

RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: TRYING TO UNDERSTAND THE PROCESS*

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* With apologies to the Committee on the Institutional Means for Assessment of Risks to Public Health, National Research Council, National Academy of Sciences, whose excellent book *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS* (National Academy Press, 1983) is frequently cited in this article.

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I. INTRODUCTION

In the context of potentially toxic substances, risk is the likelihood that an adverse outcome will occur either in a person, a group of people, or a natural resource, if exposure to a particular dose of a hazardous substance occurs.¹ Risk can be expressed in quantitative terms by taking values from zero, certainty that harm will not occur, to one, certainty that harm will occur. All human activities carry some degree of risk; however, the risks associated with various chemical substances often cannot be readily assessed and quantified and are, therefore, the focus of risk assessment methodology.

Risk assessment is the process of identifying hazards and either quantifying or describing the degree of risk they pose for exposed individuals, populations, or resources. It may also be described as the assembly, evaluation, and interpretation of all pertinent scientific information about the toxicity, human experience, environmental fate, and exposure to a particular chemical or physical agent.² The procedure is especially useful in organizing and expressing information about risks that are not subject to direct observation and measurement, but which still may pose a threat to human health or the environment.

Congress has addressed the regulation of potentially harmful substances in a multitude of statutes, which delegate the regulatory responsibilities to a number of federal agencies. Yet, none of these statutes specifically provides for "risk assessment." Nevertheless, the risk assessment process has become the basis for determining how potentially hazardous substances should be regulated.

Authority for risk assessment comes, implicitly, from the provisions of various statutes that mandate the regulation of sub-

1. The terms, "toxicity" and "hazard," are also commonly used in the field of risk assessment. Toxicity is an inherent property of any substance and simply refers to the ability of a substance to cause an adverse effect if given in a large enough dose. The term "hazard" means the capacity of a substance to cause a particular adverse effect.

2. D.J. Paustenbach, *A Survey of Health Risk Assessment*, in *THE RISK ASSESSMENT OF ENVIRONMENTAL HAZARDS* 27 (D. J. Paustenbach ed., 1989).

stances posing a significant risk to human health or the environment.³ In determining that a significant risk exists, there must necessarily be an assessment of the risk of harm to the exposed individuals or resources. Over time, the process of risk assessment has evolved to address this necessity.⁴ For example, the Environmental Protection Agency (EPA), before taking enforcement action against parties responsible for a hazardous waste site, must make a legal determination that a substantial endangerment to public health or the environment exists as a result of conditions at the site. To satisfy this legal necessity, an endangerment assessment is made using general risk assessment procedures.⁵ There is, however, no uniform risk assessment methodology in the federal government. Differing approaches to risk assessment make it difficult for parties affected by regulatory decisions to determine the extent of their responsibility as well as their potential liability.

Risk assessment has also become the subject of heated debate. Some argue that the assumptions it uses are too conservative, resulting in the setting of levels of exposure to certain contaminants at an unrealistically low level. Others argue that there are so many unknowns in the risk assessment process that extremely conservative assumptions are necessary, if only to protect human health and the environment. A need for a consistent

3. Various statutes articulate the issue in different ways. For example, under § 109 of the Clean Air Act, EPA is to establish the highest level of various air pollutants that will not harm human health and set air quality standards at or below that level. 42 U.S.C. § 7409 (1988). Additionally, these statutes often have emergency provisions for dealing with hazardous releases that pose an imminent and substantial endangerment to human health and the environment. Section 7003 of the Resource Conservation and Recovery Act (RCRA) gives EPA authority to pursue civil actions or issue administrative orders as necessary to protect health and the environment "upon receipt of evidence that the past or present handling, storage, treatment, transportation or disposal of any solid waste or hazardous waste may present an imminent and substantial endangerment to health or the environment" 42 U.S.C. 6973.

4. Federal regulatory actions are in fact based on two distinct processes; risk assessment and risk management. According to the definitions developed by the National Academy of Sciences, risk assessment is the characterization of the probability of potentially adverse effects from exposures to environmental hazards, while risk management is the process of evaluating alternative regulatory actions and selecting among them. The risk management process is guided by risk assessment information and by other considerations. COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, NATIONAL ACADEMY OF SCIENCES, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS* 18-19 (1983)[hereinafter NAS].

