ISSUES IN ENVIRONMENTAL LAW

SCIENCE AND POLICY IN RISK ASSESSMENTS: THE NEED FOR EFFECTIVE PUBLIC PARTICIPATION

Ashley C. Schannauer*

CONTENTS

---

* The author practices environmental and telecommunications law in Pittsburgh, Pennsylvania. He represented the City of Pittsburgh in litigation challenging the permitting of the WTI facility. He received his J.D. from the Dickinson School of Law and a LL.M. in environmental and resource law from the University of Utah. The author would like to thank Susan Poulter, Robert Adler, Ileana Porras, and Terri Swearingen for their help with the LL.M. thesis on which this article is based.

INTRODUCTION

Risk assessments often operate under the premise that, with sufficient funding, science and technology will provide obvious and cost-effective solutions to contaminant problems. However, in reality there are many sources of uncertainty and variability in the process of human health-risk assessment exist. These uncertainties often confuse the selection of effective solutions. Many of these uncertainties and variabilities are not reducible.[1]

This ex-post-facto risk assessment process has produced distracting verbiage that obscures a simple truth: it was wrong to permit the construction of a toxic-waste incinerator on a flood plain of a narrow river valley, adjacent to a school.[2]

It may not be worthwhile conducting a risk assessment for the WTI incinerator, since the desire to conduct a valid risk assessment does not imply the ability to conduct a valid risk assessment.[3]

A. The WTI Hazardous Waste Incinerator, the East End Elementary School, the Ohio River, and Inversions

The Waste Technology Industries (WTI) hazardous waste incinerator in East Liverpool, Ohio sits 1,100 feet from the East End Elementary School and 320 feet from the nearest home in a low-income, minority neighborhood. Four hundred children attend the elementary school, which stands on a bluff at the same elevation as the top of the WTI stack.

East Liverpool is an area of declining industrial employment located in the floodplain on the west bank of the Ohio River, at a point which separates Ohio, West Virginia, and Pennsylvania. The Ohio River serves as the water supply for downstream communities. The river valley has steep hills rising along either side, making it susceptible to frequent inversions. The area is also subject to frequent periods of air stagnation.

Residents' fierce opposition to the plant's permit ultimately prompted the U.S. Environmental Protection Agency (EPA) to conduct a study, known as a "risk

---

1. U.S. EPA, PUB. NO. 630-R94-0001, REPORT ON THE TECHNICAL WORKSHOP ON WTI INCINERATOR RISK ISSUES (1993) [hereinafter 1993 PEER REVIEW REPORT] (comts. of Thomas E. McKone)

2. WTI PEER REVIEW GROUP, ONE MORE REVIEW OF THE EPA RISK ASSESSMENT OF THE WASTE TECHNOLOGY INDUSTRIES INCINERATOR AT EAST LIVERPOOL, OHIO (May 12, 1997) (cmt. of Halstead Harrison).

3. 1993 PEER REVIEW REPORT, *supra* note 1, ch.4, at 4.

assessment," to determine the health risks posed by the facility.[4] The risk assessment—the first full-scale study performed for a hazardous waste incinerator—attempted to address the public's concerns and serve as a basis for permit conditions.[5] The final results, released on May 8, 1997, found that the risks of cancer were within acceptable levels and that noncancer health effects were not expected to occur as the result of WTI's emissions.[6]

Not surprisingly, the results are controversial. WTI, the EPA, and local supporters cite the results as proof that the plant is safe. The local opponents and critics of incineration claim that certain results actually show that the plant is unsafe and that others understate the true risks.[7]

B. The Increasing Popularity of Risk Assessments and their Less-Obvious Limitations

Risk assessments are becoming increasingly popular among regulators and industry as a means to predict and regulate the health effects of chemicals released into the environment.[8] Risk assessments offer the promise of scientific answers to

---

4. The incinerator has been one of the most controversial hazardous waste projects in the nation. Citizen suits were filed in federal district courts in West Virginia and Ohio trying to prevent the start of operations. Police arrested opponents who demonstrated at the plant's gates in East Liverpool, in state office buildings in Columbus, Ohio, and in federal buildings including the White House. WTI's financial losses forced its Swiss parent corporation to conduct a major restructuring. The company has sought attorneys' fees and sanctions against the plaintiffs' attorneys and has filed a $34 million counterclaim against its citizen opponents, alleging abuse of process, defamation, and tortious interference with its business. *See* Answer and Counterclaim, Hager v. Waste Techs. Indus., No. 97 CV 34 (Ct. C.P., Columbiana County, Ohio, filed Mar. 20, 1997). The project has become a focal point for the re-examination of the health impacts of incineration and its place in the EPA's preferred ranking of disposal methods for hazardous wastes.

5. In 1992, nine years after the issuance of a permit under RCRA, two years after the completion of construction, and just weeks before the planned start of operations, the U.S. EPA started to prepare a Phase I risk assessment. *See* U.S. EPA, PRELIMINARY RISK ASSESSMENT OF INHALATION EXPOSURES TO STACK EMISSIONS FROM THE WTI INCINERATOR (1992).

6. *See* U.S. EPA, PUB. NO. EPA 905-R97-002, RISK ASSESSMENT FOR THE WASTE TECHNOLOGIES INDUSTRIES (WTI) HAZARDOUS WASTE INCINERATOR FACILITY (East Liverpool, Ohio), vol. 1, ch. 1, at 4-5 (May 1997) [hereinafter FINAL RISK ASSESSMENT].

7. The opponents also pointed to Ohio's hazardous waste facility siting law, which, if approved sooner, may have prohibited the siting of the WTI incinerator in its present location. The law, which became effective on August 1, 1984 (three months after the WTI permit was issued), prohibits siting within 2,000 feet of any residence or school. *See* OHIO REV. CODE ANN. § 3734.05(D)(6)(g)(i) (Anderson 1994). The prohibition does not apply, however, if the applicant demonstrates that the limitations are not necessary (1) "because of the nature or volume of the waste and the manner of management applied, the facility will impose no substantial danger to the health and safety of persons occupying the structures" and (2) because the activities "will not be incompatible with existing land uses in the area." *Id.*

8. Risk assessments have had changing ranks of supporters and opponents. In the 1970s, industry complained that regulators were making policy decisions with respect to the uncertainties in risk assessments that were resulting in unnecessarily restrictive regulatory standards. *See, e.g.*, Ethyl Corp. v. EPA, 541 F.2d 1, 20-29 (D.C. Cir. 1976) (upholding regulation of lead additives in gasoline on the basis

public health issues, which many in government and industry believe are often distorted by uninformed emotionalism. Risk assessments also provide perspective, encouraging comparisons between a facility's risks and the relatively higher risks of more commonly understood day-to-day activities.

The attractions, however, may be illusory. Risk assessments are subject to so many unknowns and such uncertainty that their results are of doubtful reliability. To address the unknowns and uncertainty, the assessors make an extensive series of judgments and assumptions, and results can vary widely based on the choices.

It has been estimated that, based on one's choice of assumptions, a 1-in-1 million risk of cancer can reasonably vary by a factor ranging from 10,000 to 100,000, producing risk estimates ranging from 1-in-100 to 1-in-10 billion.[9] Detractors argue that such risk estimates are virtually meaningless. They claim that the results merely reflect the values of the assessors who can and do tailor the assumptions to produce the desired results.[10]

The absence of formal standards on how to prepare risk assessments, including how to resolve the crucial uncertainties, adds to the controversy. The EPA has developed guidance documents on how to conduct certain parts of risk assessments, but the documents do not address many of the most controversial issues. They, therefore, leave open many additional issues for site-specific decision making. The

---

of risk assessment). By the 1990s, however, industrial interests were promoting the greater use of risk assessments, including their use in cost-benefit analyses and comparative risk assessment (i.e., the prioritization of regulatory efforts based on the relative risks of activities potentially regulated) in reform legislation proposed in the 104th Congress. *See, e.g., Risk Assessment and Cost-Benefit Act of 1995*, H.R. 9, 104th Cong. (1995); *Risk Reform Action Shifts to Senate*, INSIDE EPA RCRA REP., February 21, 1995, at 3-4. *See also* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION (1993). The EPA has also recently started to use risk assessments to evaluate ecological impacts. The EPA included a screening level ecological risk assessment in its review of the WTI project. *See infra* notes 81-86 and accompanying text.

9. *See* Robert Ginsburg, *Quantitative Risk Assessment and the Illusion of Safety*, NEW SOLUTIONS 9 (Winter 1993).

10. One critic of the use of risk assessments in permitting argues that the EPA and industry downplay the pervasiveness of policy choices in risk assessments and use the results to justify less aggressive regulation:

> The question becomes why a methodology based on "inferences" and subject to dramatic variations in results has come to dominate EPA and industry policy and practice? Curiously, the public rhetoric from EPA and industry downplays the problems and paints [Quantitative Risk Assessment] as just "good science" that gives "objective" (as opposed to the hysteria of citizen groups) and "scientific" evaluations of contamination problems. Furthermore, they focus on the supposed "excessively conservative assumptions" used in QRA calculations and suggest that spending money to save maybe a few lives from cancer over the next century is a waste . . . . [A]ny objection to QRA-based decisions is due to ignorance and mindless opposition to science and technology.

Id.

guidance documents also have not been subject to full public comment and judicial review, and they are not binding on the agency or the permit applicant.[11]

Even more importantly, the EPA's permitting standards for hazardous waste incinerators lack a clearly defined role for the results of the risk assessments and for health risks in general. The standards, promulgated under the Resource Conservation and Recovery Act (RCRA), consist largely of "technology-based" performance standards, including levels of combustion efficiency that existing technology can feasibly satisfy.[12]

RCRA also requires that hazardous waste incinerators conduct business in a manner protective of human health and the environment. The EPA enforces this requirement, in part, with risk assessments, despite the fact the Agency has not formally defined a sufficiently protective level of risk. To date, the EPA has only informally defined acceptable risk levels in guidance documents, not through formal regulations. It has also made notice of its determinations through guidance documents. Accordingly, the question of whether any estimated health risks are acceptable is left to the EPA's discretion on a case-by-case basis.

This article describes the basics of risk assessments, their major areas of uncertainty, and the need to resort to policy-laden assumptions to resolve them. It then describes the WTI risk assessment, the major uncertainties in that assessment, the range of potential assumptions, and the choices the EPA made.

In view of the extensive uncertainties in risk assessments and the frequent use of policy decisions to resolve them, the article emphasizes the need for public participation—both in designing standards for performing risk assessments and in making scientific and policy decisions during the course of specific risk assessments. Public participation is important in providing technical evidence and as input for the policy choices.[13] The public's views—including perhaps a set of alternative risk estimates based on the public's choices of assumptions can help ensure that the risk estimates depict the likely range of estimated risk (i.e., from over- to under-conservatism).

On an even more fundamental level, however, the risk assessment results will have little significance unless the EPA establishes standards that define acceptable levels of risk. This article recommends that risk standards be established with full

---

11. The EPA's practice on seeking public comment on guidance documents is uneven. *See infra* Part III.A.2.

12. *See* 42 U.S.C. § 6924(a) (1994); *see also infra* Part I.B. (discussing and outlining technology-based standards under RCRA). The Clean Air Act and Clean Water Act require similar standards. *See* 42 U.S.C. §§ 7411(a)(1), 7412(d) (describing "best achievable control technology" and "maximum achievable control technology"); *See also* 33 U.S.C. §§ 1314(b)(1)(A), (b)(4)(A) (outlining use of "best practicable control technology" and "best conventional pollutant control technology").

13. Although this article will discuss the manner in which the overall scope of a risk assessment is determined, it will focus primarily on the Human Health Risk Assessment (and less on the ecological and accident analyses) and, unless otherwise noted, the term "Risk Assessment" will refer to the Human Health Risk Assessment.

public input and that the standards rely only minimally on quantitative risk standards and more on qualitative factors, including siting restrictions.

I. THE BASICS OF RISK ASSESSMENT, APPLICABLE STANDARDS, AND A SUMMARY OF THE WTI RISK ASSESSMENT

A. The Processes of Risk Assessment and Risk Management

Risk assessments historically have been used on a relatively narrow chemical-specific basis: to review the safety of new drugs, to establish chemical-specific emissions and effluent standards, and, at times, more broadly, to review the feasibility of cleanup plans under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA).[14] Risk assessments use in a facility permitting process is new, and involves a greater number of pollutants and risk factors and a greater range of potential results.

Traditional risk assessments contain four elements: hazard identification, dose-response assessment, exposure assessment, and risk characterization.[15] Hazard identification determines whether exposure to a chemical can cause an increase in the incidence of an adverse health condition (such as cancer or birth defects). It thereby determines the hazards to be evaluated for each chemical being studied.[16] Dose-response assessment characterizes the relationship between the dose of a chemical and the incidence of an adverse health effect, estimating the incidence of the adverse effect as a function of human exposure to the chemical.[17] Exposure assessment

---

14. *See* Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. §§ 9601-9675 (1994).

15. The four elements were described in a 1983 report prepared by the National Research Council (NRC) of the National Academy of Sciences. The NRC wrote the report in response to a request from Congress to address the manner in which federal regulatory programs conduct and use the results of risk assessments. *See* NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 3 (1983) [hereinafter 1983 NRC REPORT].

16. The NRC stated that:

> [Hazard identification] involves characterizing the nature and strength of the evidence of causation. Although the question of whether a substance causes cancer or other adverse health effects is theoretically a yes-no question, there are few chemicals on which the human data are definitive. Therefore, the question is often restated in terms of effects in laboratory animals or other test systems, e.g., 'Does the agent induce cancer in test animals?' Positive answers to such questions are typically taken as evidence that an agent may pose a cancer risk for any exposed humans. Information from short-term in vitro tests and on structural similarity to known chemical hazards may also be considered.

Id. at 19.

17. Dose-response assessment takes account of intensity of exposure, age pattern of exposure, and possibly other variables that might affect response, such as sex, lifestyle, and other modifying factors. A dose-response assessment usually requires extrapolation from high to low dose and extrapolation from animals to humans. A dose-response assessment should describe and justify the methods of extrapolation

estimates the intensity, frequency, and duration of human exposures to a chemical in the environment.[18] Risk characterization combines the results of the exposure and dose-response assessments and estimates the incidence of a health effect under the various conditions of human exposure calculated in the exposure assessment.[19]

Several additional steps are required to assess the risks of hazardous waste incinerators. These facilities emit hundreds of chemicals, many of which have not been identified. The health effects of many chemicals and the dose levels that cause adverse health effects are largely unknown.[20] The chemicals also reach humans through a number of exposure routes including inhalation, food consumption (as chemicals bio-accumulate in the food chain), and skin contact. To address these additional factors, the WTI risk assessors added three preliminary steps: identification of substances of concern, estimation of emission rates, and prediction of the atmospheric transport of the substances.[21]

According to the National Research Council (NRC) of the National Academy of Sciences, risk assessments are one of many factors considered in the decision-making process called "risk management."[22] Risk managers establish permitting standards and decide whether to grant permits. Risk managers balance risk estimates with statutory requirements, the public's risk preferences, the economic importance of the activities, and the cost of controls.[23] Policy issues, such as the level of

---

used to predict incidence and should characterize the statistical and biologic uncertainties in these methods. *See id.* at 19-20.

18. In its most complete form, exposure assessment describes the magnitude, duration, schedule, and route of exposure; the size, nature, and classes of the human populations exposed; and the uncertainties in the estimates. Exposure assessment is often used to identify feasible prospective control options and to predict the effects of available control technologies on exposure. *See id.* at 20.

19. *See id.*

20. Also unknown are the potential synergistic effects of a person's exposure to more than one chemical at a time.

21. *See infra* Part IV.B.

22. The NRC describes "risk management" as the process of evaluating alternative regulatory actions and selecting among them. It is carried out by regulatory agencies under various legislative mandates and entails the consideration of political, social, economic, and engineering information with risk-related information to develop, analyze, and compare regulatory options and to select an appropriate regulatory response to a potential chronic health hazard. It "necessarily requires the use of value judgments on such issues as the acceptability of risk and the reasonableness of the costs of control." 1983 NRC REPORT, *supra* note 15, at 18-19.

23. The chairperson of the 1996 WTI Peer Review Group, a committee of scientists nominated by the EPA, WTI, and the public and selected by the EPA, similarly described the difference between risk assessment and risk management:

> The goal of risk assessment is to estimate a risk; that is, to produce a specific risk value and explain the precision of this estimate. The goal of risk management is to establish the significance of the estimated risk, compare the costs of reducing this risk to the benefits gained, compare the estimated risk to the societal benefits derived from incurring the risk, and implement any political and institutional processes needed to reduce the risk. As a risk assessment document, the main goal of the draft WTI incinerator risk assessment is to give the public and decision-makers adequate information about the nature and likelihood of any health detriment associated with

acceptable risk, are, therefore, at the core of risk management. By contrast, risk assessments are supposed to provide scientifically objective estimates of risk for risk managers to use. The NRC recognized, nevertheless, that certain risk assessment policy choices are unavoidable. Science is not able to provide clear answers on all of the issues in risk assessments. Information may be missing or ambiguous, and scientific theory may not have conclusive answers.[24] Assumptions must, therefore, be chosen among plausible possibilities. In the end, those choices often depend on policy decisions.[25] The NRC calls the points at which this uncertainty occurs "components" and the choices among scientifically plausible assumptions "inference options."[26]

This article explains that policy decisions have a substantial role in risk assessments. Policy decisions in risk assessments should be coordinated with the policy decisions in risk management and both should be fully informed with public input.

B. The EPA's Regulations and Guidance Documents

Hazardous waste facilities are permitted and regulated largely on the basis of technology-based performance standards. RCRA requires the EPA to establish performance standards that regulate factors such as combustion efficiency, operating practices, emergency plans, training plans, and financial responsibility.[27] The Act, however, also requires the EPA to establish permit conditions that are protective of human health and the environment.[28]

The EPA has established performance standards but concedes that the standards may not be sufficient to protect human health and the environment. The EPA

> the WTI facility. Prescriptions for technological, social, legal, or political control actions are risk management decisions and are not explicitly discussed in the draft assessment. Neither the draft risk assessment nor this workshop considered risk management issues.

U.S. EPA, PUB. NO. EPA-630-R96-001, REPORT ON THE U.S. EPA TECHNICAL WORKSHOP ON WTI INCINERATOR RISK ASSESSMENT ISSUES, ch. 2, at 1-2 (May 2, 1996) [hereinafter 1996 PEER REVIEW REPORT]. The WTI peer review process is described more fully at *infra* notes 87-93 and accompanying text.

24. *See* 1983 NRC REPORT, *supra* note 15, at 28.

25. The NRC stated that:

> [a] key premise of the proponents of institutional separation of risk assessment is that removal of risk assessment from the regulatory agencies will result in a clear demarcation of the science and policy aspects of regulatory decision-making. *However, policy considerations inevitably affect, and perhaps determine, some of the choices among the inference options.*

Id. at 33 (emphasis added).

26. *Id.* The NRC identified 25 specific components in hazard identification, 13 components in dose-response assessment, eight components in exposure assessment, and four components in risk characterization. *See id.* at 29-33.

27. *See* 42 U.S.C. § 6924(a) (1994).

28. *See id.* § 6925(c).

acknowledges gaps in knowledge about the emissions and their health effects as well as the lack of sufficient monitoring technologies.[29] The EPA's 1998 Risk Assessment Protocol, in particular, states that the performance standards may not fully address potentially significant risks of dioxin, mercury, and other chemicals absorbed through food chain exposure pathways.[30]

On September 30, 1999, the EPA approved a technology-based National Emission Standard for Hazardous Air Pollutants (NESHAPS) for hazardous waste incinerators under the joint authority of the Clean Air Act and RCRA.[31] The EPA's intent, when it initiated the rulemaking in 1996, was to establish a NESHAPS, based upon Maximum Achievable Control Technologies (MCAT), that would be sufficient to protect human health and the environment and eliminate the need for heath-based regulations under RCRA, including the performance of site-specific risk assessments.[32]. Nevertheless, when approving the final rule in 1999, the EPA still found that the combination of technology-based NESHAPS and RCRA controls would not always be sufficiently protective.[33]

---

29. The preambles to the regulations establishing the original performance standards in 1981 state these concerns. *See* 46 Fed. Reg. 7666 (1981) (codified in 40 C.F.R. pts. 122, 264, and 265). The EPA was still reciting them in 1991 when promulgating standards for boilers and industrial furnaces. *See* 56 Fed. Reg. 7134 (1991) (codified in 40 C.F.R. pts. 260, 261, 264, 265, 266, 270, and 271).

The EPA has not been able to identify all of the chemical compounds that are emitted. The "fuel" for a hazardous waste incinerator is not a consistent substance. Hazardous waste differs among customers/suppliers, and wastes are mixed for storage and to promote efficient burning. As a result, the combustion efficiency for different waste feeds is likely to vary.

In addition, the burning of any particular waste feed produces the emission of thousands of products of incomplete combustion (PICs). PICs can be unburned organic compounds that are present in the waste or compounds generated during or immediately after combustion. Some, such as dioxins and furans, are more hazardous than the wastes from which they were produced. The EPA stated recently that it has been able to identify at most 60 percent of the number of compounds emitted and, in many tests, only five to ten percent. *See* 56 Fed. Reg. 7134, 7149-50, 7153-54 (1991).

The technology for emissions monitoring is also limited. Monitoring technology is available only for a few chemical compounds, and most of the equipment does not record emissions on a continuing basis. Instead, the RCRA permit controls emissions indirectly through waste feed analysis and monitoring of operating conditions affecting combustion efficiency.

The means and knowledge of assessing health risks are also limited. Not only does the EPA lack information about the compounds being emitted, it also lacks information about the health impacts of the emissions which it has identified. *See infra* Parts IV.B.1, IV.C.1.

30. U.S. EPA, PUB. NO. EPA-530-D98-001A, PEER REVIEW DRAFT, HUMAN HEALTH RISK ASSESSMENT PROTOCOL FOR HAZARDOUS WASTE COMBUSTION FACILITIES, vol. 1, ch. 1, at 2 (July 1998) [hereinafter 1998 RISK ASSESSMENT PROTOCOL].

31. *See* 64 Fed. Reg. 52,828 (Sept. 30, 1999). The EPA established the NESHAPS under section 112 of the Clean Air Act, 42 U.S.C. § 7412, and in pursuit of its duty under RCRA to ensure that hazardous waste combustion is conducted in a manner that is protective of human health and the environment. *See* 42 U.S.C. § 6925.

32. *See* 61 Fed. Reg. 17,360 (April 19, 1996).

33. *See* 64 Fed. Reg. 52,828, 52,841 (Sept. 30, 1999). The 1999 NESHAPS established emissions limits for dioxins and mercury—two of the EPA's previous concerns in 1981 and 1991—but stated that it lacked sufficient information to show that the controls adequately address risks from mercury and non-dioxin PICs or the enhanced risks from other compounds under the unique characteristics of each site (i.e.,

Despite these limitations, the EPA has not formally established health risks as an explicit criterion in its permitting standards and has not determined acceptable levels of those risks. The EPA implements its "omnibus" authority to protect human health with case-by-case reviews, based on policies and non-binding guidance documents. In May 1993, the EPA established a policy that requires the performance of risk assessments for new incinerators, but the policy did not establish standards of acceptable risks for a permit decision.[34] The policy left the issue of acceptable risk to the EPA's case-by-case discretion.[35]

In April 1994, the EPA published draft guidelines that recommended standards of acceptable risk, i.e., 1 in 100,000 for cancer and a "hazard index" of less than 0.25 for noncancer risks.[36] The EPA defined the risks of cancer in probabilities, based upon the assumption that there is no single line that divides safe from unsafe exposures.[37] The Agency calculated the risks of health effects other than cancer, however, based upon the assumption that each chemical has a threshold exposure level (Reference Dose (RfD)) for such effects.[38]

"Hazard quotients" and "hazard indices" are ratios that express the relationship of the expected doses to the RfDs.[39] Hazard quotients are determined for individual

---

"unusual terrain and dispersion features, particularly sensitive ecosystems, unusually high contaminant background concentrations and mercury methylation rates in surface water." *Id.*

34. The requirement for risk assessments in the permitting of hazardous waste incinerators was included in the EPA's 1993 Draft Strategy for the Combustion of Hazardous Waste in Incinerators and Boilers. *See* U.S. EPA, PUB. NO. EPA 530-R94-044, DRAFT STRATEGY FOR THE COMBUSTION OF HAZARDOUS WASTE IN INCINERATORS AND BOILERS: INTERIM FINAL GUIDANCE ON WASTE MINIMIZATION FOR HAZARDOUS WASTE GENERATORS (May 18, 1993), *reprinted in* 24 Env't. Rep. (BNA) No. 3, at 157-161 (May 21, 1993) [hereinafter 1993 DRAFT COMBUSTION STRATEGY]. The Draft Strategy was finalized in 1994. *See* U.S. EPA, FINAL EPA STRATEGY FOR HAZARDOUS WASTE MINIMIZATION AND COMBUSTION (Nov. 8, 1994), *reprinted in* Daily Env't. Rep. (BNA) (Nov. 21, 1994) [hereinafter 1994 FINAL COMBUSTION STRATEGY].

35. *See* 1993 DRAFT COMBUSTION STRATEGY, *supra* note 34, at 160.

36. U.S. EPA, PUB. NO. EPA-530-R94-021, IMPLEMENTATION GUIDANCE FOR CONDUCTING INDIRECT EXPOSURE ANALYSIS AT RCRA COMBUSTION UNITS, DRAFT (April 22, 1994) [hereinafter 1994 DRAFT RISK ASSESSMENT GUIDELINES]. The guidelines use these levels over the less stringent levels of 1 in 10,000 and a hazard index of 1.0 to account for exposures to background levels of contaminants. *See id.* at 15. The EPA's designation of guidance documents as "drafts" notes that the guidelines have not been finally approved by the agency, but the Agency nevertheless generally follows the advice of the "draft" documents as soon as they are published.

37. *See infra* Part IV.C.3.a.i.

38. *See* U.S. EPA, PUB. NO. 600-690-003, METHODOLOGY FOR ASSESSING HEALTH RISKS ASSOCIATED WITH INDIRECT EXPOSURE TO COMBUSTOR EMISSIONS, INTERIM FINAL, at ch. 15 (1990) [hereinafter 1990 INDIRECT RISK GUIDELINES]. According to the 1990 Indirect Risk Guidelines, a RfD is an "estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime." *Id. See also* U.S. EPA, PUB. NO. EPA 600-AP93-003, ADDENDUM TO METHODOLOGY FOR ASSESSING HEALTH RISKS ASSOCIATED WITH INDIRECT EXPOSURE TO COMBUSTOR EMISSIONS, EXTERNAL REVIEW DRAFT (1993) [hereinafter 1993 ADDENDUM TO THE 1990 INDIRECT RISK GUIDELINES].

39. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. VIII, at 3-4. If the expected dose of a chemical (i.e., the numerator) exceeds the RfD (i.e., the denominator), the expected dose is considered

chemicals. Hazard indices are the sum of the hazard quotients for the chemicals assessed.[40]

In December 1994, the EPA published a recommended standard for use in screening level risk assessments for dioxin exposures to breast-feeding infants.[41] The guidelines noted the uncertainty and the need for further research on the issue but established the value recommended in the EPA's Dioxin Exposure Document as an acceptable standard.[42]

The EPA's 1998 Draft Human Health Risk Assessment Protocol, which had been developed by EPA Region Six, confirmed as "target levels" of acceptable risk for cancer and noncancer effects the 1 in 100,000 and 0.25 hazard index values used in the previous guidance documents.[43] The Protocol also increased the dioxin exposure standard for breast-feeding infants and established separate risk targets for lead exposures and acute exposures resulting from direct inhalation.[44] It declined,

---

sufficient to cause noncancer effects, and the ratio, or "hazard quotient," will exceed 1.0. If the expected dose is less than the RfD (i.e., the "hazard quotient" is less than 1.0), the risk assessors conclude that no noncancer effects will be anticipated from that chemical. *Id.*

If the sum of the hazard quotients (i.e., the "hazard index") of all of the chemicals is less than 1.0, no noncancer effects are expected. *See id.* If the sum is greater than 1.0, the hazard quotients are segregated according to the organs which they are expected to affect, and separate per-organ hazard indices are calculated to determine whether each organ is expected to experience an adverse health effect. *See id.*

40. *See* 1990 INDIRECT RISK GUIDELINE, *supra* note 38, at 2.

41. The EPA conducts "screening" risk assessments based upon limited data and assumptions intended to be conservative. Screening risk assessments can be performed relatively quickly and inexpensively and are intended to determine whether a more detailed risk assessment is warranted. *See* OFFICE OF EMERGENCY AND REMEDIAL RESPONSE AND OFFICE OF SOLID WASTE, U.S. EPA, GUIDANCE FOR PERFORMING SCREENING LEVEL RISK ANALYSES AT COMBUSTION FACILITIES BURNING HAZARDOUS WASTES (December 14, 1994). [hereinafter DECEMBER 1994 SCREENING RISK ASSESSMENT GUIDELINES]. The December 1994 guidelines revised an almost identical version of the guidelines approved on April 15, 1994. *See* OFFICE OF EMERGENCY AND REMEDIAL RESPONSE AND OFFICE OF SOLID WASTE, U.S. EPA, GUIDANCE FOR PERFORMING SCREENING LEVEL RISK ANALYSES AT COMBUSTION FACILITIES BURNING HAZARDOUS WASTES (April 15, 1994) [hereinafter APRIL 1994 SCREENING RISK ASSESSMENT GUIDELINES].

The December 1994 guidance is controversial due in large part to the potential ramifications of the breast-feeding infant standard. The guidance document states that the average daily dose for one year of breastmilk exposure should be compared to (and presumably not exceed) the average adult background exposure level for dioxin of 0.5 pg/kg/day, as suggested in the EPA's 1993 Dioxin Reassessment. *See* DECEMBER 1994 SCREENING RISK ASSESSMENT GUIDELINES, *supra* at C-5 to C-53. EPA officials have since informally disavowed the document, claiming that its release was not fully approved. *See* Interview with Alec McBride, Office of Solid Waste and Emergency Response.

42. *See* DECEMBER 1994 SCREENING RISK ASSESSMENT GUIDELINES, *supra* note 41, at C-5 to C-53. The EPA's Dioxin Exposure Document was prepared in connection with the EPA's formal reassessment undertaken in 1991 of the hazards posed by dioxins and furans. *See* U.S. EPA, OFFICE OF RESEARCH AND DEVELOPMENT, ESTIMATING EXPOSURE TO DIOXIN-LIKE COMPOUNDS, WORKSHOP REVIEW DRAFT (August 1992).

43. *See* U.S. EPA, PUB. NO. EPA-R698-002, REGION SIX RISK MANAGEMENT ADDENDUM - DRAFT HUMAN HEALTH RISK PROTOCOL FOR HAZARDOUS WASTE COMBUSTION FACILITIES 2-3 (July 1998) [hereinafter 1998 RISK ASSESSMENT PROTOCOL ADDENDUM].

44. *See id.* at 4-7. The 1998 Risk Assessment Protocol recommends that the average infant intake be compared to the estimated average exposure in breast milk of 60 pg/kg/day, up from the 0.5 pg/kg/day

however, to establish a risk target for "cumulative risk" which would have included the risks of the emissions from the hazardous waste combustion units and also the risks from other pollutants and processes at the facility and from other sources of pollutants in the community.[45]

The Risk Assessment Protocol also assumed that the risk estimates would be overly conservative. If the risk estimates satisfied the target levels, the facility would be considered safe. If the risk estimates exceeded the target levels, however, the EPA would perform more detailed analyses, leaving the establishment of restrictive permit conditions and the potential denial of the permit as last resorts.[46]

None of the guidelines are binding, however. The EPA also left to the discretion of the risk assessors many important policy issues, many of which had to be addressed in the WTI risk assessment.

C. The WTI Risk Assessment

1. The Process

The state and federal permits for the WTI hazardous waste incinerator were issued in 1983 and 1984.[47] Construction began in 1990, and the plant was completed in 1992. "Shakedown" operations began in November 1992, and a trial burn was conducted in March 1993.[48] The plant failed part of the trial burn, but the EPA

---

level recommended in the December 1994 Screening Risk Assessment Guidelines. *See id.* at 6.

The Protocol also recommended that the noncancer risks from dioxins for adults be assessed by comparing a facility's emissions with national average background exposures for adults. The Protocol stated that the emissions will not be expected to cause noncancer effects "[i]f exposures due to the facility's emissions . . . are *low* compared to background exposures." 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 43 (emphasis added). The recommendation was contained in the risk assessment portion of the Protocol, not in the section of the Risk Management Addendum establishing the target levels of acceptable risk. *Id.*

45. The EPA stated that the Agency does not typically evaluate cumulative risks in its permitting decisions. It stated that the agency is evaluating new programs, such as the Common Sense Initiative, which may address cumulative risks and that the agency may, on a case-by-case basis, conduct cumulative risk analyses where there are site-specific concerns. *See* 1998 RISK ASSESSMENT PROTOCOL ADDENDUM, *supra* note 43, at 8-9.

46. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, at 3, 6-7, ch. 7, at 9, and ch. 8, at 2.

47. *See* Permit to Install (Ohio EPA Feb. 2, 1983); Hazardous Waste Management Permit (U.S. EPA June 24, 1983); Hazardous Waste Facility Installation and Operation Permit (Ohio EPA April 27, 1984).

48. When a RCRA permit is issued for a hazardous waste incinerator, operating conditions are established for a shakedown period, a trial burn and a post-trial burn period of indefinite length. *See* 40 C.F.R. § 270.62 (1998). The shakedown consists of a period of limited operations over a period of 720 hours, with one potential renewal, during which the operator brings the incinerator to a point of operational readiness to conduct a trial burn. *See id.* The trial burn consists of a series of burns over a one to two week period under different operating conditions during which the operator tests the incinerator's ability to satisfy EPA's technology-based performance standards. During the post-trial burn, the agency reviews the trial

allowed it to continue operating in its "post-trial burn" mode until the state and federal government established final operating conditions, based on the results of a further successful trial burn.[49] The EPA postponed the establishment of final operating conditions until after the release of the final risk assessment.[50]

In the interim, the EPA decided to do the risk assessment in the summer of 1992. The EPA performed the risk assessment in two parts. First, it did an initial "screening risk assessment" based on limited site-specific data and addressed only the human health impacts resulting from inhalation.[51] The second, more extensive part included certain site-specific meteorological data, actual emissions data collected during the facility's testing, and demographic studies of the populations in the East Liverpool area.[52] In addition to inhalation risks, it considered risks from indirect exposures through the food chain. In response to the recommendations of the EPA's peer review groups, the EPA also included separate assessments for the risk of accidents and risks to the environment.[53]

The screening risk assessment, issued in 1992,[54] and the full-scale assessment, issued on May 8, 1997,[55] concluded that WTI's emissions were not expected to cause cancer or noncancer health effects.[56]

No immediate opportunity for judicial review of the risk assessment methods and results existed. The only judicial review was of the final agency action taken on the basis of the risk assessment. In this case, that final action came in the form of the approval of final operating conditions, more than two years after the original ten-year RCRA permit expired.[57]

---

results and establishes final operating conditions. The WTI risk assessment was started during shakedown, shortly before the start of the trial burn. *See generally* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30 (describing timing of incinerator risk assessments).

49. *See* Letter from William E. Muno, U.S. EPA, to Waste Technology Industries (May 7, 1993).

50. The final risk assessment was released in May 1997, five years after its start and two years after the 10-year RCRA operating permit expired. The facility was allowed to continue operations upon the filing of its application for renewal. *See* 40 C.F.R. § 270.51(a)(1)(2) (1998).

51. U.S. EPA, PRELIMINARY RISK ASSESSMENT OF INHALATION EXPOSURES TO STACK EMISSIONS FROM THE WTI INCINERATOR (1992) [hereinafter PHASE I RISK ASSESSMENT].

52. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. I, ch. 1, at 2.

53. *See infra* notes 87-93 and accompanying text; *see also infra* Part V.D.4 (discussing the selection and work of the WTI peer review groups).

54. *See* Muno, *supra* note 49.

55. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. I, at 4-5. *See also* U.S. EPA, RISK ASSESSMENT FOR THE WASTE TECHNOLOGIES INDUSTRIES (WTI) HAZARDOUS WASTE INCINERATOR FACILITY, DRAFT (East Liverpool, Ohio) (November 1995) [hereinafter 1995 DRAFT RISKASSESSMENT].

56. *See* 1993 PEER REVIEW REPORT, *supra* note 1, ch. 1, at 3-4. *See also* 1995 DRAFT RISK ASSESSMENT, *supra* note 55, vol. I, ch. IV, at 4-5.

57. *See* 42 U.S.C. § 6976(b) (1994). *See generally* 40 C.F.R. § 124.15 (1998) (setting forth effective dates for final permit decisions).

2. The Human Health Risk Assessment

The human health risk assessment did not produce a single comprehensive risk estimate for the plant or a single estimate of cancer and noncancer risks.[58] It produced a series of quantitative and qualitative risk estimates, including separate risk estimates for stack emissions and fugitive emissions; separate risk estimates for a primary group of chemicals; and separate risk estimates for dioxins and furans, lead, and other criteria pollutants.[59] The EPA also calculated separate risk estimates for the exposures expected from the behavior patterns of various population groups and the different concentrations occurring throughout the study area.[60] For each of these categories, the EPA also calculated separate risk estimates for cancer and noncancer risks.

The 1994 Risk Assessment Guidelines recommend that the risk estimates be calculated for populations of individuals at the "high end" (i.e., at or above the 90th percentile) of individual exposures in that population.[61] For any given ambient concentration of a pollutant, individuals in a population will absorb varying amounts of the pollutant. Their exposures will depend upon individual physical characteristics and behavior patterns, such as breast-feeding infants, or eating homegrown foods.[62]

The WTI risk assessment, however, calculated high end risks only for a subsistence farmer and the child of a subsistence farmer. In particular, the EPA did

---

58. The risk assessment calculated risk estimates only for selected chemicals and for selected health effects of such chemicals. Many compounds and health effects were omitted due to the lack of EPA-approved toxicity values. *See infra* Parts IV.B.1., IV.C.1.

59. "Criteria pollutants" are air pollutants which the EPA has determined, pursuant to section 108 of the Clean Air Act, are widespread and which may endanger public health and welfare, and for which the EPA has published "criteria" documents describing their health effects. *See* 42 U.S.C. §§ 7408(a)(2)(A)-(C). The pollutants include carbon monoxide, sulfur dioxide, nitrogen oxides, lead, ozone, and PM-10 (particulate matter of 10 microns or less). *See id.* § 7412(b)(1). The EPA has established National Ambient Air Quality Standards for the criteria pollutants under section 109 of the Clean Air Act. *See id.* § 7409(b)(1)-(2).

The risk assessment assessed quantitatively the inhalation risks of approximately 200 chemicals and the risks of indirect exposures to a 45-chemical subset of the inhalation list (comprised of 13 metals and 32 organic residues, including 17 dioxin and furan congeners). *See infra* Parts IV.B.1, IV.C.1. Of the 213 chemicals assessed for inhalation risks, 154 lacked toxicity values for cancer and 94 lacked toxicity values for noncancer effects. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, at tbls. III-1, III-18, III-24. The subset was chosen in part because they were considered the most significant contributors to risk and partly because of the unavailability of EPA-approved toxicity values for others. The analysis of both groups was hampered by the lack of EPA-approved toxicity values which generally led the EPA to omit their risks. For chemicals lacking EPA-approved toxicity values, such as dioxins and furans, lead and the other criteria pollutants, the EPA devised separate risk analyses and results. *See id.*

60. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, at ch. VII.

61. *See id. See also* 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 36, at 15. The guidelines define "high end" exposures as plausible estimates of individual exposures for those persons at the upper end of the distribution of such exposures. It means exposures above the 90th percentile of the population distribution but not higher than the individual in the population who has the highest exposure. *See id.* at 12.

62. *See* 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 36, at 12.

not calculate the high-end risks for breast-feeding infants which is the population with the highest risk, based upon average exposures. The EPA's risk estimates for subsistence farmers and children of subsistence farmers only narrowly satisfied the acceptable risk levels in the draft guidelines:[63]

High-End Cancer Risks[64]
(Compared to the standard of 1×10^{-5})

	Subsistence Farmer Adult	Subsistence Farmer Child
Area Average	7×10^{-6}	7×10^{-6}

High-End Noncancer Hazard Indices[65]
(Compared to the standard of 0.25)

	Subsistence Farmer Adult	Subsistence Farmer Child
Area Average	0.02	0.10

The rest of the risk estimates focused on average risks, based on average emission rates and "typical" exposure factors.[66] The highest average risk at the average and maximum level of exposures was for breast feeding infants. These risks also came close to the EPA's limits but still satisfied them:

Average Cancer Risk for Breast-Feeding Infants:[67]
(Compared to the standard of 1×10^{-5})

	Resident	Farmer	Subsistence Farmer
Area Average	4×10^{-7}	7×10^{-7}	2×10^{-6}
Maximum Location	1×10^{-6}	2×10^{-6}	5×10^{-6}

63. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. 8, at 12.
64. *Id.* tbls. VIII-14 and VIII-15.
65. *Id.*
66. *See id.* tbl. VIII-8 to VIII-11.
67. *Id.* tbl. VIII-20.

No noncancer risks were calculated for breast-feeding infants. The EPA stated that the application of noncancer toxicity data to infants was subject to "significant uncertainty."[68]

The next highest average risks were calculated for the subsistence farmer and the child of the subsistence farmer. These also satisfied the EPA's draft guidelines:

Average Cancer Risks[69]

	Subsistence Farmer Adult	Subsistence Farmer Child
Area Average	1×10^{-6}	1×10^{-6}
Maximum Location	4×10^{-6}	4×10^{-6}

Average Noncancer Hazard Indices[70]

	Subsistence Farmer Adult	Subsistence Farmer Child
Area Average	0.02	0.07
Maximum Location	0.05	0.20

The quantitative estimates just noted, however, do not include the noncancer risks of dioxins for any population group;[71] the cancer and non-cancer risks of criteria pollutants, including lead; the risks of chemicals lacking EPA-approved toxicity values and unidentified emissions.[72] The EPA developed ad hoc analyses and standards for these chemicals and determined that the risks satisfied the standards.[73]

---

68. *Id.* tbl. VIII-17 to VIII-18. Such an analysis, however, would probably be performed under the 1998 Risk Assessment Protocol. The risks of dioxin exposures to breast-feeding infants are not discussed in the Risk Characterization portion of the Protocol, but the Risk Management Addendum to the Protocol establishes standards of acceptable risk for such exposures. 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 7; *see generally* 1998 RISK ASSESSMENT PROTOCOL ADDENDUM, *supra* note 43, at 4-6 (establishing standards of acceptable risk for dioxin exposures).

69. FINAL RISK ASSESSMENT, *supra* note 6, vol. V, at tbl. VIII-12.

70. *Id.* tbl. VIII-13.

71. Instead, the EPA used a separate "margin of exposure" approach (i.e., comparison of incremental exposures from WTI to national average background levels) that merely determined that "the probability is low that the incremental exposure due to emissions from WTI would result in a significantly increased body burden of dioxin-like compounds for the majority of the population in the vicinity of the incinerator." *Id.* at VIII-31 to VIII-32.

72. *Id.* at III-8 to III-10; *see also infra* Part VI.

73. The ad hoc approaches for noncancer effects of dioxins and the general health effects of lead exposures were later approved for continuing use in the 1998 Risk Assessment Protocol. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 42, 59. The Protocol also stated that the Agency might develop further alternative approaches in the future. *See id.* at 43.

Based upon the combination of results, the EPA concluded that cancer and noncancer health effects were not anticipated.

3. The Accident Analysis

The accident analysis produced separate qualitative results. It characterized the risks of accidents in terms of probability and severity and reached the following conclusions on the risks of accidents occurring at the facility:[74]

-- Only events with *minor* off-site consequences are considered *likely* to occur.[75]

-- Only events with *minor* or *moderate* off-site consequences are considered *reasonably likely* to occur.[76]

-- Events with potentially *major* off-site consequences are considered *unlikely* to occur.[77]

-- Events with potentially *catastrophic* off-site consequences are considered *very unlikely*.[78]

Professor Thomas McKone of the WTI Peer Review Group interpreted these descriptions as suggesting that accident represented the greatest of the facility's risks.

---

74. Probability was defined in the following five categories:
-- Common: Expected to occur one or more times each year on average.
-- Likely: Expected to occur at least once every 10 years on average.
-- Reasonably Likely: Predicted to occur between once every 10 years and once every 100 years on average.
-- Unlikely: Predicted to occur between once every 100 years and once every 1,000 years.
-- Very Unlikely: Predicted to occur less than once in 1,000 years.
FINAL RISK ASSESSMENT, *supra* note 6, vol. I, at VII-9.
Severity was defined in terms of EPA Level of Concern (LOC) values and National Institute of Occupational Safety and Health (NIOSH) Immediately Dangerous to Life or Health (IDLH) values:
-- Minor: No exceedance of an LOC or IDLH value in inhabited off-site areas; and negligible potential for off-site fatalities or serious injuries due to heat effects from a fire.
-- Moderate: Exceedance of LOC values in inhabited off-site areas over distances of 200 meters or less; injuries due to heat effects limited to a distance of 200 meters into inhabited areas; or exceedance of IDLH values in inhabited off-site areas over distances of 100 meters or less; injuries due to heat effects limited to a distance of 100 meters into inhabited areas.
-- Major: Exceedance of LOC values in inhabited off-site areas over distances between 200 meters and 2,000 meters; injuries due to heat effects limited to a distance of 2,000 meters into inhabited areas; or exceedance of IDLH values in inhabited off-site areas over distances between 100 meters and 1,000 meters; injuries due to heat effects limited to a distance of 1,000 meters into inhabited areas.
-- Catastrophic: Exceedance of LOC values in inhabited off-site areas over distances greater than 2,000 meters; injuries due to heat effects extend to distances greater than 2,000 meters into inhabited areas; or exceedance of IDLH values in inhabited off-site areas over distances greater than 1,000 meters; injuries due to heat effects extend to distances greater than 1,000 meters into inhabited areas.
Id. vol. I, at VII-9.

75. *See* id. vol. I, at VII-10.

76. *See id.*

77. *See id.*

78. *See id.*

He stated that, based upon the results, there is a likelihood of at least one fatality in the community as the result of accidents every ten years.[79]

The 1998 Risk Assessment Protocol did not include a means to address accident risks. It did give risk assessors the discretion, however, to investigate the issue on a case-by-case basis.[80]

4. The Screening Ecological Risk Assessment

The EPA's Screening Ecological Risk Assessment (SERA) presented risk estimates in still another format. As a "screening level" analysis, the SERA was intended to provide an initial conservative evaluation to determine whether the potential risks to plants and wildlife warranted a more detailed study, on the order of the human health risk assessment.[81] The SERA used as applicable emissions rates the average rates expected for routine operations (i.e., the rates used in the human health risk assessment) and, unlike the human health risk assessment, rates that used the maximum metals emissions allowed under WTI's permit.[82]

The SERA calculated "low to negligible" risks for the "expected" emissions rates.[83] The "permit limit" scenario, however, produced risks of "relatively high magnitude" for terrestrial plants and animals from the metals.[84] Although screening level analyses are used to determine the need for further, more detailed analyses, the risk assessors concluded that the permit limit scenario did not warrant further study.[85] They stated that the routine operations scenario produced acceptable levels of risk and they did not expect the permit limit scenario to occur.[86]

5. The 1993 and 1996 Peer Review Groups

A scientific peer review group oversaw the work of the WTI risk assessors at two stages—after the preparation of a scope and plan (the 1993 WTI Project Plan) and

---

79. *See* 1996 PEER REVIEW REPORT, *supra* note 23, at D-114. McKone stated that "much of the public health risk (in terms of likelihood of harm) is associated with accidents and not with routine stack and fugitive emissions." *Id.* at D-106. The accident risk "is a very large risk relative to the one in a million chance of cancer per individual." *Id.* at D-114. *See infra* notes 83-86 (describing the work of the WTI peer review group).

80. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 3.

81. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. I, ch. VI, at 1.

82. *See id.* at 4. The SERA also used a set of high-end emission rates (i.e., 95 percent upper confidence limit values) for certain organic stack emissions. *See id.* These rates also produced "low to negligible" risks for ecological receptors. *See id.* vol. VI, ch. VI, at 16-17.

83. *Id.* at 7.

84. *Id.* at 8.

85. *See id.* at 9.

86. *See id.* The 1998 Risk Assessment Protocol only addresses human health risk assessments. It does not address ecological risk assessments. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30.

after the completion of the 1995 Draft Risk Assessment.[87] The EPA chose the peer review members from a list of scientists nominated by Agency staff and the public, including the hazardous waste industry and citizen opponents.[88]

Further, although the EPA did not allow public comment on the project plan or the risk assessment, the peer review groups did—albeit in a limited scope. The groups' meetings were open to the public, and members of the public were allowed to ask questions, make statements, and submit written materials.

Both peer review groups made substantial comments. The first group recommended a significantly expanded scope, which may have contributed to a delay in the process for more than a year. The final risk assessment addressed the near-term recommendations of the second peer review group[89] and generally omitted the group's long-term recommendations.[90] The final risk assessment made only a few changes to

---

87. The NRC recommended the concept of peer reviews in 1983 for risk assessments studying exposures to individual toxic chemicals, with the caveat that the Agency not be required to accept the group's recommendations. The EPA has not, however, adopted peer review groups in regulation or guidance. *See* 1983 NRC REPORT, *supra* note 15, at 156-60.

The groups' recommendations were presented in the 1993 and 1996 PEER REVIEW REPORTS, *supra* notes 1 and 23.

88. *See* 1993 PEER REVIEW REPORT, *supra* note 1, at V. The first group, comprised of 13 members, was divided into four study groups to analyze combustion engineering, meteorological/air dispersion, exposure assessment, and toxicology. *See id.* The second group, comprised of 19 members including 11 from the first group, was divided into five study groups, reflecting the expanded risk assessment plan recommended by the 1993 Peer Review Group. The air dispersion group was expanded to include accident analysis. A fifth group was established to review the ecological risk assessment recommended by the 1993 Peer Review Group.

89. The following are the 1996 Group's primary conclusions and recommendations:

> -- The scientific quality of the draft WTI incinerator risk assessment is considerably better than that of the 1993 risk assessment plan.
>
> -- In preparing the assessment, EPA addressed the major recommendations of the 1993 peer review panel.
>
> -- Some important uncertainties (the confidence with which accident scenarios and impacts can be specified, the influence of data gaps on emission and health impact estimates, the quantification of noncancer impacts of dioxin-like compounds) need to be addressed prior to closure.
>
> -- Emissions of WTI chemicals of concern from other proximate industrial sources and even from local residential combustion sources should be factored into the assessment to facilitate the calculation of better cumulative dose and impact estimates and the development of validation studies.
>
> -- The goals and conclusions of the [Screening Ecological Risk Assessment] are vague.
>
> -- In the accident analysis, the accident scenarios are incomplete and their contribution to information on possible health detriment is inadequately addressed; also, accident-related risks are not fully quantified.

1996 PEER REVIEW REPORT, *supra* note 23, at 2-3.

90. The EPA stated that the long-term recommendations generally addressed future risk assessments. However, the risk assessors did provide such a response where they "believed that either a long-term recommendation or a specific element of a background narrative could benefit from an Agency response." FINAL RISK ASSESSMENT, *supra* note 6, vol. I, ch. VIII, at 2.

the body of the 1995 draft document and did not recalculate the risk estimates. The risk assessors addressed the peer reviewers' comments in a separate volume.[91]

Several members of the second group criticized the EPA's response to their recommendations. They stated that the responses were insufficient, and they criticized the EPA's failure to give the members adequate time to review the risk assessors' responses to the peer review group's comments before releasing the 1997 report as final.[92] The EPA stated later that it would accept comments from the second peer review group—after they had a chance to review the final document—and that the EPA would prepare an addendum if it considered the group's comments sufficiently serious to require further analysis.[93]

II. RISK MANAGEMENT VERSUS "RISK ASSESSMENT POLICY"—THE MIX OF SCIENCE AND POLICY CHOICES

The NRC's 1983 report on risk assessments warned that scientists, not policy-makers, may be making policy decisions in the risk assessment process, unbeknownst to the public and the Agency policy-makers:

> A review of the list of components [i.e., the points at which the uncertainties occur] reveals that many components lack definitive scientific answers, that the degree of scientific consensus concerning the best answer varies (some are more controversial among scientists than others), and that the inference options available for each component differ in their degree of conservatism. The choices encountered in risk assessment rest, to various degrees, on a mixture of scientific fact and consensus, on informed scientific judgment, and on policy determinations (the appropriate degree of conservatism)....That a scientist makes the choices does not render the judgments devoid of policy implications. Scientists differ in their opinions of the validity of various options, even if they are not consciously choosing to be more or less conservative....*As a result, the choice made may be perceived by the scientist as based primarily on informed scientific judgment. From a regulatory*

---

91. *See id.* vol. VIII.

