrative standards permit.

D. Technology-Based Statutes: The Safe Drinking Water and Clean Water Acts

While virtually all environmental statutes embrace protection of public health as a goal, the operative narrative standard for regulatory decisions is often a technology-based criterion. These standards seek to reduce human exposures to carcinogens to the lowest level that is technologically feasible. As case studies of technology-based statutes, we consider the Safe Drinking Water Act (the SDWA)²³⁹ and the Clean Water Act (the CWA).²⁴⁰ The SDWA is implemented by EPA's Office of Drinking Water (the ODW), while the CWA is implemented by EPA's Office of Water. As we shall see, risk assessments play a subtly different role in EPA's implementation of these statutes.

The Safe Drinking Water Act has numerous regulatory provisions,²⁴¹ although its primary focus is setting drinking water standards

241. For a concise description of the scope and application of the SDWA, see Alon Rosenthal, Nitrates in Drinking Water, in HARNESSING SCIENCE, supra note 75, at 159, 161-64.

^{236.} Id.

^{237.} See Prohibition of the Manufacture, Importation, Processing, and Distribution in Commerce of Certain Asbestos-Containing Products; Labeling Requirements, 40 C.F.R. §§ 763.160-.179 (1991).

^{238.} See Asbestos: Proposed Mining and Import Restrictions and Proposed Manufacturing, Importation, and Processing Prohibitions, 51 Fed. Reg. 3738, 3744, 3748-49 (1986) (preamble to proposed rule). The asbestos risk assessment included multiple exposure pathways and sources, including mining and milling, repair, and disposal. *Id.* at 3738-57. The cost estimates included substitutes for each major asbestos use and risk assessments for their usage. *Id.* In addition, the assessment considered costs to consumers, decreased performance of products, costs in foregone capital stock, and job loss and salary reduction to asbestos workers. *Id.* For a description of the asbestos ruling and a general review of the TSCA regulatory scheme, see Ronald B. Outen, *Toxic Chemicals, in* LAW OF ENVIRONMENTAL PROTECTION 15-21 to 15-26 (Sheldon M. Novick et al. eds., 1990).

^{239. 42} U.S.C. §§ 300f to 300j-26 (1988).

^{240. 33} U.S.C. §§ 1251-1387 (1988).

for the nation.²⁴² The statute creates two types of standards for drinking water in the United States: nonenforceable "maximum contaminant level goals" (MCLG's), which are concentrations at which no adverse human health effects are believed to occur;²⁴³ and enforceable standards, maximum contaminant levels (MCL's), which, according to the terms of the SDWA, must be set as close to the MCLG's as is "feasible with the use of the best technology, treatment techniques, and other means which the EPA finds after examination for efficiency under field conditions . . . are available (taking costs into consideration)."²⁴⁴ While the MCLG's are derived from health-based language, the MCL's are derived from technology-based language that permits some consideration of economic impacts.

EPA's consideration of health and feasibility under the SDWA differs from the risk-benefit balancing it conducts under TSCA and FIFRA. The ODW interprets the statute as mandating an affordability analysis of the analytical technology for detecting contaminants, and not as mandating treatment options per se.²⁴⁵ In other words, ODW tends to require the lowest levels of contaminants that can be detected with affordable analytical technology. Hence, zero or negligible risk of cancer ostensibly provides an objective function under the SDWA, with feasible detection technology acting as the key constraint on regulatory stringency.²⁴⁶

In practice, the ODW sets MCLG's for substances that are probable animal or human carcinogens (chemicals classified as either Group A or Group B carcinogens) at zero.²⁴⁷ It sets MCLG's for Group C (possible) carcinogens on the basis of acceptable risk benchmarks (e.g., 10⁻⁶) or on the basis of a noncarcinogenic endpoint with safety factors added to compensate for possible carcinogenicity.²⁴⁸ Thus, MCLG's tend to be highly protective, particularly for carcinogenic substances.

^{242.} Ironically, under the Act, small, private water supply systems, often the most vulnerable to contamination, are exempt from these standards. SDWA § 1411, 42 U.S.C. § 300g (1988).

^{243.} SDWA § 1412(b)(4), 42 U.S.C. § 300g-1(b)(4) (1988).

^{244.} SDWA § 1412(b)(5), 42 U.S.C. § 300g-1(b)(5) (1988).

^{245.} See, e.g., National Primary Drinking Water Regulations; Synthetic Organic Chemicals; Monitoring for Unregulated Contaminants, 52 Fed. Reg. 25,690, 25,697-701 (1987) (preamble to final rule).

^{246.} Interview with Dr. Margaret Stasikowski, Deputy Director, Criteria and Standards Division, Office of Drinking Water, U.S. Envtl. Protection Agency, in Washington, D.C. (Aug. 30, 1990).

^{247.} See 40 C.F.R. § 141.50-.52 (1991). In its explanation, EPA states that it assumes that there is no threshold below which exposure to a carcinogen poses no risk. The agency therefore rejects proposals which would set MCLG's on the basis of analytical detection limits and negligible cancer risks. See National Primary Drinking Water Regulations: Synthetic Organic Chemicals, Inorganic Chemicals and Microorganisms, 50 Fed. Reg. 46,936, 46,948 (1985). For a discussion of the no-threshold theory, see supra text accompanying notes 54-58.

^{248.} The D.C. Circuit affirmed EPA's approach to MCLG's in National Resources Defense Council v. EPA, 824 F.2d 1211 (D.C. Cir. 1987).

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In contrast, EPA typically sets the enforceable MCL standards at the so-called "practical quantitative limit" (the PQL), the smallest quantity detectable using available analytical methods.²⁴⁹ Regardless of the technological obstacles, however, the ODW tries to ensure that MCL's do not impose lifetime cancer risks in excess of a range of 10^{-4} to $10^{-6.250}$ In several cases, however, estimated residual risk from MCL's has exceeded $10^{-4.251}$

The QRA's conducted by the Office of Drinking Water are not based entirely on conservative assumptions. While the ODW frequently relies on the CRAVE potency estimates,²⁵² it attempts to integrate all available toxicological data into its potency estimates rather than relying on a formulaic approach.²⁵³ The ODW bases its exposure assessments on risk to an average exposed person with no consideration of either unusually sensitive or maximally exposed populations. For example, its risk calculations assume a two-liter-per-day consumption pattern over a seventy-year lifespan, based on research which indicates that the average individual consumes 1.4 liters of water a day.²⁵⁴ The office does not consider groups with potentially higher exposures (e.g., manual laborers in Arizona) in its risk assessments.

In the final analysis, drinking water carcinogens are regulated on the basis of what agency officials believe a state drinking water program, as authorized by the SDWA, can reasonably be expected to detect. ODW officials argue that the analytical methods necessary to meet existing standards are "not inexpensive," and that small systems already cannot afford to meet the required detection limits.²⁵⁵ However, the ODW's judgment regarding what is feasible is highly subjective and state drink-

250. Interview with Jennifer Orme, supra note 249.

- 252. See supra note 67 and accompanying text.
- 253. Interview with Jennifer Orme, supra note 249.
- 254. Id. For a discussion of drinking water consumption patterns, see NATIONAL ACAD-EMY OF SCIENCES, DRINKING WATER AND HEALTH 11-12 (1977).

255. Interview with Dr. Margaret Stasikowski, *supra* note 246; *see also* Interview with Dr. Ed Ohanian, *supra* note 251; Interview with Jennifer Orme, *supra* note 249.

^{249.} EPA officials who promulgate the standards are highly critical of the SDWA standard-setting approach. They argue that many of the chemicals Congress required the agency to regulate pose no public health threat. (Sulfates in water, for example, pose no threat to human health and yet are regulated under the Act.) "Zero" MCLG levels are considered misleading, in that they imply that any exposure to a substance is dangerous, and they bear no relation to the actual risk posed by trace quantities of the carcinogens. In most cases, therefore, the agency makes no real effort, and indicates no real desire, to ratchet MCL's down to MCLG's, as marginal benefits to public health are considered negligible. *See* Interview with Dr. Margaret Stasikowski, *supra* note 246; Interview with Jennifer Orme, Toxicologist, Health Effects Branch, Office of Drinking Water, U.S. Environmental Protection Agency, in Washington, D.C. (Aug. 30, 1990).

^{251.} Among the examples cited by EPA Drinking Water Office officials are the standards for vinyl chloride, EDB, and radon, which allowed residual risks between 10^{-3} and 10^{-4} . See *id.*; Interview with Dr. Ed Ohanian, Chief, Health Effects Branch, Office of Drinking Water, U.S. Environmental Protection Agency, in Washington, D.C. (Aug. 30, 1990).

ing water programs occasionally disagree. For example, California, Florida, and New Jersey consider EPA's MCL of five micrograms per liter (μ g/l) for benzene excessively lenient, and each of these states has set a standard of one μ g/l standard instead.²⁵⁶

Critics of EPA's implementation of the SDWA argue that the more demanding MCLG's become functionally irrelevant due to the ODW's emphasis on detection technology.²⁵⁷ While MCLG's may indeed have a limited impact under the SDWA, we shall see below that they have important indirect regulatory impacts under the Superfund program.²⁵⁸

Like the SDWA, the Clean Water Act Amendments of 1972²⁵⁹ authorized the creation of federal technology-based standards. The CWA requires EPA to publish a list of toxic pollutants²⁶⁰ and to promulgate technology-based effluent limitations for these pollutants.²⁶¹ According to section 304 of the CWA, EPA must set two water quality criteria for toxic substances listed pursuant to section 307: one to protect aquatic habitats and one to protect human health.²⁶²

States remain responsible for setting their own ambient water quality standards, which must satisfy a health-based narrative test which states, "Such standards shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this chapter."²⁶³ These ambient water quality standards, like the maximum contaminant level goals (MCLG's) under the SDWA, are the ultimate health goal that technology-based effluent standards seek to achieve. In practice, EPA criteria often influence the setting of state water quality stan-

258. See infra part II.E.2.

259. Pub. L. No. 92-500, 86 Stat. 816 (1972).

260. CWA § 307(a), 33 U.S.C. § 1317(a) (1988). The definition of toxic pollutants under the CWA goes far beyond carcinogenicity and stipulates a range of health endpoints including "death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations" CWA § 502(13), 33 U.S.C. § 1362(13) (1988).

261. "Each toxic pollutant listed in accordance with paragraph (1) of this subsection shall be subject to effluent limitations resulting from the application of the best available technology economically achievable for the applicable category or class of point sources" CWA § 307(a)(2), 33 U.S.C. § 1317(a)(2) (1988). For a general discussion of EPA's promulgation of regulations under this statute, see Bradford W. Wyche, *The Regulation of Toxic Pollutants Under the Clean Water Act: EPA's Ten Year Rulemaking Nears Completion*, 15 NAT. RESOURCES LAW. 511 (1983); Khristine L. Hall, *The Control of Toxic Pollutants Under the Federal Water Pollution Control Act Amendments of 1972*, 63 IOWA L. REV. 609 (1978).

262. The criteria are to be published in the *Federal Register* and reflect "the latest scientific knowledge... on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics and recreation." CWA § 304(a)(1), (3), 33 U.S.C. § 1314(a)(1), (3) (1988).

263. CWA § 303(c)(2)(A), 33 U.S.C. § 1313(c)(2)(A) (1988).

^{256.} See Chemical Communication Subcomm., Fed.-State Toxicology and Regulatory Alliance Comm. (FSTRAC), Summary of State and Federal Drinking Water Standards and Guidelines 1 (1990).

^{257.} See, e.g., id.; Telephone Interview with Jackie Warren, Senior Attorney, Natural Resources Defense Council (Aug. 28, 1990).

dards. States promulgate their water quality standards under EPA guidance and in accordance with the designated use of the stream.²⁶⁴ Standards for streams designated for industrial use or irrigation tend to be more lenient than those for streams earmarked for recreation or fishing.²⁶⁵ Once adopted, state standards are reviewed for approval by the EPA's regional offices.²⁶⁶

To assist the states, which have widely varying technical capabilities, EPA's Office of Water uses quantitative risk assessment to publish nonbinding federal water quality criteria.²⁶⁷ Theoretically, the statutory language does not allow EPA to consider technological and economic factors in developing these criteria.²⁶⁸

In developing its water quality criteria, the Office of Water assumes that no concentration of a carcinogen is safe and sets its criteria for carcinogens in water according to an acceptable level of individual risk of 10^{-6} .²⁶⁹ States under EPA supervision have been given discretion to choose acceptable risk levels within the range of 10^{-5} to 10^{-7} , although the Office of Water encourages states to select the one-in-a-million, or 10^{-6} level.²⁷⁰

In conducting its risk assessments under the CWA, the office applies a series of generic assumptions regarding exposure rather than focusing on an MEI exposure scenario. For example, EPA calculates human exposure from eating freshwater fish, assuming a daily consumption of 6.5 grams per person, although certain subpopulations (e.g., subsistence fishermen) consume much greater amounts, possibly as much as 165 grams per person per day.²⁷¹

E. Hybrid Narrative Statutes

While some insight is gained by categorizing environmental statutes according to the type of narrative language that governs regulatory decisions, some statutes are either difficult to categorize or combine elements

^{264. 40} C.F.R. §§ 131.1-.22 (1991).

^{265.} See CWA § 303(c)(2)(A), 33 U.S.C. § 1313(c)(2)(A) (1988).

^{266.} See CWA § 303(a), 33 U.S.C. § 1313(a) (1988); 40 C.F.R. § 131.5 (1991); supra part II (discussing the review process in the EPA regional offices and the resulting inconsistent levels of protection).

^{267.} See CWA § 304, 33 U.S.C. § 1314 (1988).

^{268.} See id. For a discussion of the role of economics in implementation of the Clean Water Act's toxic provisions, see Wyche, supra note 261, at 516.

^{269.} Telephone Interview with Ken Potts, Criteria and Standards Division, Office of Water, U.S. Environmental Protection Agency (Aug. 16, 1991).

^{270.} See generally OFFICE OF WATER, U.S. ENVTL. PROTECTION AGENCY, EPA GUI-DANCE—ASSESSING HUMAN HEALTH RISK FROM CHEMICALLY CONTAMINATED FISH AND SHELLFISH (no date).

^{271.} Exposure parameters were set forth 12 years ago. See Water Quality Criteria, 45 Fed. Reg. 79,318-19 (1980). EPA's Office of Water is currently revising its fish consumption numbers.

of each type of narrative language described above. For lack of a better term, we call these hybrid narrative statutes.

As illustrations of this more complex statutory approach, we consider the two major federal statutes regulating hazardous waste management, the amended Resource Conservation and Recovery Act of 1976 (RCRA)²⁷² and the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA or Superfund),²⁷³ as amended in 1986.²⁷⁴ RCRA and CERCLA were designed to constitute a long-term, comprehensive strategy for confronting America's waste disposal problem.²⁷⁵

Under both RCRA and CERCLA, EPA utilizes QRA extensively.²⁷⁶ While both statutes are administered by EPA's Office of Solid Waste (the OSW) and are aimed at protecting the public health from exposure to wastes, there are some rather intriguing and inexplicable patterns in the use of risk assessment under the two statutes.

1. The Resource Conservation and Recovery Act

Hazardous wastes are regulated under subchapter III of RCRA which requires EPA to design and promulgate a "cradle to grave" disposal system.²⁷⁷ Until recently, EPA's standards governing disposal were basic design standards: they required use of certain technology (e.g., liners at landfills) without considering the degree of health risk that might exist with and without the mandated technology.²⁷⁸ More recently, the OSW has begun to incorporate QRA into several aspects of the RCRA program.

EPA places some reliance on QRA in setting its criteria for defining "hazardous waste." These criteria are important because the identifica-

^{272. 42} U.S.C.A. §§ 6901-6992k (West 1983 & Supp. 1992).

^{273. 42} U.S.C. §§ 9601-9675 (1988). CERCLA establishes a trust fund generated primarily from taxes levied on the petrochemical industry. This "superfund" is used to finance cleanup of hazardous waste sites selected by EPA as posing particular dangers to public health. See CERCLA § 111, 42 U.S.C. § 9611 (1988); 26 U.S.C.A. § 9507 (West Supp. 1992). 274. See Superfund Amendments and Reauthorization Act of 1986 (SARA), Pub. L. No.

^{99-499, 100} Stat. 1613 (1986).

^{275.} See Donald A. Brown, Superfund Cleanups, Ethics and Environmental Risk Assessment, 16 ENVTL. AFF. 181 (1988).

^{276.} Marcia E. Williams & Jonathan Z. Cannon, Rethinking the Resource Conservation and Recovery Act for the 1990's, 21 Envtl. L. Rep. (Envtl. L. Inst.) 10,063 (Feb. 1991).

^{277.} Under this subchapter, EPA must identify those hazardous wastes that are to be regulated; promulgate standards for generators and transporters of hazardous waste; and establish standards covering owners and operators of hazardous waste treatment and storage facilities, including a permitting program and guidelines for storage and disposal. RCRA §§ 3001-3005, 42 U.S.C.A. §§ 6921-6925 (West 1983 & Supp. 1992).

^{278.} Williams & Cannon, *supra* note 276. The definition of hazardous waste, however, has involved consideration of health impacts. For a critique of the Act, see COUNCIL ON ECONOMIC PRIORITIES, HAZARDOUS WASTE MANAGEMENT: REDUCING THE RISK 120-22 (1986).

tion of a substance as a hazardous waste triggers standard-setting activities. The criteria have traditionally included the substance's ignitability, corrosivity, reactivity, toxicity, and leachability.²⁷⁹ Traditionally, the OSW has utilized EPA's drinking water standards (MCL's), which are sometimes based on QRA, to determine the "hazardousness" of any chemicals that might leach into the groundwater.²⁸⁰ When MCL's are unavailable or inadequate, the OSW uses QRA to determine the hazardousness of chemicals that pose chronic health risks such as cancer. If the analysis establishes a 10^{-5} lifetime risk associated with the leaching of a particular chemical waste, the waste is classified as hazardous.²⁸¹

The agency uses QRA in listing and delisting hazardous wastes, but its standards for the two operations are not symmetric. According to the agency, "delisting [a waste as hazardous] uses a more conservative risk factor of 10^{-6} for carcinogens, compared to the use of a 10^{-5} risk factor in the TC [toxicity characteristic] rule," which governs listing.²⁸² The language of the RCRA statute neither authorizes nor discourages such a distinction in the use of QRA.