5. ENVIRONMENTAL PROTECTION AGENCY, 1 PART A RISK ASSESSMENT GUIDANCE FOR SUPERFUND, HUMAN HEALTH EVALUATION MANUAL 2-9 (1989) [hereinafter RAGS].

methodology that can be used by the regulated community to predict agency response to their activities does exist, and several suggestions to that effect have recently been made.⁶

However, even in the absence of such uniformity, there are many risk assessment principles that are regularly used. The purpose of this article is to present, in nontechnical language, some of these principles for those who must deal with various types of risk assessments. A simplified form of risk assessment, the recently revised Hazard Ranking System (HRS) for scoring Superfund sites under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA),⁷ will be used to provide examples of how some risk assessment decisions are made.

II. A BRIEF HISTORY OF THE RISK ASSESSMENT PROCESS⁸

The Food and Drug Administration (FDA) was the first government agency to formally incorporate risk assessment into regulatory decisionmaking. Risk assessment is used by the FDA as a basis for regulating substances added to or contaminating food. In 1958, Congress passed an amendment to the Federal Food, Drug and Cosmetic Act that has become known as the Delaney Clause. The Delaney Clause prohibits human or

6. FEDERAL FOCUS INC., TOWARD COMMON MEASURES: RECOMMENDATIONS FOR A PRESIDENTIAL EXECUTIVE ORDER ON ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT POLICY 103-08 (1991).

7. 42 U.S.C. §§ 9601-75 (1988).

8. It should be pointed out, at this juncture, that most of the discussion about the history of risk assessment deals with how various agencies have dealt with the treatment of substances which may be carcinogens, even though risk assessment principles are also used to regulate noncarcinogens. The basic reason for this is that regulatory agencies have traditionally looked at noncarcinogens differently than carcinogens and have regulated them on the assumption that there was a threshold for their effects. According to the regulators, once the threshold was identified, by the use of experimentally derived no-observed-effect exposure levels, the permissible level of exposure (*i.e.* acceptable intakes), could be set below that threshold, using some criterion for a "margin of safety," and that exposure level would, by definition, not be harmful. See NAS, *supra* note 4, at 52-53. Thus, for example, the Federal Food, Drug and Cosmetic Act provides:

In determining . . . whether a proposed use of a food additive [which is non-carcinogenic] is safe, the Secretary shall consider . . .

(A) The probable consumption of the additive

(B) The cumulative effect of such additive in the diet of man or animals

(C) Safety factors which in the opinion of experts . . . are generally recognized as appropriate for the use of animal experimentation.

21 U.S.C. § 348(c)(5) (1988).

animal carcinogens in food additives.⁹ In 1962, the Act was amended again to allow the use of substances like diethylstilbesterol (DES) as food animal growth promoters, so long as "no residue" of the substance remained in the animal product intended for human consumption.¹⁰ Yet, it soon became apparent that there was no such thing as "no residue." Even if it could not be measured, the residue remained, and as analytic measurement techniques continued to improve, the residue even became measurable. The FDA, therefore, interpreted the "DES Proviso" to mean that no residue could be permitted above a level posing "no significant increased risk of cancer in humans."¹¹

Using a risk assessment methodology published in 1961, the FDA proposed that a lifetime carcinogenic risk of an extremely low number was acceptable. That number was originally one excess cancer case in one hundred million people. This proposal "established the notion that some very low level of cancer risk would not pose a significant public health threat."¹² Although the maximum acceptable lifetime risk was later increased to one in one million and the risk assessment methodology was updated, risk assessment became firmly lodged as a regulatory tool of the FDA. Today, the FDA's position has evolved to the standard that a carcinogen can be considered safe as long as exposure to it is restricted to levels posing insignificant risks.¹³

Another important milestone in the adoption of risk assessment principles for use in federal regulatory decisions occurred when the United States Supreme Court ruled on the validity of the Occupational Safety and Health Administration's (OSHA)

9. 21 U.S.C. § 348(c)(3)(A). The Delaney Clause provides: "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal"

10. *Id.* That section provides, in pertinent part:

[T]his proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds . . . that no residue of the additive will be found . . . in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal.

11. NATIONAL RESEARCH COUNCIL, *REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX* 38 (1987).

12. Joseph V. Rodricks, *Origins of Risk Assessment in Food Safety Decision Making*, J. AM. C. TOXICOLOGY 541 (1988).

13. However, in a recent case involving color additives, which are subject to the "zero risk" requirement of the Delaney Clause, the court rejected the FDA's argument that insignificant risks were the practical equivalent of Congress' zero risk mandate. *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987), *cert. den. sub nom.*, *Cosmetic, Toiletry and Fragrance Assn. v. Public Citizen*, 485 U.S. 1006 (1988).