92. *See* 1996 PEER REVIEW REPORT, *supra* note 1, at comts. of Halstead Harrison; *see also* Margaret Newkirk, *Scientists Fired Up About Incinerator*, AKRON BEACON J., May 24, 1997, at A1. Halstead Harrison, professor of atmospheric sciences at the University of Washington, complained that the release of the final risk assessment before the peer reviewers had submitted their final comments made their work moot. *See* 1996 PEER REVIEW REPORT, *supra* note 2, at comts. of Halstead Harrison. Thomas McKone, professor in the School of Public Health at the University of California at Berkeley, stated that he "looked at the new material carefully. And I still had concerns. You can't consider what I did a thorough audit. There wasn't enough time. [The risk assessors] did address every one of our comments. But they didn't address all of our comments completely." Newkirk, *supra* at A5.

93. *See* Newkirk, *supra* note 92, at A5.

> *official's point of view, the same choice may appear to be a value decision as to how conservative regulatory policy should be, given the lack of a decisive empirical basis for choice.*[94]

The NRC did not recommend that the practice change, i.e., that policy-makers take greater control over "risk assessment policy." Instead, the NRC recommended that the risk assessors merely identify the uncertainties, the assumptions selected to address them, and the basis for the selections.[95]

Likewise, the NRC did not recommend that the policy decisions receive public input. It recommended that the risk assessment document containing the bases for the policy decisions "be made accessible to the public at a time and in a form that facilitates public participation in any attendant *risk management* decision."[96]

The NRC distinguished the policy elements of risk assessment decisions, which it called "risk assessment policy," from the policy elements in risk management.[97] Risk assessment policy weighs the use of alternative scientific theories, while risk management weighs political, social, and economic factors with the risk assessment results.[98]

The NRC did not rule out the possibility of public comment on risk assessment policy issues, but it did not encourage it. It stated that public comment was no substitute for scientific peer review and that its influence, or the likelihood that it would interject risk management policy into risk assessment policy, would undermine the credibility of the risk assessment results.[99]

In 1994, the NRC revisited the use of risk assessments in regulatory matters and concluded that agencies were not doing a sufficient job in

---

94. 1983 NRC Report, *supra* note 15, at 36-37 (emphasis added).

95. *See id.* at 48-49, 153-54.

96. *Id.* at 153 (emphasis added).

97. *See* NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 184-85 (1994) [hereinafter 1994 NRC REPORT].

98. *See id.* at 37.

99. *See id.* at 49.

> Risk management policy, by its very nature, must entail value judgments related to public perceptions of risk and to information on risks, benefits, and costs of control strategies for each substance considered for regulation. . Such information varies from substance to substance, so the judgments made in risk management must be case-specific. *If such case-specific considerations as a substance's economic importance, which are appropriate to risk management, influence the judgments made in the risk assessment process, the integrity of the risk assessment process will be seriously undermined. Even the perception that risk management considerations are influencing the conduct of risk assessment in an important way will cause the assessment and regulatory decisions based on them to lack credibility.*

Id. (emphasis added).

identifying the uncertainties and policy choices in the risk estimates.[100] The NRC stated that the "EPA should not necessarily abandon the use of single-point estimates for decisionmaking, but such numbers must be the product of a consideration of both the estimate of risk and its uncertainties, not appear out of nowhere from a formulaic process."[101]

The NRC recommended the development of risk assessment standards to provide predictability and consistency, to articulate the Agency's treatment of uncertainty, and to keep "risk assessment and risk management from unduly influencing each other" (i.e., to reduce the potential for ad hoc decisions based on political influences).[102] It also recommended that the Agency identify its policy and science bases for the standards.[103] It recommended the adoption of standards as guidelines rather than regulations to provide flexibility to depart from the standards on a case-by-case basis, and it proposed the development of criteria to guide when and how to depart from the standards.[104]

The NRC also recommended that the public be allowed to participate in the development of the standards, although it suggested no clearly defined methods for the participation to occur. The NRC recommended peer reviews, "workshops and other devices," but emphasized that the focus of the reviews should be on science.[105] It also suggested that the Agency should be required to prepare responses to the comments to assure the public that the methods chosen are scientifically justifiable.[106] Further, the NRC proposed that the public have the ability to petition the Agency for departures from the guidelines.[107] The NRC did not, however, address the possibility of public comment in individual risk assessments.

The NRC noted the conceptual distinction between science policy and risk management, but stated that greater interaction should be provided.[108] Clearer, more informed direction by the Agency's priorities and risk management goals would improve the risk assessors science policy

---

100. *See* 1994 NRC Report, *supra* note 97, at 184-85. The NRC's study was performed pursuant to the requirement in the 1990 Clean Air Act Amendments that the EPA contract with the NRC to review the EPA's risk assessment methodologies. *See* 42 U.S.C. § 7412(o) (1994).

101. 1994 NRC REPORT, *supra* note 97, at 184.

102. *Id.* at 85-90.

103. *See* id. at 88.

104. *See id.* at 90-91.

105. *Id.* at 105. The purpose of the peer and public reviews was to "ensure broad peer and scientific participation to guarantee that [EPA's] risk assessment decisions will have access to the best science available through a process that allows full public discussion and peer participation by the scientific community." *Id.*

106. *See id.* at 267.

107. *See id.*

108. *See id.* at 27-28, 260.

judgments.[109] It did not recommend specific ways to accomplish the interaction. The NRC recommended only that the "EPA should increase institutional and intellectual linkages between risk assessment and risk management so as to create better harmony between the science-policy components of risk assessment and the broader policy objectives of risk management."[110]

The Executive Director of the EPA's Risk Assessment Forum, Dorothy E. Patton, writing in 1993, also adopted the NRC's characterizations of policy issues—(1) "science policy" issues, which address the "scientific uncertainties"[111] in the risk assessment process and (2) risk management issues, which address the question of what to do about the levels of risk determined in the risk assessment.[112]

Patton also argued that the two classes are distinct and that the policy decisions underlying the risk management standards can be kept separate from the science policy decisions on risk assessments. She noted that the use of different assumptions on science policy issues may produce a range of risk estimates for the same chemical[113] but recommended only that risk assessments identify the science policy choices made.[114]

The 1998 Risk Assessment Protocol includes standards both for risk assessments and for risk management. The risk assessment and risk management standards are separated physically (the risk management standards are located in an addendum), but the same people developed both. The Protocol defines "risk assessment" as "the *scientific* evaluation of potential health impacts that may result from exposure to a particular substance or mixture of substances under specified conditions."[115] The Protocol also states that the "science of risk assessment is evolving" and that

---

109. *See id.* at 260. The NRC stated that the "principle of separation of risk assessment from risk management has led to systematic downplaying of the science-policy judgments embedded in risk assessment." *Id.* at 267.

110. *Id.*

111. Patton defined "science policies" as "technically reasonable positions assumed in lieu of scientific data." Dorothy E. Patton, *The ABCs of Risk Assessment*, 19 EPA J. 10, 14 (Jan.-Mar. 1993). They include the "use (or nonuse) of animal data to predict human risk, models used to quantify or project cancer risk and the size of uncertainty factors for health effects other than cancer." *Id.* Patton indicates that uncertainty and variability in results arise from measurement uncertainty, data and information gaps (missing data or lack of understanding about a scientific phenomenon). *See id.* She also states that state of the art limitations on risk assessment methods, resource limitations, and statutory timetables "often require EPA . . . to complete risk assessments in the face of data gaps and other scientific uncertainties," and "science policies" are developed to address them. *Id.*

112. Risk management issues include EPA practice, technological feasibility, costs, economics, politics, law, and social concerns and values. *See id.* at 12.

113. *See id.* at 14-15.

114. *See id.* at 15.

115. 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, at 1 (emphasis added).

"science policy assumptions must be made" where "the science base is incomplete and uncertainties exist."[116]

But how distinct are "science policy" decisions in risk assessments from the policy decisions in risk management? Is there not a class of science policy issues in which social, political, and/or economic factors have a primary significance? And why, in any event, should public comment be excluded on the scientific basis of a risk assessment decision?

Two kinds of policy choices, with differing mixes of science and policy, illustrate the scope of the choices. The first involves extrapolations to address gaps in human toxicity data. There are generally more toxicity data available for animal toxicity tests than for humans, and the animal tests are usually conducted at high doses. Estimating the likely toxicity of chemicals to humans requires extrapolations from animals to humans and from high to low doses. Scientific theories may be available for each of the extrapolations, but generally none have been proven. Moreover, the selection of one assumption over another has a significant impact on the range of risks that result. A choice—characterized by the NRC as a policy choice, although based partly upon scientific knowledge—must therefore be made among these plausible alternatives.[117] This is an example of a "policy choice" that involves the degree of the assessor's preference for conservatism.

Broader policy dimensions, however, are involved with decisions on the choice of hazards to assess and the choice of toxicity values for the evaluations. The available toxicity studies may not have fully identified the scope of health risks arising from each chemical, and the results of the studies may be inconclusive or conflicting.[118] Decisions must thus be made on whether to do more studies, perhaps to address the special concerns of a community. Decisions must also be made whether to select a controversial toxicity value, to use substitute values and analyses, or to omit the risk.

The noncancer health effects of dioxins exemplify the latter category of policy choices. The EPA chose not to include these risks in its quantitative assessment due to what it states is a lack of scientific consensus on the dose at which dioxins cause noncancer health effects.[119] In the case of dioxins, the

---

116. *Id.* vol. 1, ch. 8, at 7. The Protocol states that risk assessors should fully explain the areas of uncertainty in the assessments and identify the key assumptions selected. *See id.*

The Protocol was developed by EPA Region 6 without public comment and adopted by the EPA as a peer review draft in October 1998. The EPA thereafter solicited public comment on the risk assessment and risk management standards and is establishing a peer review process for the document. *See* 63 Fed. Reg. 58,381 (Oct. 30, 1998) (establishing public notice and comment period).

117. *See* 1983 NRC REPORT, *supra* note 15, at 23-27.

118. *See generally* DAVID ROE, TOXIC IGNORANCE: THE CONTINUING ABSENCE OF BASIC HEALTH TESTING FOR TOP-SELLING CHEMICALS IN THE UNITED STATES (Environmental Defense Fund ed., 1997) (discussing lack of safety data for important chemicals in American commerce).

119. The EPA decided not to consider the noncancer health effects of dioxins and dioxin-like

social and economic implications of using toxicity values that predict significant health risks likely played a role in their exclusion and in the use of a special "margin of exposure" analysis, which predicted a low risk. This class of policy choices is not based upon conservatism, but rather on risk management considerations.

John Mendeloff, a scientist writing in 1988, and Wendy Wagner, a law professor writing in 1995, also acknowledge the prevalence of policy issues in risk assessments but disagree on their impact.[120] The impact, according to Mendeloff, has been to make regulators overly cautious. The regulators hold off on the promulgation of necessary health-based standards, concerned that the scientific uncertainties will be exposed and used to defeat the standards.

John Mendeloff discussed, in particular, the uncertainty involved with the extrapolation of toxicity results from animals to humans and from the high doses used in the studies to the lower doses expected for humans. He stated that "reliance on bioassays [from animal studies] has grown because there are both strong political and analytical pressures to quantify risks and because there is often indeed no alternative basis for doing it."[121] He noted, however, that the extrapolations do not produce accurate estimates of human toxicity values.[122] It may be debated how far the science has improved since 1982, but EPA toxicity values today are routinely based on the extrapolation of animal toxicity values to humans.[123]

---

compounds in the WTI risk assessment, because it had not formally established threshold Reference Doses for them. It omitted them despite the conclusions in the EPA's 1994 Dioxin Reassessment that dioxins likely cause a broad range of serious noncancer effects and despite the availability of a reference dose approved by the Agency for Toxic Substances and Disease Registry. *See* FINAL RISK ASSESSMENT, *supra* note 6.

120. *See* Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1614 (1995); *see generally* JOHN M. MENDELOFF, THE DILEMMA OF TOXIC SUBSTANCE REGULATION: HOW OVERREGULATION CAUSES UNDERREGULATION AT OSHA (1988) (arguing that standard setting for toxic substances in the workplace has been characterized by both over regulation and underregulation).

121. MENDELOFF, *supra* note 120, at 64.

> [T]oday few experienced experimental oncologists would make any attempt to extrapolate mathematically the degree of human risk from animals.... Exact estimates as to the number of cases of a cancer that might be expected to occur in man based on a single experiment are silly and simply ignore biological realities. The fact that no better methods exist does not make these statements any better or more valuable.

Id. (quoting *Formaldehyde: Review of Scientific Basis of EPA's Risk Assessment, 1982: Hearings on H. 165 before the House Comm. on Science and Tech.*, 97th Cong., 2d Sess. 122 (1982) (statement of John Higginson, former director of the International Agency for Research on Cancer)).

122. *See id.*

123. *See* Integrated Risk Information System Fact Sheet, *Limitations of IRIS Information* (last modified Feb. 4, 1998) <http://www.epa.gov/iris/limits/htm>. Internal EPA workgroups in the Agency's Integrated Risk Information System (IRIS) have developed and periodically update an on-line database of chemical toxicity values. IRIS is discussed at more length in Part IV.C.1. The Fact Sheet noted that IRIS values are based on animal-to-human and other extrapolations but also explained that the results might not provide accurate predictions of toxicity in humans:

Wagner's article, written seven years later, states that the policy issues are broader than acknowledged by the NRC and Patton and that regulators have overcome Mendeloff's concerns by characterizing the policy decisions as objective science. Wagner describes the process as a "science charade."[124] She argues that risk assessors characterize policy decisions as science, both intentionally and unintentionally. She suggests that "agencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions."[125] The science charade occurs "by failing first to identify the major interstices left by science in the standard-setting process and second to reveal the policy choices they made to fill each trans-scientific gap."[126] "While contemporary science can provide only partial answers to pressing environmental problems, this limitation is esoteric and often escapes the lay observer, leaving the capabilities of science susceptible to successful overstatement."[127]

Wagner argues that the issues are often cast as choices between jobs and public health, forcing public officials to resort to the charade "out of sheer political necessity."[128]

> In general, [risk values, such as those used in IRIS] cannot be validly used to accurately predict the incidence of human disease or the type of effects that chemical exposures [may] have on humans. This is due to the numerous uncertainties involved in risk assessment, including those associated with extrapolations from animal data to humans and from high experimental doses to lower environmental exposures. The organs affected and the type of adverse effect resulting from chemical exposure may differ between study animals and humans. In addition, many factors besides exposure to a chemical influence the occurrence and extent of human disease.

Id.

124. Wagner, *supra* note 120, at 1617.

125. *Id.*

126. *Id.* at 1629.

> Toxic standards promulgated under science-based mandates are covered—from the preamble to the regulatory impact analysis—with scientific explanations, judgments, and citations. Major policy decisions that undergird a quantitative toxic risk standard are at best acknowledged as agency judgments or health policies, terms that receive no elaboration in the often hundreds of pages of agency explanations given for a proposed or final toxic standard and appear in a context that gives readers the impression they are based on science.

Id. at 1629-31.

Wagner adopted the term "trans-science" as the equivalent of the term "component" used by the NRC. Wagner stated that "[n]uclear physicist Alvin Weinberg first identified these gaps in knowledge as 'trans-science'— 'questions which can be asked of science and yet which cannot be answered by science.'" *Id.* at 1619 (quoting Alvin M. Weinberg, *Science and Trans-Science*, 10 MINERVA 209, 209 (1972)).

127. *See id.* at 1617.

128. *Id.* at 1653.

> If the public insists upon regulatory goals that are mutually exclusive, and improved public education remains only a distant goal, the best or indeed the only way to pacify the public and ensure political survival is to conceal the underlying social compromise between protection of public health and the loss of jobs under the veneer of scientific truth.[129]

Legal incentives also exist. By characterizing the policy elements of risk assessments and standards as science, agencies "will limit the pool of commenters to those with at least modest fluency in the scientific and technical jargon" to be able to separate the policy from the scientific elements of the process.[130] This relieves the agency of the time-consuming and potentially politically difficult responsibility to respond to public comments and incorporate them into the agency's actions.[131]

For all of these reasons, the issues of who performs risk assessments and whether the agency allows public input on science policy and risk management policy issues are important.

III. PUBLIC PARTICIPATION UNDER RCRA AND IN RISK ASSESSMENTS

A. Discretionary Public Participation in Risk Assessments and Guidance Documents

1. Public Comment on Permit Decisions —Not on Risk Assessments

The EPA uses two major methods to solicit public participation in RCRA permitting, but none directly related to the preparation of risk assessments.[132] The EPA provides information to the public in informal consultation processes throughout the permitting period and solicits input on the draft

---

129. *Id.*

130. *Id.* at 1656.

131. *Id.* at 1655. "It would appear, then, that a bureaucrat's life would be much easier if participation were not integrated into policy analysis." *Id.* (quoting Mary G. Kweit & Robert W. Kweit, *The Politics of Policy Analysis: The Role of Citizen Participation in Analytic Decision Making, in* CITIZEN PARTICIPATION IN PUBLIC DECISION MAKING 19 (Jack DeSario & Stuart Langton eds., 1987)).

Other incentives, according to Wagner, are the tendencies of interest groups to respond with scientific arguments, for reviewing courts to defer to the scientific expertise of agencies, the establishment by Congress of science-based standards and various institutional standards of the agency officials involved in the project. *See* Wagner, *supra* note 120, at 1657-73.

132. Section 7004 of RCRA requires public notice of the proposed issuance of permits and an informal public hearing to receive oral and written comments if the Agency receives notice of opposition within 45 days, "or if the Administrator determines on his own initiative" to hold public hearings. 42 U.S.C. § 6974(b)(2) (1994).

permit through a formal opportunity for public comment.[133] The informational process includes materials prepared by the Agency and the applicant, repositories of documents, and access to documents at no or low cost.[134] Consultation includes public hearings, public meetings, and public advisory groups.[135]

Public comment is not solicited during the risk assessment process. It is only allowed at the time that a draft permit is prepared and issued for comment—after the risk assessment has been completed.[136] The EPA also provides no technical assistance for the public's preparation of comments. Further, after the risk assessment is completed and the Agency has issued a draft decision for public review, there are strong disincentives—time and cost—against substantially revising the risk assessment.

The 1993 Draft Combustion Strategy indicated that the EPA would provide some form of opportunity for public participation in risk assessments. It stated that the EPA would immediately provide for greater public participation in permitting, including "the opportunity to participate during the risk assessment process at combustion facilities."[137] It also stated that the EPA would initiate amendments to its regulations to establish the requirements formally.[138]

---

133. *See* 40 C.F.R. § 124.1 (1998).

134. *See id.* § 25.4(b).

135. *See id.* § 25.4(d). The advisory groups are comprised of private citizens, representatives of public interest groups, public officials and citizens or representatives of organizations with substantial economic interests in the plan or project. *See id.* § 25.7(c)(i)-(iv).

136. *See id.* § 124.10(b). The EPA's public participation regulations appear to support more timely public comment on risk assessments:

> Public consultation must be preceded by timely distribution of information and *must occur sufficiently in advance of decision-making to allow the agency to assimilate public views into agency action.* EPA, State, interstate, and substate agencies shall provide for early and continuing public consultation in any significant action covered by this part. *Merely conferring with the public after an agency decision does not meet this requirement.*

Id. § 25.4(d) (emphasis added).

137. 1993 DRAFT COMBUSTION STRATEGY, *supra* note 34, at 160. The 1993 Draft Combustion Strategy states:

> EPA will immediately provide for greater public participation in the permitting of BIFs and incinerators, and will initiate amendments to its rules to reflect new avenues for public participation. Prior to these amendments being finally adopted, EPA will direct all regions and states to provide immediately for additional public participation opportunities during permitting of combustion units—particularly at earlier stages than now provided for under EPA's current permitting regulations. These should include, but are not limited to, public comment on the trial burn plan. *EPA will also direct that local citizens be given the opportunity to participate during the risk assessment process at combustion facilities.*

Id. (emphasis added).

138. *See id.*

The 1994 Final Combustion Strategy reaffirmed the Agency's stated interest in increasing opportunities for public participation in the permitting process, but it limited the EPA's commitment to public participation in the risk assessment process. It suggested that public participation be informal and that it be between the applicant and the public—outside the formal permit process.[139]

The new public participation regulations, adopted in 1996, were consistent with the Final Strategy. They included no new provisions for formal public participation in the risk assessment process.[140] They also established no new programs to provide citizens with the technical and financial resources required to participate effectively in the process.

To the contrary, the new regulations suggested (consistent with the 1994 Draft Risk Assessment Guidelines) that applicants may be allowed to perform the risk assessments on behalf of the Agency with only informal input from the public. The preamble to the new regulations encouraged facility owners to "work with their local communities in designing these risk assessments and in carrying out the testing and analysis, so that the confidence of local communities is maximized."[141] Neither the 1994 Draft Risk Assessment Guidelines nor the 1998 Risk Assessment Protocol provides an opportunity for public input during the risk assessment process.

2. Public Participation in Guidance Documents

Public participation is mandatory for the adoption of regulations but not for guidance documents. Section 7004 of RCRA requires the EPA to provide for "[p]ublic participation in the development, revision, implementation, and enforcement of any *regulation, guideline,* information, or program" under RCRA's hazardous waste program.[142] It also requires the Agency to "develop

---

139. *See* 1994 FINAL COMBUSTION STRATEGY, *supra* note 34, at 16.

140. The December 11, 1995 preamble to the 1996 expanded public participation regulations nevertheless states the EPA's intention to enhance the opportunity for public participation:

> Many stakeholders have expressed the concern that the current RCRA permitting process does not involve the public at an early stage in the process, does not provide adequate information, and does not provide an equitable opportunity to participate. EPA is responding to these concerns in today's rule. In fact, EPA has emphasized the need for more public involvement in all its activities.

40 C.F.R. pts. 9, 24, 270 (1995).

141. 61 Fed. Reg. 17,358, 17,372 (1996). The possibility of applicants performing their own risk assessments— and the risks it poses—is discussed more fully in Part V.D.3.

142. 42 U.S.C. § 6974(b)(1) (1994) (emphasis added). This and the regulations at 40 C.F.R. § 25.10 supplement the requirements under the Administrative Procedure Act for notice and public comment on proposed regulations. *See* 5 U.S.C. § 553 (1994); 40 C.F.R. § 25.10 (1998) (emphasis added).

and publish minimum guidelines for public participation in such processes."[143] Neither RCRA nor its regulations, however, define the term "public participation."[144]

EPA's regulations require the Agency to "invite and consider written comments on proposed and interim regulations from any interested or affected persons and organizations."[145] The regulations also require the issuance of a responsiveness summary to the comments in the preambles to interim and final regulations.[146]

The regulations authorize public participation for guidance documents but leave that decision to the discretion of the Agency.[147] The EPA does not appear to have a consistent policy on when it seeks public comment on guidance documents and the manner in which it does so. The EPA attempts to gain public input, through the Federal Register or in a less formal manner, before it characterizes a "draft" document as "final."[148] However, the EPA often uses "draft" documents in its decision making for indefinite periods before it makes them "final."[149]

The EPA has published notice in the Federal Register and sought public comment for certain guidance documents with wide-ranging applicability, such as the EPA's Guidelines for Carcinogen Risk Assessment.[150] The 1993 Addendum to the 1990 Draft Indirect Risk Guidelines and the 1998 Risk Assessment Protocol were also noticed in the Federal Register, but it does not appear that the 1990 Draft Indirect Risk Guidelines and the 1994 Draft Risk Assessment guidelines were.[151] Still others, such as the EPA's Draft and Final Combustion Strategies, were noticed informally outside the Federal Register,

---

143. 42 U.S.C. § 6974(b)(1).

144. Section 7004(b) grants the EPA the authority to determine the elements of public participation: "The Administrator, in cooperation with the States, shall develop and publish minimum guidelines for public participation in such processes." 42 U.S.C. § 6974(b)(1).

145. 40 C.F.R. § 25.10(a). The Agency may also determine to hold a public hearing. *See id.*

146. *See id.*

147. The regulations state that the Agency's public participation requirements apply to the "[d]evelopment by EPA of strategy and policy guidance memoranda *when a Deputy Assistant Administrator determines it to be appropriate*." *Id.* § 25.2(a)(4) (emphasis added).

148. The EPA does not consistently seek comment through the Federal Register for guidance documents, because the requirement for such comment only applies to proposed regulations. Interview with Alec McBride, EPA Office of Solid Waste and Emergency Response.

149. The 1993 Draft Strategy, for example, directed that risk assessments be performed in accordance with the EPA's draft indirect risk assessment guidance. *See* 1993 DRAFT STRATEGY, *supra* note 34, at 160. The draft guidance was first published in 1990. It was revised in 1993 and 1994 by draft documents, but none have been made final.

150. *See also* Proposed Process for Reevaluating Cancer Assessments, 61 Fed. Reg. 32,799 (1996); Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992 (1986); Guidelines for Exposure Assessment, 57 Fed. Reg. 22,888 (1992).

151. *See* 63 Fed. Reg. 58,381 (1998); 58 Fed. Reg. 61,688 (1993).

and comment was elicited at a series of regional meetings before creating a final document.[152]

IV. UNKNOWNS, ASSUMPTIONS, AND POLICY DECISIONS IN THE WTI RISK ASSESSMENT

This section identifies some of the controversial unknowns, assumptions, and policy decisions in the WTI risk assessment. It illustrates the room for policy choices in risk assessments and the ability of public comments to identify alternative assumptions and check any tendencies by risk assessors to manipulate results.

As noted earlier, the EPA added three steps to the NRC's risk assessment process to address the more complicated risks of a hazardous waste incinerator. These new steps might be characterized as elements of a more broadly construed four-step NRC process, but, for the purposes here, they are discussed separately. The scoping of the risk assessment, which could be considered as an element of hazard identification, will be described separately and first.

A. Scope – Normal Emissions vs. Upsets and Accidents

RCRA and its regulations do not define the scope of risks to be addressed in a risk assessment in the RCRA permitting process. The 1983 and 1994 NRC reports also do not address the issue.[153]

The EPA's Draft and Final Combustion Strategies state that risk assessments should follow the EPA's indirect risk assessment guidelines.[154] In terms of exposures, the guidelines recommend the evaluation of the risks of inhalation, food chain, and dermal exposures.[155] In terms of the emissions that create the exposures, the 1990 Indirect Risk Guidelines recommend the evaluation of emissions from normal operations.[156] The November 1993 Addendum to the 1990 Guidelines, however, recommended that upsets should

---

152. *See* 1993 DRAFT COMBUSTION STRATEGY, *supra* note 34; 1994 FINAL COMBUSTION STRATEGY, *supra* note 34.