EPA bases its risk assessments for delisting decisions on numerous, somewhat arbitrary, assumptions that are designed to generate upper bound estimates of human exposure and risk. The OSW typically constructs a single scenario of individual exposure, making no attempt to estimate current or future population risk. Risk assessors then use a mathematical model to predict the concentration of wastes in groundwater, which they apply to a hypothetical drinking water well near a hypothetical disposal area.²⁸³ They typically assume that the well is 500 feet downgradient from the disposal area, and that this disposal area is a municipal landfill without a protective lining or other safeguards.²⁸⁴ In determining the level of concentration at the well, the assessors use the eighty-fifth percentile level from the frequency curve describing the probable extent of the waste's dilution, and they consider only one route of exposure: ingestion of drinking water.²⁸⁵

The agency also uses risk assessment to decide, among other things, whether to take corrective actions at active waste sites, and how much

284. Id.

285. Telephone Interview with Alex McBride, Chief of the Technical Assessment Branch, Office of Solid Waste, U.S. Environmental Protection Agency (Sept. 11, 1990).

^{279.} For a description and critique of EPA's process for listing a solid waste as hazardous, see Williams & Cannon, *supra* note 276, at 10,064-71.

^{280.} See Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Toxicity Characteristics Revision, 55 Fed. Reg. 11,798, 11,813-14 (1990) (preamble to final rule).

^{281.} Id. at 11,813-15. "The chosen risk level of 10^{-5} is at the midpoint of the reference risk range for carcinogens (10^{-4} to 10^{-6})." Id. at 11,815.

^{282.} Id. at 11,832; see also Williams & Cannon, supra note 276, at 10,065 n.24 (confirming use of the 10^{-6} risk factor for delisting).

^{283.} Williams & Cannon, supra note 276, at 10,065.

action to take.²⁸⁶ The agency considered selecting a stringent bright line standard, defined as constituent-specific action levels (i.e., levels of risk for particular chemical constituents in a waste stream that contains multiple chemicals) to guide such decisions. For its bright line, it considered risk levels from 1×10^{-4} to 1×10^{-6} .²⁸⁷ However, the OSW ultimately took a different approach, in which the identification of a risk greater than 10^{-6} at a site triggers a detailed study of cleanup options. After the study is completed, the OSW must select a cleanup alternative which will reduce risks into the 10^{-4} to 10^{-6} range.²⁸⁸ EPA considers a number of facts in reaching a decision as to how clean is clean enough, including the potential use of the site and the feasibility and cost of cleanup.²⁸⁹ The choice of a risk range, rather than a single bright line, provides some administrative flexibility in making cleanup decisions.

While risk assessments for corrective action do not generally draw distinctions among categories of carcinogens,²⁹⁰ other risk assessments conducted under RCRA do make such distinctions. For example, the OSW considers such information when setting standards based on QRA for waste incineration, industrial boilers, and furnaces, which are called for under RCRA. In these standard setting decisions, the OSW maintains a unique risk management position for carcinogenic metals, based on both the carcinogen classification of the metal²⁹¹ and the numerical risk level.²⁹²

In 1990, the OSW proposed this somewhat novel and complex risk management policy:

For purposes of today's rule, we are proposing the following risk levels as acceptable incremental lifetime cancer risk levels to the hypothetical maximum exposed individual (MEI): (1) for Group A and B carcinogens, on the order of 10^{-6} , and (2) for Group C carcinogens, on the order of 10^{-5} . These risk levels are within the range of levels historically used by EPA in its hazardous waste and emergency response programs— 10^{-4} to $10^{-7,293}$

293. Standards for Owners and Operators of Hazardous Waste Incinerators and Burning

^{286.} See Corrective Action for Solid Waste Management Units (SWMU's) at Hazardous Waste Management Facilities, Fed. Reg. 30,798, 30,804 (1990) (preamble to proposed rule) [hereinafter Proposed Rule on Corrective Action].

^{287.} Id. at 30,815. EPA officials note that this range is consistent with the Superfund approach. Interview with Mr. Alex McBride, Chief of the Technical Assessment Branch, Office of Solid Waste, U.S. Environmental Protection Agency, in Washington, D.C. (July 30, 1991).

^{288.} See Proposed Rule on Corrective Action, supra note 286, at 30,825-27.

^{289.} Telephone Interview with Alex McBride, supra note 285.

^{290.} See supra note 65 and accompanying text (describing EPA's classification system).

^{291.} See Burning of Hazardous Waste in Boilers and Industrial Furnaces, 52 Fed. Reg. 16,982, 17,004-08 (1987) (preamble to proposed rule and request for comment).

^{292. &}quot;We are proposing that a 1×10^{-5} lifetime incremental risk level is reasonable for this regulation because the MEI risk posed by coal and oil fired boilers is generally in the range of 1×10^{-5} ." Id. at 16,994 (footnote omitted).

OSW also proposed a limit on aggregate lifetime risk to an MEI from all metals of 10^{-5} .²⁹⁴ These subtle distinctions, which have no specific roots in RCRA, are not made when QRA is used in other facets of RCRA regulation.

2. Superfund

Under EPA's "Superfund" program (CERCLA), which regulates the cleanup of inactive hazardous waste sites, a rather elaborate process of risk assessment and management has evolved from a somewhat ambiguous narrative statutory mandate.

The narrative directives for risk management under Superfund are found in section 121(d)(2), which sets forth a two-part standard for cleanup of hazardous waste sites. First, onsite cleanups must satisfy standards from other federal and state environmental programs that are "applicable" or "relevant and appropriate [requirements (ARAR's)] under the circumstances."²⁹⁵ Second, the cleanup must protect human health and the environment.²⁹⁶ In applying this two-part standard on a site-specific basis, the Superfund program makes widespread use of QRA.

Under CERCLA, EPA undertakes remedial actions, generally involving cleanup around hazardous waste sites that pose an environmental or public health threat.²⁹⁷ EPA utilizes QRA at two points in this process. After the agency deems a site sufficiently hazardous to rank it on the "National Priorities List,"²⁹⁸ it conducts a baseline risk assess-

298. See CERCLA § 105(c)(1), 42 U.S.C. § 9605(c)(1) (1988). To compile the list, EPA utilizes a less formal process/model called the "Hazard Ranking System" which determines which sites will be addressed. See 40 C.F.R. § 300.425 (1991); National Priorities List for

of Hazardous Wastes in Boilers and Industrial Furnaces, 55 Fed. Reg. 17,862, 17,873 (1990) (preamble to proposed rule, supplementary proposed rule, technical corrections, and request for comments).

^{294.} See id.

^{295.} CERCLA § 121(d)(2)(A), 42 U.S.C. § 9621(d)(2)(A) (1988). CERCLA defines ARAR's as

any standard, requirement, criteria or limitation under any Federal environmental law, including but not limited to the Toxic Substances Control Act, the Safe Drinking Water Act, the Clean Air Act, the Clean Water Act, the Marine Protection, Research and Sanctuaries Act, or the Solid Waste Disposal Act; or ... any promulgated standard, requirement, criteria, or limitation under a State environmental or facility siting law that is more stringent than any Federal standard, requirement, criteria, or limitation contained in a program approved, authorized or delegated by the Administrator under a statute cited in sub-paragraph (A), and that has been identified to the President by the State in a timely manner.

CERCLA § 121(d)(2)(A)(i)-(ii), 42 U.S.C. § 9621(d)(2)(A)(i)-(ii) (1988) (citations omitted). 296. CERCLA § 121(d)(1), 42 U.S.C. § 9621(d)(1) (1988).

^{297.} See CERCLA §§ 101(24), 104, 42 U.S.C. §§ 9601(24), 9604 (1988). The Act also authorizes EPA to act in a number of other areas, including assessment of liability and response to release of hazardous substances into the environment. See CERCLA §§ 101(23), 104, 107, 42 U.S.C. §§ 9601(23), 9604, 9607 (1988).

ment to judge whether the health risk justifies cleanup under section 121.²⁹⁹ Once EPA decides to undertake remedial action at a site (note that here QRA serves a priority-setting function),³⁰⁰ EPA uses risk assessment to determine appropriate cleanup levels (note that here QRA serves a standard-setting function).³⁰¹

CERCLA does not specify which ARAR standards are applicable under any given circumstances,³⁰² but in utilizing them, EPA considers the levels of risk that they represent.³⁰³ For example, where exposure is limited to a single substance, EPA cleanup demands are generally met by fulfilling the relevant ARAR requirement (e.g., a drinking water standard for the substance). In contrast, when a mixture is present,³⁰⁴ the agency evaluates the cumulative risk after completion of the cleanup.³⁰⁵

Since the program's inception, EPA has conducted site-specific QRA's. These are particularly complex because sites generally house a host of chemicals to which humans may be exposed through multiple routes.³⁰⁶ EPA usually does not calculate population risks under Superfund, in part because it typically cannot determine the size of the current (or future) exposed population at a specific site. Instead, the OSW attempts to make exposure assumptions that reflect a reasonable

301. See National Oil and Hazardous Substances Pollution Contingency Plan, 55 Fed. Reg. 8666, 8715-17 (1990) (preamble to final rule) [hereinafter Contingency Plan].

302. Due to the difference in various state standards, ARAR's vary across the country and among EPA regions. The Agency, however, has created three categories: location-specific ARAR's (e.g., wetlands treatment), chemical-specific ARAR's (such as primary drinking water standards under the Safe Drinking Water Act), and action-specific ARAR's (e.g., technology standards like RCRA design standards). For a discussion of ARAR's, see Richard G. Stoll, *Comprehensive Environmental Response, Compensation & Liability Act, in* ENVIRON-MENTAL LAW HANDBOOK 471, 485-94 (11th ed. 1991).

303. EPA comments on proposed regulations point out that many ARAR's are less protective than a 10^{-6} level of risk, which is one of the reasons that the OSW does not use a single point estimate standard for cleanup. See Contingency Plan, supra note 301, at 8715-17.

304. The program generally assumes that risk is additive. For example, if there are two chemicals present at the site with MCL's that correspond to lifetime risks at 1×10^{-4} level, then the office assumes a 2×10^{-4} risk, which exceeds the acceptable risk range.

305. Telephone Interview with Bruce Means, Toxics Integration Branch, Office of Solid Waste, U.S. Environmental Protection Agency (July 29, 1991). Once again, the Superfund approach includes utilization of risk-based goals with a 10^{-6} point of departure. The program generally assumes that risk is additive. For example, if there are two chemicals present at the site with MCL's that correspond to lifetime risks at 1×10^{-4} level, then the office assumes a 2×10^{-4} risk, which exceeds the acceptable risk range.

306. See 1 Office of Emergency and Remedial Response, U.S. Envtl. Protection Agency, Risk Assessment Guidance for Superfund: Human Health Evaluation Manual, Interim Final 4-5 (1989).

Uncontrolled Hazardous Waste Sites: Proposed Update No. 10, 54 Fed. Reg. 43,778, 43,778-83 (1989) (preamble to proposed amendment of the National Priorities List).

^{299.} See Joseph Freedman, Proposed Amendments to the National Contingency Plan, Explanation and Analysis, 19 Envtl. L. Rep. (Envtl. L. Inst.) 10,103 (Mar. 1989).

^{300.} Prioritization at this stage does not provide a numeric ranking. Rather, QRA serves a threshold function by determining whether or not a site warrants intervention.

maximum exposure (RME).³⁰⁷ This concept, which is intended to be more realistic than the "maximally exposed individual,"³⁰⁸ combines upper bound and midrange exposure assumptions.³⁰⁹ For example, while the Office of Drinking Water uses a fixed two-liter-per-day estimate of water consumption for adults,³¹⁰ a Superfund exposure assessment for sites in warm regions in theory may exceed this. On the other hand, the generic assumptions used in QRA's for Superfund sites are not always as conservative as those typically used in other EPA offices. For example, QRA's for Superfund sites assume a thirty-year rather than a seventyvear residence.311

If QRA suggests action is required, Superfund allows EPA to pursue various risk management strategies. For instance, institutional controls can limit population proximity to a site through zoning restrictions. Furthermore, recent regulations establish quantitative risk ranges that guide cleanup decisions.³¹² The use of a range of acceptable risks permits the agency to use some discretion in setting standards. Although the subject of both criticism³¹³ and litigation,³¹⁴ the National Contingency Plan final rule states that, generally, remedies must reduce the threat from carcinogenic contaminants at a site until the excess lifetime cancer risk to a highly exposed individual (e.g., reasonable worst case) is within or below the range of 10^{-4} to $10^{-6.315}$

Historically, EPA's policy inclination under Superfund, all things being equal, has been to select remedies that produce results at the more protective end of the risk range.³¹⁶ Therefore, when developing its pre-

311. Id. A 30-year residence assumption reflects residency patterns of only the top 10% of the population, rather than the top 1%. Interview with David Bennett, Integration Branch Chief, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, in Washington, D.C. (Sept. 10, 1990).

312. See, e.g., Contingency Plan, supra note 301, at 8715-17; Lawrence E. Starfield, The 1990 National Contingency Plan-More Detail and More Structure, But Still A Balancing Act, 20 Envtl. L. Rep. (Envtl. L. Inst.) 10,222, 10,236-37 (June 1990).

313. For a critique of the regulations, see Donald A. Brown, What Is Wrong With the 1990 National Contingency Plan?, 20 Envtl. L. Rep. (Envtl. L. Inst.) 10,371 (Sept. 1990). Brown argues that, since a risk range of 10^{-4} to 10^{-6} offers the agency considerable discretion to consider costs, it is inconsistent with the statutory provisions which prohibit such consideration until after environmental protection goals have been met. Id. at 10,375-76.

314. The Plan has been challenged by several states, including New York, five companies, and the Chemical Manufacturers Association. Superfund: States, CMA, Five Companies Challenging National Contingency Plan, 21 Env't Rep. (BNA) 340 (June 15, 1990).

315. See Contingency Plan, supra note 301, at 8718-23, 8768.

316. Id. at 8716.

^{307.} Id.

^{308.} See supra note 116 and accompanying text.

^{309.} Telephone Interview with Bruce Means, supra note 305.

^{310.} See 1 OFFICE OF EMERGENCY AND REMEDIAL RESPONSE, U.S. ENVTL. PROTEC-TION AGENCY, RISK ASSESSMENT FOR SUPERFUND: HUMAN HEALTH EVALUATION MAN-UAL, SUPPLEMENTAL GUIDANCE, STANDARD DEFAULT EXPOSURE FACTORS, INTERIM FINAL 5-6 (1991).

liminary remediation goals, the OSW establishes 10^{-6} as a point of departure and allows higher risk levels only if cleanup is not reasonable and practical.³¹⁷ More recently, EPA has become more lenient. If a baseline risk assessment (BRA) shows a risk of less than 10^{-4} , the agency can make a "no action" record of decision.³¹⁸ Nonetheless, there have been cases in which a BRA indicated risks in the higher part of the risk range, and in which EPA initiated remedial action to achieve a 10^{-6} remediation level. EPA is most likely to take such action when cleanup costs are low or when population density suggests potentially high incidence of disease.³¹⁹

F. Use of Risk Assessment at EPA: A Summary

Our survey of risk assessment and management practices at EPA reveals considerable diversity in the methods of calculating cancer risks and in the managers' use of carcinogen classifications and risk numbers. This survey is compiled below in Table 1. At a superficial level, there seems to be a tendency for EPA offices to insist on reducing lifetime cancer risk below the broad range of 10^{-4} to 10^{-6} . Although the agency has no uniform policy on acceptable and de minimis risk (indeed, it couldn't have one in light of the statutory differences described above), it appears that individual risks greater than 10^{-4} are highly likely to be regulated, while risks less than 10^{-6} are rarely regulated.

318. Memorandum from Don R. Clay, Assistant Administrator, Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency, to Directors of Regional Divisions, U.S. Environmental Protection Agency, Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions 1, 4, 6 (Apr. 22, 1991) (on file with author).

^{317.} Id. at 8715-18. Among the factors that EPA will use in determining whether a remediation should permit 10^{-6} risk levels are exposure factors, uncertainty factors, and technical factors. Among the exposure factors are the cumulative effect of multiple contaminants, the potential for human exposure from other pathways at the site, population sensitivities, potential impacts on environmental receptors, and cross-media impacts of alternatives. Factors related to uncertainty may include the reliability of alternatives, the weight of scientific evidence concerning exposures or toxicity, individual and cumulative health effects, and the reliability of exposure data. Technical factors may include detection/quantification limits for contaminants, technical limitations to the proposed remedy, the feasibility of monitoring and controlling movement of contaminants, and background levels of contaminants. Id. at 8717.

^{319.} Interview with David Bennett, supra note 311.

TABLE 1RISK ASSESSMENT AND MANAGEMENT INEPA'S PROGRAM OFFICES320

Program Office	Statute	Classifi- cation Matters?	Uses CRAVE Potencies?	Considers Individual Risk Scenario?	Considers Size of Exposed Population?	Key Risk Levels
OPTS	FIFRA	Yes	Yes	No	Yes	10 ⁻⁵ -10 ⁻⁶
	Delaney	Yes	Yes	No	No	0
	TSCA	No	Yes	Yes	Yes*	
OSW	CERCLA	No	Yes	Yes	No	10 ⁻⁴ -10 ⁻⁷
	RCRA	Yes	Yes	Yes	No	10-4-10-6
OA&R	CAA	Yes	Yes	Yes	Yes	< 10 ⁻⁴ -10 ⁻⁶
ODW	SDWA	Yes	Yes	No	No	<10 ⁻⁴ -10 ⁻⁶
ow	CWA	No	Yes	No	No	10 ⁻⁵ -10 ⁻⁷

* Only for existing chemicals

This apparent coherence in agency policy should be interpreted cautiously, as we also saw profound differences in how risk estimates are calculated across the agency. If two risk estimates are calculated under different assumptions, any comparison of the two numbers is really a comparison of apples and oranges.

Thus, the fact that two program offices within EPA have reported the same numerical risk level does not imply that the offices have identified the same degree of carcinogenic threat. As we have seen, some program offices compute risks to the maximally exposed individual, others consider reasonable worst-case exposure scenarios, while others calculate the average level of risk experienced by members of the exposed population. Furthermore, some program offices consider estimates of population risk, while others do not.