effort to lower the permissible exposure limit to benzene in the workplace.¹⁴ OSHA is the federal agency with the primary responsibility for assuring worker safety and health. The Occupational Safety and Health Act¹⁵ provides that OSHA may set safety and health standards. With respect to toxic substances, OSHA specifically provides:

The Secretary, in promulgating standards dealing with toxic materials . . . shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.¹⁶

When OSHA revised the benzene standard,¹⁷ it did not use risk assessment principles. Instead, the Agency stated that the section of the Act quoted above required it to set this standard either at a level demonstrated to be safe, or at the lowest level that was technologically feasible, whichever was higher. Since OSHA acknowledged benzene as a human carcinogen, and since OSHA's position regarding carcinogens was that there was no level of a carcinogen that did not present some increased risk of cancer,¹⁸ OSHA concluded that there was no safe level of exposure to benzene. Therefore, the permissible exposure level must be zero, unless that level was not feasible. As OSHA found a standard of zero was, in fact, not feasible, it set the standard at the lowest feasible value, one part per million.¹⁹

The Supreme Court rejected this approach. The Court held that another section of the Occupational Safety and Health Act provides that standards must be "reasonably necessary or appropriate to provide safe or healthful employment and places of

14. *Indus. Union Dep't., AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607 (1980).

15. 29 U.S.C. § 651-78 (1988).

16. *Id.* § 655(b)(5).

17. The revised standard, among other things, lowered the permissible exposure limit to benzene from 10 part per million, to 1 part per million, on an 8 hour time weighted average (TWA) basis. 29 C.F.R. § 1910.1028(c) (1979).

18. "Although these [benzene] studies, for the most part involve high exposure levels, it is OSHA's view that once the carcinogenicity of a substance has been established qualitatively, any exposure must be considered to be attended by risk when considering any given population. OSHA therefore believes that occupational exposure to benzene at low levels poses a carcinogenic risk to workers." *Occupational Exposure to Benzene*, 43 Fed. Reg. 5918, 5932 (1978).

19. *Indus. Union Dep't., AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 634-37 (1980).

employment.”²⁰ Therefore, the Act requires, before any standard is promulgated, a determination that a “significant risk” exists and that the proposed standard will reduce that risk.²¹ The Court’s description of what amounts to a “significant risk” has been embraced by numerous federal agencies:

First, the requirement that a “significant” risk be identified is not a mathematical straitjacket. It is the Agency’s responsibility to determine, in the first instance, what it considers to be a “significant” risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it

Second, OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty. Although the Agency’s findings must be supported by substantial evidence, 29 U.S.C. § 655(f), § 6(b)(5) specifically allows the Secretary to regulate on the basis of the “best available evidence.” As several Courts of Appeals have held, this provision requires a reviewing court to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge. Thus, so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection.²²

The Supreme Court also noted that, in determining whether a particular level of risk was “significant,” the Agency could use such methods as “dose-response curves,” even when the levels of exposure were below the doses associated with adverse effects.²³

While the FDA essentially arrived at the conclusion that, except for cases which fell squarely within the Delaney Clause, it would not regulate a substance in the absence of a significant

20. 29 U.S.C. § 652(8).

21. *Industrial Union Dep’t.*, 448 U.S. at 642.

22. *Id.* at 655-56. In an accompanying footnote, the Court stated, “while the agency must support its finding that a certain level of risk exists by substantial evidence, we recognize that its determination that a particular level of risk is ‘significant’ will be based largely on policy considerations.” *Id.* at 655-56, n.62.

23. *Id.* at 656 n.63, 657 n.64.

risk of harm, the Supreme Court held that regulation could not occur unless there is a significant risk of harm, at least in the context of the Occupational Safety and Health Act's statutory language.²⁴ Although statutory language varies considerably, most agencies' regulatory mandates adopt this rationale, and the agencies use risk assessment principles to guide that determination.

EPA's first foray into risk assessment took place as a consequence of its analysis of several pesticides in the 1970s. As a result of the testimony of expert witnesses in the administrative hearing concerning the pesticides, attorneys for EPA set forth what were referred to as "cancer principles," conveying the idea that the only acceptable degree of regulation would be a total ban on exposures to the pesticides. In response to the criticism from the scientific community, the private sector, and Congress on this zero-risk standard for a large number of economically important chemicals, the Agency adopted formal guidelines embracing a two-step process of risk assessment. Indeed, by so doing, EPA became the first federal agency to adopt formal risk assessment guidelines.²⁵ In those guidelines, the Agency first determined whether a particular substance constituted a cancer risk (hazard identification) and then made a determination whether regulatory action should be taken to reduce that risk. As part of this process, the Agency explicitly endorsed the use of quantitative risk assessment as the method of determining the extent of the impact of a potential human carcinogen on public health.²⁶

EPA engages in risk assessment in regulating the myriad hazardous substances falling under its jurisdiction. Risk assessment methods are dictated by the wording of various statutory mandates. For example, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is required to perform a risk/benefit analysis in regulating carcinogenic pesticides.²⁷ It

24. *Id.*

25. NAS, *supra* note 4, at 57-58.

26. Health Risk and Economic Impact Assessments of Suspected Carcinogens, 41 Fed. Reg. 21402, 21404 (1976). See also, NAS, *supra* note 4, at 57-58.