153. The NRC reports focus on chemical-specific risk assessments and not the multi-chemical risk assessments proposed for hazardous waste incinerators. *See* 1983 NRC REPORT, *supra* note 15; *see also* 1994 NRC REPORT, *supra* note 97.

154. *See* 1993 DRAFT COMBUSTION STRATEGY, *supra* note 34, at 160; 1994 FINAL COMBUSTION STRATEGY, *supra* note 34, at 17-18.

155. *See* 1990 INDIRECT RISK GUIDELINES, *supra* note 38, at 1-6.

156. *See id.* at 1-7.

also be considered, and it established methods to incorporate their risks into the quantitative risk estimates.[157]

The 1998 Risk Assessment Protocol, of course, was not in place for the WTI risk assessment, but the Protocol recommended the consideration of the risks of inhalation and food chain exposures (omitting dermal exposures), and the consideration of normal stack emissions, upset emissions, and fugitive emissions.[158] The Protocol recommended that estimated emissions rates be increased to account for the expected likelihood of upsets.[159]

The EPA originally proposed a scope for the WTI risk assessment that calculated quantitative risk estimates for inhalation, food chain, and dermal exposures resulting from routine stack emissions.[160] The EPA proposed to address the risks from fugitive emissions,[161] upset emissions,[162] and the risks of on-site and off-site (i.e., transportation) accidents qualitatively in a separate section addressing the uncertainty of the quantitative estimates.[163]

The initial Peer Review Group, which reviewed the proposed scope, emphasized the special importance of upsets and accidents in view of the incinerator's proximity to schools and residences.[164] It recommended the

---

157. *See* 1993 ADDENDUM TO INDIRECT RISK GUIDELINES, *supra* note 38, at 3-13 to 3-15. The 1994 Draft Risk Assessment Guidelines recommended that upsets be considered in screening level risk assessments and that ecological assessments be prepared with the screening level human health risk assessments. *See* 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 36, at 11-12.

158. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 2-3.

159. *See id.* vol. 1, ch. 2, at 15.

160. U.S. EPA, PUB. NO. 98061354, WTI PHASE II RISK ASSESSMENT PROJECT PLAN 27 (Nov. 1993) [hereinafter 1993 PROJECT PLAN].

161. The Risk Assessment described fugitive emissions as atmospheric emissions from a variety of sources other than the incinerator stack. They typically involve waste unloading, processing and storage, and the handling of incinerator ash. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. III, ch. IV, at 1.

162. "Upset" emissions include a broad category of increased stack emissions for relatively short periods of time. *See* 1993 PROJECT PLAN, *supra* note 142, at 93. They include abnormal emissions during plant startup and shutdown, minor process upsets, and equipment malfunctions. *Id.*

163. *See id.* at 27.

164. Due to the proximity of this plant to schools and residences, one of the critical factors affecting health impacts associated with emissions from the WTI facility is the assessment of emissions occurring during abnormal operation and accidents. These conditions potentially include the following scenarios:

- -- Transients due to non-steady state operations such as startup and shutdown.
- -- System upsets such as malfunctions or perturbations in equipment operation that could result in a waste feed cutoff if severe enough to approach or exceed permit limits.
- -- Fugitive emissions due to leaks and spills.
- -- Very low frequency events such as fires and natural disasters that could lead to accidental releases.

1993 PEER REVIEW REPORT, *supra* note 1, at 3-10 to 3-11.

inclusion of upsets in the quantitative results[165] and a more complete analysis of accidents.[166]

In accordance with the 1994 Draft Risk Assessment guidelines, the 1995 Draft Risk Assessment addressed inhalation, food chain, and at least some forms of dermal exposure. It also included quantitative risk estimates for fugitive emissions, a qualitative accident analysis, and a quantitative screening level ecological assessment, which were not specifically recommended by the guidelines.[167]

The EPA omitted upsets entirely, however. It based its decision on "(1) the significant uncertainties associated with characterizing emissions during these short-duration events; (2) the expectation that the magnitude and duration of such potential emissions would be quite limited; and (3) the measures in place at WTI to reduce the frequency and impact of such emissions."[168]

The 1996 Peer Review Group and public observers criticized the omission of upsets and the EPA's accident analysis. The group stated that the accident analysis did not address all potentially important accident scenarios and the EPA's database (which was used to predict the likelihood of accidents) was incomplete.[169]

In response to the continuing criticism, the EPA included a limited analysis of upsets in the final document. The EPA did not redo the emissions estimates to add the risk of upsets to the quantitative risk estimates as was recommended; instead, it reviewed the total hydrocarbon (THC) values downstream from the incineration process as an indicator of combustion efficiency and the likelihood of upsets. The EPA compared continuously monitored emissions data (which included upsets) for a one-year period to the baseline data (which did not include upsets) used to calculate the original risk estimates and concluded that upsets could cause a thirty percent increase in the emission of organic compounds.[170]

Nevertheless, the EPA chose not to include the potentially increased risk in its quantitative estimates. The EPA concluded that the increase in the non-

---

165. *See id.* at 1-2 and 3-10 to 3-12.

166. *See id.* at 3-12.

167. *See* 1995 DRAFT RISK ASSESSMENT, *supra* note 55, vols. VI and VII.

168. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. III, ch. V, at 10. *See also* 1996 PEER REVIEW REPORT, *supra* note 23, at 3-10.

169. The 1996 Peer Review Group questioned the accuracy of the EPA's accident database, noting that: "the risk assessment's assumption of 'one emergency incident involving hazardous waste release for every 25 or 30 years of operation' may be inconsistent with the two hazardous release incidents already reported at the WTI site (on December 1993 and October 1994) and the 'frequent occurrence of kiln overpressures.'" 1996 PEER REVIEW REPORT, *supra* note 23, at 3-19. It also recommended that the risk assessment should be based "on a truly worst case accident scenario." *Id.* at 3-20.

170. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. VIII, ch. II, at 5-6.

dioxin organic compounds would not make a significant difference in the results, because the nondioxin compounds account for a relatively small portion of the overall risk.[171] The EPA noted that upsets could also cause a thirty percent increase in dioxin emissions (which account for the majority of the facility's risk),[172] but it did not analyze the impact of the increased emissions on the facility's risk estimates.[173]

B. Three Preliminary Analyses

1. Identifying Substances of Concern: Unidentified Emissions and Undetermined Toxicity Values

In the next step, the EPA identified the substances to be addressed in the risk assessment. Hazardous waste incinerators emit potentially thousands of chemical compounds, many of which have yet to be identified. The EPA guidance documents available at the time did not address how to assess compounds lacking EPA-approved toxicity values. The EPA's 1994 Draft Risk Assessment Guidelines noted that the 1993 Draft Strategy recommended the expansion of the number of compounds analyzed in risk assessments to identify as large a fraction of the emissions as is realistically possible.[174] The 1994 guidelines included suggested lists of 236 chemicals to be evaluated in risk assessments.[175] The guidelines recommended a list of twelve metals and 174 products of incomplete combustion and suggested the consideration of sixty-three additional compounds that were being evaluated by the EPA for inclusion at the time.[176]

---

171. *See id.* at 6.

172. For example, the Final Risk Assessment stated that dioxins and furans represent seventy-six percent of the total cancer risk for a subsistence farmer. *See id.* vol. V, ch. VIII, at 10.

173. In the Uncertainty Section of the Final Risk Assessment, the EPA stated that "[a]lthough the emission composition during abnormal operations is unknown, if it is assumed that the cancer potency of constituents in emissions during abnormal operations is equal to the cancer potency of constitutents in normal emissions, the overall cancer risk would increase by no more than 30 percent." *Id.* vol. V, ch. VIII, at 28. It stated that a 30 percent increase in the 1.3 in 1 million cancer risk estimate for the subsistence farmer and child would not result in significant cancer risks to the population. *See id.* Nothing was said about the risks of noncancer effects.

174. *See* 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 34, at 2.

175. *See id.* attach. A, tbls. 1 & 2.

176. *See id.* at 2. The 1998 Risk Assessment Protocol includes a similar list of compounds but states that the purpose of a risk assessment is not to evaluate every metal and PIC listed. 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 33. It states that the list should be narrowed to focus on compounds that are likely to be emitted, potentially toxic to humans and/or have a propensity to bioaccumulate or bio-concentrate in humans and ecological food chains. *See id.* Nevertheless, the Protocol requires the development of a single list of compounds, evaluated both for inhalation and indirect

For the WTI risk assessment, the EPA attempted to select for analysis the most toxic chemicals, but the lack of complete data on emissions and toxicity values for many chemicals may have excluded highly toxic chemicals for the wrong reasons. The EPA developed an initial list of approximately 200 substances of potential concern based upon the Agency's analyses of WTI's emissions, the 1993 Peer Review Group's recommendations, and the PICs recommended in the EPA's 1994 Draft Risk Assessment Guidelines.[177] The EPA analyzed the entire list for inhalation risks (to the extent that the EPA had previously developed toxicity values for the compounds),[178] but narrowed the list for the food chain analysis. The EPA stated that it wanted to focus on the organic residues and PICs[179] that are emitted in the greatest quantities, that are highly toxic and have the greatest potential to bioaccumulate—but, as noted below, the lack of EPA-approved toxicity values was the major factor prompting the shortening of the list.[180]

a. Undetermined Toxicity Values

The lack of information about toxicities and likely emissions rates was most influential in narrowing the list of compounds to be addressed. Seventy-seven compounds were deleted from the food chain analysis due solely to the lack of EPA-determined toxicity values for cancer[181] and seventy-two other compounds (including the seventeen dioxins and furans) were deleted due to the lack of EPA-determined Reference Doses for noncancer effects.[182] The EPA deleted thirty-one additional compounds because the Agency could not estimate its emission rates.[183]

---

exposures. *See id.* at 38.

177. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. IV, at 1.

178. *See id.*

179.

> However, despite the high temperatures typical of hazardous waste incinerators, a fraction of the organic compounds in the waste feed can still pass through the incineration process without being combusted. In addition to the uncombusted residues of the waste feed, fragments of the partially combusted organics from the feed may be emitted along with organic chemicals formed through reactions in the combustion or post-combustion zones. These compounds, known as products of incomplete combustion (PICs), can be different in chemical structure from the original organic compounds in the waste feed. Other potentially hazardous substances, such as metals, may also be present in the stack emissions.

Id. vol. III, ch. I, at 1.

180. *See id.* ch. IV, at 1-2.

181. *See id.* at 3.

182. *See id.* at 4.

183. *See id.* at 2.

The EPA's narrowing of compounds resulted in a list containing 15 of 174 organic residues plus seventeen dioxin/furan congeners. Most could only be evaluated for cancer risks, since the EPA has not determined noncancer toxicity values for dioxins and furans.[184] The risk assessment also examined the risks of thirteen metals, although again the analysis was limited by the lack of EPA-approved toxicity values.[185]

Neither the EPA nor the Peer Review Group recommended a method to estimate the risks omitted due to the lack of toxicity values, despite the potential impact of the omission.[186] Dioxins and furans were evaluated in the WTI cancer analysis, and the EPA noted that they accounted for approximately ninety-five percent of the hazard ranking used to narrow the initial list of 200 chemicals. They were completely deleted from the quantitative noncancer analysis, however, because the EPA had not finally determined a toxicity value for the chemicals.[187]

This issue was not addressed in EPA guidance available at the time of the WTI risk assessment. The 1998 Risk Assessment Protocol, however, states that compounds lacking EPA-approved toxicity values should be deleted from the quantitative risk estimate process, and evaluated qualitatively in the Uncertainty Section of the risk assessment, using surrogate toxicity data from a similar compound.[188] Part IV.C.1.a. addresses the EPA's reliance upon its own databases of toxicity values to determine which chemical compounds it will address in a risk assessment.

b. Unidentified Compounds

The Peer Review Group recommended several compounds for the initial list[189] and noted the uncertainty that results from the less than complete identification of emitted compounds.[190]

> It is well documented in the technical incineration literature that only 20 to 70 percent of the organic emissions from hazardous

---

184. *See id.* at 4. The EPA maintains cancer toxicity values ("slope factors") for dioxins and furans, but it has not finally determined noncancer toxicity values (reference doses (RfDs)). Potential RfDs have been approved by others and the EPA estimated RfDs, which have not been finally approved in its 1994 Dioxin Reassessment. *See infra* notes 253-61 and accompanying text.

185. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. IV, at 4 and tbl. 3.

186. *See id.* at 2-3.

187. *See id.* ch. III, at 7.

188. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 37.

189. *See* FINAL RISK ASSESSMENT, *supra* note 6, ch. III, at 1.

190. *See* 1993 PEER REVIEW REPORT, *supra* note 1, ch. 3, at 3. The Risk Assessment states that only about forty percent of the mass of the organic emissions from the trial burn for the WTI incinerator was identified. FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. VIII, at 27.

> waste incinerators have been chemically characterized and quantified, even at the most extensively tested facilities. The lack of 100 percent quantification and the potential risk incurred on the exposed population by the uncharacterized fraction is at the center of the controversy surrounding siting of hazardous waste incinerators.[191]

To account for the risks associated with these unidentified emissions, the EPA originally proposed to assume that the toxicity of the unidentified compounds was proportional to those already identified.[192] This is consistent with one of the two approaches recommended in the 1994 Draft EPA Guidelines.[193] The 1993 Peer Review Group recommended a method to estimate the toxicity of the uncharacterized emissions similar to the EPA's proposal, but also recommended a number of alternative methods to confirm the accuracy of the estimates.[194] In the draft and final risk assessments, however, the EPA deleted this adjustment altogether.[195] The 1998 Risk Assessment Protocol uses similar mechanisms to establish the risks.[196] The Protocol excludes the risks from the quantitative estimates and requires that

---

191. 1993 PEER REVIEW REPORT, *supra* note 1, ch. 3, at 2. The 1996 Peer Review Group stated its concern about the likelihood of a "supercarcinogen" in the uncharacterized portion of the incinerator's emissions:

> The work group is still concerned, however, about the nature of the 60 percent of organic emissions that remain uncharacterized. This means that 60 percent of the total *mass* of organics are uncharacterized. Although as much as 90 percent of this 60 percent might be light hydrocarbons such as methane or ethane, more than 99 percent of the *number* of organics are probably uncharacterized. The large number of uncharacterized emissions increases the likelihood that one of the organics is a "supercarcinogen."

1996 PEER REVIEW REPORT, *supra* note 23, at 3-7.

192. *See* 1993 PROJECT PLAN, *supra* note 160, at 33-34, 41-42. The 1996 Peer Review Group questioned the reliability of this approach:

> As a final point on the subject of stack emissions, the report makes a good point that it is the nature, as opposed to quantity, of the uncharacterized fraction of emissions that creates the most uncertainty in risk. How can we ever eliminate this concern? If just one of the uncharacterized chemicals has the toxicity of 2,3,7,8 TCDD, then the calculated risk would probably increase by orders of magnitude. As I see it, this is the *only* real issue about stack emissions. This is certainly not to say that the event is likely, but I am not sure that I can say it is unlikely. Can we arrive at a scientific basis for assessing this uncertainty?

1996 PEER REVIEW REPORT, *supra* note 23, comts. of Barry Dellinger, at D-12.

193. *See* 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 34, at 4-6.

194. *See id.* ch. 3, at 3-4.

195. *See* 1995 DRAFT RISK ASSESSMENT, *supra* note 55, vol. V, ch. VIII, at 25; *see also* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. VIII, at 27-28. Although the EPA deleted the adjustment, it did discuss the uncertainty arising from the issue and described a second way to address it. *See id.*

196. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 11.

they be addressed qualitatively in the Uncertainty Section of the risk assessment.[197]

2. Estimating Emissions Rates

a. How to Predict "Expected" Emissions Rates?

The EPA originally proposed to use emission rates from WTI's March 1993 trial burn as the primary basis for the rates used in the risk assessment.[198] The 1993 peer reviewers criticized this approach because the chemicals burned during the trial burn were unlike the waste feeds burned during normal operations.[199] The peer reviewers recommended that the EPA develop a waste feed chemical composition profile for WTI using the waste feed manifests for the facility during its first year of operation.[200] The peer reviewers recommended that, based upon those waste feeds, combustion chemistry experts develop a list of likely combustion byproducts and estimate their likely emission rates.[201]

The EPA accepted the peer reviewers' recommendation, in part, using trial burn data and data from "performance testing" conducted subsequent to the trial burn.[202]

b. "Expected" Versus Permitted Rates

Both the EPA and the peer review group failed to suggest that the emissions levels in WTI's permits be used in the risk assessment. WTI's Clean Air Act permit established numerical emissions limits for seven compounds, total suspended particulates, and "organic compounds."[203]

---

197. *See id.* at 8-12.

198. *See* 1993 PROJECT PLAN, *supra* note 160, at 34-44.

199. *See* 1993 PEER REVIEW REPORT, *supra* note 1, ch. 1, at 1.

200. *See id.* ch. 3, at 3.

201. *See id.*

202. Emissions for certain chemicals were measured during the March 1993 and February 1994 trial burns and during performance tests in August 1993 and April, August and December 1994. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. III, ch. III, at 2. Although the EPA stated that the December 1994 test data was obtained too late for inclusion in the full risk assessment process, the Agency explained that the data were comparable to the August 1994 tests. *See id.* at 4.

203. Permit to Install (Ohio EPA Feb. 2, 1983), at condition P. The permit established the following annual emissions limits:

Total suspended particulates	78.7	tons per year
Sulfur dioxide	99.8	tons per year
Nitrogen dioxide	249.5	tons per year
Carbon monoxide	194.1	tons per year

WTI's RCRA permit adopted the hourly emissions rates for metals, hydrogen chloride, and chlorine established in the EPA's regulations on Boilers and Industrial Furnaces.[204] The emission rates used by the risk assessors for emissions regulated under the Clean Air Act and for hydrogen chloride and chlorine are not clearly identified, but the metals' emissions rates were one to five orders of magnitude less than the permitted rates.[205]

The 1993 Project Plan provided for the evaluation of two scenarios: an average emissions scenario and a conservative scenario.[206] The average scenario was to be based upon mean emissions rates calculated from the March 1993 trial burn, the August 1993 performance test (for dioxins) and the literature on emissions rates at other facilities.[207] The conservative scenario was to be based upon either permit levels or the ninetieth or higher percentile emissions rates.[208]

Organic compounds	58.4	tons per year
Lead	4.7	tons per year
Hydrogen chloride	75.0	tons per year
Mercury	1.28	tons per year
Beryllium	0.004	tons per year

Id.

204. *See* WTI RCRA Permit (U.S. EPA Region 5 July, 24, 1983), at condition C.4(e).

205. The Screening Ecological Risk Assessment, which used an emissions scenario based upon the facility's permit limits for metals, converted the emissions rates under the permit and average scenarios as follows:

	Projected Permit Limit (g/sec)	Estimated Rate (g/sec)
Aluminum	----	2.4×10^{-4}
Antimony	1.6×10^{-4}	4.2×10^{-6}
Arsenic	1.1×10^{-4}	3.7×10^{-5}
Barium	5.5×10^{1}	1.5×10^{-4}
Beryllium	3.6×10^{-6}	3.3×10^{-8}
Cadmium	1.9×10^{-4}	1.6×10^{-5}
Chromium	1.5×10^{-4}	7.1×10^{-7}
Copper	----	9.4×10^{-5}
Lead	1.2×10^{-3}	4.3×10^{-5}
Mercury	8.8×10^{-2}	1.4×10^{-3}
Nickel	2.2×10^{1}	5.0×10^{-6}
Selenium	4.4×10^{0}	4.7×10^{-4}
Silver	3.3×10^{0}	1.5×10^{-5}
Thallium	5.5×10^{-1}	3.4×10^{-5}
Zinc	----	1.2×10^{-4}

See FINAL RISK ASSESSMENT, *supra* note 6, vol. VI, ch. IV, at 4-5, 30 (tbl. 2).

206. *See* 1993 PROJECT PLAN, *supra* note 160, at 38-39.

207. *See id.* at 39.

208. *See id.* The 1993 Project Plan abandoned permitted emissions limits for dioxins and furans in favor of rates based on the 1993 trial burn. It originally proposed to use the 30 ng/dscm (i.e., dry standard cubic meter) permit limit for dioxins and furans as the conservative scenario, when the EPA was

The final risk assessment dropped the plans for separate expected and permit level scenarios, using only the expected "average" emission rate scenario. The risk assessment calculated a limited number of "high end" exposures based on different populations and the various exposures they would receive from chemicals emitted at average emissions rates.[209] It did not calculate similar measures of risk based upon a conservative permit level emissions scenario.[210]

The EPA stated that the scenarios were consistent with Agency guidelines.[211] However, the 1994 Draft Risk Assessment Guidelines recommend use of the high end range of individual risks for any given emissions rate[212] and the permitted emissions rates.[213] The risk assessors explained neither why they deleted the use of the conservative emission rate scenario nor why a permit scenario was unreasonable as a conservative high end prediction. Curiously, in an addendum released with the Final Risk Assessment, the risk assessors responded to the comments of the second peer review group, and the EPA stated that it would revise, at some future date, the human health risk assessment to evaluate the potential risks from metals under a permit limit scenario.[214]

The EPA's switch was particularly significant for metals. The initial Screening Risk Assessment showed that the permitted 4.7 tons per year of lead emissions would exceed EPA's screening level standard for inhalation risk.[215] The Draft and Final Risk Assessments, however, used the lower

---

faced with trial burn results ranging from twenty to sixty-four ng/dscm. *See id.* at 39-41; *see also* FINAL RISK ASSESSMENT, *supra* note 6, vol. III, ch. III, at 2-3. When subsequent tests conducted with modified pollution controls showed lower levels, the EPA abandoned the permit limit in favor of the mean and 95 percent upper confidence limit of the latter test results. *See id.* vol. III, ch. III, at 2-3 and vol. V, ch. VIII, at 11-12.

The 1993 Peer Review Group recommended that further testing be performed to estimate emissions rates for dioxins and furans. *See* 1993 PEER REVIEW REPORT, *supra* note 1, at 3-7.

209. The exposures would vary based upon behavior patterns, locations of the populations, and varying assumptions on atmospheric dispersion, deposition, and biological uptake.

210. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. VIII, ch. V, at 6-7 (including tbl. 2); *see also id.* vol. III, ch. III, at 2-3 and vol. V, ch. VIII, at 11-12. The "high end" assessments produced food consumption cancer risks and noncancer (hazard indices) risks for the subsistence farmer and child which are generally two to six times higher than average cancer risks and hazard indices. *See id.* vol. V, ch. VIII, at 12; *see also id.* vol. V, ch. VIII, at 49-50, tbls. 14 & 15.

211. *See id.* vol. V, ch. VII, at 1 (citing Memorandum from F. Henry Habicht, Deputy Administrator, U.S. EPA, to Assistant Administrators (Feb. 26, 1992)); *see also* U.S. EPA, *Guidance for Risk Characterization*, SCIENCE POLICY COUNCIL (Feb. 1995).

212. *See* 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 34, at 8.

213. *See id.* attach. B, at 3-4.

214. The EPA stated that "[t]o ensure consistency between the SERA and the human health risk assessment (HHRA), the HHRA is being revised to evaluate the potential risks from metals emitted at the current permit limit." FINAL RISK ASSESSMENT, *supra* note 6, vol. VIII, ch. VII, at 3.

215. *See* PHASE I RISK ASSESSMENT, *supra* note 51.

emissions rates for lead and other regulated metals from the March 1993 trial burn results even though the rates were lower than the permitted levels.[216] There was no corresponding discussion by the EPA about reducing the permitted emissions rates to conform with the purportedly more realistic estimates.[217]

By contrast, the screening level ecological analysis performed in 1995 used emissions rates from the 1994 performance testing *and* from the permit.[218] The results based on the 1994 levels produced "low to negligible" levels of risk.[219] The results based on the permitted levels, however, showed "moderate to high" levels of risk.[220]

The 1998 Risk Assessment Protocol gives the agency the discretion to determine on a case-by-case basis whether to use (1) reasonable maximum emission rates tested in the trial burn which become the basis of permit conditions or (2) normal emissions rates (longer-term average rates adjusted for upsets) during the burning of worst-case wastes.[221] The Protocol establishes a procedure for a "risk burn"—performed in conjunction with the trial burn—to determine normal emissions under likely operating conditions.[222]

c. Exclusion of Background Exposures

The WTI risk assessment did not include in its exposure calculations the background levels of chemicals in the environment and in human bodies. The 1990 Indirect Risk Guidelines recommended that background exposures be determined on a site-specific basis and be factored into a total exposure for the indirect risk analysis for noncancer effects:[223]

---

216. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. III, ch. III, at 6-10.

217. *See* 1996 PEER REVIEW REPORT, *supra* note 23, at 3-38.

218. *See supra* notes 81-86.

219. FINAL RISK ASSESSMENT, *supra* note 6, vol. VI, ch. IX, at 1-6.

220. *Id.* The risk analysis for the stack projected permit limit metal scenario indicated a moderate to high risk to ecological receptors exposed via air, soil, or the food chain for 6 of the 12 metals included in the current permit: barium, mercury, nickel, selenium, silver, and thallium. Hazard quotients for each of the six metals (except mercury) were 10 or higher for one or more ecological receptors (compared to a no effects level of one). The magnitude of the hazard quotient exceedances ranged from 1.1 (for the kingfisher exposed to mercury through the food chain pathway) to 4250 (for the short-tailed shrew exposed to thallium through the food chain pathway) at the maximum impact points. *See id.*

221. 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 2-3.

222. The choice of emissions rates depends in part upon the toxicity and variability of the wastes to be burned and in part upon the facility's preference for the additional permit conditions the agency will attach for facilities assessed using normal conditions. *See id.* at 5-6.