The program offices also treat carcinogen classifications differently. Some offices never apply QRA to Group C (possible) carcinogens, while other offices apply QRA to Group C chemicals on a case-by-case basis. These differences are not trivial, since a 10^{-4} risk from a Group C carcinogen does not necessarily pose the same threat as a 10^{-4} risk from a Group A (known) carcinogen. One program office (the OSW) even modifies its benchmark of acceptable risk according to the classification of the chemical, although it does not do so in all of its risk management decisions. It is important to keep in mind the variety in EPA's current practices as we consider the implications of statutory intervention in the process.

^{320.} For a more detailed discussion of each of the statutes, see *supra* part II.A (Delaney Clause); *supra* part II.B (Clean Air Act); *supra* part II.C (Federal Insecticide, Fungicide, and Rodenticide Act); *supra* part II.D (Safe Drinking Water Act and Clean Water Act); *supra* part II.E.1 (Resource Conservation and Recovery Act); and *supra* part II.E.2 (Comprehensive Environmental Response, Compensation and Liability Act).

While the patterns of risk assessment practice at EPA are complex and variable, statutory language does not appear to explain the practices of the program offices. Risk assessment practice clearly varies in regulatory programs with similar types of narrative statutes. Risk assessment practices also vary among programs with different narrative statutes, but we found no examples where the specific statutory language was responsible for the different methods of calculating risks. While some offices use bright lines to govern risk management decisions, the specific numbers are not authorized or discussed in the relevant statutes.

In summary, we found no evidence that the considerable diversity in risk assessment practice within EPA program offices can be attributed to explicit or discernible differences in the narrative statutes that govern the agency's regulatory activities. Environmental statutes do dictate whether rules should be based on health considerations alone, whether they must take into account technical feasibility, and whether they must balance risks, costs, and benefits. However, they never prescribe how cancer risks are to be calculated and rarely specify what levels of cancer risk are unacceptable (with the possible exception of the zero-risk interpretation of the Delaney Clause). Our conclusion—that the diversity of risk assessment practice cannot be explained by the difference in narrative standards—should not be surprising, since risk assessment is virtually never mentioned in these statutes.

III LEGISLATING BRIGHT LINES

The United States Congress is just beginning to recognize the powerful role that cancer risk assessment plays in regulatory decisions at the Environmental Protection Agency. In this part of the article, we review several recent congressional efforts to constrain agency discretion in the conduct and use of risk assessment.

We begin by discussing the legislative history of the Clean Air Act Amendments of 1990. After much contentious debate, the United States Congress mentioned a quantitative cancer risk level in a statute for the first time in these amendments.³²¹ We also describe less prominent legislative proposals on food safety and water quality that provide an indication of current Congressional thinking about risk assessment. In each case, the prevailing narrative statute had been criticized as unworkable. Interest group reactions to these proposed bright lines provide a fascinating illustration of politics before principle.

^{321.} Clean Air Act Amendments of 1990, Pub. L. No. 101-549, § 301, 104 Stat. 2399, 2538-39 (1990) (codified as amended at 42 U.S.C.A. § 7412(c)(9)(B)(i) (West Supp. 1992)).

A. The Clean Air Act Amendments of 1990

President Bush's proposed Clean Air Amendments, introduced in Congress as Senate Bill 1490, included a narrative standard for controlling the residual risks from air toxics remaining after implementation of best available control technology (BACT). The bill introduced an "unreasonable risk" standard modeled after those in TSCA and FIFRA.³²² Under this plan, the Administrator of EPA would have been granted wide discretion to determine which residual risks warranted additional regulation and the authority to consider costs to industry and society as a whole.

Environmentalists and their allies in Congress, already impatient with EPA's lenient regulatory record under section 112, advocated more aggressive bills in the House and Senate. Like the Bush plan, the major House and Senate bills³²³ offered a two-stage strategy for regulating air toxics.³²⁴ Unlike the Bush plan, the House and Senate bills included "bright line" standards in the second stage.³²⁵ The proposed bright lines became one of the more controversial aspects of the reauthorization, with the Senate and the House of Representatives eventually passing different bills.

The original Senate bill required EPA to promulgate emission standards which would eliminate lifetime cancer risks to the MEI³²⁶ greater than $10^{-6.327}$ Facilities that failed to meet an interim 10^{-4} risk level would be closed.³²⁸ Over time, all facilities would be required to achieve the 10^{-6} risk level.³²⁹ The original Senate language also forbade EPA from considering nonhealth factors when setting emissions levels in conformance with the aforementioned bright lines.³³⁰ The bill mandated use

325. See S. 816, supra note 27, § 2 (proposed amendment to CAA § 112); H.R. 2585, supra note 27, § 2 (proposed amendment to CAA § 112).

326. See supra text accompanying note 116.

328. See id. (proposed amendment to CAA § 112(f)(1)(A), (i)(1)-(2)).

329. See id. (proposed amendment to CAA § 112(e)(5)(C)).

330. "No consideration of cost, cost effectiveness, economic, energy, or other factors or technological feasibility shall be included in the determination of the appropriate level of any

^{322.} S. 1490, 101st Cong., 1st Sess. §§ 301(d), (f) (1989) (proposed amendment to CAA §§ 112(d), (f)). The term "unreasonable risk" is not new to environmental legislation in general. See supra part II.C.

^{323.} S. 816, supra note 27; H.R. 2585, supra note 27.

^{324.} With regard to the initial technology-based standards, the 1990 amendments state: "Emissions standards promulgated under this subsection . . . shall require the maximum degree of reduction in emissions of the hazardous air pollutant . . . that the Administrator, taking into consideration the cost of achieving such emission reductions . . . determines is feasible." Pub. L. No. 101-549, § 301, 104 Stat. 2399, 2539 (1990) (codified at 42 U.S.C.A. § 7412(d)(2) (West Supp. 1992)).

^{327.} The language of the bill stated this standard as: "a standard which eliminates all lifetime risks of carcinogenic effects greater than one in one million to the individual in the population who is most exposed to emissions of a pollutant (or stream of pollutants) from a source in the category or subcategory." S. 816, *supra* note 27, § 2 (proposed amendment to CAA § 112(f)(1)(B)).

of conservative assumptions when calculating risks³³¹ and directed EPA to set standards for Group A, B, and C carcinogens.³³²

The approach to air toxics in the major House bill initially resembled that in the Senate bill.³³³ The House bill also adopted a two-stage approach, with an initial technology-based standard³³⁴ and a subsequent bright line to control residual risk. However, the House's bright line was tougher, setting negligible residual risk for the MEI at 10^{-6} without an interim step of 10^{-4} .³³⁵

Most interest groups participating in the legislative debate accepted the new first stage of air toxics control, the technology-based standards. In contrast, the residual-risk provisions sparked vociferous controversy.³³⁶ Despite considerable public support for clean air,³³⁷ and despite lobbying by environmentalists and state environmental officials,³³⁸ subse-

emissions standard under this subsection." Id. § 2 (proposed amendment to CAA § 112(f)(1)).

331. See S. REP. NO. 101-228, 101st Cong., 2d Sess. 178-79 (1989).

332. "The Administrator is authorized to promulgate emissions standards under this subsection applicable to categories or subcategories of sources of any hazardous air pollutant which is a *known, probable, or possible human carcinogen.*" S. 816, *supra* note 27, § 2 (proposed amendment to CAA § 112(f)(1)) (emphasis added). Known, probable, and possible carcinogens are Group A, B, and C carcinogens, respectively. See supra text accompanying note 65.

333. For example, the language describing source reduction, process redesign, and traditional controls is very similar. Compare H.R. 2585, supra note 27, § 2 (proposed amendment to CAA § 112(e)(1)(A-E)) with S. 816, supra note 27, § 2 (proposed amendment to CAA § 112(d)(1)-(2)(A-E)).

334. The House bill proposed:

The Administrator shall promulgate emission standards under this subsection which reflect the degree of emission reduction achievable through the application of the best available control technology for the control of hazardous air pollutants from new and existing major emitting facilities Such standards shall require the maximum degree of reduction in emissions . . . taking into consideration the cost of achieving such emissions reduction . . .

H.R. 2585, supra note 27, § 2 (proposed amendment to CAA § 112(e)(1)) (BACT standard). 335. See id. § 2 (proposed amendment to CAA § 112(g)(2)).

A standard revised under this subsection shall be adequate to eliminate all lifetime risks of carcinogenic effects and other serious adverse effects to human health attributable to emissions of the hazardous air pollutant from major emitting facilities in the category concerned greater than one in 1,000,000 for the individual in the population who is most exposed to such emissions.

336. See Senate Air Toxics Provisions Need Work, Amendments Likely Breaux Tells Industry Group, 20 Env't Rep. (BNA) 1327 (Nov. 24, 1989). For a general presentation of industry's objection, see Hearing on S. 816 Before the Subcomm. on Environmental Protection of the Senate Comm. on Environmental and Public Works, 101st Cong., 1st Sess. 238-76 (1989) [hereinafter S. 816 Hearing] (statement of William F. O'Keefe, Vice President and Chief Operating Officer, American Petroleum Institute); *id.* at 12-13 (statement of H. Eugene McBrayer, President, Exxon Chemical Co.; Chairman, Executive Committee, Chemical Manufacturers Association, Clean Air Working Group).

337. See Riley E. Dunlap & Rik Scarce, Trends: Environmental Problems and Protection, 55 PUB. OPINION Q. 651 (1991).

338. See, e.g., S. 816 Hearing, supra note 336, at 60-74 (testimony of Bruce Maillet, Director, Massachusetts Division of Air Quality Control, representing the State and Territorial Air

Id.

quent Senate versions of the amendments either watered down the bright lines³³⁹ or delayed their implementation.³⁴⁰ Indeed, the bright lines aroused so much opposition, including the threat of a filibuster, that the Senate Committee's bill was drastically revised before it reached the Senate floor for a vote.³⁴¹

The revised Senate proposal would have gone beyond setting numerical risk management directives by legislating methods for calculating risk. The provisions created a new concept called "the most exposed actual person" to replace the MEI, requiring that exposure calculations be based on information gathered by the Administrator concerning persons living under comparable socio-economic conditions and reflecting expected exposure of one standard deviation above the mean level of exposure which would be expected for such persons.³⁴² Environmentalists were appalled at this attempt to eliminate the conservatism inherent in the MEI with only a relatively modest statistical compensation.³⁴³

The revisions of the House bill made in the Committee deliberations were even more dramatic.³⁴⁴ The residual-risk provisions no longer made any mention of a bright line.³⁴⁵ Rather, the bill would have in-

Pollution Program Administrators and the Association of Local Air Pollution Control Officials); *id.* at 181-97 (testimony of David Doniger, Senior Attorney, Natural Resources Defense Council, on behalf of the National Clean Air Coalition).

339. As one committee staffer reported, "[i]nitially, the subcommittee had a difficult time agreeing as to where to set a bright line. As soon as they reached a consensus on where to draw the line, industry attacked the risk assessment itself, using the [conservative assumptions inherent to] MEI as a caricature in the debate." Telephone Interview with Jimmie Powell, Minority Counsel, Senate Subcommittee on Environmental Protection (Aug. 24, 1990).

340. For example, the final Senate Bill made bright lines contingent on the absence of an alternative residual risk approach. Specifically, the proposed amendments would have established a Risk Assessment and Management Commission to recommend legislation for the regulation of residual risk. The Commission would base its recommendations in part on a report commissioned from the National Academy of Sciences reviewing EPA's risk assessment methodology. If the recommended legislation was not enacted, the original bright line provisions would go into effect. See S. 1630, 101st Cong., 2d Sess. § 301 (1990) (proposed amendment to add CAA § 112(u)).

341. Telephone Interview with U.S. Senator Daniel Patrick Moynihan (Dec. 27, 1990); John D. Graham, Improving Chemical Risk Assessment, REGULATION, Fall 1991, at 14, 15.

342. S. 1630, supra note 340, § 301 (proposed amendment to CAA § 112(i)).

343. See, e.g., Telephone Interview with David Doniger, Senior Attorney, Natural Resources Defense Council (Aug. 28, 1990); see also Telephone Interview with Jimmie Powell, supra note 339; Interview with Phil Barnette, Majority Counsel, Subcomittee on Health and the Environment of the House Committee on Energy and Commerce, in Washington, D.C. (Aug. 23, 1990).

344. See House Clears Bill for Floor, Compromise Reached on Several Amendments, 21 Env't Rep. (BNA) 261 (May 25, 1990).

345. H.R. 3030, 101st Cong., 2d Sess. § 301 (1990) (proposed amendment to CAA § 112(f)). Nevertheless, the modifications in the House proposal did not expunge bright lines from the statute altogether. The House version also included an alternative emissions limitation allowing a specific source to exceed a standard if they could demonstrate site-specific risks for the "actual person who is most exposed to emissions" below 1×10^{-6} . The bill, however, contained no language defining this most exposed actual person. *Id.* § 301 (proposed amendment to CAA § 112(g)).

structed the EPA Administrator to investigate residual risk from air toxics and, after consulting with the Surgeon General, to recommend "legislation regarding such remaining risk."³⁴⁶ The existing narrative language in section 112 requiring an ample margin of safety to protect the public health served as a fallback provision.³⁴⁷

The compromise that emerged from the Conference Committee and that was signed into law by President Bush reflected the Congressional dissension over risk assessment. The enacted amendment retained the House's narrative standard for the permissible level of residual risk (an "ample margin of safety to protect the public health") as a default standard pending future Congressional action.³⁴⁸ On the other hand, the amendment preserved the Senate's "bright line" as a screening tool³⁴⁹ and priority-setting device.³⁵⁰ If eight years after the initial technologybased standard takes effect, the residual risk to the MEI from a specific category of industrial sources is greater than 10^{-6} , then EPA must promulgate health-based standards.³⁵¹

Congress was so confused by and divided over the risk assessment issue that it ordered the National Academy of Sciences to conduct an

347. It reads:

Id. § 301 (proposed amendment to CAA § 112(f)(2)).

348. See H.R. CONF. REP. NO. 952, 101st Cong., 2d Sess. 339 (1990), reprinted in 1990 U.S.C.C.A.N. 3867, 3871.

349. The enacted amendment reads:

(B) The Administrator may delete any source category from the list under this subsection . . . whenever the Administrator makes the following determination or determinations as applicable:

(i) In the case of hazardous air pollutants emitted by sources in the category that may result in cancer in humans, a determination that no source in the category ... emits such hazardous air pollutants in quantities which may cause a lifetime risk of cancer greater than one in one million to the individual in the population who is most exposed to emissions of such pollutants from the source.

Clean Air Act Amendments of 1990, Pub. L. No. 101-549, § 301, 104 Stat. 2399, 2538-39 (1990) (codified as amended at 42 U.S.C.A. § 7412(c)(9)(B)(i) (West Supp. 1992)).

350. The relevant provisions state:

[T]he administrator shall ... 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 the date of enactment of the Clean Air Act Amendments of 1990).... If standards promulgated pursuant to subsection (d) 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.

Id. § 301, 104 Stat. at 2543-44 (codified at 42 U.S.C.A. § 7412(f)(2)(A) (West Supp. 1992)). 351. Id.

^{346.} Id. § 301 (proposed amendment to CAA § 112(f)(1)).

If Congress does not act on any recommendation submitted under paragraph (1), the Administrator shall, within 8 years after promulgation of standards for each category or subcategory of sources pursuant to subsection (d), promulgate standards for such category or subcategory in accordance with this section if promulgation of such standards is required in order, in the Administrator's judgment, to provide an ample margin of safety to protect public health

independent study of EPA methods, which is currently underway.³⁵² In addition, Congress created a Bipartisan Commission on Risk Management to study the proper use of risk assessment in environmental legislation and regulation and to propose appropriate legislation.³⁵³

B. Recent Legislative Proposals

Congress has also considered enacting bright lines in legislation governing food safety and water quality standards. A brief review of these proposals provides a good indication of the degree of sophistication in Congressional thinking on these issues.

Amendments to the Federal Food, Drug and Cosmetic Act (the FFDCA) incorporating risk levels were first proposed in 1989.³⁵⁴ The amendments' sponsors sought to resolve the "Delaney Paradox."³⁵⁵ The proposals would have eliminated the dichotomy between acceptable tolerance levels for pesticides in raw agricultural produce and those in processed foods by enacting a single "negligible risk" standard.³⁵⁶ Rather than allowing EPA to define negligible levels of risk, the bills specified a bright line³⁵⁷ and extensive QRA methodology.³⁵⁸

The 1991 proposed amendments to the FFDCA,³⁵⁹ entitled "Safety of Pesticides in Food Act of 1991," also contain a bright line provision for pesticide residues. The bill calls on the Administrator of EPA to

353. Id.

356. See S. 722, supra note 354, § 4 (proposed amendment to FFDCA §§ 408, 409).

357. For carcinogenic residues or cases in which adverse human health effects are likely, the bill combined qualitative and quantitative standard-setting criteria:

(I) is not likely to cause or contribute to any additional adverse human health effects in the population exposed to the pesticide chemical residue; and

(II) will not cause or contribute in the population exposed to the pesticide chemical residue to a risk of adverse human health effects which exceeds a rate of one in a million, using conservative risk assessment models.

Id. § 4 (proposed amendment to FFDCA § 408(b)(2)(B)(ii)). The proposed amendments were never enacted.

358. Specifically, calculations of dietary exposure are to assume exposure to the pesticide residue at the tolerance level for a period equal to a lifetime. Id. § 4 (proposed amendment to FFDCA § 408(b)(2)(C)(ii)). The Bill also directed EPA to incorporate certain "conservative" components in its risk assessment. For example, it called for calculations to include all other sources of possible dietary exposure (including drinking water) to the same pesticide chemical residue. Id. § 4 (proposed amendment to FFDCA § 408(c)(2)(B)(i)). While the bills did not direct the agency to consider a maximally exposed individual, they did direct the agency to establish tolerances to protect identifiable population groups (such as infants and other children) with special food consumption patterns. Id. § 4 (proposed amendment to FFDCA § 408(b)(2)(A)(i)).