27. 7 U.S.C. § 136a(C)(5)(C) (Supp. I 1990) provides that a pesticide may be registered if, among other things, "it will perform its intended function without unreasonable adverse effects on the environment." 40 C.F.R. § 162.11(1)(i)(F), (ii)(F) and (iii)(D) (1987) provide that exposure to the pesticide must not have "adverse effects on the physiology . . . of nontarget organisms." With limited exceptions, unregistered pesticides may not be distributed, sold, shipped or received. 7 U.S.C. § 136a(a) (1988).

appears in most FIFRA cases that EPA has used a lifetime cancer risk of one in one million as a guide to significant risk decisions.²⁸

Section 112 of the Clean Air Act provides for the promulgation of National Emissions Standards for Hazardous Air Pollutants.²⁹ In assessing the risk from these hazards, EPA looks to two estimates, individual risk and population impact, to determine the overall health risk from hazardous air pollutants. Generally, the maximum cancer risk found to be insignificant by EPA is one in one hundred thousand over an average lifetime of seventy years of exposure.³⁰

EPA's interpretation of the Safe Drinking Water Act³¹ provides for a zero exposure goal for carcinogens in drinking water. Therefore, EPA's Drinking Water Office rejects as unsafe, at least in principle, any risk of carcinogenesis. In reality, however, technical limitations have forced EPA to accept carcinogen contamination limits greater than zero. As a result, the Agency has proposed Maximum Contaminant Levels (MCL) based on consideration of technical feasibility. MCLs are to be reduced whenever it becomes technically feasible to do so. Thus, this notion rejects any use of risk assessment beyond the hazard identification stage, because any release of a carcinogenic chemical into drinking water would pose an unacceptable risk.³²

No clear standard has emerged regarding cleanup of Superfund sites under CERCLA. EPA generally seeks cleanup levels that achieve a residual risk between one in ten thousand and one in one million for carcinogenic contaminants at Superfund sites.³³ However, "[d]ecisions on cleanup goals at most Superfund sites appear to be based in part on risk analysis, but the magnitude of risk reduction achieved at Superfund sites as a function of cost is not readily identifiable from agency decision documents."³⁴

As a consequence of the divergent risk assessment practices among the various regulatory agencies, the National Academy

28. Joseph V. Rodricks et al., *Significant Risk Decisions in Federal Regulatory Agencies*, 7 REG. TOXIC & PHARM. 307, 310 (1987).

29. 42 U.S.C. § 7412 (d)(1) (1988).

30. Rodricks et al., *supra* note 28, at 312.

31. *Id.* at 316.

32. *Id.* at 316.

33. 40 C.F.R. Pt. 300 National Oil and Hazardous Substances Pollution Contingency Plan (1990).

34. Rodricks et al., *supra* note 28, at 312.

of Sciences (NAS) was authorized by Congress³⁵ to assess the merits of separating the "analytic functions" in developing risk assessments from the "regulatory functions," to consider the feasibility of establishing a "single organization to do risk assessments for all regulatory agencies," and to consider "the feasibility of developing uniform risk assessment guidelines for use by all regulatory agencies."³⁶

The NAS's finding was that a standardized risk assessment procedure using uniform guidelines would be beneficial to regulatory agencies. Along with the problem of divergent standards and procedures among the various agencies, the Committee found other difficulties in the risk assessment process. It concluded that clear definitions of the terms "significant" and "insignificant" risk had not been established by any consistent analytic approach, despite the wide usage of the terms. The problem of uncertainty, caused by a lack of scientific data on the extent of exposure or health effects associated with chemical agents, tended to make conclusions based on direct evidence of a threat to human health rare. In most cases, agencies simply noted that the predicted risks were likely upper limits and that the actual risks may be lower. Other problems included determining the proper background risk against which the potentially harmful agent should be compared, and determining whether significant risk decisions should relate to individuals, the larger population, or both.³⁷

III. PRINCIPLES OF RISK ASSESSMENT

A. Introduction

Although many of the NAS's recommendations have not been implemented, one of the very useful things the NAS Committee accomplished was to define the process of risk assessment, so that a standardized language and approach could begin to be used. According to the Committee, there are four steps in every complete risk assessment: hazard identification, dose-response modeling, exposure assessment, and risk characterization. These terms have been defined as follows:

35. Appropriations - Agriculture, Rural Development, and Related Agencies Program - Fiscal Year 1981, Pub. L. No. 96-528, 94 Stat. 3095 (1980); see also NAS, *supra* note 4, at letter of transmittal, 3/1/83.