223. Total Background Intakes are not considered in determining excess cancer risks, since excess risk is an expression of incremental risk due to the facility and not an expression of total carcinogenic risk. *See* 1990 INDIRECT RISK GUIDELINES, *supra* note 38, ch. 15, at 14. The Guidelines stated that it may be

> It is important to recognize that there may be sources of exposure other than the combustor emissions, and that total exposure should be maintained below the RfD or a specific risk level. These sources of exposure include background levels (whether natural or anthropogenic) in drinking water, food or air. .Other types of exposure that are due to occupation or habits such as smoking might also be included, depending on data availability and regulatory policy. These exposures are summed to estimate [Total Background Intake].[224]

The 1993 and 1996 Peer Review Groups also recommended that background values include background ambient air concentrations[225] and existing body burdens.[226]

The 1994 Draft Risk Assessment Guidelines recommended that background exposures be addressed by lowering acceptable levels of risk. It recommended that the acceptable level of risk be reduced to 1 in 100,000 from 1 in 10,000 for cancer risks and from a hazard quotient of 0.25 from 1.0 for noncancer risks.[227] The 1994 Guidelines also state that background exposures may be included into the quantitative risk estimates if sufficient local information is available.[228]

The WTI risk assessors' final approach was confusing. Consistent with the 1994 Guidelines, they chose not to include background exposures explicitly in their quantitative estimates. The risk assessors also compared the quantitative cancer estimates to the 1 in 100,000 standard of the 1994 Guidelines, but used the 1.0 hazard quotient for noncancer risks instead of the more stringent 0.25 standard recommended in the guidelines. The results, however, appeared to satisfy both standards.[229]

---

useful to compare Total Background Intake with Daily Intake or Total Daily Intake to determine the fraction of exposure to a given carcinogen that is contributed by the facility. *See id.* at 22.

224. *Id.* at 12; *see also id.* at 4.

225. *See* 1993 PEER REVIEW REPORT, *supra* note 1, ch. 3, at 28; 1996 PEER REVIEW REPORT, *supra* note 23, ch. 3, at 18-19, 28.

226. James Butler described in the 1993 Peer Review Report the need to model body burdens:

> For some contaminants (e.g., mercury, lead) it is essential to factor in estimates of existing body burdens and intakes from other sources. The project plan needs to address the issue of background exposures in the population subgroups, especially for compounds that are retained in the body, have relatively low thresholds, or have other significant sources in the environment.

1993 PEER REVIEW REPORT, *supra* note 1, app. I (comts. of James Butler).

227. *See* 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 34, at 15.

228. *See id.* The 1998 Risk Assessment Protocol also adopts this approach. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1; *see also* 1998 RISK ASSESSMENT PROTOCOL ADDENDUM, *supra* note 43, at 2.

229. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. X, at 1-6. The WTI risk assessment

Nevertheless, in response to community criticisms after the release of the Final Risk Assessment, the EPA conducted a limited assessment of risks from background exposures and released it in an addendum. The EPA used a "margin-of-exposure" style of analysis, similar to its analysis of the noncancer risks from dioxin exposures, and compared WTI's contribution to the emissions values reported in the EPA's Toxic Release Inventory[230] to local ambient dioxin measurements recorded by the Trilateral Environmental Committee. The committee is a controversial informal group funded, in part, by WTI to monitor the environmental impacts of the WTI incinerator.[231] In the TRI comparison, the EPA found that WTI was not a major contributor of the top ten chemicals released through stack air emissions, but that it could be considered a major contributor of ethylbenzene and mercury.[232] The dioxin comparisons showed that WTI's contribution was one to two percent of the ambient background value and that the ambient background level was within the national average for areas not impacted by industrial sources.[233]

Critics have also challenged the credibility of the Committee's data. The Committee, which is an informal body, initially consisted of the North Ohio Valley Air Authority (NOVAA) (the local agency responsible for air quality monitoring on behalf of the State), the East Liverpool Board of Health and

---

used the 0.25 hazard quotient standard only to evaluate risks calculated for the inhalation route of exposure. *Id.*, vol. V, ch. III, at 4.

230. The TRI was established under the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 and expanded under the Pollution Prevention Act of 1990. *See* 42 U.S.C. §§ 11,023, 13,106 (1994). It requires facilities to submit annual reports on the following: (1) the maximum amount of covered chemicals present on-site during the reporting year, (2) the amounts of each chemical shipped from the facility to other locations for recycling, energy recovery, treatment or disposal, (3) the types of activities conducted using each chemical, (4) the amounts of each chemical recycled, burned for energy recovery, or treated at the facility, and (5) the amounts of each chemical released to the environment during the reporting year. *See id.* §§ 11,023(g)(1)(c), 13,106(b). Facilities subject to the TRI requirements include those which: (1) conduct manufacturing operations within "Standard Industrial Classification [(SIC)] Codes 20 through 39," (2) "have 10 or more full-time employees," and (3) manufactures or processes more than 25,000 pounds or uses more than 10,000 pounds of any listed chemical during the calender year. *Id.* § 11,023(b)(1)(A).

231. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. VIII, ch. VI, at 22-32. The Trilateral Environmental Committee was comprised of the North Ohio Valley Air Authority (an agency that monitors air quality for the State of Ohio), the East Liverpool Community Advisory Council, and Von Roll (Ohio), Inc., one of the partners comprising the WTI partnership. The primary goal of the program was to monitor levels of dioxins and furans, toxic organics, and heavy metals in ambient air as well as heavy metals in local homegrown vegetables and fruits. *See id.* at 28.

232. *See id.* at 27. The WTI emissions were the average emission scenario used in the risk assessment calculations. *See id.* at 25.

233. *See id.* at 31. The ambient dioxin measurements were recorded at five monitoring stations on October 30-31, 1995, March 27-28, 1996, and July 2-3, 1996. *See id.* at 28. Furthermore, the TRI data exclude emissions from major sources of pollutants, including hazardous and other waste treatment and disposal facilities, such as WTI, electric power plants, oil and gas drilling operations and mines. *See id.* at 25.

one of the corporations comprising the WTI partnership. The Board of Health subsequently dropped out and was replaced by a citizens group organized by WTI.[234] NOVAA, which collected the ambient dioxin data used in the WTI risk assessment, was subsequently fired by the State following a 1997 state audit that disclosed that NOVAA employees received payments from the companies they regulated, including WTI.[235]

3. Predicting Atmospheric Transport: The Lack of Local Meteorological Data

Risk assessments predict the atmospheric dispersion of expected pollutants with computer models. The models make predictions based upon emissions and meteorological data.[236] As discussed above, estimated emissions for WTI were determined from emissions data that was not representative of actual operating conditions or the incinerator's actual waste feed.[237] Local meteorological data was limited, consisting of a year's worth of data collected between April 1992 and March 1993, which may or may not have been representative of long-term or normal meteorological conditions.[238]

The 1993 Peer Review Group criticized the suitability of the air model proposed by the EPA (and available air models in general) for the local topography (steep river valley with adjacent industrial buildings) and for the risk scenarios considered most significant (accidents and short-term emissions spikes during inversions and stagnations).[239] It also recommended the collection of a more comprehensive set of local meteorological data.[240] According to one peer reviewer, these and other problems created a level of

---

234. *See* Margaret Newkirk et al., *Trouble in the Air: Monitoring Agency Operating in Ozone?*, AKRON BEACON J., May 4, 1997, at A10.

235. NOVAA, moreover, was criticized in a March 1997 state audit for employees receiving payments directly from the companies they regulated (without the knowledge of the Ohio EPA and in addition to the sums paid by the Ohio EPA to NOVAA). *See id.* at A10. Other reasons for the firing included a record of incompetence in air monitoring and the hiring of politically connected staffers with little or no training in air monitoring. *See id.* at A1, A10. The Akron Beacon Journal reported that the twelve NOVAA employees received $56,000 in 1995 and $72,000 in 1996 in extra compensation from Von Roll. *Id.* at A10.

236. *See* 1993 PROJECT PLAN, *supra* note 160, at 63-70.

237. *See supra* notes 198-202 and accompanying text.

238. *See* 1993 PROJECT PLAN, *supra* note 160, at 67-69. The 1992 Screening Risk Assessment used meteorological data collected from a nuclear power plant in Shippingport, Pennsylvania, 10 miles east of the site and 25 miles from the Pittsburgh Airport. *See id.* at 13.

239. *See* 1993 PEER REVIEW REPORT, *supra* note 1, ch. 3, at 14-16.

240. *See id.* Despite the collection of local meteorological data, the data collected was limited, requiring the continued use of meteorological data from the nearest National Weather Service station at the Pittsburgh Airport. *See id.*

uncertainty greater than estimated by the EPA.[241] The 1995 Draft Risk Assessment attempted to address the concerns of the 1993 Peer Review Group,[242] but the 1996 Peer Review Group was not satisfied.[243]

C. *The Traditional Steps of the Risk Assessment Process*

1. Hazard Identification and Dose-Response Assessment

a. Failure to Conduct Independent Hazard Identification and Dose-Response Assessments: Reliance Solely on EPA Databases

The WTI risk assessment bypassed the first two steps of the traditional risk assessment process. It failed to conduct an independent Hazard Identification[244] or an independent Dose-Response Assessment.[245] Instead, in a step it called "toxicity assessment,"[246] the EPA used its databases of EPA-approved toxicity values to determine toxicity values for the list of chemicals selected for analysis.[247] The adverse health effects associated with the toxicity values reported in the databases were defined as hazards. In this way, the

---

241. *See id.*

242. *See* 1995 DRAFT RISK ASSESSMENT, *supra* note 55, vol. IV, ch. I, at 1-4 and ch. V, at 1-4.

243. *See* 1996 PEER REVIEW REPORT, *supra* note 1, ch. 3, at 14-21.

244. The 1983 NRC Report describes Hazard Identification as an independent step in the risk assessment process. *See* 1983 NRC REPORT, *supra* note 15, at 19. In hazard identification, the agency determines whether exposure to a chemical can cause an increase in the incidence of a health condition. *See id.* The process involves the review of data from epidemiological studies, animal experiments, short-term tests and chemical analyses. *See id.* at 20-23.

245. Dose-response assessment is the second step of the risk assessment process. *See* 1983 NRC REPORT, *supra* note 15, at 19-20, 23-27; 1990 INDIRECT RISK GUIDELINES, *supra* note 38, ch. 14, at 1. Hazard Identification and Dose-Response assessment both involve qualitative analysis (i.e., the exercise of "scientific judgment"), but only dose-response assessment produces a quantitative toxicity value. *See* 1990 INDIRECT RISK GUIDELINES, *supra* note 38, ch. 14, at 1-2. The value reflects "a concentration or dose of a chemical above which humans are at risk for systemic toxicity, or an estimate of carcinogenic potency or risk when humans are exposed for a lifetime." *Id.* This quantitative measure is termed the reference dose (RfD) for noncancer effects and the "slope factor" for carcinogenic potency. *See id.* The guidance states that many RfD and cancer slope factor values are available on the U.S. EPA Integrated Risk Information System (IRIS), but it does not state that IRIS is intended to be the determinant of the hazards identified in hazard identification or the sole determinant of dose-response values in dose-response assessment. *See id.* at 1.

246. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. III, at 1.

247. The databases are developed by the EPA for "many of the most frequently occurring environmental chemicals." *Id.* The EPA uses toxicity data based primarily on the EPA's IRIS, an on-line data base of toxicity values maintained by the EPA. *See id.* If unavailable in IRIS, toxicity values were compiled from the EPA's Health Effects Assessment Summary Tables (HEAST), consultation with U.S. EPA, or, in the case of Reference Air Concentrations, based on route-to-route extrapolation (i.e., use of an oral RfD for deriving a RAC). *See id.* ch. III, at 4. *See also* Memorandum from F. Henry Habicht, Deputy Administrator, U.S. EPA, on Guidance on Risk Characterization for Risk Managers and Risk Assessors, (Feb. 26, 1992).

EPA combined the two steps into a single search and avoided any independent consideration of toxicity values and hazards.[248]

The EPA's database, therefore, determines the hazards to be addressed and the toxicity values to be used in each risk assessment. The databases are established by internal EPA working groups, without formal public comment or judicial review.[249] The absence of case-by-case review avoids the confirmation and updating of toxicity values and public proposals for more potentially accurate research. [250] This approach is also adopted in the 1994 Draft Risk Assessment Guidelines and in the 1998 Risk Assessment Protocol.[251]

The early EPA guidance documents, however, describe hazard identification as an independent step in the risk assessment process. The 1990 Indirect Risk Guidelines state that hazard identification is the first step in the risk assessment process, a step "to determine the type of toxicity that is

---

248. The only independent analysis of toxicity values occurred for chemicals which lacked EPA-approved values. For these chemicals, the risk assessors either developed alternative analyses or omitted the risks altogether. *See infra* notes 253-62 and accompanying text.

249. The public has informal opportunities to present information to the IRIS workgroups. *See* 58 Fed. Reg. 11,490-93 (1993). The IRIS process is not established by statute or regulation, and similarly, there is no statutory or regulatory requirement for public participation. *See id.* EPA workgroups review literature and develop toxicity values on a periodic basis determined by the EPA. *See id.* at 11,490. The process is governed by EPA policy, which provides for the consideration of public input in four ways. *See id.* The EPA designates two staff members as scientific contacts for specific assessments. *See id.* at 11,491. It maintains a public reading room for IRIS information. *See id.* It maintains an IRIS Information Submission Desk to receive scientific literature for distribution to the appropriate agency offices for subsequent use in IRIS information development processes. *See id.* at 11,492. It also conducts scientific seminars. *See id.* at 11,493.

In 1993, the EPA requested public comment on ways to improve IRIS, including the possibility of external peer review and public involvement. *See id.* at 11,490. It stated that it wanted "to identify mechanisms that can involve qualified outside scientists and members of the public in improving the quality of information in IRIS, while not unduly delaying the process of adding critical new information to the data base." *Id.* at 11,491.

As a consequence, the EPA established a pilot program in 1996 in which, for eleven pilot substances, it intended to develop or update cancer and noncancer toxicity values with a certain amount of public involvement and external peer review. *See* 61 Fed. Reg. 14,570 (1996). The pilot process consists of (1) a call for technical information on the eleven substances from the public, (2) a search of the current literature, (3) internal peer review (within EPA), (4) external peer review (outside EPA), (5) consensus review and management within EPA, (6) preparation of final IRIS summaries and supporting documents, and (7) entry of summaries into the IRIS data base. *See id.* at 14,570-71. The EPA stated that the appropriate level of external peer review will depend upon the complexity of the scientific information, and the form of peer review will be by mail, forums of experts, or formal federal advisory committees. *See id.*

250. The 1994 NRC Report noted the limitations of the EPA's IRIS database and stated that if they "are to be used for risk assessments that lead to major risk-management decisions, then EPA must ensure their quality and keep them up to date." 1994 NRC REPORT, *supra* note 97, at 251; *see also supra* note 247.

251. *See* 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 34, at 1-7; *see also* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 3.

produced by a chemical agent (e.g., mutagenicity, developmental toxicity, carcinogenicity)."[252]

b. Missing Toxicity Values and Omitted Risks

As noted earlier, the WTI risk assessors generally excluded from analysis chemicals and health risks lacking EPA-approved toxicity values. EPA's databases of toxicity values have many gaps. Therefore, risk assessments may exclude substantial health risks and underestimate total risks.

There are several reasons for these gaps. Toxicity studies have not been conducted for many compounds and the EPA lacks internal agreement on toxicity values. For many compounds, the studies that have been done fail to detect the most sensitive health effects.[253] Perhaps most significantly, the adoption of toxicity values for chemicals such as dioxins and furans is often politically controversial.[254]

Table III-1 of the Risk Assessment lists the toxicity values used. Of 852 possible values for 213 chemicals, 478 (or fifty-six percent) are blank,[255] meaning that the risks associated with these blanks were not included in the risk results. The 1996 peer reviewers characterized the gaps as sources of uncertainty that required further discussion.[256] One result is that dioxins and furans were excluded from the quantitative estimates of total noncancer health risks.[257]

Dioxins and furans have EPA-determined toxicity values for cancer but not noncancer effects. Nevertheless dioxins and furans cause adverse health

---

252. 1990 INDIRECT RISK GUIDELINES, *supra* note 38, ch. 13, at 1. The Guidelines consider hazard identification to be a qualitative assessment "in which all available experimental animal and human data are reviewed to determine if the agent is likely to cause a particular type of toxicity." *Id.* Hazard identification reviews data providing "principal evidence," which consists of epidemiologic studies, human studies, and long-term animal studies. *See id.* at 2-3. "Supporting evidence is derived from short-term tests for genotoxicity, toxicologic effects other than cancer, metabolic and pharmacokinetic properties, structure-activity relationships, and physical/chemical properties of the agent." *Id.* at 3.

253. The lack of recognition of the adverse effects of the chemicals known as endocrine disrupters in the toxicity values for those chemicals represents an example. *See infra* notes 265-71 and accompanying text.

254. The EPA noted in the 1995 Risk Assessment that a chemical may lack a toxicity value, because the compound may not have exhibited adverse health effects in toxicity studies or because the EPA considered the available data insufficient to determine a value. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. IV, at 3.

255. *See id.* tbl. III-1.

256. *See* 1996 PEER REVIEW REPORT, *supra* note 23, ch. 3., at 29 and comts. of George V. Alexeeff, at D-126 to D-128. For a more general discussion of the lack of definitive research on toxicity values, see Ellen K. Silbergeld, *The Risks of Comparing Risks*, 3 N.Y.U. ENVTL. L.J. 405, 413 (1995).

257. The health effects of dioxins and furans are addressed in a separate "margin of exposure" analysis, which is not incorporated into the final risk assessment calculations. *See* discussion *infra* at Part IV.C.1.d.

effects other than cancer and likely at lower doses.[258] In its 1994 Dioxin Reassessment, the EPA cited studies which showed a wide range of noncancer health effects in animals and concluded that similar effects were likely in humans.[259] Remarkably, the EPA suggested that the chemicals were so toxic and their concentrations in the environment so substantial that it was impracticable to develop a traditional noncancer reference dose (RfD).[260] The EPA stated that the RfD would be 10 to 100 times less than the average national daily exposure.[261]

The current apparent overexposure is controversial and might, of course, supply a reason to drastically reduce current emissions and prevent new sources.[262] Perhaps for these reasons, the EPA has not reached a consensus opinion on toxicity values for noncancer effects.[263] Coincidentally, the alternative, qualitative analysis used in the WTI risk assessment for dioxins and furans found their noncancer risks acceptable. The EPA used a "margin of exposure" analysis that compared the incremental dioxin exposures from the WTI incinerator to the relatively higher national background levels and concluded (without examining the actual risks of either the background or incremental exposures) that the incremental risk was acceptable.[264]

---

258. *See* Final RISK ASSESSMENT, *supra* note 6, vol. V, ch. III, at 4-7.

> In addition to the potential for dioxins to cause cancer, there is also concern for the potential noncancer effects from these chemicals. U.S. EPA concludes that adequate evidence exists to suggest that exposure to 2,3,7,8-TCDD and related dioxin-like compounds results in a broad spectrum of effects in animals, some of which may occur in humans.

Id., vol. V, ch. III, at 5-6.

> It is not clear to me what effects will be evaluated for which chemicals. Many of the chemicals have both cancer and noncancer effects, and cancer does not necessarily have the most sensitive dose-response curve. Will multiple effects be evaluated for the chemicals? If not, how will it be decided which effects will be evaluated? *For instance, for 2,3,7,8-TCDD, enzyme induction, immunotoxicity and reproductive toxicity occur at lower doses than cancer.*

1993 PEER REVIEW REPORT, *supra* note 1, at comts. of Mary E. Davis, app. I. (emphasis added).

259. U.S. EPA, PUB. NO. 600-P9-201, HEALTH ASSESSMENT DOCUMENT FOR 2,3,7,8-TETRACHLORODIBENZO-P-DIOXIN (TCDD) AND RELATED COMPOUNDS, REVIEW DRAFT, vol. III, ch. 9, at 36-53 (Aug. 1994) [hereinafter 1994 DRAFT DIOXIN REASSESSMENT]. These included, for example, chloracne, cancer, reproductive and developmental effects, immunological effects, hormonal effects, diabetes, and endometriosis. *See id.*

260. *See id.* at 84.

261. *See id.* at 84-86.

262. *See id.* at 1-89. *See also* THEO COLBORN ET AL., OUR STOLEN FUTURE 210-30 (1996); LOIS MARIE GIBBS, CITIZENS CLEARINGHOUSE FOR HAZARDOUS WASTE, DYING FROM DIOXIN 47-62, 277-90 (1995).

263. The federal Agency for Toxic Substances Disease Registry (ATSDR) has recommended an RfD for dioxins. Toxicity Profile for 2,3,7,8-Tetrachlorodibenzo-p-dioxin (ATSDR), June 1989. The EPA has not adopted the ATSDR RfD, however, and it was, accordingly, not used in the WTI risk assessment.

264. *See* discussion *infra* at Part IV.C.1.d.

The risks from "endocrine disruptors" were also omitted due to the lack of EPA-approved toxicity values for these risks.[265] The term "endocrine disruptors" (sometimes referred to as "environmental hormones") includes a broad class of chemicals that interfere with the finely-tuned endocrine system that is fundamental to the normal function of cells, tissues, and organisms.[266] They may include: PCBs; dioxins and furans; and pesticides, such as atrazine, DDT, endosulfan, chlordane, heptachlor, 2,4,5-T, and 2,4-D.[267] Recent research shows that endocrine disruptors can have adverse effects, in particular, on reproduction.[268] Given the broad class of chemicals and controversy involved, the EPA has been cautious to regulate:

> [t]he data that have contributed to this working hypothesis stem from a number of different disciplines. These include wildlife reproduction (feminization of birds, alligators, and certain terrestrial mammals); wildlife population ecology (population declines); *human reproductive physiology* (decreased sperm count in males in industrialized nations); epidemiology (observed increases in breast cancer in industrialized nations); molecular biology (receptor-mediated mode of action data); and endocrinology (increased understanding of mechanisms of hormone regulation and impacts of perturbations). These findings serve as a basis for further experimentation to determine whether the fundamental hypothesis is correct, and, if so, to what extent....*The broad definition of chemicals which could qualify as endocrine disruptors is particularly problematic for the process of risk assessment.* Given the current limited state-of-the-science, it is premature to attempt to evaluate the potential risks from human exposure to chemicals from the standpoint of endocrine disruption. Therefore, the U.S. EPA has not yet developed a methodology for the quantitative assessment of risks due to exposures to potential endocrine disruptors. However, the Agency and other federal health regulatory and research agencies are sponsoring significant amounts of research to better understand the phenomenon of endocrine disruption so that it can be addressed in future risk assessments.[269]

---

265. The EPA defined an endocrine disruptor "as an exogenous agent that interferes with the synthesis, secretion, transport, binding, action, or elimination of natural hormones in the body." FINAL RISK ASSESSMENT, *supra* note 6, vol. VIII, ch. VI, at 21. The hormones affected are responsible for the maintenance of homeostasis, reproduction, development, and behavior. *See id.* Examples of chemicals suspected of being endocrine disruptors include the pesticides atrazine, DDT, endosulfan, chlordane, heptachlor, 2,4,5-T, and 2,4-D, and chemicals such as PCBs and dioxins and furans. *See id.*

266. *See id.*

267. *See id.*

268. *See id.*

269. *Id.* vol. V, ch. III, at 13-14. This is modified at FINAL RISK ASSESSMENT, *supra* note 6, vol.

The 1998 Risk Assessment Protocol acknowledges the apparent health risks of endocrine disruptors, but notes that the EPA has not approved toxicity values or alternative ways to assess those risks.[270] The Protocol recommends that permit writers and risk assessors stay up-to-date for the latest policy on this issue.[271]

c. Toxicity Studies Not Addressing Most Sensitive Noncancer Effects: Potential Manipulation and Exclusion of Risks from Quantitative Estimates.

When determining a noncancer toxicity value, the assumption is made that if the first adverse health effect that occurs as doses are increased (the "critical toxic effect") is prevented from occurring, then all toxic effects are prevented.[272] If so, the determination of the "critical toxic effect" is crucial to the validity of the RfD.

Members of the peer review panels questioned, however, whether the studies underlying EPA-approved databases identify the "critical toxic effect" for many compounds. Eula Bingham, Chairperson of the 1993 Peer Review Group, stated that unstudied health effects might be caused at levels lower than the toxicity values determined by the EPA:

> My reaction to the plan is that it only seeks to respond to a legal mandate using EPA guidelines. My greatest concerns are that EPA in its guidelines for risk assessment has *many* areas where there are

---

VIII, ch. VI, at 21. *See also* COLBORN, *supra* note 262, at 198-209. The risk assessors modified their discussion of endocrine disruptors in the Final Risk Assessment in response to the 1996 Peer Review Group's concerns but stated that the available research was in its initial stages:

> [D]iscovering and verifying the actual biological effects in humans caused by endocrine disruption is one of the chief goals of the scientific research in this area. This is a new area of scientific research, and many of the critical studies are in their initial phases.

FINAL RISK ASSESSMENT, *supra* note 6, vol. VIII, ch. VI, at 20.

270. 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 72-73.

271. The 1998 Risk Assessment Protocol provides the following advice:

> Because the information currently available on endocrine disruptors is inconsistent and limited, U.S. EPA has not yet developed a methodology for quantitative assessments of risk resulting from potential endocrine disruptors. Currently, no quantitative U.S. EPA methods exist to specifically address the effects of endocrine disruptors on the human endocrine system in a risk assessment. Because the methods for addressing endocrine disruptors are developing at a rapid pace, permits writers and risk assessors should contact the Economics, Methods and Risk Analysis Division (EMRAD) of the Office of Solid Waste for the latest policy on how to deal with endocrine disruptors in site specific risk assessments.

Id. at 73.

272. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. III, at 3.

> *no* toxicological data and inadequate toxicological data on possible target organs....Are there any data from human populations exposed to such emissions that provide data as to eye or nasal irritation, increases in upper respiratory and respiratory problems, asthma? There are investigators, many of them physicians who should help review the plan and offer advice. EPA guidelines for risk assessment do not address such effects on human populations and these adverse health effects are not ordinarily listed in the data bases.[273]

James Butler, another peer reviewer, stated, for example, that recent research shows that the most sensitive adverse health effect for methylmercury consists of developmental effects, not paraesthesia (i.e., irritated skin).[274] The research also shows that the developmental effects occur at a dose of one order of magnitude less than the currently recognized value.[275]d. Alternative toxicity analyses

d. Alternative toxicity analyses

Despite the practice of omitting risks that lack toxicity values, the WTI risk assessment conducted alternative risk analyses (which were not integrated into the quantitative risk estimates) for a few chemicals lacking toxicity values. The EPA ultimately addressed the noncancer risks of dioxins and furans with a "margin of exposure" analysis, comparing the incremental exposures of dioxins and furans with the "predicted or expected background exposure levels."[276] It calculated the estimated contribution from WTI to be less than one percent of the average daily background dose. Therefore, the EPA concluded that "the probability is low that the incremental exposure due to emissions from WTI would result in a significantly increased body burden of dioxin-like compounds for the majority of the population in the vicinity of the incinerator."[277]

---

273. 1993 PEER REVIEW REPORT, *supra* note 1, app. I, at cmts. of Eula Bingham.

274. *See* 1996 PEER REVIEW REPORT, *supra* note 23, at cmts. of James Butler.