359. The Senate and House bills proposed in April, 1991, were again identical. S. 1074, 102d Cong., 1st Sess. (1991); H.R. 2342, 102d Cong., 1st Sess. (1991). While similar in their overall objectives, the 1991 bills are somewhat less ambitious than the 1989 efforts.

^{352.} See Freedman, supra note 299.

^{354.} The Senate and House Bills originally were identical. S. 722, 101st Cong., 1st Sess. (1989); H.R. 1725, 101st Cong., 1st Sess. (1989).

^{355.} The term was coined by the National Academy of Sciences. NATIONAL RESEARCH COUNCIL, *supra* note 126, at 22.

determine which pesticides might be carcinogenic at any dose (so-called nonthreshold pesticides) and to set tolerance levels that will "not cause or contribute in individuals exposed to such pesticide chemical residue a lifetime risk of an adverse human health effect which occurs at a rate of one in a million."³⁶⁰ The bill makes special mention of young children, adding a second, annualized 10^{-6} risk level to exposures incurred during the first five years of life.³⁶¹ While the current bill does not specify risk assessment practices in detail, it does call for "conservative risk assessment"³⁶² and consideration of multimedia exposure routes.³⁶³

Legislation also has been introduced that would specify a national bright line for determining water quality standards for dioxin. The Clean Water Act currently commits to the states the authority to set water quality standards in surface waters³⁶⁴ subject to EPA approval.³⁶⁵ As a result, there is currently considerable variability in state water quality standards. This variability is particularly dramatic in the case of dioxin, for which EPA-approved state water quality standards reflect cancer risks that differ by several orders of magnitude.³⁶⁶

A recent proposal in Congress³⁶⁷ seeks to amend the CWA by requiring that a minimum water quality criterion for dioxin be established which will "limit the probability to not more than 1 in 1,000,000 that an individual with high exposure to dioxins in such waters will be diagnosed with cancer as a result of such exposure over a lifetime."³⁶⁸

Although this proposal is the subject of some controversy,³⁶⁹ it is yet another indication of the promise some lawmakers see for bright lines as a means of solving environmental policy problems.

367. H.R. 2084, 102d Cong., 1st Sess. (1991) (proposed April 24, 1991).

368. Id. § 1(a).

^{360.} S. 1074, supra note 359, § 3 (proposed amendment to FFDCA § 408(b)(2)(B)(iii)(I)).

^{361.} The bill defines annualized risk as that "which occurs at a rate of one in a million divided by 70 for any single year of exposure during the first 5 years of the life of an exposed person, using conservative risk assessment models." *Id.*

^{362.} Id.

^{363.} Id. § 3 (proposed amendment to FFDCA § 408(c)(2)(C)).

^{364.} CWA § 303(a), 33 U.S.C. § 1313(a) (1988).

^{365.} Id. § 303(c), 33 U.S.C. § 1313(c).

^{366.} See Memorandum from Martha G. Prothro, Director, Office of Water Regulations and Standards, U.S. Environmental Protection Agency, to EPA Water Management Division Directors and State Water Quality Administrators (Mar. 13, 1991) (discussing EPA's dioxin policy) (on file with author).

^{369.} The Environmental Defense Fund contends the proposal is necessary to force states to meet their commitment under the CWA to protect water quality. The American Paper Institute and the National Forest Products Association oppose the bill, arguing that it usurps state rights and paves the way to imposition of federal land use regulations. See Testimony on H.R. 2084 Before the Subcomm. on Water Resources of the House Comm. on Public Works and Transportation, 102d Cong., 1st Sess. (June 25, 1991) (yet unpublished) (statements of Peter L. deFur, Environmental Defense Fund, and Michael C. Farrar, American Paper Institute and the National Forest Products Association).

The current food safety and clean water bills are not likely to pass soon, primarily because the Bush Administration has not made these issues a top legislative priority. If these issues should become priorities on Capitol Hill in the future, the bright line issue is likely to emerge again.

IV

STATUTORY BRIGHT LINES: A HOST OF POSSIBILITIES

Risk assessment has a profound influence on environmental policymaking, but current laws do not effectively constrain the risk assessment process. A good case can be made that Congress should participate in decisions about risk assessment and management. The apparently arbitrary diversity of agency cancer risk assessment practices, along with disappointment over the number and stringency of EPA rules, has fueled sentiments in favor of adding bright lines to new environmental legislation.³⁷⁰

This part of the article examines how Congress might use bright lines to control agency discretion. If Congress wants to use bright lines to better control agency discretion, it must carefully consider how to construct and apply those bright lines. Congress could devise a variety of bright lines aimed at achieving different policy goals; in any given situation, Congress should consider which type of bright line would best serve its goals.

A. Bright Lines in Priority Setting

Although many proposed uses of bright lines have addressed the stringency of standards, bright lines can also be used as a priority-setting

Industry groups, on the other hand, have long advocated greater agency use of risk assessment but are staunchly opposed to bright lines. Some industry groups and the Bush Administration have flirted with a nonzero bright line to replace the Delaney Clause, although a political consensus within industry on how to reform the Delaney Clause has never emerged. Telephone Interview with Kathryn Rosica, Chemical Manufacturers Association (Dec. 15, 1991).

^{370.} In public discussions of risk assessment, the position of major national environmental organizations such as the Natural Resources Defense Council (the NRDC) has evolved considerably since the 1970's.

Environmentalists historically have been suspicious of risk assessment and have opposed its use in major decisions regarding standards. However, EPA's increasing utilization of QRA, along with some degree of consensus within the scientific community that risk assessment can be useful, induced environmentalists to reconsider their position. Judge Robert Bork's *Vinyl Chloride* decision under section 112, originally heralded as a victory for NRDC in its efforts to increase the stringency of air toxics control, prompted EPA to set MEI risk levels that the NRDC felt were too permissive. *See* Natural Resources Defense Council v. EPA, 824 F.2d 1146 (D.C. Cir. 1987), *rev'g* 804 F.2d 710 (D.C. Cir 1986). In response, NRDC departed from its traditional position decrying QRA in the belief that flaws in present EPA air policy were best remedied by congressional intervention to establish a more appropriate maximum allowable risk level. Telephone Interview with David Doniger, Senior Attorney, Natural Resources Defense Council (Sept. 4, 1990).

technique. Legislation might direct an agency to target for regulatory consideration those chemical exposures which exceed a bright line.³⁷¹ EPA's solid waste programs currently utilize QRA in precisely this fashion without specific legislative authorization.³⁷² Used in this way, bright lines encourage sensible use of scarce resources.

More generally, Congress might require that EPA initiate rulemakings if risk assessments suggest that the magnitude of a particular health problem exceeds some specified numerical standard. Likewise, Congress might require EPA to refrain from rulemakings if risk assessments suggest that the magnitude of the health problem is less than some specified numerical value. Currently, agencies have considerable discretion in targeting rulemaking activity; this type of bright line might enable Congress to influence EPA's priority setting. Congress made use of this type of bright line to trigger residual emission standards for air toxics under the 1990 Clean Air Act Amendments.³⁷³

From a scientific perspective, the use of cancer risk estimates in priority setting is less problematic than it is in standard setting.³⁷⁴ Risk assessment techniques may establish relative risk with more certainty than they establish an absolute level of risk protection.³⁷⁵ EPA has relied on risk assessment to make just such judgments in the past. For example, EPA made limited use of risk assessments to set priorities across agency programs in its *Unfinished Business Report*.³⁷⁶ More recently, the EPA Science Advisory Board (the SAB) employed comparative risk assessment in its highly publicized report, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*.³⁷⁷

B. Bright Lines in Standard Setting

The most simplistic bright line is a single risk number that establishes the maximum cancer risk a particular rule may permit. Several

376. OFFICE OF POLICY ANALYSIS, supra note 185.

^{371.} On the implicit bright lines that governed EPA decisions in the 1980's, see Travis et al., supra note 147.

^{372.} See supra part II.E.

^{373.} See supra notes 348-51 and accompanying text.

^{374.} Not all risk assessors are optimistic that cancer risk assessment methods will be useful in priority setting. For example, if the degrees of uncertainty in the estimates of risk for two chemicals are both very large, it may not be clear which chemical deserves higher priority. FINKEL, supra note 44, at 60-62.

^{375.} See Rodricks et al., supra note 147, at 316-17; Russel and Gruber, supra note 130, at 286-87; JOSEPH C. RODRICKS ET AL., USE OF RISK INFORMATION IN REGULATION OF CAR-CINOGENS (1987).

^{377.} SCIENCE ADVISORY BD., U.S. ENVTL. PROTECTION AGENCY, REDUCING RISK: SETTING PRIORITIES AND STRATEGIES FOR ENVIRONMENTAL PROTECTION (1990). For a review of the report and its implications, see David Clarke, *Looking at Risk*, ENVTL. FORUM, Mar.-Apr. 1991, at 12. EPA's own *EPA Journal* devoted an entire edition to the SAB report, recording a variety of viewpoints on the issue of priority setting through QRA. See 17 EPA J., Mar.-Apr. 1991.

states and the Food and Drug Administration have experimented with this approach.

New Jersey's 1984 Amendments³⁷⁸ to its Safe Drinking Water Act³⁷⁹ embody this approach:

The commissioner, after considering the recommendations of the Drinking Water Quality Institute, shall, within two years of the effective date of this amendatory and supplementary act . . . establish, within the limits of medical, scientific, and technological feasibility, maximum contaminant levels for each chemical or chemical compound on the list which, with respect to carcinogens, permit cancer in no more than one in a million persons ingesting that chemical for a lifetime³⁸⁰

Within three years of the Amendments' enactment, the Department of Environmental Protection recommended drinking water standards for twenty-two toxic compounds.³⁸¹

California's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986,³⁸² does not contain a bright line, but prohibits the discharge of carcinogens into potential sources of drinking water unless the emitter can prove that the discharges do not present a significant risk, assuming lifetime exposure at the level in question.³⁸³ Potential exposures to carcinogens through other media which exceed the significant risk level trigger Proposition 65's warning provisions.³⁸⁴ Subsequently promulgated regulations set the level of significant risk at 10^{-5} on a lifetime basis,³⁸⁵ effectively a bright line.³⁸⁶ To date, fifty standards have been set under Proposition 65.³⁸⁷

382. Safe Drinking Water and Toxic Enforcement Act, CAL. HEALTH & SAFETY CODE §§ 25249.5-.6 (West Supp. 1992). For a description of the Act, see Kristen R. Stevens, Regulating Toxics at the State Level, Proposition 65's Warning Requirement, 9 STAN. ENVTL. L. J. 84 (1990). The Act was passed through the voter initiative process and amends the California Constitution.

383. CAL. HEALTH & SAFETY CODE § 25249.10 (West Supp. 1992). For a discussion of the implementation of Proposition 65, see Kenneth W. Kizer et al., Sound Science in the Implementation of Public Policy: A Case Report on California's Proposition 65, 260 J. AM. MED. Ass'N 951 (1988).

384. "Expose" is defined in the subsequent regulations. See CAL. CODE REGS. tit. 26, § 22-12201(f) (1992).

385. "[T]he risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question." Id. § 22-12703(b) (1992).

386. For a comparison of California's risk assessment methodology with EPA's QRA practices, see William S. Pease et al., *Risk Assessment for Carcinogens Under California's Proposition 65*, 10 RISK ANALYSIS 255 (1990).

387. Pursuant to Proposition 65, the Office of Environmental Health Hazard Assessment, now part of California's Department of Toxic Substances Control, has published a list of 376

^{378.} Act of Jan. 9, 1984, ch. 443, 1983 N.J. Laws 1801.

^{379.} N.J. STAT. ANN. § 58.12A-1 to -25 (West Supp. 1990)).

^{380.} N.J. STAT. ANN. § 58.12A-13(b) (West Supp. 1990).

^{381.} N.J. DRINKING WATER QUALITY INST., MAXIMUM CONTAMINANT LEVEL REC-OMMENDATIONS FOR HAZARDOUS CONTAMINANTS IN DRINKING WATER (1987) (submitted to N.J. Dep't of Envtl. Protection).

Wisconsin's surface water quality standards also employ a conventional bright line.³⁸⁸ The regulations expressly set the bright line, stating that "the incremental cancer risk from exposure to surface waters may not exceed 1 in 100,000."³⁸⁹ Moreover, the regulations specify how this number is to be calculated, including use of a specific risk formula.³⁹⁰ The Wisconsin regulations stipulate use of a linear dose-response model and make several other assumptions more commonly left to the individual risk assessor.

In each of the above cases, the legislature has employed a bright line to establish the appropriate degree of regulatory stringency. While the specific risk levels are arbitrary, they provide a numeric definition of how safe is safe enough.

C. Maximum Individual Risk Versus Population Risk

In drawing bright lines, legislators should state what fraction of the exposed population must meet the mandated risk level. For example, a proposal to protect the public against cancer risks of one in a million lifetimes should indicate whether such protection must be provided for the average exposed person, the maximally exposed person, or some highly exposed person at, say, the ninety-fifth percentile of the exposure distribution.

An ethical argument has been made that every person should receive some minimum level of health protection from involuntary expo-

- 388. WIS. ADMIN. CODE § NR 105.09 (Mar. 1989).
- 389. Id.
- 390. The mandated formula is:

 $HCC = (RAI \times 70) / (W_{H} + (F_{H} \times BAF))$

Where:

- HCC = Human cancer criterion in milligrams per liter (mg/L);
- RAI = Risk associated intake in milligrams toxicant per kilogram body weight per day (mg/kg/d) that is associated with a life time incremental cancer risk equal to one in 100,000;
- 70 = Average weight of an adult male in kilograms;
- W_{H} = Average per capita daily water consumption of two liters per day (L/d) for surface waters classified as public water supplies;
- F_H = Average per capita daily consumption of sport caught fish by Wisconsin anglers equal to 0.02 kilograms per day (kg/d); and
- BAF = Aquatic life bio-accumulation factor in liters per kilogram (L/kg).

Id. § 105.10 (Mar. 1989).

carcinogens and 127 reproduction toxicants "known to the state to cause cancer or reproductive toxicity." See William S. Pease, Identifying Chemical Hazards for Regulation: The Scientific Basis and Regulatory Scope of California's Proposition 65 List of Carcinogens and Reproductive Toxicants, 3 RISK: ISSUES IN HEALTH & SAFETY 127, 130 (1992); CAL. HEALTH & SAFETY CODE § 25249.8 (West Supp. 1992). It has set standards, or "risk specific" allowable daily intake levels, for 50 of the most widely used ones. Leslie Roberts, A Corrosive Fight over California's Toxics Law, 243 SCIENCE 306, 307 (1989); see also David Roe, An Incentive-Conscious Approach to Toxic Chemical Controls, 3 ECON. DEV. Q. 179 (1989) (discussing implementation of Proposition 65).

sure to toxic chemicals.³⁹¹ At the same time, public health officials generally seek a greater level of protection for the average exposed person than for the maximally exposed person because of concern for the number of people exposed.³⁹² As the size of the exposed population increases, standards should (and do) become more stringent.³⁹³

Because the background cancer risk in the United States is one in four,³⁹⁴ an incremental lifetime cancer risk of one in a million is a trivial change to any individual—an increase from .25 to .250001. An individual exposed to 100 agents, each imposing an incremental risk of one in a million, suffers only a slight increase in total risk, from 0.2500 to 0.2501, probably still not a major concern.

However, a lifetime risk of one in a million arguably attains public health significance if millions of people incur that level of risk. For example, if 200 million people are each exposed to a lifetime cancer risk of one in a million, the expected consequence is 200 additional cases of cancer. (For a rough annual figure, one can divide 200 by 70 years, or fewer than 3 cases per year.) On the other hand, if only 2,000 people are exposed, the expected consequence is only a small fraction of a single additional cancer (0.002).

The FDA's choice of a 10^{-6} risk level reflects in part this type of consideration. In choosing this risk level, the FDA was seeking to protect the American public from carcinogens in the meat supply.³⁹⁵ Because the population of concern was the entire meat consuming population of the United States, the FDA initially choose a risk level of 10^{-8} , which it regarded as essentially zero risk. It later revised this number to 10^{-6} when it enacted a more protective method of risk calculation.³⁹⁶ In summary, policymakers can account for public health sig-

Discrimination in housing applies to individuals. You don't get more protection because you belong to a group with a large number of individuals. And if you belong to a minority group with a small number of individuals, that doesn't mean that you should only receive a small amount of protection.

Telephone Interview with David Doniger, *supra* note 370. For more technical versions of this argument, see Travis & Hattemer-Frey, *supra* note 147.

392. See Paul Milvy, A General Guideline for Management of Risk from Carcinogens, 6 RISK ANALYSIS 69 (1986); Goldstein, supra note 120.

393. See Chris Whipple, Preface to DE MINIMIS RISK ix (Chris Whipple ed., 1987).

394. See Herbert Seidman et al., Probabilities of Eventually Developing or Dying of Cancer-United States, 1985, 35 CA-A CANCER JOURNAL FOR CLINICIANS 36 (1985).

396. The more conservative a method of risk assessment, the more it tends to overestimate

^{391.} See, e.g., Anthony D. Cortese, Preventing Hazardous Air Pollution, ENVTL. FORUM, Nov.-Dec. 1988, at 22, 24. Groups such as the National Resources Defense Council believe that citizens should have a right not to be subjected involuntarily to hazards in their living environment.

^{395.} See Compounds Used in Food Producing Animals—Procedures for Determining Acceptability of Assay Methods Used for Assuring the Absence of Residues in Edible Products of Such Animals, 38 Fed. Reg. 19,226 (1973); Criteria and Procedures for Evaluating Assays for Carcinogenic Residues, 42 Fed. Reg. 1042 (1977) (relying largely on Mantel & Bryan, *supra* note 142, at 455).

nificance by enacting tougher bright lines for the average exposed person than for the MEI and by making the bright line even tougher as the size of the exposed population increases.³⁹⁷

Policymakers can also give weight to the size of the exposed population by drafting a bright line capping the number of expected cases of cancer, or "population risk," arising from a particular source. For example, the public might accept a national population risk due to a pesticide or category of polluters of less than one (that is, less than one additional case of cancer per year).³⁹⁸ Indeed, EPA interprets current legislative proposals for pesticide tolerances as specifying such a test.³⁹⁹ Unlike the MIR measure, which is not sensitive to the size of the exposed population, the population risk measure requires stricter controls if the size of the exposed population increases.

Bright line standards based on population risk are sometimes determined on a piecemeal basis (i.e., state by state, pesticide by pesticide, plant by plant, or site by site). Unless these risks are aggregated, these standards may conceal the total population risk due to the activity. For example, if 250 Superfund sites each pose an acceptable cancer risk of 0.8 cases per year, the total incidence permitted at all 250 Superfund sites would be 200 cases of cancer per year, which the public might regard as unacceptable.

Some risk analysts have proposed that risk managers might consider both maximum individual risk and population incidence by establishing a

397. On the importance of considering population risk, see Joseph C. Reinert et al., A Discussion of the Methodologies Used in Pesticide Risk-Benefit Analysis, 12 ENVTL. PROF. 94 (1990).

398. EPA decided on this standard as an option for consideration during its benzene rulemaking. See National Emission Standards for Hazardous Air Pollutants, 54 Fed. Reg. 38,044, 38,045-46 (1989) (referencing Approach B, which considers cancer incidence of less than one case per year a measure of acceptability).

399. "S. 722 codifies this standard and then adds a second criterion... I understand that this language means that it is not likely that there will be an additional cancer case in the entire U.S. population from the residues of a pesticide in food." Hearing on S. 722 to Amend the Federal Food, Drug, and Cosmetic Act to Revise the Authority Under that Act to Regulate Pesticide Chemical Residues in Food Before the Senate Comm. on Labor and Human Resources, 101st Cong., 1st Sess. 104, 114 (June 6, 1989) [hereinafter Hearing on S. 722] (statement of Victor J. Kimm, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency).

actual risk. In the first notice, FDA stated: "Absolute safety can never be conclusively demonstrated experimentally. The level defined by the Mantel-Bryan procedure is an arbitrary but conservative level of maximum exposure resulting in a minimal probability of risk to an individual (e.g. 1/100,000,000)..." 38 Fed. Reg. 19,227 (1973). When FDA replaced the Mantel-Bryan procedure with a linear low-dose model, they replaced the 10^{-8} isk level with a 10^{-6} risk level. Hutt, *supra* note 10, at 22-24. On the early history of FDA's use of the one-ina-million risk test, see COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, *supra* note 2, at 56-57. A recent survey conducted by Kathryn Kelly indicates that neither government officials, environmentalists, nor industry leaders know the origins of the one-in-a-million risk level or can provide a normative basis for this level of protection. Kelly, *supra* note 15.

bright line based on the product of the two values.⁴⁰⁰ According to this view, any product of the two risk measures that exceeds, say, 1 in 10,000 might be regarded as unacceptable. For example, an MIR of 1 in 10,000 combined with 1 case of cancer in the population would be on the borderline of unacceptability. If population risk is less than one case, a higher level of risk to the MEI would be tolerable. This proposal, although mathematically arbitrary, has the intuitive appeal of incorporating both MIR and population incidence into the bright line of risk acceptability. Some other function of MIR and population incidence (rather than a simple product of the two) could allow for different weighting of the measures depending on policy judgments about the relative importance of protecting individuals and reducing incidence.

D. Cost-Effectiveness Bright Lines

Professional economists generally prefer bright lines that incorporate information about both risk reduction and the economic costs of regulation. Responding to such concerns, the Office of Management and Budget (the OMB) has often argued for limits on the amount of money that a regulatory program may spend to avert one case of cancer.⁴⁰¹ This proposal has not been adopted by any organized political constituency, and its methodological and ideological legitimacy is challenged by environmentalists.

As an example of such an approach, Congress could require EPA to reduce residual cancer risks until the marginal cost of preventing another case of cancer exceeded \$5,000,000.⁴⁰² The maximum expenditure could be revised periodically to adjust for inflation.⁴⁰³ Alternatively, one can justify this rough level of expenditure on the basis of economic studies of people's willingness to pay money to reduce mortality risks,⁴⁰⁴ although

402. Note that this type of analysis would require accurate estimates of costs, which may be as difficult as estimating risks. See Evans et al., supra note 8.

403. This particular figure might be offered in light of one study's estimates that each \$5,000,000 spent on regulatory measures is associated with one premature fatality due to reduced family incomes. See Ralph L. Keeney, Mortality Risks Induced by Economic Expenditures, 10 RISK ANALYSIS 147 (1990) (developing a model for estimating the number of fatalities possibly induced by economic expenditures).

404. See, e.g., W. Kip Viscusi, The Valuation of Risks to Life and Health, in BENEFIT ASSESSMENT: THE STATE OF THE ART 193-210 (Judith D. Bentkover et al. eds., 1986). See

^{400.} See e.g., Adam Finkel, Resources for the Future: A Way Out of the "Individuals Versus Populations Dilemma in Air Toxics Regulation (Feb. 26, 1990) (unpublished manuscript, on file with author); see also Peter Preuss, Making Acceptable Risk Acceptable, ENVTL. FORUM, Nov.-Dec. 1988, at 22, 27-28 (proposing a resolution of this issue).

^{401.} See OMB Position on Use of Risk Assessment, Cost-Effectiveness Analysis, Benefit-Cost Review in Setting Standards for Toxic Air Pollutants, 14 Env't Rep. (BNA) 1593 (Dec. 8, 1983) (generally criticizing EPA's bright-line approach and use of risk assessment); John D. Graham & James W. Vaupel, The Value of Life: What Difference Does It Make?, 1 RISK ANALYSIS 89, 94 (1981) (concluding that comparing opportunities for saving lives may contribute to the political process of setting health standards).

such estimates reflect defects in the marketplace, such as imperfect information about risks to health and inequities in ability to pay to reduce risk.

Contrary to popular belief, the OMB does not employ a specific cost-effectiveness ratio when it reviews proposed environmental regulations.⁴⁰⁵ In fact, the federal government has never assigned an acrossthe-board monetary value of saving a life. Historical studies have demonstrated that cost-effectiveness considerations play a critical role in EPA decisions, particularly when maximum individual risks are between one in 10,000 and one in a million.⁴⁰⁶

Economists have noted that some environmental rules are far more expensive per life saved than many chronically underfunded public health programs.⁴⁰⁷ Reformers frequently cite this fact in support of recommendations for more efficient allocations of resources.⁴⁰⁸ A cost-effectiveness bright line could provide interagency and interprogram consistency. To the extent that Congress wishes to maximize public health protection through the rationing of finite resources, it could use bright lines based on cost-effectiveness to leverage the process toward more efficient allocations of resources.

E. Fuzzy Bright Lines

The above approaches to bright lines all mandate a single numeric value to restrict regulatory discretion. An alternative approach would be to draft legislation specifying a range of numeric values within which regulators could exercise discretion. For example a statute might permit the agency to set standards for lifetime cancer risk from exposure to carcinogens between 10^{-4} and 10^{-6} . During congressional discussions on

406. Travis et al., supra note 147.

408. "Congress can see the whole playing field. We don't think that EPA makes decisions that reflect the best allocation of society's resources. The Surgeon General can equalize between agencies and dollars per life saved." Interview with Leslie King, Chemical Manufacturing Association, in Washington, D.C. (Aug. 30, 1990). See generally W. Kip Viscusi, The Value of Life and Limb, in RISK BY CHOICE: REGULATING HEALTH AND SAFETY IN THE WORKPLACE, supra note 404. A general call for greater cost-effectiveness in EPA regulatory activity can be found in U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-91-97, ENVIRONMENTAL PROTECTION: MEETING PUBLIC EXPECTATIONS WITH LIMITED RESOURCES (1991).

generally W. KIP VISCUSI, RISK BY CHOICE: REGULATING HEALTH AND SAFETY IN THE WORKPLACE (1983).

^{405.} Interview with Dr. Richard Belzer, Office of Information and Regulatory Affairs, Office of Management and Budget, in Washington, D.C. (Sept. 13, 1990).

^{407.} See generally Graham & Vaupel, supra note 401, at 94 (discussing the value of avoided death); MARTIN J. BAILEY, REDUCING RISKS TO LIFE 52-66 (1980) (discussing compensation per death for risk averse workers); LESTER B. LAVE, THE STRATEGY OF SOCIAL REGULATION: DECISION FRAMEWORKS FOR POLICY 19-21 (1981) (discussing cost-effective-ness as compared to cost-benefit analysis).

the Clean Air Act, such a risk range became known informally as a "fuzzy bright line."⁴⁰⁹

Risk managers in several EPA program offices already use such ranges to guide their decisions, without statutory directives.⁴¹⁰ So does the New Jersey Department of Environmental Protection's Division of Environmental Quality:

Incremental 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.⁴¹¹

Similarly, cost-effectiveness benchmarks based on expenditures per case of cancer averted need not be written into laws as single numbers. Legislators could require that the marginal cost of a decision to protect public health fall within a range, for example five to fifty million dollars per life saved. Congress could then establish criteria to help regulators decide where within the acceptable range regulators should set the level of expenditure in specific rulemaking contexts. For example, Congress might compel expenditures towards the high end of the range if the maximum individual risk exceeded a specific value, such as 10^{-4} .

A risk range guarantees a minimum level of protection against risk, while allowing additional factors to have influence when risks fall in the fuzzy region. The fuzzy bright line shares the chief virtue of narrative statutes: it allows government agencies to balance a number of factors when setting standards within the permissible range of risk. The marginal cost of more stringent environmental controls might constitute an additional consideration in the policy equation, but there are many others. The size of the population exposed, the classification of the carcinogen, the degree of public concern about the risk, the potential for concomitant ecological damage, the availability of technological solutions, and the possibility of risk-risk tradeoffs are all salient factors to be considered.

One disadvantage of the fuzzy bright line is that it might allow residual risk to cluster at the high end of the risk range. Experience under Superfund has shown that a "point of departure" approach can minimize this danger. Under Superfund, risk managers seek to attain the smallest risk within the range. In effect, a burden of proof is created for those advocating a more permissive risk within the risk range. A risk

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^{409.} The idea had been advocated by a group of moderate Democrats, led by Representative Tauzi.

^{410.} See supra part II.

^{411.} J.L. Held & O. Boyko, New Jersey Risk Assessment Guidelines for Resource Recovery Facilities (June 1991) (unpublished paper presented at the 84th Annual Meeting of the Air and Waste Management Association, on file with author).

manager selecting a more lenient risk level must provide ample justification.⁴¹²

On the plus side, a risk range might enable regulators to be more open and forthcoming about how they make their decisions. The full range of issues which arise in the policy considerations would be presented for public scrutiny, rather than considered secretively or implicitly. Concerns about manipulation of QRA assumptions and factors would be reduced as government agencies would be able to express openly the obstacles to attaining de minimis risks through environmental regulation.

Furthermore, a "risk range" enables risk managers to consider the full breadth of scientific information, including uncertainty, when risks fall in the fuzzy region. Risk managers could consider information on biological mechanisms of carcinogenicity and the quality of exposure and toxicity data, using their professional judgment, rather than being forced to make their operational decisions on the basis of inaccurate point (i.e. single number) estimates of risk.

Despite these advantages, it must be recognized that the current state of the art of cancer risk assessment cannot provide the degree of accuracy implied by a risk range that covers only one or two orders of magnitude. In consequence, neither regulators nor the public can be certain that cancer risks fall within a risk range that spans a factor of only 100. The width of the fuzzy bright line should be determined with an understanding of the magnitude of the scientific uncertainties in the risk estimates.

In summary, if Congress decides to replace narrative statutes with bright lines, it has a number of options. In any given situation, Congress could enact any of a variety of types of bright lines. To choose an appropriate type of bright line, Congress must have a clear sense of the public policy goals that it seeks to promote. For example, a simple cost-effectiveness bright line may not offer meaningful protection to a person at maximum individual risk, while a bright line designed to protect only the maximum exposed individual may not provide adequate protection against population risk.⁴¹³ Current proposals to legislate bright lines do not reflect much understanding of how public policy goals would be either served or shortchanged.

V

NARRATIVE VERSUS BRIGHT-LINE STATUTES

When Congress considers statutory approaches for regulating chemical carcinogens, the first issue is often how much discretion to afford the

^{412.} See supra part II.E.2 (discussing CERCLA).

^{413.} Goldstein, supra note 120.

administrative agency. In this part of the article, we examine whether bright lines will serve as an effective means of constraining agency discretion. A legislative decision to replace traditional narrative criteria with numerical levels of acceptable risk will also have ramifications beyond any ostensible attempt to constrain agency discretion. Therefore, we examine a range of other arguments for and against the use of legislated risk levels in the regulation of human exposure to carcinogenic chemicals. We evaluate the alternative statutory designs by considering the following questions:

(A) Which approach to statutory construction will offer the greatest de-

gree of democratic control over sensitive policy judgments?

(B) Which approach will best encourage both public health and economic efficiency in the regulation of chemical carcinogens?

(C) Which approach will best promote the use of existing scientific knowledge by regulators while encouraging the generation of improved scientific information about chemical risks?

(D) Which approach will best encourage regulators to educate Congress and the public about the critical issues and conflicting values in regulating human exposure to carcinogenic chemicals?

(E) Which approach will most effectively reduce the inconsistencies in risk assessment practices and risk management decisions within EPA and between executive agencies?

A. Promoting Democratic Control

The current process of making risk management decisions requires unelected administrative officials to make fundamental policy judgments about what levels of carcinogenic risk are acceptable.⁴¹⁴ Many observers are dissatisfied with the placement of such power in the hands of administrators who are not directly accountable to the public. Such critics argue that bright lines would promote democratic control of policymaking by forcing Congress to make the fundamental value judgments about how much incremental cancer risk from pollution is acceptable.⁴¹⁵

Under current laws, administrative agencies are free to exploit the inherent ambiguity of narrative statutory criteria when determining the scope and stringency of chemical regulations. Agency discretion is broad because courts are inclined to defer to agency rulemaking decisions unless they clearly violate the statutory mandate, represent a clear error in judgment, or are the product of an arbitrary or capricious response to the

^{414. &}quot;Some will say this is an issue for the EPA, not Congress. But the Coalition [consisting of environmental groups such as NRDC, EDF, and ALA] asks why *shouldn't* there be a limit on how long an unelected administrative agency can allow an industry to put off protection of public health?" S. 816 Hearing, supra note 336, at 191 (statement of David Doniger) (emphasis in original).

^{415.} Interview with Phil Barnette, *supra* note 343; Telephone Interview with Jimmie Powell, *supra* note 339.
evidence at hand. From a separation of powers perspective, narrative statutes governing regulation of carcinogens may also violate the constitutional requirements of bicameralism and of approval of policy decisions by both the executive and the legislature.

In considering the democracy argument, we should remember that the Administrator of EPA and the Commissioner of the FDA are appointed by the President with the approval of the United States Senate.⁴¹⁶ Those who favor a representative democracy with a strong President and a weak Congress will dispute the claim that executive branch discretion is undemocratic. Since the President, like the members of Congress, is an elected official, this issue can be resolved only by a coherent and precise theory of how power should be divided among Congress, the President, and subordinate executive branch officials. Nonetheless, it might be desirable for executive branch officials to receive more explicit guidance from Congress about how stringently to control human exposures to carcinogenic chemicals.⁴¹⁷

During the Reagan Administration, in particular, environmentalists and their allies in Congress felt that the ambiguity of narrative statutes permitted administrative agencies to set excessively lenient standards.⁴¹⁸ The opposite problem could occur under future administrations, of course, with administrative agencies setting standards under narrative criteria that are more stringent than industry and its allies in Congress would prefer.

Even within the same administration, inconsistencies in the application of narrative statutory standards are often widespread. There is no assurance that the differing risk assessment practices and levels of protection at the various administrative agencies (such as the FDA and EPA)

417. For an argument against unnecessary congressional delegation of power, see Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 670 (1983) (Rehnquist, J., concurring).

418. See generally Stewart Udall, Encounter with the Reagan Revolution, in CROSSROADS, ENVIRONMENTAL PRIORITIES FOR THE FUTURE 99 (Peter Borrelli ed., 1988) (noting the ability of the Reagan administration to fulfill its antienvironmentalist agenda by lack of enforcement and budget cuts, rather than repeal of environmental laws); Thomas Walton & James Langenfeld, Regulatory Reform under Reagan—The Right Way and the Wrong Way, in REG-ULATION AND THE REAGAN ERA, POLITICS, BUREAUCRACY AND THE PUBLIC INTEREST 41 (Roger Meiners & Bruce Yandle eds., 1989) (arguing that regulatory improvements made during the Reagan Administration were largely the result of the work of agency heads); JONATHAN LASH ET AL., A SEASON OF SPOILS: THE STORY OF THE REAGAN ADMINISTRA-TION'S ATTACK ON THE ENVIRONMENT (1984) (providing a narrative account of the Reagan Administration's approach to environmental laws).

^{416.} Recently, Congress passed the "FDA Charter," which officially delineates the position of Commissioner. See 21 U.S.C.A. § 393(b) (West Supp. 1992). EPA's Administrator derives authority from the 1970 Executive Reorganization Plan. See GOVERNMENT'S ENVI-RONMENTALLY RELATED ACTIVITIES—MESSAGE FROM THE PRESIDENT, H.R. DOC. No. 366, 91st Cong., 2d Sess. (1970), 116 CONG. REC. 23,528-31 (1970). The President acted pursuant to 5 U.S.C.A. § 901 (West Supp. 1992) (giving the Executive the power to reorganize agencies).

are anchored in congressional policy judgments,⁴¹⁹ nor is it clear that congressional drafting can control this diversity of response. Furthermore, as we observed in part II, different program offices within EPA seem to strive for different numerical levels of risk protection when setting standards for carcinogenic exposure.⁴²⁰ These differences have no obvious basis in different statutory criteria for determining the stringency of standards. Moreover, program offices applying similar narrative statutes make different uses of risk assessment in regulatory decisions.

Concerned by the ambiguities and inconsistent administrative activities which narrative criteria produce, some have argued that Congress should make the critical policy judgments by mandating a numerical level of risk to which regulatory decisions must conform. According to this view, Congress has not only the prerogative, but also the responsibility, to make these crucial policy judgements.⁴²¹ By deciding what numerical level of protection is required, Congress would replace the judgments of unelected and unaccountable administrative officials with the judgments of elected officials who are directly accountable to the public.