275. *See id.*

276. FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. VIII, at 25-26. According to the EPA, this was expected to "serve as an indicator of the potential impact on human health by showing the additional contribution of the incremental exposure from incinerator emissions to the overall body burden of dioxin-like compounds from background exposures." *Id.* at 26. Because measurements of actual background levels were not available, the EPA used the estimates of background exposure to dioxins and furans expected for the U.S. adult population that the EPA made in its 1994 "Draft Dioxin Reassessment." *See id.*

277. *Id.*

The EPA did similar piecemeal analyses for lead, sulfur oxides, nitrogen oxides, and particulate matter, which also lacked EPA-approved toxicity values. Instead of a Hazard Index analysis, the EPA used an "uptake/biokinetic" model to estimate the adverse health effects of WTI's lead emissions.[278] The model predicts blood lead levels in children based upon background and predicted incremental exposures to lead.[279] Based upon exposures estimated for WTI, the EPA concluded that children's blood lead levels would not be increased above a level considered to cause neurobehavioral effects in children.[280] The EPA's approach, however, did not produce risk estimates for cancer, and the noncancer estimates could not be incorporated into the EPA's hazard index of noncancer risks.[281]

The 1996 Peer Review Group recommended that the risk assessors calculate a cancer risk for lead using the toxicity value developed by the California EPA.[282] The EPA acknowledged that its "uptake/biokinetic" model only addressed noncancer risks, but, without explanation, still declined to expand its analysis.[283] The 1998 Risk Assessment Protocol adopted EPA's approach for dioxins and lead.[284]

There are two major problems with the use of ad hoc alternative analyses for chemicals lacking toxicity values. First and foremost is the potential for manipulation. For example, the EPA's alternative analysis for dioxins converted the potential exceedance of a Reference Dose into an acceptable risk estimate.[285] The potential for manipulation is exacerbated by the lack of

---

278. *Id.*, ch. III, at 8.

279. *See id.* The model is unable to predict blood lead levels in adults, but the EPA considered it sufficient, in view of the greater susceptibility of children to lead exposures. *See id.*

280. *See id.* ch. III, at 8-9, ch. VIII, at 12-14.

281. Similarly, there are no inhalation toxicity values for the criteria pollutants of sulfur oxides, nitrogen oxides and particulate matter classified as PM10. *See id.* ch. III, at 9-10. As a result, the EPA compared estimated air concentrations to the National Ambient Air Quality Standards for the pollutants and determined that the WTI emissions are "not expected to pose a significant health risk." *Id.*

Again, the Risk Assessment's analysis does not produce Hazard Quotients that can be incorporated into a cumulative estimate of cancer and noncancer risks. Furthermore, the NAAQS do not represent risk-free standards. They include an undetermined level of risk which was deemed acceptable, but which was not incorporated into the Risk Assessment's total characterization of risks from the plant.

282. 1996 PEER REVIEW REPORT, *supra* note 23, at 3-29 and cmts. from George V. Alexeef, at D-128.

283. FINAL RISK ASSESSMENT, *supra* note 6, vol. VIII, ch. VI, at 5. The risk assessors refused to use the alternative value to estimate a cancer risk: "The California EPA's slope factor for lead could be employed to estimate a cancer risk from lead exposure. However, the EPA's position will continue to be that a noncancer endpoint is the most sensitive one to evaluate for lead exposure." *Id.*

284. 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 42-43, 59-60; 1998 RISK ASSESSMENT PROTOCOL ADDENDUM, *supra* note 43, at 4.

285. The EPA did not technically step over the line into risk management by stating that the Margin of Exposure results showed acceptable risks. The form of its characterization of the results, however, clearly suggested no other conclusion. *See supra* note 59 and accompanying text.

standards for the use of alternative analyses. Second, the results of the alternative analyses cannot be combined with the quantitative risk estimates of the primary analysis to produce a cumulative risk estimate.[286]

2. Exposure Assessment

a. Identifying Exposed Populations and Exposure Pathways

Instead of estimating exposures for each person in the study area, the EPA grouped individuals into "exposure populations" based upon similar characteristics and behavior patterns that determine one's exposures.[287] The EPA identified seven subgroups: adult nonfarming residents, child nonfarming residents, adult farmers whose diet consists partially of homegrown food products, children of farmers whose diet consists partially of homegrown food products, children who attend school in the area, adult farmers whose entire diet is home grown (i.e., subsistence farmers) and children of subsistence farmers.[288]

The EPA rejected the Peer Review Group's recommendation that children who live near the facility and attend school near the facility, elderly people,[289] those who are already highly exposed to metals and dioxin-like compounds from other sources, hunters of deer and waterfowl, individuals who both work at the WTI facility and live near it, and "very active people" with higher breathing and food consumption rates be considered as additional sensitive exposure groups.[290] It also defined the pathways by which the contaminants reach the populations. The EPA included air exposures, soil exposures, terrestrial food chain exposures (through vegetables, beef, poultry, pork products, eggs, and dairy products), and surface water exposures.[291] The

---

286. *See infra* Part IV.C.3.a.i.

287. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. V, at 1.

288. *See id.* at 2.

289. The 1993 Peer Review Group described elderly people as a group "who apparently make up a larger than expected fraction of the East Liverpool community." 1993 PEER REVIEW REPORT, *supra* note 1, at 3-20.

290. *See id.*; 1996 PEER REVIEW REPORT, *supra* note 23, ch. 3, at 31-32.

291. FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. V, at 3-4. The risk assessment considered exposures through breast milk (of organic emissions) and fish consumption in its analysis of high-end exposures. *Id.* at 4. It chose not to evaluate groundwater contamination as a potential pathway, concluding that the potential for groundwater contamination was "very limited." *Id.* at 5.

The 1996 Peer Review Group questioned the EPA's failure to address exposure to metals through the breast milk pathway. The EPA justified the exclusion on the basis that EPA guidelines did not include breast milk as a potential pathway for metals exposures and, further, that the exposures were not expected to be a significant source of risk. *See* 1996 PEER REVIEW REPORT, *supra* note 23.

EPA also addressed the 1993 Peer Review Group's recommendation to consider exposures through household dust.[292]

b. Estimating Concentrations of Chemicals Absorbed into Environmental Media

The next step was to estimate the concentrations of chemicals in the media through which humans would be exposed. These include direct exposures through inhalation and indirect exposures. Indirect exposures result from the deposition of chemical-carrying particles and vapor onto soil and vegetation and the subsequent migration of the chemicals into media which come into contact with humans.[293] Accordingly, the EPA risk assessors estimate concentrations in air, soil, vegetables, animal products (meat, eggs, milk, and game), surface water, fish, and mothers' breast milk.[294]

This was done with air modeling (for direct inhalation exposures) and "fate and transport models" (for indirect exposures) designed to simulate the "transport" of substances through the environment over time.[295] The models are expressed in equations which use site-specific and EPA-determined default values as parameters.[296]

The models are also subject to uncertainties and potentially different assumptions.[297] The risk assessment noted, for example, that the modeling assumed that vegetables were exposed to contaminants solely through root uptake (not through direct deposition and air-to-plant transfers) and that animals were exposed solely through food and soil (not through inhalation and surface water).[298]

---

292. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. VIII, ch. V, at 8 and vol. V, app. V-8, at 3-4. The 1993 Peer Review Group stated:

> No discussion of exposure via household dust is included in the plan. Since this is a significant route of exposure for sensitive subgroups, such as infants and children, it should not be discounted. Dermal and ingestion pathways for outdoor soil do not necessarily represent how these exposures occur inside houses.

1993 PEER REVIEW REPORT, *supra* note 1, at 3-21.

293. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. VI, at 1.

294. *See id.*

295. *Id.*

296. *See id.*

297. *See id.* at 14-16.

298. *See id.* tbl. 2, at 21. It relied upon EPA guidelines for the first set of assumptions and its analysis of literature for the second. *See id.*

3. Risk Characterization

In this step, the EPA compared the dose estimates calculated for each of the population subgroups to the toxicity values for each of the chemicals. Based on the comparisons, the EPA calculated risk estimates and described the uncertainties associated with the estimates. Part IV.C.3.a discusses the various measures that the risk assessors chose to express the risk estimates. Part IV.C.3.b addresses the risk assessors' communication of the results, including the manner in which they depicted the uncertainties.

a. Measures of Risk

i. Probabilistic Versus Threshold Expressions of Risk

The EPA followed its traditional practice of using probabilistic estimates for cancer risks and threshold measures for noncancer risks.[299] The EPA assumes that there is no "safe dose" of cancer-causing chemicals, meaning there are probabilities of contracting cancer at all doses.[300] Accordingly, the EPA calculated toxicity values in probabilistic terms which generate probabilistic estimates of excess cancers.[301]

The EPA assumes, however, that there are "safe doses" of chemicals below which no noncancer health effects will occur. These threshold safe doses are called Reference Doses (RfDs), which are used as the basis for calculating hazard indices.[302]

The basis for these assumptions is uncertain. Some research suggests that there may be threshold exposures, at very low levels, which do not cause cancer.[303] Furthermore, Reference Doses, Hazard Quotients, and Hazard Indices have inherent probabilities.[304] Indeed, the 1990 Indirect Risk

---

299. *See* 1990 INDIRECT RISK GUIDELINES, *supra* note 38, ch. 15, at 2.

300. *See id.*

301. *See id.* "Excess risk" is defined in the 1990 Indirect Risk Guidelines "as the incremental lifetime cancer risk above background occurring in a hypothetical population in which all individuals are exposed continuously to a concentration equal to the daily intake of the contaminant." *Id.*

"The [excess risk] is derived from the daily incremental dose of the contaminant above background and the human cancer potency factor as established by the U.S. EPA." *Id.* at 2. "For example, an [excess risk] of 10^{-6} means that lifetime exposure to that specific concentration (or administered dose) would have an upper-bound excess cancer risk of one case in one million individuals." *Id.* at 15.

302. *See id.* at 2. According to the 1990 Indirect Risk Guidelines, a "RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime." *Id.*

303. *See* 1994 NRC REPORT, *supra* note 97, at 65-66.

304. The 1994 NRC Report stated that hazard indices are not actual measures of risk. If a hazard index exceeds 1.0, "adverse health effects are more likely and some remedial action is called for." *Id* at

Guidelines state that "it should not be concluded that all doses below the RfD are 'safe' or without risk and that all doses greater than the RfD are 'unsafe' or pose a risk to human health."[305] Doses less than the RfD "are not likely" to be associated with adverse health risks, and "the probability of adverse effects" increases as the doses increase beyond the RfD.[306]

ii. The Lack of a "Common Metric"

The WTI risk assessment produced a series of risk estimates expressed in different measures, which could not be compared with each other or aggregated to produce an estimate of total facility risk. The EPA calculated probabilistic measures of cancer risks, threshold yes/no measures of noncancer risks for most chemicals, various other threshold measures for lead and other criteria pollutants and qualitative measures for accident and ecological risks.[307]

The Presidential/Congressional Commission on Risk Assessment and Risk Management, established under the 1990 Clean Air Act Amendments (to review the use of risk assessments in establishing emissions standards for hazardous air pollutants), acknowledged this problem.[308] The Commission recommended the development of a "common metric" to compare and aggregate expressions of cancer and noncancer risks.[309] Risks expressed in a

---

69. The measure does not express the size of the risk. *See id.*

305. 1990 INDIRECT RISK GUIDELINES, *supra* note 38, ch. 14, at 4-5.

306. *Id.*

307. The EPA stated in the Addendum to the final risk assessment that combining the sources of risk into a single quantitative risk estimate was beyond the scope of the risk assessment and current risk assessment methodology. FINAL RISK ASSESSMENT, *supra* note 6, vol. VIII, ch. V, at 15-16.

308. *See* Clean Air Act Amendments, Pub. L. No. 101-549, § 303, 104 Stat. 3385, 3588-3589 (1990).

309. The Presidential/Congressional Commission recommended the establishment of a "common metric":

> Chemicals suspected of causing cancer are regulated by assuming that every exposure has some risk. In contrast, chemicals suspected of causing other effects, such as developmental or reproductive toxicity, are regulated by assuming that there is a safe level of exposure. That simple dichotomy is not fully supportable by current scientific evidence. Furthermore, it results in expressions of risk for cancer and for other kinds of toxicity that cannot be compared and in striking discrepancies among maximal exposures considered to have negligible risk . . . [t]o assist in comparative risk assessment and risk communication, a *common metric* for comparing health risks should be sought by environmental protection and public health agencies.

PRESIDENTIAL/CONGRESSIONAL COMMISSION ON RISK ASSESSMENT AND RISK MANAGEMENT, RISK ASSESSMENT AND RISK MANAGEMENT IN REGULATORY DECISION-MAKING, FINAL REPORT, vol. 2, at 43 (1997) (emphasis added).

common form can thereby be better compared and aggregated to derive more cumulative measures of risk.

iii. The Scientific Rigor of "Hazard Indices": The Use of Arbitrary Uncertainty Factors

The 1994 NRC Report stated that "[t]he NOAEL-safety factor approach, [is] useful, [but] not scientifically rigorous."[310] The RfDs lump all noncancer risks into a single measure of "non-cancer health effect."[311] They fail to indicate the range of noncancer effects that comprise the risk.[312]

RfDs also include arbitrary uncertainty factors to account for the scientific uncertainty in the EPA's toxicity data. The EPA applies "uncertainty factors of ten each . . . to extrapolate from animals to humans, to provide protection for unusually sensitive individuals, to expand from subchronic to chronic exposure, to estimate a NOAEL from a lowest-observed-adverse-effect level (LOAEL) and to reflect deficiencies in the data base [sic]."[313] The NOAEL may also be adjusted by "modifying factors" to reflect "additional uncertainties in the estimation of the RfD, such as scientific uncertainties in the key study, chemical-specific issues, and/or deficiencies in the overall data base [sic]."[314] Modifying factors may range from greater than zero to ten. The total uncertainty factor, however, may not exceed 10,000.[315] It is for reasons such as these that some in industry and academia state that risk assessments "systematically overestimate" risks.[316] The results might be more accurately characterized as arbitrary.

---

310. 1994 NRC REPORT, *supra* note 94, at 41.

311. *See id.*

312. The 1996 Peer Review Group recommended that the scope of noncancer risks be addressed in the risk assessment:

> The treatment of noncancer effects through the use of the Hazard Index does not provide adequate discussion of noncancer health effects. The atmospheric work group recommends [short term] that the present discussion in the risk assessment be expanded to include an analysis of the likely range of risks associated with noncancer health effects.

1996 PEER REVIEW REPORT, *supra* note 23, at 3-19.

313. 1990 INDIRECT RISK GUIDELINES, *supra* note 38, ch. 14, at 5.

314. *Id.*

315. *See id.* at 6.

316. Adam M. Finkel, *A Second Opinion on an Environmental Misdiagnosis: The Risky Prescriptions of Breaking the Vicious Circle*, 3 N.Y.U. ENVTL. L.J. 295, 298-99 (1994); *see also* ALBERT L. NICHOLS & RICHARD J. ZECKHOUSE, THE DANGERS OF CAUTION: CONSERVATISM IN THE ASSESSMENT AND MISMANAGEMENT OF RISK, IN ADVANCES IN APPLIED MICRO-ECONOMICS: RISK, UNCERTAINTY, AND THE VALUATION OF BENEFITS AND COSTS 55 (V. Kerry Smith ed., 1986).

iv. Failure to Account for Synergistic Effects of Multiple Chemical Exposures

The risk assessment assumed that chemical exposures do not have synergistic effects; meaning, the risk of exposure to multiple chemicals is merely the sum of the risks of exposures to the individual chemicals and that the risks are neither enhanced by synergisms nor diminished by antagonisms.[317] The risk assessors stated that reliable methods do not exist to predict the extent to which synergistic effects occur.[318] In response to the 1996 Peer Review Group's request for elaboration,[319] the EPA cited several studies which the EPA claims suggest that the combined effects of multiple exposures are additive, rather than synergistic.[320]

b. Risk Communication: The Uncertainty Analysis

The NRC reports and EPA guidelines agree that numerical risk estimates should be presented with a qualitative description of their uncertainties.[321] The description should convey the major strengths and weaknesses of the assessment that arise from data availability and the limits of understanding toxicity mechanisms.[322] It should give a clear picture of any consensus or lack thereof about significant aspects of the assessment.[323] When more than one view is supported by the data and the policies underlying the guidelines, and choosing between them is difficult, the views should be presented together. If one is selected over another, the rationale should be given; if not, then both should be presented as plausible alternatives.[324]

---

317. *See* 1990 INDIRECT RISK GUIDELINES, *supra* note 38, ch. 15, at 23.

318. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. VIII., at 1-2.

319. Recent studies have shown that synergistic effects potentially dwarf the individual impacts of single chemical exposures. *See* Jocelyn Kaiser, *New Yeast Study Finds Strength in Numbers*, 272 SCI. 1418, 1418 (June 7, 1996); WORK SESSION ON ENVIRONMENTAL ENDOCRINE DISRUPTING CHEMICALS: NEURAL, ENDOCRINE, & BEHAVIORAL EFFECTS, INTERNATIONAL SCHOOL OF ETIOLOGY AT THE ETTORE MAJORANA CENTRE FOR SCIENTIFIC CULTURE, STATEMENT ON CHEMICALLY-INDUCED ALTERATIONS IN SEXUAL & FUNCTIONAL DEVELOPMENT: THE WILDLIFE/HUMAN CONNECTION (1995).

320. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. VIII, at VI-6 to VI-11.

321. *See* 1983 NRC REPORT, *supra* note 15, at 148, 153-54; 1994 NRC REPORT, *supra* note 199, at 83-84; 1992 Guidance on Risk Characterization for Risk Managers and Risk Assessors, in 1994 NRC REPORT, *supra* note 94, at 366; 1992 Guidelines for Exposure Assessment, 57 Fed. Reg. 22,888, 22,926, 22,929-30 (May 29, 1992).

322. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 8; 1992 Guidelines for Exposure Assessment, 57 Fed. Reg. 22,888, 22,930 (1992).

323. 1992 Guidelines for Exposure Assessment, 57 Fed. Reg. at 22,930.

324. *See id.*; *see also* 1994 NRC REPORT, *supra* note 97, at 83-84.

The WTI risk assessors used point estimates of risk and stated in summary terms that cancer and noncancer effects are not anticipated.[325] The EPA appended discussions of uncertainties to each section of the risk assessment document and an overall uncertainty analysis at the end. The discussions identified the key assumptions selected in each step, the basis for their selection and their potential to overestimate or underestimate risks.

Characterizations of overestimated or underestimated risks are, of course, subject to different perspectives. The EPA characterized the use of EPA-determined toxicity values, for example, as having a low to medium impact on the estimates in the direction of an overestimate of risk.[326] This characterization does not fit well with the generally accepted view that toxicity assessment involves substantial uncertainty. The 1993 Project Plan stated that the "primary sources of uncertainty in a risk assessment are associated with the dose-response evaluation (toxicity assessment of chemicals of concern) and the exposure assessment."[327] The uncertainty analysis in the final risk assessment did not address these issues.[328]

The 1998 Risk Assessment Protocol cited the selection of the compounds to be included in the risk assessment as "[p]ossibly the most important aspect" for risk estimates.[329] It also acknowledged the uncertainty underlying the EPA-verified toxicity values but declined to estimate the degree of that uncertainty.[330]

V. RECOMMENDATIONS

A. The Role of Health Risks and Risk Assessments in Permit Decisions

Three basic issues confound the use of risk assessments in permitting:

1. the lack of a clearly defined role for health risks in permit decisions;
2. the lack of a clearly defined role for risk assessments in determining health risks; and
3. the inherent uncertainty of quantitative risk estimates.

This Part discusses the role that health risks should play in RCRA permitting decisions. It evaluates whether facilities should satisfy formal standards of acceptable risk or whether the EPA should continue to determine acceptable risk on a case-by-case basis. With the role of health risks better

---

325. *See supra* Part I.C.2.

326. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. III, at 32, tbl. 6.

327. 1993 PROJECT PLAN, *supra* note 160, at 101.

328. The peer reviewers also criticized several of the EPA's characterizations of uncertainty. *See* 1996 PEER REVIEW REPORT, *supra* note 23, ch. 3, at 25.

329. 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 8, at 4.

330. *See id.* at 4-5.

established, this part then discusses how risk assessments should be used to evaluate risks; for example, whether the EPA should establish quantitative point standards of risk or whether the standards should include or rely principally upon qualitative factors. The uncertainty of risk assessment results may militate toward lesser reliance on quantitative factors and greater reliance on qualitative factors.

There are three primary approaches for incorporating health risks and risk assessments in a permitting standard:

1. technology-based standards and discretionary ad hoc standards for health risks;
2. technology-based standards and formal quantitative standards for health risks; or
3. technology-based standards and a mix of explicit quantitative and qualitative health risk standards, including a greater emphasis on minimum siting standards.

Risk assessments would play a discretionary role in the first approach and a primary role in the second approach. The third approach reduces the role of risk assessments, in view of their inherent uncertainties and policy judgments.

The level of public participation allowed under the approaches will also influence the results. The third approach, for example, could actually involve the same criteria that the EPA uses in its discretionary ad hoc approach. The differences consist of the more explicit nature of the standards under the third approach and the greater role of the public in developing and applying the standards.

1. Ad Hoc Health Risk Standards

Under the EPA's current permitting approach, the acceptability of a facility's health risks is reserved to the EPA's discretion on a case-by-case basis. The EPA holds in reserve its omnibus authority to protect human health and the environment as a check against residual hazards not addressed by the technology-based standards. Although the EPA could solicit public input, it does not generally do so.

The EPA assesses the health risks of a project on a case-by-case basis without soliciting public input and determines whether the risks are sufficient to require the exercise of authority. EPA authority is exercised without definitive standards and the decision to exercise it is subject to the EPA's discretion. Without confining regulatory standards, the process effectively excludes judicial review of the exercise or non-exercise of the EPA's

authority. It also provides the opportunity for arbitrary or inconsistent action or non-action.[331]

The EPA's "target levels" of acceptable risk, the 1 in 100,000 standard for cancer risks, the 0.25 hazard quotient for noncancer risks, and the new target levels for dioxin exposures for breast-feeding infants (for lead and for acute inhalation exposures), establish what appear to be fairly definite health-based standards. But the standards address only a limited subset of a facility's total risks and the EPA decides on a case-by-case basis which additional risks to address and how to address them. The 1998 Protocol, for example, recommends that these other risks be evaluated qualitatively, without regard to any particular standards.

Further, the EPA reserves discretion on how to address risk estimates that fail the target levels. The target levels represent standards of acceptable risk but not *unacceptable* risk. Risk estimates that satisfy the target levels are considered acceptable. However, risk estimates that exceed the standards trigger further study.[332] The 1998 Risk Assessment Protocol first requires further analysis with additional site-specific data. If the risk estimates continue to exceed the levels, the Agency then may impose operating restrictions and, as a last resort, deny the permit (after the facility has been built).[333]

Finally, because the target levels are established by a guidance document instead of regulations, the target levels are neither binding on the Agency nor enforceable in a permit challenge. Estimates that exceed the target levels may be used by the EPA to add permit conditions or even to deny a permit, but the public may not rely upon the target levels to require the EPA or the facility to address a health risk.

This approach does not inspire public confidence, even if it is well-intentioned and successful in protecting human health and the environment. The public may believe the EPA is advancing its programmatic interests in

---

331. The EPA's use of guidelines instead of regulations (to produce limited risk assessment standards) further simplifies the adoption of the standards by avoiding judicial review, but it adds to the potential for public distrust.

332. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 7, at 9.

> Target values are not a discrete indicator of observed adverse effect. If a calculated risk falls within target values, a regulatory authority may, without further investigation, conclude that a proposed action does not present an unacceptable risk. A calculated risk that exceeds these targets, however, would not, in and of itself, indicate that the proposed action is not safe or that it presents an unacceptable risk. Rather, a risk calculation that exceeds a target value triggers further careful consideration of the underlying scientific basis for the calculation.

Id.

333. *See id.*, *supra* note 30, vol. 1, ch. 1, at 6-7 and ch. 7, at 9; 1998 RISK ASSESSMENT PROTOCOL ADDENDUM, *supra* note 43, at 3.

ensuring adequate capacity for the treatment and disposal of hazardous wastes, rather than acting as a disinterested administrator of environmental laws or as a guardian of public health.[334] In addition, after the EPA makes the initial permit decision to allow construction, the EPA may become defensive and bias subsequent studies to support the original decision. Public confidence is especially unlikely if the EPA excludes public input and reserves the exercise of the omnibus authority to its discretion.

2. Formal Quantitative Health Risk Standards

The second approach would require compliance with the technology-based standards and one or more point standards of acceptable health risk. Risk assessments would calculate point estimates of risk and compare them to the point permitting standards.

Quantitative risk estimates, however, lack the reliability to be used as the primary basis of a permit decision.[335] Their inherent uncertainties make it impossible to calculate an accurate point estimate of risk.[336] The uncertainties require the extensive use of assumptions (many of which have policy components) and the range of assumptions makes possible a wide range of

---

334. Even with the de-emphasis on permitting of new hazardous waste incinerators, stated in the EPA's Combustion Strategy, the EPA still considers incineration to be a valuable method to dispose of hazardous waste. *See* 1993 DRAFT COMBUSTION STRATEGY, *supra* note 34, at 159; 1994 FINAL COMBUSTION STRATEGY, *supra* note 34, at 222.

335. The 1983 NRC Report identified uncertainty as an unavoidable feature of risk assessments:

> The dominant analytic difficulty is pervasive uncertainty. Risk assessment draws extensively on science, and a strong scientific basis has developed for linking exposure to chemicals to chronic health effects. However, data may be incomplete, and there is often great uncertainty in estimates of the types, probability, and magnitude of health effects associated with a chemical agent, of the economic effects of a proposed regulatory action, and of the extent of current and possible future human exposures.... Fewer than 30 agents are definitely linked with cancer in humans; in contrast, some 1,500 substances are reportedly carcinogenic in animal tests, although they include substances tested in studies of questionable experimental design. We know even less about most chemicals; only about 7,000 of the over 5,000,000 known substances have ever been tested for carcinogenicity -- a small fraction of those theoretically under regulatory jurisdiction. We know still less about chronic health effects other than cancer.