Regardless of one's theory of democracy, our analysis of the risk assessment process suggests that mandated risk levels per se would do little to assert democratic control over the standard setting process. The numerous semitechnical, semipolicy judgments pervasive in the calculation of carcinogenic risk could frustrate any congressional attempt to control regulatory decisions through specification of risk levels.

We saw, for example, that alternative choices of exposure assumptions and dose-response models can lead to plausible risk estimates that vary by several orders of magnitude.⁴²² If 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. For example, if EPA's initial estimate of the cancer risk from exposure to formaldehyde

^{419.} For example, the FDA believes that some carcinogens have a threshold and at low levels do not impair human health. It bases this belief on information about their mechanisms of action. Accordingly, the FDA believes that these substances should be regulated like all other chemicals. This position runs counter to EPA's nonthreshold position. See Hearings on S. 1074 Before the Senate Comm. on Labor and Human Resources, 102d Cong., 1st Sess. 48 (July 10, 1991) [hereinafter Hearings on S. 1074] (testimony of Fred R. Shank, Director, Center for Food Safety and Applied Nutrition, FDA, Public Health Service). There is no basis in the authorizing statutes that would explain the agencies' choice of such fundamentally different scientific paradigms.

^{420.} As described in part II, there have been environmental standards set by EPA that differ by as much as three orders of magnitude, ranging from permissible risks under 10^{-4} to those as small as 10^{-7} , the range of risk levels historically used by EPA in its hazardous waste emergency response program. See supra notes 282-94 and accompanying text. Such discrepancies also exist among other federal agencies.

^{421.} Interview with Phil Barnette, supra note 343.

^{422.} Sielken, supra note 95, at 95-131.

appears to be so great as to require huge dislocations in current activities, EPA can reduce its exposure estimates by replacing the hypothetical MEI with the actual MEI, or it can reduce the cancer potency factor by censoring information about the incidence of noncancerous tumors in rats. Likewise, the agency can make more pessimistic assumptions in risk assessment if it believes that Congress has not required a sufficiently stringent level of protection from a specific risk. The large degree of scientific uncertainty permits agency risk assessors to make such changes without undermining the scientific credibility of the risk assessment process. 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. Because courts are poorly equipped to detect such behavior, judicial review would not prove effective in counteracting such evasion of the congressional standard.

As long as the degree of scientific uncertainty in cancer risk assessment is large, the choice of acceptable risk levels for use in regulatory decisions will be of secondary significance. A statutorily mandated risk level could in fact mislead the public about the actual level of public health protection, which can only be ascertained by scrutinizing the risk calculation.⁴²³

Advocates of bright lines are not convinced that agencies would respond by manipulating risk calculations. Administrative agencies historically have been reluctant to depart from their standard risk assessment assumptions despite pressure from both industry and environmentalists. For years, industry groups have urged, with minimal success, changes in risk assessment practice that would replace conservative assumptions with what industrial advocates believe are more realistic ones.⁴²⁴ At the same time, environmentalists have contested claims that risk assessment is too conservative and articulated reasons why cancer risk estimates might be underestimated.⁴²⁵ Interest groups and their allies on the EPA

425. "Interactions [among chemicals] are not considered, the [animal] cancer tests may not have been done adequately, and there may be alternatives to the particular chemical. Moreover, bright lines will center standard setting decisions around cancer risk which is only one of many irreversible health effects." Telephone Interview with Jackie Warren, Staff Attorney, Natural Resources Defense Council (August 28, 1990). See also J.P. Myers & Theo Coloborn, Blundering Questions, Weak Answers Lead to Poor Pesticide Policies, CHEM. & ENG'G NEWS, Jan. 7, 1991, at 40 (arguing that the debates over the carcinogenic risks of pesticides focus too narrowly on residues in foods and should consider other exposure factors).

^{423.} See Hearings on S. 1074, supra note 419, at 26 (comments by Linda Fisher, Assistant Administrator for Pesticides and Toxic Substances, U.S. Environmental Protection Agency).

^{424. &}quot;EPA's current methodology for estimating risk uses multiple assumptions that virtually guarantee a dramatic overstatement of actual risk. Therefore, legislation should not specify risk levels when the methodology is inadequate to realistically estimate actual risk." See S. 816 Hearing, supra note 336, at 12 (comments of Eugene McBrayer, President, Exxon Chemical Co.; Chairman, Executive Committee, Chemical Manufacturers Association, Clean Air Working Group).

Science Advisory Board, an independent group of scientists which advises the EPA Administrator, can effectively block any policy-driven at-

tempt to instigate wholesale departures from standard risk assessment practice.⁴²⁶

One of the reasons that departures from standard assumptions in QRA practice historically have been rare is that existing narrative statutes provide regulators substantial discretion in making regulatory decisions — regardless of the precise numerical findings of QRA. Bright line statutes, as discussed above, shift policy decisions to an earlier stage. By giving more policy weight to quantitative risk estimates, mandated risk levels would encourage agencies to examine more closely the assumptions in their risk assessments. With bright lines occasionally compelling some uncomfortable decisions, regulators might insist that the judgment calls in risk assessments be scrutinized on a case-by-case basis, making departures from the standard assumptions more frequent. Since many departures can be justified as scientifically plausible, they might be welcomed by the EPA Science Advisory Board.

Some advocates of mandated risk levels, recognizing the influential role of assumptions and judgments in QRA, have gone further and advocated that Congress compel agencies to calculate cancer risk estimates in a particular way.⁴²⁷ According to this view, only by specifying both the maximal allowable risk level and the method of calculation can Congress ultimately determine the degree of protection provided to the public. While such an approach would shift some additional power to Congress, it poses some serious problems.

Congress lacks the attention span, expertise, and appreciation of the scientific process to prescribe methods of QRA. The potential for error in translating an evolving science into statutory QRA procedures is enormous.⁴²⁸ Moreover, as we will argue in part V.C. below, mandating a particular QRA methodology might freeze scientific progress in risk assessment.⁴²⁹ In short, in its zeal to control executive agencies, Congress

429. As one expert has testified,

See generally Finkel, supra note 63 (questioning the criticism of quantitative risk analysis and addressing misconceptions about quantitative risk analysis).

^{426.} Graham, supra note 75, at 212-15.

^{427.} Interview with Phil Barnette, *supra* note 343. This appears to underlie California's Proposition 65 regulations and the Wisconsin surface water quality standards described above. See supra notes 382-90 and accompanying text.

^{428.} Even the limited efforts of Congress to specify QRA guidelines reveal how prone legislators are to err in this area. Adam Finkel, of Resources For the Future, points out that Congressional unfamiliarity with basic statistical concepts undermined the legislature's efforts to fashion a "most exposed actual person" in S. 816 that would supplant the MEI. The compromise Senate plan called for exposure levels to lie one standard deviation from the *mean* exposure. The *median* would have made more sense, since the mean plus one standard deviation does not designate a predictable point in the distribution and, in fact, could even exceed the extreme value of the distribution. Telephone Interview with Adam Finkel, Resources for the Future (August 30, 1990).

might sabotage the scientific progress that is critical to advancing the policy goals it wishes to further.

Congress has ample power to exert influence over regulatory decisions without mandating risk levels or prescribing QRA practices. These powers include control of the appropriations process, confirmation of appointments, and the use of oversight hearings.⁴³⁰ Such tools may require more political skill and subtlety than use of authorization language, but Congress frequently uses these tools effectively to exert legislative control over the policymaking process.⁴³¹ Finally, when agencies persist in making regulatory decisions that Congress abhors, Congress can pass specific legislation to correct the situation, as it did in the case of the FDA's attempted ban of saccharin.⁴³²

Advocates of bright lines who see them as a device to guarantee particular policy outcomes should be wary, as congressional participation in risk assessment procedures can have unpredictable outcomes. For example, one version of the Senate's 1990 Clean Air Act Amendments would have required EPA to protect the maximally exposed *actual* person near a factory rather than a hypothetical maximally exposed individual⁴³³—a change that could have reduced estimated exposures by a factor of 100 at some sources.⁴³⁴ Others have suggested that Congress might compel use of "conservative" risk assessment practices such as use of linear dose-response modeling and use of data from the most sensitive tested animal species.⁴³⁵ If Congress were to specify methods of risk calculation, it is not obvious whether the specifications would be more or less conservative than those used in current EPA practice.

While bright lines are unlikely to enhance democratic control over administrative decisions dramatically, there is still ample reason for Congress to learn more about the technical aspects of risk assessment. Even

Hearing on S. 722, supra note 399, at 113-14 (statement of Victor J. Kimm).

430. See generally RANDALL B. RIPLEY & GRACE A. FRANKLIN, CONGRESS, THE BU-REAUCRACY AND PUBLIC POLICY 47-70 (1976) (describing various forms that congressionalagency interaction takes, particularly methods by which Congress tries to influence agencies).

431. See generally GARY ORFIELD, CONGRESSIONAL POWER: CONGRESS AND SOCIAL CHANGE (1975) (analyzing Congress' role in influencing the development of social policy).

432. For a synopsis of the saccharin case, see Merrill, supra note 10, at 29-32.

- 433. See supra note 342 and accompanying text.
- 434. See Hawkins, supra note 117, at 109-11, 115-16.

I note the adoption of a negligible risk standard.... [T]he bill is overly restrictive, both in setting criteria for determining whether a particular risk is negligible and in attempting to set forth just how EPA should calculate risk levels.... Knowledge is advancing rapidly in several scientific areas that bear upon risk assessment, and the bill should give EPA discretion to adopt new scientific methods as appropriate, rather than attempting to specify precisely what methods should be used to carry out the various steps in a risk assessment To lock the risk assessment into place by statute will make it impossible for risk assessments in the future to take advantage of developments in our knowledge of carcinogenesis and other biological effects.

^{435.} Language in the aforementioned proposed Safety of Pesticides in Food Act of 1991 moves in that direction. See supra notes 359-63 and accompanying text.

if Congress decides not to legislate bright lines, it needs some understanding of the intricacies of QRA to use its other powers intelligently, particularly in overseeing agency risk management decisions which affect both highly exposed and susceptible subpopulations and the economic well-being of the nation.

B. Promoting Public Health and Economic Efficiency

In considering whether particular bright lines are a good idea, Congress should consider the ramifications for both public health efficiency and economic efficiency. By public health efficiency, we mean the maximization of public health protection given limited rulemaking and enforcement resources. By economic efficiency, we mean placing some upper limits on the amount of societal resources that will be expended to achieve a given amount of public health protection.

Under existing statutory regimes, both of these efficiency considerations have played a significant role in regulatory decisionmaking.⁴³⁶ Some narrative statutory regimes, such as TSCA's "unreasonable risk" test, permit agencies to consider efficiency concerns,⁴³⁷ while others, such as the Clean Air Act's "ample margin of safety to protect the public health," may restrict agency consideration of economic efficiency.⁴³⁸ Throughout this section, it should be kept in mind that administrative agencies appear to take efficiency concerns into account even when a legal analysis of the prevailing narrative statute suggests that such considerations are unauthorized or explicitly forbidden.⁴³⁹

Bright lines, if set too stringently or too leniently, can compromise public health efficiency by stimulating intense opposition, thereby squandering agency resources in the defense of weak decisions. If EPA must

^{436.} See Curtis C. Travis et al., Cost-Effectiveness as a Factor in Cancer Risk Management, 13 ENVTL. INT'L 469 (1987); Arthur G. Fraas & Vincent G. Munley, Economic Objectives Within a Bureaucratic Decision Process: Setting Pollution Control Requirements Under the Clean Water Act, 17 J. ENVTL. ECON. & MGMT. 35 (1989); Jonathan K. Baum, Legislating Cost-Benefit Analysis: The Federal Water Pollution Control Act Experience, 9 COLUM. J. ENVTL. L. 75 (1983).

^{437.} TSCA § 6(a), 15 U.S.C. § 2605(a) (1988).

^{438.} CAA § 112(b)(1)(B), 42 U.S.C.A. § 7412(b)(1)(B) (West 1983 & Supp. 1992); see also Natural Resources Defense Council v. Environmental Protection Agency, 824 F.2d 1146 (D.C. Cir. 1987) (holding that cost and technological feasibility cannot be considered when determining the safety of an emission). It is not absolutely clear that even these kinds of statutes forbid consideration of costs. For example, the "ample margin of safety" language might be read to permit consideration of the indirect health effects of the economic burdens of regulation.

^{439. &}quot;The [Clean Air] Act forbids the Agency to consider economic costs in setting the primary ambient standards, even though the absence of a threshold for pollution's health effects means that the standards must inevitably constitute a balance between health and the cost of protecting health. The upshot is a fiction." David Schoenbrod, Goals Statutes or Rules Statutes: The Case of the Clean Air Act, 30 UCLA L. REV. 740, 776 (1983); see also Travis et al., supra note 147.

take too much time defending each risk estimate that exceeds a stringent bright line, the agency will not be able to perform very many risk assessments. The end result would be a reduction in the number of rulemakings. This dilemma in regulatory strategy has been summarized by the slogan "overregulation causes underregulation."⁴⁴⁰

While these concerns argue primarily against overly stringent bright lines, rather than against bright lines per se, legislators should keep in mind that it is not always apparent how stringent (or lenient) a bright line is when it is originally constructed. When the Delaney Clause was passed in 1958, for example, it was not thought to be extremely stringent. Few people realized how many chemicals would be found to cause cancer when tested at high doses in animals. When statutes are written to cover multiple products and industries, the cost to industry of compliance with a bright line may not be clear initially. As a result, it also will be difficult to anticipate the costs the agency will face in responding to the ensuing opposition from industry spokesmen and others who allege that the standards are overly stringent. By their very nature, narrative statutes do not require such foresight on the part of Congress, because they allow a practical regulator to seek public health efficiency through case-by-case decisionmaking.

From an economic efficiency standpoint, standards should be set at a level of stringency that is appropriate in light of the resulting reductions of cancer risk and the added societal costs of that risk reduction.⁴⁴¹ A standard is understringent if additional reduction of risk could be achieved at an acceptable cost to society. A standard is overstringent if the incremental costs of risk reduction already exceed the incremental benefits of risk reduction. The economic efficiency of a standard can be assessed in a judgmental fashion, broadly balancing risks and costs, or it can be considered in a formal quantitative analysis that monetizes all risks and costs.

A fundamental flaw of any uniform mandated risk level is that it cannot achieve economic efficiency. The mandated level of risk will be understringent for some pollution sources and overstringent for others, depending on the marginal costs of risk reduction at each source.⁴⁴² For example, a uniform lifetime cancer risk level of one in 10,000 will cause understringency for those sources that can achieve a one in 1,000,000 risk level at little or no incremental cost to society. In contrast, a mandated risk level of 1 in 1,000,000 will cause overstringency at those

^{440.} See John M. Mendeloff, The Dilemma of Toxic Substance Regulation: How Overregulation Causes Underregulation (1988).

^{441.} See BAILEY, supra note 407, at 15-27, 48; EDWARD J. MISHAN, COST-BENEFIT ANALYSIS 109-60 (1976); LAVE, supra note 407, at 1-7.

^{442.} See ROBERT E. LITAN & WILLIAM D. NORDHAUS, REFORMING FEDERAL REGULA-TION (1983).

sources that can achieve a one in 1,000,000 risk level only at unacceptably high costs to society (e.g., plant shutdowns, unemployment and/or substantial reductions in standard of living).

The only case in which a uniform risk level can achieve efficiency is where the marginal cost of reducing risk at each pollution source is identical. Such circumstances are rare. Numerous studies have demonstrated huge disparities in the marginal costs of pollution control at industrial sources;⁴⁴³ these disparities result from such factors as the design of the industrial process, the age of the facility, the atmospheric and temperature conditions at the facility, and the facility's access to the capital and materials needed for pollution control.⁴⁴⁴ While most bright lines would prove inefficient by these criteria, a bright line could be devised that would assure some consideration of economic efficiency. For example, one could construct a bright line which required each source to reduce risk until the ratio of incremental cost to incremental risk reduction exceeds a specified value.

Some environmental advocates have urged Congress to prohibit economic considerations in environmental regulation on philosophical,⁴⁴⁵ symbolic,⁴⁴⁶ or pragmatic grounds.⁴⁴⁷ While we do not address this complex matter directly, we note that Congress must take economic factors into account in order to achieve public health efficiency. Promulgation of costly standards that are intended to reduce the risks of chemical ex-

444. Advocates of emissions trading offer numerous concrete examples of these phenomena. See, e.g., Barry Elman et al., Acid Rain Emission Allowances and Future Capacity Growth in Electric Utility Industry, 40 J. AIR & WASTE MGMT. ASS'N 979 (1990). See generally RALPH A. LUKEN, EFFICIENCY IN ENVIRONMENTAL REGULATION (1990); CRANDALL, supra note 443.

445. Many in the deep ecology movement, for example, regard it as unethical to consider economic feasibility when setting standards to control involuntary environmental risk. See, e.g., Paul Merrell & Carol Van Strum, Negligible Risk: Premeditated Murder?, 10 J. PESTICIDE REFORM 20, 21 (1990).

446. Professor Dwyer describes the political dynamics of environmental statutes in which such statutes prohibit economic considerations as follows: "The political benefits of supporting symbolic legislation may be significant. More importantly, the risks of taking a position that can be viewed as favoring profits over people often are too great for a legislator to oppose symbolic legislation." Dwyer, *supra* note 180, at 247.

447. As Professor Dwyer has put it:

^{443.} For an in-depth documentation of the enormous range of dollar-per-ton pollution control costs, see GENERAL ACCOUNTING OFFICE, PAD-82-15, A MARKET APPROACH TO AIR POLLUTION CONTROL COULD REDUCE COMPLIANCE COSTS WITHOUT JEOPARDIZING CLEAN AIR GOALS 20 (1982). See generally ROBERT W. CRANDALL, CONTROLLING INDUSTRIAL POLLUTION (1983).

The argument is not just that cost-sensitive standards are inherently weaker than health-based standards, but that explicit consideration of costs overemphasizes costs and underemphasizes health concerns. Implementation costs seem quantifiable and their impact is felt immediately, while public health risks are difficult to quantify, statistical, and remote In addition, industry generally has the best information about the costs and feasibility of pollution controls, and thus it is able to present data supporting predictions of dire economic consequences if strict standards are adopted.

posure can indirectly create risks to public health by reducing standards of living⁴⁴⁸ and/or by encouraging use of substitute chemicals or industrial processes that create new health risks.⁴⁴⁹ Under the 1990 Clean Air Amendments, Congress for the first time alluded to this "risk-risk" tradeoff in the implementation of standards for air toxics. The amendments required EPA to investigate and report on "any negative health or environmental consequences to the community [resulting from] efforts to reduce such risks."⁴⁵⁰

Finally, excessive emphasis on reducing insignificant or minute risks⁴⁵¹ of chemical carcinogens necessarily diverts valuable resources needed to address more significant carcinogenic risks, as well as other, more pressing environmental problems involving protection of ecological systems and natural resources.⁴⁵² If Congress is primarily concerned about reducing net health risks to acceptable levels, any bright line should be devised with enough flexibility to allow such risk-risk tradeoffs to be taken into account.⁴⁵³

C. Promoting Good Regulatory Science

Some have expressed concern that bright lines might freeze scientific progress in risk assessment.⁴⁵⁴ From a policy perspective, it is important to consider the implications of bright lines for the scientific maturation of the risk assessment process. Those statutes that mandate use of specific technical assumptions, types of data, and mathematical models are of particular concern. In the final analysis, the scientific integrity of the regulatory process should be nurtured because it is critical to both the competence and the legitimacy of toxic chemical regulation.⁴⁵⁵

^{448.} Ralph L. Keeney & Detlof von Winterfeldt, Why Indirect Health Risks of Regulation Should Be Examined, 16 INTERFACES 13, 17 (1986); Ralph L. Keeney, Mortality Risks Induced by Economic Expenditures, 10 RISK ANALYSIS 147-59 (1990); see also Aaron Wildavsky, Richer is Safer, 60 PUB. INTEREST 23 (1980).

^{449.} LAVE, supra note 407, at 15-17.

^{450.} Pub. L. No. 101-549, § 301(f)(1)(C), 104 Stat. 2399, 2543 (1990) (codified at 42 U.S.C.A. § 7412(f)(1)(C) (West Supp. 1992)).

^{451.} See generally DE MINIMIS RISK, supra note 393.

^{452.} William K. Reilly, Why I Propose a National Debate on Risk, 17 EPA J., Mar.-Apr. 1991, at 2.

^{453.} See generally Chris Whipple, Redistributing Risk, REGULATION, May-June 1985, at 37-44 (describing strict regulation of some substances with relatively minor health effects); Zeckhauser & Viscusi, supra note 134, at 559 (discussing society's overreaction to many risks and the need for efficient risk management).

^{454.} See Hearing on S. 722, supra note 399, at 113-14 (statement of Victor J. Kimm); Robert C. Barnard, The Clean Air Act: A Challenge and Opportunity for Science, Address at the 1991 Annual Summer Toxicology Forum, Given Institute of Pathology 2 (July 19, 1991) (transcript on file with author).

^{455.} John D. Graham, Science and Environmental Regulation, in HARNESSING SCIENCE, supra note 75, at 1, 1-7; Graham, supra note 75, at 211-23.

We indicated earlier that there are serious gaps in scientific understanding of chemical carcinogenesis, although the information base is expanding at a rapid rate.⁴⁵⁶ Given these conditions, Congress should be reluctant to enact a statutory scheme that would preclude or discourage regulators from making use of additional scientific knowledge; it should certainly avoid statutory designs that would discourage development of additional information about the effects of chemical exposure on human health.

Under the prevailing narrative statutory tests, regulators have retained considerable discretion to interpret scientific information for use in risk assessment and management. Although the development of risk assessment guidelines at federal agencies has placed some constraints on the use of new scientific information (particularly on the use of mechanistic information about how chemicals cause cancer),⁴⁵⁷ no statute has placed explicit restrictions on an agency's ability to consider, interpret, and utilize scientific knowledge. The only possible exception is the Delaney Clause, if one interprets it as a restriction on considering any science other than epidemiology or the results of a long-term laboratory animal bioassay. Moreover, federal agencies have been flexible enough to depart from standard risk assessment practice in several situations in which compelling scientific information suggested that the standard practice was inappropriate.⁴⁵⁸

If Congress replaces narrative statutes with numerical bright lines, administrative agencies would presumably retain the freedom to use scientific information in generating risk estimates. Hence, absent congressional direction as to QRA procedures, bright lines would not restrict directly an agency's ability to use new scientific information in QRA.

^{456.} See generally Barry L. Johnson, Change Anticipated in Scientific Assessments of Risk, Remarks to Conference on Risk Assessment and Risk Communication, Institute for Alternative Futures (Nov. 7, 1990) (discussing possible changes in QRA and recommending certain directions) (transcript on file with author); supra part I.

^{457.} Risk assessments for vinyl chloride, chloroform, and benzene have all been criticized for failing to consider toxicokinetic and other mechanistic information. Interview with Lorenz Rhomberg, Deputy Director, Human Health Assessment Group, Office of Health and Environmental Assessment, U.S. Environmental Protection Agency, in Washington, D.C. (Aug. 14, 1991). For a more in-depth discussion of how EPA's generic cancer risk assessment guidelines restrict consideration of chemical-specific data, see GRAHAM ET AL., *supra* note 3, at 57-59, 201-02, 205-06, 208-11.

^{458.} Most notable of these is the case of methylene chloride. See OFFICE OF HEALTH AND ENVTL. ASSESSMENT, U.S. ENVTL. PROTECTION AGENCY, EPA/600/8/87/030A, UPDATE TO HEALTH ASSESSMENT DOCUMENT AND ADDENDUM FOR DICHLOROMETHANE (METH-YLENE CHLORIDE): PHARMACOKINETICS, MECHANISMS OF ACTION AND EPIDEMIOLOGY (1987) (external review draft); Public Comment Sought on Degreasers as EPA Weighs Designation as Hazardous, [1987 Current Developments] Env't Rep. (BNA) at 1101 (Aug. 21, 1987). Other current examples include formaldehyde and arsenic. Interview with Lorenz Rhomberg, supra note 457.

There is a danger, however, that bright lines would induce regulators to consider only that information that can be incorporated into existing mathematical models of dose-response evaluation. Narrative statutory tests provide incentives to produce mechanistic data, such as biological information on the relevance of high-dose animal tumors to low-dose human responses.⁴⁵⁹ Even if such data cannot readily be incorporated into standard mathematical models of risk assessment, the statutes provide the regulator ample discretion to consider such data. In contrast, bright lines might discourage consideration and generation of mechanistic data that are difficult or impossible to incorporate into standard dose-response models,⁴⁶⁰ unless improved models that incorporate these data can be developed quickly.

Currently, regulators consider the entire weight of scientific evidence about a chemical's carcinogenicity in the classification of carcinogens as known, probable, or possible carcinogens, but not in their quantitative estimates of a carcinogen's potency.⁴⁶¹ The classification provides a vehicle for conveying scientific information and judgments that presently cannot be reflected in mathematical models of risk assessment.⁴⁶² A bright line would effectively censor any data and technical judgments not embedded in the quantitative estimate of risk.

Consider an extreme hypothetical example. Chemicals X and Y both have the same cancer potency factor as estimated by EPA procedures. While X has been shown to be carcinogenic in humans and animals, Y has been shown to be carcinogenic only in the livers of male rats at high doses. It has tested negative in female mice and in both male and female rats, and no evidence of human carcinogenicity has been found. A bright line based on current EPA risk assessment procedures would draw no distinction between X and Y: exposure to both chemicals would be treated as equally risky. In the long run, new mathematical models probably will be developed for cancer potency which can incorporate all of the information currently considered in classification.⁴⁶³

The danger of censoring qualitative scientific evidence and interpretations can be illustrated with the example of unleaded gasoline. EPA has been reluctant to classify unleaded gasoline as a probable human car-

^{459.} For examples of studies on the application of control bioassay results to humans, see Arthur R. Gregory, *Species Comparisons in Evaluating Carcinogenicity in Humans*, 8 REG. TOXICOLOGY & PHARMACOLOGY 160 (1988); Stephen L. Brown et al., *Review of Interspecies Risk Comparisons*, 8 REG. TOXICOLOGY & PHARMACOLOGY 191 (1988).

^{460.} Telephone Interview with Roger McClellan, President, Chemical Industry Institute of Toxicology (Dec. 5, 1991).

^{461.} See supra note 65 and accompanying text; supra text accompanying notes 98-103.

^{462.} Gray & Graham, supra note 132, at 286-95.

^{463.} Robert L. Sielken, Useful Tools for Evaluating and Presenting More Science in Quantitative Cancer Risk Assessments, 9 TOXIC SUBSTANCES J. 353 (1989); Todd W. Thorslund et al., Biologically Motivated Cancer Risk Models, 7 RISK ANALYSIS 109 (1987); James A. Popp, Risk Assessment Practices in the Federal Government, CIIT ACTIVITIES, Nov. 1991, at 1-2.

cinogen because the weight of the scientific evidence suggests that the tumors observed in animal studies may not be relevant to humans.⁴⁶⁴ However, EPA has published cancer potency factors for unleaded gasoline, based on standard QRA methods which assume that unleaded gasoline is a human carcinogen.⁴⁶⁵

In 1987, when EPA Administrator Lee Thomas made a regulatory decision about how to control gasoline vapors at service stations, he was free to consider both the qualitative weight of the evidence and the quantitative risk assessment.⁴⁶⁶ If Thomas had been constrained by statute to consider only the QRA, he would have had to ignore highly relevant scientific information. Such consequences will not be easy for advocates of bright line standards to avoid. Although risk assessment, valid methods for doing so are only in the early stages of development.⁴⁶⁷

Furthermore, censoring information about the weight of the scientific evidence occasionally may induce regulators to regulate chemicals less stringently than they might if they were allowed to consider the entire body of scientific knowledge. Under narrative statutory tests, regulators are free to regulate more stringently those animal carcinogens which mechanistic data suggest are highly relevant to humans than those animal carcinogens which evidence suggests behave differently in humans. Regardless of the stringency outcomes, the key point is that scientists and agencies will be less likely to generate such expensive data if the results are unlikely to be used in risk assessment.

A bright line could be drafted, however, that also gives some consideration to carcinogen classification. For example, the Office of Solid Waste uses different bright lines for carcinogenic metals from boilers depending upon the weight of the evidence.⁴⁶⁸ Such a standard might retain incentives for generation of new scientific data.

The threat to good science from bright lines alone is speculative, but the threat would be heightened enormously if Congress goes beyond leg-

^{464.} Recent mechanistic evidence suggests that the kidney tumors observed in male rats and the liver tumors observed in female mice may not be indicative of human responses to unleaded gasoline. For a basic description of the Chemical Industry Institute of Toxicology's research regarding the causes of kidney tumors in male rats, see Susan Egan-Keane et al., Unleaded Gasoline Vapors, in HARNESSING SCIENCE, supra note 75, at 84.

^{465.} U.S. ENVTL. PROTECTION AGENCY, EVALUATION OF THE CARCINOGENICITY OF UNLEADED GASOLINE 5-12 to 5-16 (1987). Note, however, that CRAVE has not endorsed these CPF's for unleaded gasoline. For an in-depth description of EPA's risk assessment and the surrounding policy deliberations concerning regulation of unleaded gasoline vapors, see Egan-Keane et al., *supra* note 464.

^{466.} Egan-Keane et al., supra note 464, at 84-87.

^{467.} See Thorslund et al., supra note 463, at 109; Suresh H. Moolgaukar & Anup Dewanji, Biologically Based Models for Cancer Risk Assessment: A Cautionary Note, 8 RISK ANALYSIS 5, 5-6 (1987).

^{468.} See supra part II.E.1 (discussing RCRA).

islating simple bright lines and attempts to prescribe how risk estimates are to be calculated. Some members of Congress favor moving in this direction, especially those who recognize how sensitive cancer risk estimates are to subtle changes in data and modeling assumptions.

For example, if Congress required agencies to calculate human cancer risk on the basis of data from the most sensitive tested animal species, industry and the agencies would have less incentive to produce innovative (yet expensive) biological data indicating whether the most sensitive tested animal species is in fact relevant to humans. Furthermore, while in some cases the congressionally mandated procedure would produce a reasonable risk estimate, in other cases it might grossly overestimate (or even underestimate) human risk.⁴⁶⁹

Drafters of legislation should be particularly careful about introducing scientifically inappropriate standards and inhibiting scientific progress in light of the relative permanence of statutes and standards. While there is nothing in theory which sets environmental statutes or standards in stone,⁴⁷⁰ in practice they are rarely revised. Congress has revisited the Clean Air Act three times in twenty-five years. The few cases where EPA has sought to relax existing standards⁴⁷¹ were the source of intense controversy⁴⁷² and litigation.⁴⁷³ Agency efforts to modify risk assessments have produced similar conflicts.⁴⁷⁴

In addition to the limitations discussed above, it should be kept in mind that legislation is typically drafted by attorneys who may tend to overestimate the potential of even well-crafted law to ensure optimal policy outcomes. While the individual congressional staff members who actually draft the statutes may have considerable technical literacy, they may still lack the necessary scientific expertise to ensure that language

472. For a comprehensive discussion of the efforts to relax the ambient air standard for ozone from .08 to .12 ppm, see MARC K. LANDY ET AL., THE ENVIRONMENTAL PROTECTION AGENCY: ASKING THE WRONG QUESTIONS 49-88 (1990); GARY C. BRYNER, BUREAUCRATIC DISCRETION, LAW AND POLICY IN FEDERAL REGULATORY AGENCIES 105-08 (1987).

^{469.} See Finkel, supra note 63, at 454-57.

^{470.} Despite its extremely ambitious standard-setting schedule, the Office of Drinking Water program reviews its standards every three years as required by law. The office points to its present reconsideration of fluoride as an example of its responsiveness to new scientific data. Interview with Dr. Ed Ohanian, *supra* note 251; Interview with Jennifer Orme, *supra* note 249.

^{471.} In response to the 1977 CAA amendments, the Office of Air and Radiation has tried to revise ambient standards for carbon monoxide. See CAA § 109(d), 42 U.S.C.A. § 7409(d) (West Sup. 1992); Carbon Monoxide: Proposed Revisions to the National Ambient Air Quality Standards, 45 Fed. Reg. 55,066 (1980). For a description of the case, see John D. Graham & David Holtgrave, Carbon Monoxide, in HARNESSING SCIENCE, supra note 75, at 197.

^{473.} American Petroleum Inst. v. Costle, 665 F.2d 1176 (D.C. Cir. 1981), cert. denied, 455 U.S. 1034 (1982).

^{474.} For example, early attempts to include mechanistic information in the dioxin risk assessment were the source of considerable consternation. See Frederica Perera, Letter to Science, March 11, 1988, 739 SCIENCE 1227 (1988); Adam Finkel, Dioxin: Are We Safer Now Than Before?, 8 RISK ANALYSIS 161 (1988).

specifying QRA procedures will achieve its intended effect. If congressional attorneys focus exclusively on policy ideals, ignoring the potential impact of the methods of achieving these ideas on incentives for scientific progress, they may inadvertently write restrictive language that hampers long-term scientific progress in risk assessment. Ultimately, such an outcome could sabotage their policy goals as well, by undermining efforts to identify the most significant risks and by reducing the scientific justification for regulatory action.

In summary, while the scientific integrity of risk assessment and regulation is certainly not a preeminent value, there is good reason to be concerned about the sensitivity of any political process to scientific values. Given these factors, legislators and their staffs should be cautious if they choose to draft bright lines.

D. Promoting Civic Education

When drafting environmental statutes, some members of Congress and their staffs focus primarily on designing legislation that will produce the environmental outcomes that they desire. Others focus on conveying a symbolic commitment to environmental protection to the electorate, without paying much attention to what the actual consequences for the environment would be. While we recognize the importance of both environmental outcomes and symbolism, legislators should also consider how well the statutory design would foster civic education about public policy choices in a modern industrial society. In particular, we fear that some types of bright lines (for example, the zero-risk mandate of the Delaney Clause) will perpetuate certain myths about environmental policymaking. Generally, narrative statutes are less prone to this sort of defect. Regardless of the outcomes of environmental legislation, we believe there is inherent virtue in an administrative process that fosters candor and public debate about the real issues in regulatory choice.

After more than twenty years of federal environmental regulation, many officials in administrative agencies have become sophisticated about the real stakes that must be weighed in pursuing the public interest.⁴⁷⁵ Today, many regulators recognize that decisions must be made in the face of scientific uncertainty and that industry and environmental advocates will tend to exaggerate the ramifications of environmental regulations or their absence. Regulators also recognize that efforts to reduce some health risks will increase other risks (for example, banning use of one hazardous pesticide may simply induce farmers to choose another one). Finally, regulators know that EPA operates in a political climate and must be sensitive to other national policy objectives, such as industrial competitiveness, environmental equity, energy independence, ecological protection, rational public health priorities, and sustained economic growth.

When contrasted with the plethora of issues considered by environmental agencies today, the decisionmaking of twenty years ago appears primitive. However, to a large extent the paradigms of early environmentalism still constitute the salient statutory model of environmental protection for the American public. This model is certainly apparent in the Delaney Clause, which embraces a no-risk approach to decisions about the safety of processed foods.⁴⁷⁶ It is also manifested in what one commentator has called "symbolic legislation," which are bright line or narrative provisions that "impose short deadlines and stringent standardsetting criteria that are designed to address a single environmental concern to the exclusion of other factors."⁴⁷⁷ Such statutes identify environmental risks as unacceptable and register public concern about the seriousness of the problem. Their drafters assume—either naively or dishonestly—that complete elimination of risk is an attainable and preeminent public goal.

Symbolic legislation tends to force agency officials to misrepresent regulatory decision rationales in their statements to the media and the public, and even in their statements to Congress and the courts.⁴⁷⁸ Misrepresentation of the rationales for agency decisions ultimately undermines civic education. It serves to perpetuate antiquated societal attitudes and expectations about how environmental risks are managed in a modern industrial society.