1983 NRC REPORT, *supra* note 15, at 11-12.

336. The 1998 Risk Assessment Protocol acknowledges the inherent uncertainties of risk assessment results and requires a full discussion of the uncertainties when the results are reported. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 8, at 2. Nevertheless, the Protocol gets carried away with the sophistication of the risk assessment process at times and, at one point, suggests that the results can have enough accuracy to establish protective permit conditions that control emissions to precise standards of acceptable risk. "In some situations, it may be possible to select target risk levels and back-calculate the risk assessment to determine the appropriate emission and waste feed rate levels." *Id.* vol. 1, ch. 1, at 7.

results. The assumptions, and their underlying policies, can thereby determine whether the risk estimates are acceptable.[337] Accordingly, the comparison of a point estimate of risk to a "bright line" standard of acceptable risk is not meaningful.[338]

Reliance on point standards would also require full cognizance of the limited scope of the compounds and risks being assessed. The EPA's quantitative standards of acceptable risk (1 in 100,000 for cancer and a hazard index of less than 0.25 for noncancer effects) suggest that the standards address cancer and noncancer risks from all sources of risk (normal emissions,

---

337. *See* Ginsburg, *supra* note 9, at 11-12. Based on this degree of uncertainty, Ginsburg questions the validity of using risk assessments as the basis for permitting decisions:

> The dominance of risk assessment in EPA site-specific decision-making is clearly at odds with the academic and scientific literature on the use of risk assessment. Most of those discussions argue for the need to provide comparisons between environmental risks and to provide an objective component for establishing funding and regulatory priorities. They argue that risk assessment is not accurate enough to provide an absolute basis for site-specific decisions due to the subjective nature of the process and the large uncertainty in the calculation.... Acknowledgments of the limits of QRA are not hard to find.... A 1986 study of various estimates of TCE carcinogenic risk published by a group of EPA staff found the risk assessments legitimately could vary by seven to eight orders of magnitude when exposure estimates and transport modeling errors are included. They compared the choice provided by the risk estimates to trying to decide whether you had enough money to buy a cup of coffee or pay off the national debt. *While this may be acceptable to some for establishing priorities, it is clearly a dubious basis for issuing permits, setting clean-up levels, and setting standards.*

Id. at 9 (emphasis added).

Writing about risk assessments used to prioritize risks for regulatory action, Ellen Silbergeld stated that "[s]ince it is practically impossible to satisfy the methodological requirements or data demands required to conduct sound and reliable comparative risk assessments, proposals for the use of such assessments in establishing regulatory priorities will not promote good and efficient government." Silbergeld, *supra* note 253, at 406. She noted that, as of 1984, "between 73 and 89 percent of chemicals in commerce have almost no toxicity data upon which even a qualitative identification of hazard can be made." *Id.* at 413; *See also* Howard Latin, *Good Science, Bad Regulation & Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 105 (1988).

338. The Presidential/Congressional Commission on Risk Assessment and Risk Management described the difficulty in using a "bright line" standard of acceptable risk:

> Several major problems arise in using of bright lines tied to risk levels. The all-or-nothing nature of use of a bright line could be misunderstood and construed to imply that there is an exact boundary between safety and risk, even though risk-based bright lines are burdened by all the uncertainty, variability, and assumptions inherent in cancer risk estimation. Risk assessments themselves can be manipulated so that their results emerge above or below the bright line according to a risk manager's particular policy preferences. Bright lines have the potential to be applied inflexibly, leading to decisions that do not reflect the unique characteristics of particular populations.... [H]ealth considerations, cost, and cultural differences all play a role in risk management decisions.

PRESIDENTIAL/CONGRESSIONAL COMMISSION ON RISK ASSESSMENT AND RISK MANAGEMENT, *supra* note 29, at 55. (emphasis added).

upsets and accidents) and all compounds emitted.[339] Risk assessments under the EPA's guidelines, however, usually include only normal emissions in their quantitative risk estimates. Moreover, they address only a subset of the facility's emissions. The guidelines identify an initial list of chemicals for evaluation; but, they also give risk assessors the discretion to determine on a case-by-case basis which of the chemicals on the initial list and which of the thousands of additional chemical emissions will be assessed.[340] The risk management standards remain the same, however, whether the risk assessors choose chemicals with greater or lesser risks, or a broader or narrower scope of risk sources.

Quantitative risk estimates under the EPA's guidelines also exclude risks of compounds for which the EPA has not approved toxicity values.[341] The WTI risk assessment, for example, suggested that the risk estimates represented total facility risks and satisfied applicable standards.[342] However,

---

339. *See* 1998 RISK ASSESSMENT PROTOCOL ADDENDUM, *supra* note 40, at 2-3. These levels account for background levels of carcinogenic and non-carcinogenic compounds by tightening the risk levels which would otherwise be considered acceptable. *See id.* The acceptable level of carcinogenic risk was reduced by an order of magnitude from 1 in 10,000 and the hazard index was reduced from 1.0. *See id.* The revised hazard index standard assumed that background emissions will not exceed three-fourths of the threshold level for toxic effects and required that exposures resulting from the facility be no more than one-fourth of the threshold for toxic effects. *See id.*

340. 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 2, at 32-33.

341. The 1998 Risk Assessment Protocol recommends that the toxicity values of many compounds lacking EPA-approved toxicity values be extrapolated from similar-appearing compounds which have EPA-approved toxicity values. However, the surrogate risk estimates calculated in this manner are only considered qualitatively in the uncertainty section of the risk assessment. *See id.* at 37.

The 1994 guidelines suggest the following methods to estimate risks for the unidentified compounds: (1) by assuming that the risks of the unidentified organic compounds (not metals) are proportional to the risks of the identified compounds, or (2) by assuming that all unidentified organic compounds are carcinogens and that they have a carcinogenic potency that is similar to the compounds identified for the EPA's list of products of incomplete combustion. *See* 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 34, at 4-5. It is doubtful, however, that such approximations, which assign values to the residual risk essentially as a matter of policy, provide an estimate of risk that is useful in comparison to a "bright line" standard. *See id.*

342. The risk assessment stated that the facility was not expected to cause any cancer or noncancer effects. FINAL RISK ASSESSMENT, *supra* note 6, vol. I, ch. I, at 5. It developed risk estimates expressed in probabilities but did not identify the level of probability that it used as the standard for judging whether the exposures will cause cancer. *See id.* The risk assessment did identify the standards that it relied upon for its conclusions on noncancer effects, i.e., the hazard index of 1.0 for most chemicals, the NAAQS for nitrogen oxides, sulfur oxides, and particulate matter, and the Margin of Exposure approach for dioxins and furans. *See id.* vol. V, ch. VIII, at 8, 12-14, 31-32. The risk assessment did not compare the results to the hazard index standard of 0.25 to account for background exposures, and did not incorporate background exposures, as recommended in the 1994 guidance document, in the risk estimates. *See id.* The risk assessment did not attempt to create an aggregate estimate of risks or compare the risk results to an aggregate standard of risk. *See id.*

it omitted both the risks of unidentified emissions and the risks of most compounds lacking EPA-approved toxicity values.[343]

3. Technology-Based Standards, Minimum Siting Standards and Supplemental Quantitative and Qualitative Health-Based Standards

The third approach attempts to balance the value of risk assessments with their limitations. It increases the significance of health risks in permit decisions but reduces the significance of risk assessments. This approach could conceivably be used without significant public input, but the benefits increase with greater input (both in the development of the standards and in the performance of site-specific risk assessments).

The approach relies upon technology-based standards and a mix of qualitative and quantitative health-based standards, including broader minimum siting standards. Risk assessments serve a secondary role: to help establish the minimum siting criteria, to address variances from the criteria, and to assist in the continuing case-by-case exercise of the Agency's omnibus authority.

The minimum siting standards are defined in terms of setbacks from schools, residences and important natural resources.[344] Facilities proposed within a specified distance from these sensitive activities and resources (for example, within 2,000 feet of a school) would not be permitted under any circumstances. Facilities proposed beyond those distances would be evaluated on a case-by-case basis against a risk-based standard or a standard that includes quantitative and qualitative criteria.[345] Setbacks of greater distances

---

343. The risk assessment noted the methods that could be used to develop values for the uncharacterized emissions, but did not use them to estimate the facility's risks. *See id.* vol. V, ch. VIII, at 27-28.

344. This would involve the adoption of the kinds of requirements recommended in the EPA's document entitled *Sensitive Environments and the Siting of Hazardous Waste Management Facilities*. *See* U.S. EPA, OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE, SENSITIVE ENVIRONMENTS AND THE SITING OF HAZARDOUS WASTE MANAGEMENT FACILITIES (May 1997) [hereinafter 1997 SITING GUIDELINES].

Indeed, several recent studies have measured the increased health risks to children living in close proximity to certain types of industrial facilities. *See, e.g.*, E.G. Knox and E.A. Gilman, *Hazard Proximities of Childhood Cancers in Great Britain from 1953-80*, 51 J. EPIDEMIOLOGY AND COMMUNITY HEALTH 151 (1997); E.G. Knox, *Spatial Clustering of Childhood Cancers in Britain*, 50 J. EPIDEMIOLOGY AND COMMUNITY HEALTH 313 (1996).

345. The EPA's standards for selecting a cleanup plan under CERCLA also contain a multifaceted standard of acceptable risk. The standard includes nine quantitative and qualitative criteria: (1) overall protection of human health and the environment, (2) compliance with applicable or relevant and appropriate requirements (ARARs) under federal and state environmental and siting laws, (3) long-term effectiveness and permanence, (4) reduction of toxicity, mobility, or volume through treatment, (5) short-term effectiveness, (6) implementability, (7) cost, (8) state acceptance and (9) community acceptance. *See* 40 C.F.R. § 300.430(e)(9)(iii)(A)-(I) (1998). For purposes of decision making, the nine criteria are classified

might be established, beyond which the facility might only need to satisfy RCRA's technology-based standards. The quantitative risk standards can address specific chemicals and sources of risk, based upon scientific analysis and public input, to present the most significant hazards.[346]

The quantitative standards would neither purport to measure the totality of a facility's risks, nor treat the satisfaction of a quantitative standard as a definitive indication of acceptable risk. Further qualitative standards could be used, as a matter of science and policy, to acknowledge the uncertainties in the quantitative estimates and the existence of residual risks.[347]

Beyond areas definitively considered as unacceptable sites, the EPA, for example, could establish a 1 in 1000 or higher cancer risk for specifically designated compounds as a definitively unacceptable level of risk and a risk of 1 in 1,000,000 or lower as definitively acceptable. The acceptability of risks falling between these levels might depend upon additional qualitative factors; for example, the site's proximity to sensitive populations and land uses, such as schools, residential neighborhoods and flood plains. Additional factors could include the likelihood of extreme meteorological conditions, such as inversions, or the proximity of other facilities emitting hazardous substances. The qualitative standards might also recognize and grant priority to the public's preferences.[348]

---

into three groups of priority. *See id.* The highest priority are "threshold criteria[,]" which must be met to be eligible for selection. *Id.* These include "overall protection of human health and the environment and compliance with ARARs[.]" *Id.* The second priority are "primary balancing criteria." *Id.* § 300.430(f)(1)(i)(B). These include criteria (3) through (7). *See id.* The lowest priority, "modifying criteria[,]" include state and community acceptance. *Id.* § 300.430 (f)(1)(i)(C). "Community acceptance" includes "determining which components of the alternatives interested persons in the community support, have reservations about, or oppose." *Id.* § 300.430(e)(9)(iii)(I), (f)(4)(i).

Risk assessments are used in the first criterion, "overall protection of human health and the environment." *Id.* § 300.430(e)(9)(iii)(A). This criterion characterizes cancer risks in probabilistic terms and noncancer risks in thresholds of safety. *See* § 300.430(e)(2)(i)(A)(2). The probabilistic standards include a range of acceptable risk between one in ten thousand and one in one million. *See id.* If the site has special risk issues, such as multiple contaminants or multiple pathways of exposure, the one in one million standards must be satisfied. *See id.*

346. The criteria can also include quantitative and/or qualitative standards for accident and ecological risks.

347. Under this approach, the residual risks would be considered acceptable as a matter of indefinite science and policy if the chemical-specific risk standards were satisfied. Risk managers could, alternatively, establish a standard for acceptable residual risk, which could be assessed with a similarly prescribed method on a case-by-case basis.

348. *See* 40 C.F.R. § 300.430(c)(1), (2), (4) and the discussion on the standards under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). CERCLA (also known as the "Superfund" law) was adopted in 1980 to provide for the cleanup of sites contaminated with hazardous wastes posing the threat of releases to adjoining properties and water supplies. *See* Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. §§ 9601-9675 (1994).

Several states have already adopted minimum siting standards, and the distances vary widely. Texas and Ohio prohibit the location of facilities within 1000 and 2000 feet, respectively, of residences, schools and other sensitive structures. Oregon, Pennsylvania, and Oklahoma require one mile setbacks.[349] Oregon also requires a three mile setback from population centers of 10,000 or more people.[350]

In May 1997, the EPA published a booklet that appeared to restrict the location of facilities based upon the health risks of normal operations.[351] The booklet was published as the EPA was releasing the final version of the WTI risk assessment.[352]

The booklet recommended that facilities not be sited in areas with stagnant weather conditions or in areas with land uses "incompatible" with the operation of a hazardous waste facility.[353] The incompatible uses included schools, day care centers, nursing homes, hospitals, and prisons.[354] The booklet does not establish specific setback distances but notes that many states have done so.[355] The EPA described the twenty-one page booklet as a guidance document, which was not intended to be binding.[356] The booklet states that "[i]f a company does decide to locate a facility in a sensitive area, its owner should design the facility to minimize risks to people and the environment."[357] It also states that stagnant weather conditions might be

---

349. *See* OHIO REV. CODE ANN. § 3734.05 (D)(6) (1999); OKLA. ADMIN. CODE § 252:200-11-4(e) (date); OR. ADMIN. R. §§ 340-120-0010(2)(d)(A) (1998) and 340-120-0015(1)(a)(A) (1998); 25 PA. CODE § 269.48 (1999); 30 TEX. ADMIN. CODE § 116.112(2)(A) (1998). The Ohio, Oregon, and Pennsylvania restrictions permit exceptions if the applicant can demonstrate that it can adequately protect public health, safety and the environment.

350. *See* OR. ADMIN. R. § 340-120-0015(1)(a)(c). Exceptions are permitted if the applicants can adequately protect public health, safety and the environment. *See id.* § 340-120-0015(2).

351. *See* 1997 Siting Guidelines, *supra* note 339. The booklet recommended restrictions on siting in floodplains, in or near wetlands, over high-value groundwater, in earthquake zones, and in areas with karst soils, unstable terrain, unfavorable weather conditions, and incompatible land uses. The booklet recommended complete bans on location in wetlands and incorporated the current regulation's prohibition against siting within an earthquake zone. *See id.* at 8-9, 12-13. The booklet also recommends continuing the EPA's restrictions on siting in floodplains. *See id.* at 6-7. The recommendations on the other locations were conditional; they acknowledged that special measures might be adopted to address the risks.

352. An EPA staffer was reported as stating that the "sensitive environments" addressed in the booklet were defined in part in response to the problems at the WTI facility. *Waste Office Releases First-Ever Guidance on Hazwaste Facility Siting*, INSIDE EPA RCRA REP., at 3 (May 30, 1997) [hereinafter RCRA REPORT].

353. 1997 Siting Guidelines, *supra* note 344, at 18-20. The EPA stated that stagnant weather conditions increase the rate of exposures. *See id.*

354. *See id.* at 20. The booklet stated that children, the elderly and people who are sick may be more sensitive to toxic substance exposures. *See id.*

355. *See id.*

356. *See* Amy Porter, *EPA Outlines Schools, Sensitive Areas as Places to Avoid for Locating Facilities*, Daily Envt. Rep. (BNA), June 2, 1997, at A5-6; RCRA REPORT, *supra* note 352, at 3-4.

357. 1997 Siting Guidelines, *supra* note 344, at 4. The booklet also stated that the EPA is preparing

controlled with special engineering and placement of the facility or with restricted operations during unfavorable weather conditions.[358]

Such minimum siting standards are based upon science and policy, with risk assessments perhaps helping to determine the appropriate distances. Policy considerations, however, also play a major role. The significance of the uncertainty of quantitative risk assessments is reduced by using them in this secondary role.

The uncertainties associated with the continuing use of quantitative risk assessments can be addressed further with increased public participation. As discussed further in Part V.D, public participation is important in the development of minimum siting standards, other quantitative and qualitative risk standards, and in the performance of any site-specific risk assessment. Public input, at a minimum, increases the range of data available to the risk managers and assessors. An alternative risk assessment, based upon assumptions selected by the public, also serves as a reality check on the Agency's risk estimates—suggesting a plausible range of results and the likely range of uncertainty.

B. Additional Health-Based Permitting Standards

Whichever of the three approaches is chosen for the consideration of health risks (whether health risks are considered only by the EPA, whether quantitative health risk estimates represent a primary criterion for issuing a permit, or whether health risks are considered qualitatively and quantitatively in conjunction with siting standards), risk managers (Congress or the EPA) must address the following risk management issues.

1. Who Should Perform Risk Assessments?

With so many uncertainties in risk assessments and the potential to manipulate results, the identity of the party performing the risk assessment can have a substantial impact on the results. Although the EPA's 1993 Draft Combustion Strategy stated that risk assessments were to be performed by the EPA or authorized states,[359] the 1994 draft risk assessment guidelines appeared to allow owners/operators to perform them where the region or states

---

a second guidance document to address "social concerns" about facility locations. *Id.* at 1. These "nontechnical factors" include the number, ages and health of the people living and working around the facility and the difficulty of evacuating certain sensitive facilities, such as hospitals and schools, in the event of a hazardous waste spill. *Id.* at 3.

358. *Id.* at 18-19.

359. *See* 1993 DRAFT COMBUSTION STRATEGY, *supra* note 34, at 160.

"believe the facility may be in the best position" to do so.[360] The guidelines state that the region and states should nevertheless "be intimately involved in the planning and carrying out of the risk assessment and should be formally reviewing and approving the risk assessment protocols."[361]

This approach contrasts with the EPA's policy on the preparation of risk assessments for CERCLA cleanups. Indeed, the EPA in 1990 changed its CERCLA policy, over the objections of industry, to allow only the government to conduct the risk assessments required to develop a remedial plan. The change was the result of an EPA study comparing cleanups done by private parties and those done by the government. The study found that risk assessments done by some private parties "tend to underestimate the risk posed by a site, in many cases requiring a redraft [by the EPA] . . . . Since there is extensive judgment in risk assessment development and since risk assessments serve as the basis for taking action and potentially affect what cleanup levels are established, the EPA will assume development of all risk assessments in the future."[362]

The approach suggested in the EPA's 1994 Guidelines is similar, however, to the National Environmental Policy Act's (NEPA) regulations for an environmental impact statement (EIS).[363] NEPA regulations state that an EIS shall be prepared by the agency or by a contractor selected by the agency.[364] However, agencies can require applicants to prepare the underlying analyses and studies information "for possible use by the agency in preparing an [EIS]."[365] If an agency intends to use information from an applicant, it must outline the types of information required, independently evaluate it, and be responsible for its accuracy.[366] Indeed, the propriety of using information provided by a non-federal entity appears to depend not upon the amount of

---

360. 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 35, at 1. The draft guidelines also note that owners and operators may perform risk assessments where state law requires them to do so. *See id.*

361. *Id.* The 1998 Risk Assessment Protocol does not address the issue. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch.1, at 1.

362. *EPA Will Do All Risk Assessments, Says Private Cleanups are Protective*, [Current Developments] 21 Env't. Rep. (BNA) 414, 415 (June 29, 1990) (emphasis added).

363. The Council on Environmental Quality (CEQ) rules implement the environmental review requirements of NEPA and establish binding requirements for federal administrative agencies. *See* 40 C.F.R. § 1500.3 (1998).

364. *See* 40 C.F.R. § 1506.5(c) (1998). If the document is prepared by a contractor, the agency must furnish guidance, participate in its preparation, independently evaluate it prior to its approval and take responsibility for its scope and contents. *See id.* The regulations also require that the contractor execute a disclosure statement specifying that they have no financial or other interest in the outcome of the project. *See id.*

365. *Id.* § 1506.5(a).

366. *See id.* § 1506.5(b). The agency must also list the names of the persons responsible for the independent evaluation in the EIS document's list of preparers. *See id.*

information accepted but the extent to which the federal agency makes the information its own.[367]

Also significant, however, is the public's substantial opportunity for comment during the EIS process: during the establishment of the EIS's scope, after the preparation of a draft EIS, and after the issuance of the final document (before the agency makes its decision).[368] If the EPA decides to allow an owner/operator to perform its own risk assessment, it should follow more of the procedures applicable to NEPA reviews, including the same opportunities for public comment and, perhaps also, the performance of alternative quantitative assessments based upon assumptions recommended by the public.[369]

2. Timing of the Health-Based Review

A subtle but crucial issue involves whether health risks, and the results of risk assessments, should be considered in the initial decision to permit the facility, or only after the trial burn to establish final operating conditions. If performed prior to construction, risk assessments will have a role in preventing unsafe siting. If performed to help determine final operating conditions, the results will only be used to attempt to restrict operations to safe levels.

Risk assessments are less useful in determining safe emissions limits, given the uncertainties in their results. If the risk estimates are so uncertain that a reliable point estimate of risk cannot be determined, it will be similarly difficult to extrapolate backward from the risk estimates to establish final operating conditions (such as waste feed rates and operating temperatures) expected to produce emissions rates protective of human health and the environment.[370]

---

367. *See* Life of the Land v. Brinegar, 485 F.2d 460, 468 (9th Cir. 1973) (holding that a private consulting firm with an alleged financial interest in a project could assist in preparation of EIS, so long as the agency had "significant and active participation"), *cert. denied*, 416 U.S. 961 (1974); Seattle Audubon Soc'y v. Lyons, 871 F. Supp. 1291 (W.D. Wash. 1994) (discussing contribution of the interagency team of scientists, economists, sociologists and other experts, including non-federal employees, reviewed by peer review group, EIS team and scientific advisory groups deemed acceptable without independent agency evaluation), *aff'd*, 80 F.3d 1401 (9th Cir. 1996); Westside Property Owners v. Schlesinger, 415 F. Supp. 1298 (D. Ariz. 1976) (discussing whether a federal agency properly relied upon private parties to assist it in preparing an EIS), *aff'd*, 597 F.2d 1214 (9th Cir. 1979).

368. *See* 40 C.F.R. §§ 1501.7, 1503.1, 1506.10 (1998).

369. *See infra* Part V.D.3.c.

370. The thousands of chemical emissions from a hazardous waste incinerator and the general lack of methods to monitor their emissions rates generally prevents the use of emissions limits as enforceable operating conditions. They instead involve restrictions on waste feeds and operating conditions, such as minimum combustion temperatures. The determination of these kinds of operating conditions requires an additional level of imprecise extrapolations, which further limits the usefulness of this latter use of risk

The WTI risk assessment was performed after the plant was built and during initial stages of operations. The 1993 WTI Peer Review Group stated that "future risk assessments should be conducted prior to siting and construction of other facilities in order to avoid the serious siting and design flaws that characterize the WTI East Liverpool, Ohio, incinerator."[371] Prior to the 1998 guidelines, the EPA's policy on the timing of risk assessments was unclear. The EPA's 1993 Draft Combustion Strategy states that risk assessments should be performed "in" and "during" the permitting process.[372] The Final Strategy states that risk assessments shall be performed "prior to final permit determinations."[373] The 1994 Draft Risk Assessment Guidelines characterize the Draft Strategy's statements as requiring that the risk assessments be done "prior to permitting."[374]

The 1998 Risk Assessment Protocol provides for a series of risk assessments that start after a facility is built and uses emissions information collected from the trial burn. The Protocol also states that unacceptable risk estimates will generally be re-done with more accurate, site-specific information until acceptable results are achieved; although, conceivably, the estimates may also be used to restrict operating conditions or to deny a final permit.[375] The Protocol also provides for periodic reviews after the plant starts operations to update the risk assessment process with the latest facility-specific operating and emissions data and to determine whether the best data and procedures have been used.[376]

3. Scope of Risks

Risk managers should define the scope of the health risks to be considered in a permitting decision. Further, since not all risks will be reviewable in a risk assessment, risk managers should define which risks will be evaluated in risk assessments and which will be evaluated in other quantitative and qualitative ways.

Risk managers have to decide whether to include or exclude the following risks:

- human and/or ecological risks;

---

assessments.

371. 1993 PEER REVIEW REPORT, *supra* note 1, at 3-13.

372. 1993 DRAFT COMBUSTION STRATEGY, *supra* note 34, at 159-60.

373. 1994 FINAL COMBUSTION STRATEGY, *supra* note 34, at 222.

374. 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 35, at 1.

375. *See* 1998 RISK ASSESSMENT PROTOCOL, *supra* note 30, vol. 1, ch. 1, at 6-7.

376. *See id.* vol. 1, ch. 9, at 2.

- risks of normal stack emissions, risks from fugitive emissions, risks from emissions during upset conditions, and/or risks of emissions from accidents;
- the scope of chemical emissions to be assessed;
- the scope of adverse health effects to be assessed, i.e., risks of cancer and noncancer effects and/or risks of specific noncancer effects, such as the endocrine disruption problems; and
- the pathways of exposure to be considered, i.e., inhalation, dermal exposure and/or food chain exposure.

Risks from specific chemicals or pathways of exposure should not be omitted due merely to the lack of EPA-approved toxicity values or risk assessment methods. Alternative risk analyses may be appropriate. Noncancer effects of dioxins, for example, which were not addressed quantitatively in the WTI risk assessment due to the lack of EPA-approved toxicity values, might be addressed with toxicity values approved by other agencies or with some other method. New methods comprising a mix of quantitative and qualitative analyses could also be determined, as the WTI risk assessors did to assess the risks of accidents.[377] Alternative analyses, however, should not be used merely to avoid undesired results.

If alternative analyses are used, standards should be established for their results, and these standards should be factored into an overall permitting standard. The results of alternative analyses are usually expressed in units of measurement that cannot be directly compared or aggregated with the results from the primary risk assessment method. The Presidential/Congressional Commission on Risk Assessment and Risk Management calls this the lack of a "common metric" of risk.[378] Accordingly, if risk managers want to address risks for which there exists no common metric of expression, they must develop a standard of acceptable risk which considers and assigns weights to the various risk results.[379]

C. Standards for Risk Assessment Methods

If risk assessments will have a role in permit decisions, standards should be defined for the major issues in performing risk assessments. Standards should address the three preliminary steps: selection of substances of concern, estimation of emissions rates, and prediction of atmospheric transport. They

---

377. *See* FINAL RISK ASSESSMENT, *supra* note 6, vol. VII.

378. *See* PRESIDENTIAL/CONGRESSIONAL COMMISSION ON RISK ASSESSMENT AND RISK MANAGEMENT, *supra* note 309, at 43.