If civic education is to be enhanced, a central function of administrative agencies must be to foster a mature understanding of the issues raised by modern environmental regulation among members of Congress, judges, journalists, and the general public. In our view, this obligation of civic education is inherent to the notion of public service.

A skeptic might argue that regulators are not forced by symbolic legislation to be hypocritical. Regulators confronted with impractical legislation have two choices. First, they can implement the statute's exact provisions. Bearing the consequences, the electorate may well say, "Wait a minute, we never meant that!" Alternatively, regulators might persuade the Congress to change the statute so that the administrative decision can reflect a careful and explicit balancing of competing interests. While we would prefer either of these strategies to the hypocrisy that reigns under symbolic legislation, we recognize that appointees at regulatory agencies, whose political survival depends upon a good work-

^{476.} See supra part II.A.

^{477.} See Dwyer, supra note 180, at 233.

^{478.} Dwyer argues that agencies are forced to make this sort of distortion when "the courts read symbolic legislation literally" or when "the agency feels too much political criticism for rewriting the substantive statute." *Id.* at 282.

ing relationship with the President and Congress, will rarely take either of the honest strategies described above. The ultimate villain here is the Congress, which passes laws that stimulate dishonesty and miseducation of its constituents.

Symbolic legislation hides debate about tradeoffs in the regulatory agency, or at least keep it out of the public eye. Only a small number of political appointees and career public servants are privy to the genuine considerations. In effect, regulators make decisions on two sets of books, which reflect different rationales; one set is for the real decision, and the other set, crafted by creative attorneys, is for consumption by courts, Congress, and the public. While this process allows Congress the comfort of its symbolic goals, it miseducates everyone else about the genuine issues and undermines the value of civic education.

While our primary concern here is the value of civic education, it is worth noting that the confusion which reigns may not be sustainable in the long run. To the extent that public perceptions of environmental policy differ from the reality of environmental policy, federal environmental regulations may lose public support and confidence.⁴⁷⁹ We find it interesting that in some areas power over environmental regulation is gradually shifting to the state and local governments, where pragmatism and honesty may be better rewarded than in Washington, D.C.; still, some states have been tempted to enact simplistic bright-line statutes.

It is unlikely that bright lines in federal environmental statutes, especially those which enact a single acceptable risk number, such as 10^{-6} , will contribute to civic education. The inflexibility of a bright line will encourage the EPA Administrator to conceal the genuine grounds for policy choice.⁴⁸⁰ Consideration of other interests may take the perverse form of manipulating the quantitative risk estimate to achieve the desired regulatory outcome. Despite the insistence of numerous statutes, only rarely has EPA disregarded economics and limited its considerations strictly to public health.⁴⁸¹ In short, a bright line may present federal

^{479.} In their recent historical review, *The Environmental Protection Agency, Asking the Wrong Questions*, Landy, Roberts, and Thomas criticize EPA policies pursuant to the narrative criteria of environmental legislation. They complain that EPA is not meeting government's obligation to provide civic education that strengthens the capacity of citizens for successful self-government and to accept some degree of responsibility for a collective problem. "[B]y defining the central question facing the agency as a technical one—how to provide safety—the EPA hindered meaningful political debate about critical environmental choices." LANDY ET AL., *supra* note 472, at 8; *see also* Lave & Males, *supra* note 144, at 387.

^{480.} Rather, "Congress should instruct EPA to strive for a balance, as it inevitably will have to do so, between health, economic, and technological considerations." S. 816 Hearing, supra note 336, at 30 (statement of Dr. John Graham, Department of Health Policy and Management, Harvard School of Public Health).

^{481.} See supra parts II, III.A.

decisionmakers with a choice of either lying or disobeying Congress when setting standards.⁴⁸²

The level of acceptable cancer risk proposed for bright-line legislation—typically, 10^{-6} —tends to be extremely stringent. Because one in four Americans will ultimately die of cancer, this risk level reflects an increase in risk from 0.250000 to 0.250001. These numbers are virtually indistinguishable, both scientifically and normatively, yet legislatures are often unwilling to insert more permissive risk levels, in part because they recognize the political fallout from risk levels that environmentalists perceive as too lax.⁴⁸³

Because narrative standards, such as "unreasonable risk," offer regulators more latitude than do conventional bright lines, they provide greater potential for open discussion of an agency's decision and candid debate about the interests at stake. In public hearings, for example, the interested parties will be free to debate the real issues rather than addressing only those issues that the bright line or symbolic statute recognizes as legitimate. This contributes not only to civic education, but also to democratic participation in the regulatory decisionmaking process.

More complex bright lines, such as those that incorporate information about population risk, maximum individual risk, and cost-effectiveness, would not compromise civic education as seriously as would simplistic bright lines. A "fuzzy" bright line, specifying a range of acceptable risks and allowing consideration of competing interests within the discretionary range,⁴⁸⁴ might also encourage some public discussion about the realities of environmental policymaking in a modern industrialized society.

E. Promoting Administrative Consistency

As discussed in part II, risk assessment and risk management practices vary significantly among EPA's program offices.⁴⁸⁵ Moreover, EPA's approach to risk assessment and management differs from that of other administrative agencies such as the FDA and OSHA.⁴⁸⁶ This inconsistency is problematic because it calls into question the credibility of

^{482.} New Jersey's experience regulating drinking water suggests that there will be times when the law is broken because there is no technological way to set standards for risks at acceptable levels. The result was a public outcry and tremendous political fallout, when in fact the drinking water standard was extremely protective of public health. Telephone Interview with Leslie McGeorge, Deputy Director, Office of Science and Research, N.J. Department of Environmental Protection (Sept. 7, 1990).

^{483.} Interview with Phil Barnette, supra note 343.

^{484.} See supra part IV.E (discussing fuzzy bright lines).

^{485.} See supra part II.

^{486.} See Travis et al., supra note 147. For a detailed account of agency differences in the assessment and management of formaldehyde and benzene, see GRAHAM ET AL., supra note 3, at 8-37, 80-114.

EPA's decisions and undermines the legitimacy of the federal government's risk assessment process.

The public is justifiably confused when it is told that a single risk level as estimated by different program offices in a single executive agency has multiple meanings. If the methods and assumptions used in QRA are so varied, the existence of an essential truth, which QRA purports to measure, appears dubious. Moreover, the diversity of risk levels permitted by EPA risk managers fuels opposition by citizens who resent the relative leniency or stringency of a particular decision.

The fragmentation in the federal government's current approach to risk assessment may not be all bad, however. Fragmentation allows and fosters advances in what is still a relatively immature analytic tool. As program offices and agencies experiment with different QRA approaches, new and improved methods will emerge. A monolithic approach to QRA might inhibit this process, while conveying a false sense of the accuracy and reliability of current methods of QRA.⁴⁸⁷

Even if one believes that current agency inconsistency is undesirable, it is hardly clear that new legislation would improve the situation. Were Congress to amend narrative statutes to include bright lines, it probably would not choose to include a uniform level of acceptable risk in all environmental statutes. Pluralism in bright lines would be likely to emerge from Congress, reflecting the variation in political pressures from statute to statute. Congress might introduce further confusion by mandating a variety of methods for calculating risk under the various laws.

A series of administrative reforms could help reduce inconsistency. EPA's Risk Assessment Council, under the leadership of Henry Habicht, has made some progress toward improved risk characterization,⁴⁸⁸ and agencies such as EPA and the FDA could establish centralized offices responsible for all risk assessments they undertake. While certain aspects of QRA, such as exposure assessment, are not generic and require expertise about specific media (for example, air versus water versus food), it might be possible to build a high-quality team of exposure assessors to serve all of EPA's program offices. The EPA scientists responsible for hazard identification and dose-response evaluation could certainly be housed in a single office, although possibly at some cost to the scientific competence of the individual program offices that ultimately make regulatory decisions. More radically, Congress could establish an independent agency responsible for all risk assessments in the federal government.⁴⁸⁹ Unfortunately, a complete institutional separation of

^{487.} GRAHAM ET AL., supra note 3, at 208-15.

^{488.} Memorandum from F. Henry Habicht II, Deputy Administrator of EPA, to Assistant and Regional EPA Administrators, Washington D.C. (Feb. 26, 1992) (Guidance on Risk Characterization for Risk Managers and Risk Assessors) (on file with author).

^{489.} Similar proposals calling for the creation of a "science court" have been largely un-

risk assessment from risk management might further erode the administrative efficiency of the regulatory process.⁴⁹⁰

A strong White House role coordinating agency activities offers the hope of resolving some of the current inconsistencies.⁴⁹¹ In the Bush Administration, for example, Henry Habicht, Deputy Administrator of EPA, is chairing an interagency committee on risk assessment with a mission to harmonize the risk assessment process. Sixteen federal agencies and departments are represented on this committee, although much of the day-to-day work is performed by scientists from EPA and the U.S. Public Health Service. No milestones or deadlines for this committee's work have been revealed to the public. While the Habicht Committee had a slow start, it held a major public hearing in November 1991 at the National Academy of Sciences where it reported interagency progress on several important issues, including development of a common, default interspecies scaling factor for use in chemical risk assessment. New projects include developing assessment guidelines for cancer risks and for noncancer risks such as neurotoxicity, developmental effects, and reproductive effects. 492

At the November 1991 public hearing, the Harvard Center for Risk Analysis recommended that the Habicht Committee develop the inhouse capability to evaluate risk assessments and each year revisit the risk assessments of two major chemicals that are of interest to multiple federal agencies.⁴⁹³ By taking a leadership role in developing scientific consensus among the federal agencies, the Habicht Committee could begin to rebuild the federal government's reputation for taking a scientific approach to risk assessment issues. State and local governments, which typically lack the resources and technical capabilities to undertake risk assessments, would benefit from strong federal leadership in risk assessment.

The Bush Administration is also considering an executive order that would establish uniform principles of risk assessment and management throughout EPA and possibly throughout the entire federal govern-

popular with both Congress and the bureaucracy. For samples of such proposals, see Joel Yellin, Science, Technology and Administrative Government: Institutional Designs for Environmental Decisionmaking, 92 YALE L.J. 1300, 1307-09 (1983); Simon Ramo, Regulation of Technological Activities: A New Approach, 213 SCIENCE 837 (1981); David L. Bazelon, Coping with Technology Through the Legal Process, 62 CORNELL L. REV. 817, 826-28 (1977).

^{490.} See Committee on the Institutional Means for Assessment of Risks to PUB. Health, *supra* note 2, at 6.

^{491.} See D. Allen Bromley, Science at the White House, Speech to the AIHC Annual Meeting (Nov. 28, 1990) (demonstrating White House leadership on this issue) (transcript on file with author).

^{492.} Risk Assessment Practices in the Federal Government, 56 Fed. Reg. 54,580-82 (1991).

^{493.} John D. Graham, Risk Assessment Practices in the Federal Government, Testimony Before a Public Meeting of FCCSET (Nov. 19, 1991) (transcript on file with authors).

ment.⁴⁹⁴ Some observers are skeptical of this proposal because it would provide stronger powers to the Office of Management and Budget,⁴⁹⁵ which has not always taken a balanced position on issues of risk assessment and management.⁴⁹⁶ We support the idea of an executive order to strengthen the harmonization role of the White House Office of Science and Technology Policy, possibly by expanding the activities of the Habicht Committee.⁴⁹⁷ Such interagency efforts are exciting but politically vulnerable. A similar effort begun by the Carter Administration, the Interagency Regulatory Liaison Group, was disbanded by the Reagan Administration in 1981.⁴⁹⁸

CONCLUSION

Current environmental laws provide narrative directives to EPA and other agencies responsible for protecting the public from exposure to chemical carcinogens. Regulators increasingly use quantitative risk assessment techniques to screen chemical exposures, establish priorities, and set standards under existing legal authority. Since current laws are generally silent on how estimates of cancer risks should be calculated and used in regulatory decisions, they provide agencies enormous discretion in determining the scope and stringency of chemical regulation. Decisions by the federal courts have reinforced the role of risk assessment in regulatory decisionmaking.

Recent legislative proposals would replace narrative guidance with numerical "bright lines" in an attempt to constrain regulatory discretion. For example, a lifetime cancer risk level of one in a million due to each environmental exposure has been advocated either as a de minimis level of risk or as a minimum level of protection against risk that must be provided to all U.S. citizens. Advocates of such mandated risk levels represent a curious combination of actors in the political process.

Some environmentalists, dissatisfied with the leniency of standards . adopted under narrative statutes, see mandated risk levels as a means of inducing the agencies to enact more stringent chemical regulations. Some legislators and their staffs see mandated risk levels as a means for

498. See LANDY ET AL., supra note 472, at 172-203 (discussing IRLG).

^{494.} FEDERAL FOCUS, INC., INST. FOR REGULATORY POLICY, TOWARD COMMON MEASURES: RECOMMENDATIONS FOR A PRESIDENTIAL EXECUTIVE ORDER ON ENVIRON-MENTAL RISK ASSESSMENT AND RISK MANAGEMENT POLICY 103-08 (1991).

^{495.} On OMB's view of risk assessment and management, see Office of Management and Budget, *Current Regulatory Issues in Risk Assessment and Risk Management, in* REGULA-TORY PROGRAM OF THE UNITED STATES GOVERNMENT, APRIL 1, 1990 - MARCH 31, 1991, at 13-26 (1991).

^{496.} See Evans et al., supra note 8, at 71-83 (discussing weaknesses in OMB Report on Regulatory Risk Assessment and Management).

^{497.} The Committee is currently an effort of the Federal Coordinating Council on Science, Engineering and Technology (FCCSET).

the public to assert democratic control over a regulatory process that appears to be controlled by unelected risk assessors and managers. Finally, some industrialists see mandated risk levels as an improvement on the zero-risk mentality manifested in the Delaney Clause.

Our analysis suggests that the recent push for mandating numerical levels of acceptable risk in environmental legislation is misguided. Mandated risk levels per se would do little to constrain the discretion of regulators. While EPA cancer risk estimates may appear precise, the final numbers conceal profound scientific uncertainties about chemical carcinogenesis and patterns of human exposure. Slight modifications in modeling assumptions and subtly different interpretations of data, all plausible, can change risk estimates by factors of a thousand or more. However, bright-line statutes would not prevent agencies from making the same regulatory decisions they make under narrative statutes. Regulators could simply bury these decisions in their calculation of cancer risks.

Legislators could constrain agency discretion more effectively by prescribing methods for calculating cancer risks. Regrettably, this strategy threatens to retard scientific progress in chemical risk assessment. Congress should refrain from mandating risk assessment practice precisely because the science of chemical carcinogenesis is soft and rapidly evolving. Members of the scientific community already doubt the government's interest in using science to make sound regulatory decisions.⁴⁹⁹ Tighter constraints would discourage research into innovative techniques that do not fit the congressionally mandated formula. In the long run, the scientific underpinnings of risk assessment should be nurtured because they are critical to both the competency and legitimacy of toxic chemical regulation.

Even if highly stringent, simple bright lines were faithfully implemented as Congress intended, they would create additional inefficiencies in public policy. Public health efficiency would be compromised because agencies would squander their scarce resources defending expensive regulations from a deluge of industrial opposition. Economic efficiency would be compromised since any uniform bright line will cause undercontrol of some pollution sources and overcontrol of others.

The bright lines thus far proposed would not advance popular understanding of the regulation of cancer risk, an understanding that has already been compromised by certain forms of symbolic legislation. In a modern industrialized society, regulatory decisions demand balancing, implicitly or explicitly, of competing risks, costs, and benefits. By enacting a statute that allows regulators to consider only whether a certain 1992]

risk level has been achieved, Congress would encourage regulators to conceal the array of considerations that affect public policy decisions. By driving debate about competing interests inside the agency, bright lines would further mislead the courts, Congress, the media, and the public about how environmental policy is made.

If legislators are determined to mandate risk levels, they should give careful thought to how mandated risk levels are crafted and applied. Current proposals to use one in a million as the critical level of risk should be reconsidered in light of larger public policy considerations. Few actors in the political process are even aware of the history and original intent of the one-in-a-million risk level;⁵⁰⁰ it is now a habit more than a choice. Bright lines should be adopted only after open and careful consideration.

Our analysis indicates that it makes more sense to mandate risk levels as a priority setting tool, as in the 1990 Clean Air Act Amendments, than as a tool governing the degree of stringency of final standards. Used in this way, bright lines can enhance public health efficiency by concentrating scarce agency resources on potentially significant risks.

Insofar as mandatory risk levels are used to set standards, a range of acceptable risk levels such as that used in Superfund cleanups, the socalled fuzzy bright line, is preferable to the tyranny of a single risk number. The range-of-risk approach can assure a minimum level of health protection while allowing regulators to consider key factors such as qualitative scientific evidence and biological judgments about a carcinogen's mechanism of action.

Legislators should also give more thought to incorporating population risk, individual risk, risk-risk tradeoffs, and cost-effectiveness into legislated definitions of acceptable risk. A bright line that takes into account only one policy dimension, such as the risk to the maximally exposed individual, will produce poor policy outcomes by causing regulators to neglect other policy dimensions, such as population risk, competing risks, and cost-effectiveness. A complex bright line that incorporates multiple policy dimensions is more intellectually defensible than a simplistic bright line, and could also promote civic education regarding regulatory dilemmas.

The existing inconsistency in risk assessment practices in the federal government is a serious problem that undermines the credibility of regulatory action. State and local governments, which often lack the scientific resources to undertake their own risk assessments, could benefit from strong scientific leadership in the federal government. Congressional action is unlikely to solve this problem, as individual statutes mandating risk assessments are unlikely to achieve any greater degree of consistency than exists now. We support the concept of an executive order to strengthen the role of the White House Office of Science and Technology Policy in harmonizing risk assessment practice.

Although we discourage Congress from writing numerical risk levels into law, we believe it is critical for members of Congress and their staffs to become acquainted with the seemingly arcane and complex tool called risk assessment. The most promising way for Congress to influence regulatory decisions is to utilize its traditional powers of oversight, confirmation, appropriations, and specific corrective legislation. To use these tools effectively in controlling environmental policy, Congress must understand how estimates of cancer risk are calculated by agencies and how they are used to justify rulemaking decisions. As Congress becomes more acquainted with the risk assessment process, we are confident that legislators can assert effective democratic control over regulatory choices without writing specific risk numbers or methods of calculation into authorization language.