379. The results of the alternative analyses in the WTI risk assessment were not expressed in units which could be compared or aggregated with other risks and standards. *See supra* Part IV.C.3.a.i.

should also address the four traditional steps: elements of hazard identification, dose-response assessment, exposure assessment, and risk characterization. Indeed, such crucial issues, which are usually characterized as risk assessment issues involving "science policy" (versus risk management issues), might be more appropriately addressed by risk managers.

Since risk assessments answer issues posed by risk management standards, many of the policy issues in risk assessment will be similar to the issues facing risk managers. Similarly, since risk managers should be primarily responsible for policy decisions, their standards should influence the policy choices of the risk assessors.[380] Risk management standards on scope and acceptable risk, for example, should influence the risk assessors' decisions on the selection of substances of concern, hazard identification, dose-response assessment, and risk characterization.

The 1990 Indirect Risk Guidelines, the 1993 Addendum, the 1994 Draft Guidelines, and the 1998 Risk Assessment Protocol describe a process for conducting risk assessments which suggests answers on many of the more technical risk assessment issues.[381] None is intended to be binding, however, and all leave open significant and controversial issues. The 1994 and 1998 guidelines, for example, recommend standards of acceptable risk, but leave the agency with broad discretion on the crucial issue of the compounds to be assessed.

Perhaps the most crucial issue in risk assessment is dose-response assessment. It is the step most influenced by policy considerations and, therefore, the step most tied to the risk management standards. The guidelines should address controversial dose-response assessment issues, such as the proper sources of toxicity values and how to address compounds lacking EPA-approved toxicity values. The WTI risk assessors relied generally upon EPA-approved toxicity values and, for several other selected chemicals, on arbitrarily selected values.[382] Otherwise, if the EPA database lacked a toxicity

---

380. The design of a risk assessment (and the resolution of issues relating to risk assessment methods) would ideally start with the hazards selected for study by the risk managers and the units of risk used by the risk managers to express standards. With those issues determined, the risk assessors would work backward to ensure that the substances studied and the toxicity values used are consistent with the risk managers' goals.

381. The 1990 Indirect Risk Guidelines state that the process they describe "is not intended to be prescriptive; that is, it does not comprise a set of guidelines or recommended approaches that the U.S. EPA believes should be applied in all circumstances. Rather, it provides a set of procedures that the risk assessor can draw upon, where applicable, to a given assessment." 1990 INDIRECT RISK GUIDELINES, *supra* note 38, ch. 1, at 1.

382. Although not governed by specific guidance, the EPA chooses toxicity values from among several EPA-maintained databases, including IRIS and HEAST. *See, e.g.*, FINAL RISK ASSESSMENT, *supra* note 6, vol. V, ch. III, at 3. The 1994 draft guidance document does not recommend any source of toxicity values. *See* 1994 DRAFT RISK ASSESSMENT GUIDELINES, *supra* note 35. EPA personnel determine the

value for a chemical, the chemical's hazards were omitted.[383] The risk assessors' decisions on dose-response assessment, therefore, influenced the magnitude of the risk estimates and the scope of the risks considered. The use of EPA-approved toxicity values, expressed in probabilistic terms for cancer and in threshold values for noncancer effects, thereby also determined how risks would be characterized (i.e., in probabilistic terms, hazard indices, etc.).

These and the remainder of the policy-based risk assessment standards should be coordinated and perhaps addressed jointly with the risk management standards. Major policy-influenced issues on dose-response assessment include the following:

- whether there should be a single pre-determined list of toxicity values and what the process should be for determining the values;
- whether the toxicity values should be selected on a site-specific basis, considering data presented by the public;
- the data sources upon which the risk assessors may rely for toxicity values and the process for determining those values; and
- whether risks from chemicals lacking approved toxicity values should be omitted or assessed with alternative analyses and toxicity values.

The following is a sampling of the major risk assessment issues with substantial policy implications and potentially significant impacts on risk assessment results.

Selection of substances of concern:

- whether to rely on the EPA-approved toxicity values as the basis for selecting substances or whether to consider recommendations from private parties generally (if a list of substances is approved in advance by regulation or guidance) or in site-specific cases;

---

toxicity values to be included in IRIS and HEAST through the review of EPA research and studies submitted by private parties for their consideration. *See* 58 Fed. Reg. 11,490-93 (1993). There is no established schedule for reviewing existing toxicity values or for considering submissions. *See id.* There is also no provision for public comment, although the EPA has the discretion to appoint scientific peer review panels. *See supra* note 249 and accompanying text.

The EPA's guidelines for risk assessments in the Superfund program recommend the use of EPA-approved toxicity values to prevent duplication of effort and to ensure consistency among risk assessment results. *See* U.S. EPA, OFFICE OF EMERGENCY AND REMEDIAL RESPONSE, PUB. NO. 540189002, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOL. 1, HUMAN HEALTH EVALUATION MANUAL (PART A), INTERIM FINAL 7-16 (December 1989). If EPA-approved toxicity values are not available, the guidance recommends a qualitative analysis and a discussion of the implications of the absence of the quantitative analysis, or the case-specific derivation of toxicity values using agency methodology if "adequate toxicity studies are available." *Id.*

383. *See* 1994 NRC REPORT, *supra* note 97, at 250-51.

- how to determine the limited number of substances for the food chain analysis and whether the number of substances examined should be increased;[384] and
- how to address the uncharacterized portion of incinerator emissions.

Estimation of emissions rates:

- what data to use as the basis for estimating emissions rates of facilities prior to construction (e.g., emissions from similar facilities, from literature, and whether to add margins of conservatism); and
- what data to use as the basis for estimating emissions rates of facilities after construction (e.g., permit levels, trial burn data, data from other operating periods, and whether to add margins of conservatism).

Atmospheric transport:

- kinds of meteorological data required (e.g., length of recorded data, proximity of measurements); and
- accuracy of air models and conformity with site-specific terrain.

Hazard identification:

- the independence of hazard identification from dose-response assessment (as discussed above).

Exposure assessment:

- how to define the area to be studied;
- how to define the characteristics of the populations to be studied;
- how to define the exposure pathways to be studied;
- how to estimate the rates in which chemicals are absorbed into environmental media; and
- how to estimate the rates at which chemicals in environmental media are subsequently absorbed by humans.

Risk characterization:

- whether to characterize risks in probabilistic, threshold or other units of measurement;
- whether to characterize risks in per-chemical and/or aggregate terms;
- whether and how to recognize background levels of chemicals in the environment and existing body burdens; and
- whether to characterize risks as additive, synergetic or antagonistic.

---

384. The WTI risk assessment analyzed the inhalation risks for approximately 200 chemicals and the food chain risks for 15 of 174 organic residues, 17 dioxin/furan congeners, and 13 metals. *See supra* Part IV.B.1.

D. How Should the Standards be Established? Should Public Input be Allowed?

1. Should Public Input be Allowed on "Science Policy"?

The 1983 NRC report and the 1993 article by the Director of the EPA's Risk Assessment Forum distinguished risk management issues from "risk assessment policy" (or "science policy").[385] They also suggested that public input is appropriate for the policy issues in risk management but not for the policy dimensions of risk assessment. Public comment, they reasoned, would interject policy considerations into the risk assessment process and undermine the scientific credibility of the results.[386]

The NRC and the executive director of the Risk Assessment Forum defined risk management and risk assessment narrowly and distinctly. They characterized risk management as the decision to approve or deny a project based upon the quantitative results of risk assessments and qualitative and political factors, such as cost and technical feasibility. They characterized risk assessment policy as decisions on scientific issues without recognition of their qualitative or political significance.[387]

The descriptions, however, gloss over the analytical interconnections. The underlying purpose of a risk assessment is to help answer the questions posed by risk managers. As such, risk assessors should design risk assessments to analyze the issues identified by the risk managers and to provide the data they need to make their decisions. Conversely, the risk assessors' independent and potentially contrary determinations of policy issues will inhibit the risk managers' functions.

---

385. *See supra* Part II.

386. The NRC acknowledged a "practical" interconnection but downplayed its significance:

> Risk assessment and risk management functions are analytically distinct, but in practice they do—and must—interact. Organizational arrangements that completely isolate risk assessors from regulatory policy-makers may inhibit important communication in both directions. For example, to complete risk characterization, risk assessors must know what policy options are to be used to calculate alternative projected exposures, and new options may develop as the risk management process proceeds. Moreover, direct communication with the risk assessors is desirable to ensure that the regulatory decision-maker understands the relative quality of the available scientific evidence, the degree of uncertainty implicit in the final risk assessment, and the sensitivity of the results to the assumptions that have been necessary to produce the assessment.

1983 NRC REPORT, *supra* note 15, at 152.

387. The 1983 NRC Report nevertheless stated that risk assessments properly make such potentially policy-laden statements as "summary judgments on the existence and overall magnitude of the public-health problem." *Id.* at 18.

The parties interested in a risk assessment will often have opposing scientific support on "science policy" issues, which will reflect their positions on the ultimate risk management decision. If the scientific evidence is close in reliability, risk managers should not be limited to risk assessment results based upon policy decisions that reflect only one policy choice, especially if the policies underlying their risk management standards are different. The hazardous waste industry, for example, relies upon different scientific data on dioxin emissions rates and toxicity than do most citizen groups.

The interconnection between risk management and science policy issues is even more pronounced on issues such as the proper scope of a risk assessment. Risk managers' permitting standards include a scope of the risks which they consider significant to a permitting decision. Ideally, the risk assessors should study the same scope of risks. If the risk managers determine that risks are potentially significant and should be addressed despite, for example, controversy as to the exact magnitude of toxicity values, the risk assessors should conduct a review of the risk. The review should include policy choices consistent with those of the risk managers, also including perhaps the risk managers' choices on science policy.[388]

Finally, why should the scientific issues in risk assessments, including the science policy issues, *not* be subject to public comment? Scientific issues underlying regulations and permit decisions are generally subject to public comment for reasons such as improved decision making.

2. Regulations, Guidelines, and Case-by-Case Decisions

Standards for risk management and risk assessment should be established through regulations to the extent practicable. The standards involve important policy and science issues, and, through rulemaking, the public will have maximum opportunity for input through comment and judicial review. The national scope of the process also allows the regulatory agency and the public to concentrate their resources in a single proceeding, encouraging the full development of the issues.

The rulemaking process is most appropriate for risk management standards and the major policy and scientific issues relating to risk assessment methods. The role of health risks in the permitting standard and the scope and level of acceptable risk are risk management standards that should be addressed in regulations. Major risk assessment standards, for example, could

388. The policy links between risk management and risk assessment have increased with the study of multiple chemicals (including unidentified chemicals), multiple exposed populations, and multiple pathways and causes of exposure.

address the selection of toxicity values and alternative risk assessment methods for chemicals lacking approved toxicity values.[389]

The complexity of other issues, however, and the rate of change in scientific knowledge will likely require more flexibility than is possible with rulemaking. Tentative standards on these additional issues could be developed through guidance documents, which should still be subject to public comment.[390] Judicial review might be postponed until the guidelines are applied in a site-specific risk assessment and permit decision.[391]

3. Site-Specific and Case-by-Case Issues

Even with regulations and guidance documents, many science and policy issues will remain unresolved on a site-specific and case-by-case basis. Site-specific decisions should be made with respect to the characterizations of the proposed plant, the affected population, and local environmental conditions. The regulations and guidelines also have to be applied in site-specific situations. Also, for some issues, the scientific answers may change from case to case as parties develop new scientific knowledge. Case-by-case resolution of such issues may be appropriate.

The following sub-sections recommend methods to address issues on a site-specific and case-by-case basis, including ways to enhance public participation in the decision making process. The recommendations draw on methods used in CERCLA and NEPA.[392]

a. Opportunities for Public Comment

Site-specific risk assessments should consider public comment. Opportunities should be provided at the two most significant points in a risk assessment—during the scoping and design of the risk assessment and after the release of the draft report and results. Public comment is currently provided only if the risk assessment is used as the basis for a permit decision,

---

389. *See* Ellison Folk, *Public Participation in the Superfund Cleanup Process*, 18 ECOLOGY L.Q. 173, 182-86 (1991) (discussing alternative scientific theories for inference options and alternative toxicology data).

390. Guidance documents should not be used, however, to escape judicial review of standards which, in fact, operate as regulations. The line between a guidance document and a regulation depends upon the present effect of the document and the extent to which it restricts the discretion of the agency. *See* American Bus. Ass'n v. United States, 627 F.2d 525 (D.C. Cir. 1980).

391. *See infra* Part V.D.4.

392. NEPA was adopted in 1969 to require federal agencies to assess the environmental impacts of major federal actions and reasonable alternatives before approving and undertaking the actions. National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321-4370(d) (1994).

and that opportunity is provided only after the agency has completed the final risk assessment and has issued a draft decision.

The opportunities recommended here are similar to those provided by NEPA for an EIS. The EIS process provides for public comment on the scope of an EIS and on the draft and final EIS documents.[393]

The drawbacks in the current opportunities under RCRA are similar to those under CERCLA. Public comment on a proposed cleanup plan is provided only *after* the agency's evaluation of the potential cleanup plans and its selection of a recommended plan.[394] At such a late date, public comment is unlikely to have a significant impact on the agency's actions.

b. Publicly-funded technical assistance

National environmental groups are likely to focus their attention and resources on issues of national scope, such as establishment of regulations and guidelines, leaving local citizen groups to address the site-specific issues that arise in the permitting of specific facilities. Citizen groups, however, often lack the necessary financial and technical resources to effectively participate in the process.

To address that deficiency, Congress should authorize a program of technical assistance grants (TAGs) based upon the concept established for cleanup programs under CERCLA.[395] The EPA provides TAGs to help citizens gain the technical knowledge required to understand and prepare

---

393. *See* 40 C.F.R. §§ 1501.7, 1503.1, 1506.10 (1998). Although the regulations do not specifically establish a public comment period for the final EIS document, comments may be submitted during the minimum period of 30 days required between the issuance of the final document and the time at which the agency may issue its final decision. *See id.* § 1506.10.

394. The public also, at that point, has only thirty to sixty days to prepare comments, while the EPA's evaluation has taken an average of six years. *See* Folk, *supra* note 389, at 210.

> However, the timing of [the public comment period and] the responsiveness summary limits its effectiveness.... [I]t is completed late in the decisionmaking process—after the preferred alternative has been identified. *When EPA is not required to respond to public comments until after its decision is essentially made, the value of responses in shaping EPA's decision and making the Agency justify its choice is diminished....*This time lag is exacerbated by the fact that the public has only a short time to review and comment on the cleanup plan. *While it takes an average of over six years from the time a site is placed on the Superfund inventory to the time a proposed cleanup plan is issued, the mandatory public comment period is only thirty days, with an opportunity for a thirty-day extension.* The documents supporting a cleanup decision are technically complex and extensive, and given the amount of time it takes to develop a cleanup plan, sixty days is a needlessly short time in which to review and comment on the proposed cleanup alternative.

Id. at 209-10 (emphasis added).

395. *See* 42 U.S.C. § 9617(e) (1994).

comments on the agency's recommended cleanup plan.[396] TAG grants are awarded in amounts up to $50,000 per recipient, although the $50,000 limit may be increased to a maximum of $100,000 for "especially complex" sites.[397]

Funds may be used "for the interpretation of data . . . not the generation of new data."[398] They may not be spent for epidemiological or health studies,[399] or for litigation and expert witnesses.[400] Information properly developed with the grants may nevertheless be used in litigation.[401]

The permitted size and scope of RCRA TAGs should be broader if they are expected to produce useful risk assessment comments. This is especially necessary if the public is given the opportunity to develop alternative risk assessment assumptions and alternative "public" risk assessment scenarios.

c. Publicly-developed alternatives

In view of the impact of policy decisions on risk assessment results, it might be useful to perform a series of risk assessments using alternative assumptions on key science and policy issues. The alternatives can be defined in risk management or risk assessment standards and/or in the scoping of the site-specific study.[402] The EPA can include a "public" alternative in its risk assessment based upon public comments submitted with TAG funds, or the EPA can provide funds to citizen groups to perform their own "public" risk assessments.

The concept of a "public" version of a risk assessment is similar to the approach recommended in the 1994 NRC Report to describe the results of risk assessments and their uncertainties.[403] The NRC suggested that, instead of

---

396. The grants are used "to obtain technical assistance in interpreting information with regard to the nature of the hazard, remedial investigation and feasibility study, record of decision, remedial design, selection and construction of remedial action, operation and maintenance, or removal action at such facility." *Id.* § 9617(e)(1). Regulations implementing this provision add that TAGs "shall be used to fund activities that will contribute to the public's ability to participate in the decision-making process by improving the public's understanding of overall conditions and activities." 40 C.F.R. § 35.4060 (1998).

397. 40 C.F.R. §§ 35.4085(b)-(c), 35.4090(a)(2). No more than one grant may be awarded per site. *See id.*

398. 57 Fed. Reg. 45,311, 45,314 (1992) (codified at 40 C.F.R. pt. 35).

399. *See* 40 C.F.R. § 35.4055(h). The complete list of ineligible activities is set forth in 40 C.F.R. § 35.405.

400. *See id.* § 35.4055(a). The EPA stated that it "believes that it would be inappropriate to allow costs incurred by a community group in preparing for or participating in any adjudicatory proceeding to be paid from a technical assistance grant." 52 Fed. Reg. 22,244, 22,247 (1987) (codified at 40 C.F.R. ch. I).

401. *See id.*

402. *Cf.* 40 C.F.R. § 300.430(e) (1998) (specifying alternative assumptions in CERCLA regulations).

403. *See* 1994 NRC REPORT, *supra* note 97, at 83-84.

reducing risk characterizations to a single number or even a range of numbers, the risk assessors should do risk characterizations that "are both qualitative and quantitative and both verbal and mathematical."[404] The NRC suggested that risk assessments be accompanied by a statement describing alternative assumptions presented to the agency that, although not selected by the risk assessors, satisfy some lesser test, perhaps, according to the NRC, the test of "plausibility."[405]

The NRC noted as an example the EPA's assumption that no threshold level of exposure exists for cancer, but that if allowed to comment, the public might attempt to show that there is a threshold for a particular substance based on what is known about its mechanism of action.[406] If the agency disagrees with the commentator's proposal but nevertheless finds it to be plausible, the risk assessors could note the plausibility of the assumption, its rationale, and its effect on the risk estimate.[407]

The NRC's recommendation is an extension of the approach used in the WTI risk assessment. The WTI risk assessors identified the assumptions they used and characterized qualitatively their view of the assumptions' conservatism, as either an under-or over-estimate of risk, without the benefit of public comment. The NRC would take the WTI approach a step further to consider public comments, to identify plausible alternative assumptions they may have rejected, and to describe in some way (qualitatively or quantitatively) the effect on the risk estimates if the alternative assumptions were chosen.

The approach recommended here either clarifies or expands upon the NRC's approach. It recommends public comments assisted with public funds and quantitative and qualitative forms of alternative risk assessment results.

These approaches are also consistent with the alternative analyses undertaken for CERCLA cleanups and environmental reviews under NEPA.[408] In the CERCLA process, the EPA develops alternative cleanup plans and assesses the risks of each.[409] In the EIS process under NEPA, the government

---

404. *Id.*

405. *Id.*

406. *See id.*

407. *See id.*

408. The option proposed here focuses on the impacts of using alternative analyses. It would use a range of alternative assumptions and analytical methods to address a single action. The approaches under NEPA and CERCLA focus on the impact of alternative projects, and generally use the same analytical approaches on alternative projects.

409. The CERCLA process involves, first, a remedial investigation which includes a "baseline" risk assessment to characterize the existing and potential risks from the contamination. *See* 40 C.F.R. § 300.430(d)(4). Second, the EPA performs a feasibility study to develop and assess the risks of alternative cleanup plans. *See id.* § 300.430(e).

develops alternatives to the government action under consideration and assesses the environmental impacts of each.[410]

The alternatives analysis for an EIS under NEPA is conducted with extensive public input. The alternatives are developed in a scoping process, where the public has the opportunity to present recommendations.[411] The public also has the opportunity to submit comments on the draft document in which the agency tentatively selects the alternatives and evaluates their environmental impacts.[412] Moreover, the agency is required to consider and prepare responses to the comments.[413] The CERCLA reviews, however, are performed without public comment.[414]

The proposed RCRA analyses would produce a range of risk estimates, which would have to be factored into the permitting standard. The more important estimate, if the risk managers have prescribed a single point standard of acceptable risk, would be the "public" alternative, since it would likely be more conservative. Alternatively, the risk managers could prescribe separate standards for the public and agency assessments, both of which have to be satisfied.

Regardless of the role the risk managers assign to the "public" alternative, it could still serve as a disclosure mechanism. Its results could be used as a political check to illustrate the potentially arbitrary basis of the agency's actions.

4. Peer Review Panels

A further alternative, which could be a component of the traditional and alternative methods described above, might include a peer review panel to review decisions of the risk assessors. The composition and authority of the group would be key issues. The panel could be comprised of scientists or a combination of scientists and community representatives. The presence of policy issues would militate for community representation. The entire group could be selected by the EPA; or the EPA, the permittee, and the public might select certain members. The group's recommendations could be solely advisory, as in the WTI risk assessment, or binding.

---

410. The substantive standard is provided separately by the statute which provides the authority for the action. NEPA merely requires that the environmental impacts of the action be reviewed before the agency acts.

411. *See* 40 C.F.R. § 1501.7.

412. *See id.* § 1503.1.

413. *See id.* § 1503.4.

414. Public comment is provided only for the cleanup plan which, after completing the above analyses, the EPA proposes to select. *See id.* § 300.430(f).

5. Judicial Review

Finally, to ensure accountability, the site-specific decisions should be subject to judicial review. It is tempting to recommend an opportunity for judicial review of the scope of the risk assessment at the time the scope is determined. Review at that stage would maximize the legitimacy of the process, but it might also cause unnecessary delay. The adoption of substantive standards and the prospect of requiring adherence to them through public comment and later judicial review could balance the interests of the public and the permittee, and be sufficient to check arbitrary action by the permitting authority.

This would be similar to the opportunities to challenge decisions based on NEPA reviews and be a substantial improvement over the time allowed under CERCLA. Courts have generally barred challenges to the selection of a cleanup plan until after the cleanup has been completed.[415] Unfortunately, the selection of the cleanup plan is the point at which judicial review would be most meaningful. This significantly reduces the value of the program's standards and the ability of the public to require adherence to them.

CONCLUSION

After reviewing the WTI risk assessment, one might reasonably ask the following question—if the EPA can site a hazardous waste incinerator 300 feet from an elementary school in a river valley subject to inversions and stagnation, does a site exist anywhere where the health risks would be considered unacceptable? How is such an obviously non-intuitive result possible? Are the risks of hazardous waste incinerators from normal and upset emissions and from accidents so minimal?

Do the WTI results prove that the facility is safe, or do they show that risk assessments do not fully address the risks of hazardous waste incinerators? Do they illustrate the opportunity for results based upon risk assessors' policy assumptions or preferences on crucial and controversial health risk issues?

---

415. *See* 42 U.S.C. § 9613 (1994). The reason for the postponement is to promote the public's interest in the rapid cleanup of a contaminated site, free of the delays attendant to an appeal by a party potentially liable for the costs of the work. *See, e.g.*, Barmet Aluminum Corp. v. Reilly, 927 F.2d 289, 293 (6th Cir. 1991); Schalk v. Reilly, 900 F.2d 1091, 1097 (7th Cir. 1990); Wheaton Indus. v. EPA, 781 F.2d 354 (3rd Cir. 1986). "Enforcement" has been interpreted to mean actions under sections 106 and 107 of CERCLA (i.e., EPA actions to abate imminent and substantial endangerment to human health and the environment and actions to seek recovery of costs for cleanup of a hazardous waste site). 42 U.S.C. §§ 9606, 9607 (1986). *See* Barmet Aluminum Corp., 927 F.2d at 291.

One might not interpret the results as proving that the WTI facility is safe. One might conclude that the current processes of risk assessment and risk management do not work and that the results are not sufficiently reliable or comprehensive to be used as the primary basis for a permit decision.

Agencies have to determine which sources of risk to consider (i.e., normal emissions, upset conditions, and accidents), which pathways of exposure to consider (i.e., inhalation and food chain) and which populations to consider (i.e., sensitive human populations, wildlife and plants). After the scope is determined, agencies have to decide which of the compounds in a facility's emissions to consider, although the compounds and their toxicity values have not been fully determined. The mathematical modeling of the chemicals' movement through the environment is also uncertain. The choices on the scope of risks addressed and how to address the uncertainties—to omit the risks when the answers are uncertain, or to fill in the blanks with alternative values—can substantially impact the results. Even more troubling, the choices often include a combination of science and policy.

But are risk assessments better than nothing? Should we not factor our knowledge of the toxicities of certain compounds into a permitting decision because we do not know more about the complete range of their effects or because we lack toxicity data about the toxicities of other potentially more toxic compounds? Should we not take advantage of the increasingly sophisticated air dispersion and bioaccumulation models? Do risk assessments not provide information which should be considered in a permit decision? The answer is that risk assessments can have value, but they should not be relied upon to provide an accurate or comprehensive measure of a facility's risks. Also, they should not be relied upon as a primary basis for a permit decision.

A risk assessment's use in permitting requires a clearer definition of the role that health risks should play in a decision and a clearer definition of the role that risk assessments should play in the evaluation of these health risks. These decisions require the adoption of risk management standards informed with public input.

Further, risk management and risk assessment are integrally related. Risk assessments should be designed to answer the questions posed by risk managers. That means that risk assessors should be attentive to the policy choices inherent in the risk management standards and perform risk assessments that are consistent. Indeed, it is the risk managers who should be making the policy decisions—with public input.

The risk managers' standards should also acknowledge the limitations of risk assessments. Health risks should be addressed primarily with technology-based standards and siting criteria. Risk assessments might be used in the

development of siting criteria and in the granting of variances to the criteria, but the risk estimates should not be the sole basis for decisions.

Finally, if the EPA wants the public to accepts the results, it must allow public participation in both the development of permitting standards and risk assessment guidelines, and in the performance of site-specific risk assessments. Since policy decisions play such a large role in the standards and the risk assessment process, the public should have a full opportunity to comment. Since the issues are also complicated and technical, the public's participation should be assisted with public funds.

Further, the uncertainty of risk assessment results can be placed in a better perspective if the risk assessors calculate alternative risk estimates, based upon scientific and policy assumptions recommended by the public. Risk managers, as the ultimate decision-makers, will have a clearer picture of the reliability of the results. They will also have the opportunities to choose the policies they intend to promote and to explain those policies to the public.