36. NAS, *supra* note 4, at 2.

37. ENVIRON. CORP., ELEMENTS OF TOXICOLOGY AND CHEMICAL RISK ASSESSMENT 61-62 (Rev. ed. July 1988).

Hazard identification - this is the process of determining whether human exposure to an agent could cause an increase in the incidence of an adverse health effect or whether by exposure, a nonhuman receptor, *e.g.*, birds, fish or other wildlife, might be adversely affected. In other words, hazard identification involves characterizing the nature and extent of the evidence of causation.

Dose-response assessment - this process characterizes the relation between the dose of an administered agent and the incidence of the adverse health effect in the exposed population and estimates the incidence of the effect as a function of exposure to the agent. Factors such as intensity and age pattern of exposure, gender and lifestyle are considered. The estimation of the magnitude of the risk associated with the hazard usually requires extrapolation from high to low doses and extrapolation from animals to humans, or to another species of animal. A determination is then made of the relation between the magnitude of the exposure and the probability of occurrence of the health effect in question. Dose-response relations may vary, depending on the conditions of exposure — for example, the form of the chemical, the particle size, or the dose rate. The dose-response assessment should describe and justify the method of extrapolation and should characterize the statistical and biological uncertainties of those methods.³⁸

Exposure assessment - this step measures the intensity, frequency, and duration of human or animal exposure to an agent in the environment or estimates hypothetical exposures that may arise. Some very complete exposure assessments describe the magnitude, duration, schedule, and route of exposure; the size, nature and classes of human, animal, aquatic or wildlife populations exposed, and the uncertainties of all the estimates. Theoretically, the exposure assessment can be used to identify feasible prospective control options and predict the effects of available control technologies for controlling or limiting exposure.

Risk characterization - this process estimates the incidence of a health effect under various conditions of human or animal exposure. It is performed by combining the dose-response assessment and the exposure assessment. A summary of the uncertainties of the steps should be included at this stage and the issues dealing with groups with different exposures or special sensitivities should be dealt with.³⁹

38. This aspect of dose-response assessment is frequently ignored or deemphasized in risk assessments.

39. NAS, *supra* note 4, at 19-20; *see also* Paustenbach, *supra* note 3, at 30, 32.

In simple terms, assessment of health hazards posed by workplaces, hazardous waste sites, air, water, soil, or food pollutants, is dependent on the potency of the agent and the level of exposure.⁴⁰ Each of these aspects of risk assessment will be discussed below.

B. Hazard Identification

The hazards of chemicals or physical agents have traditionally been evaluated in two ways: laboratory studies of toxicity and epidemiological studies of human populations.⁴¹ Because epidemiology studies humans, the information gained from these studies is often said to be more useful for determining whether a substance is potentially hazardous than is the information gained from animal studies. However, epidemiological studies have a number of shortcomings as well. Some of the shortcomings of epidemiology include:

1. Study results may not be consistent: that is, the result may not be able to be replicated, or different investigative approaches may not produce similar results.
2. There may be an association between an agent and an effect, but that association may not be very strong.⁴²
3. There may be no temporal relationship (*i.e.*, the presumed cause may not precede the alleged effect).
4. The results may just not be biologically plausible.
5. There may be positive bias.⁴³
6. There may be positive confounding.⁴⁴
7. The association may be due to chance alone. Statistical techniques that establish "statistical significance," are important here, but not conclusive.

40. Paustembach, *supra* note 2, at 29.

41. SAFE DRINKING WATER COMM., NAT'L ACADEMY OF SCIENCES, 1 DRINKING WATER AND HEALTH 19 (1977) [hereinafter 1 DRINKING WATER AND HEALTH].

42. The strength of an association may be expressed in terms of relative risk or an odds ratio. Many scientists argue that an odds ratio of less than 2 (*e.g.*, 4 cases expected, 8 found), or 3 (*e.g.*, 10 cases expected, 30 seen) are not of much significance.

43. Positive bias means that factors in the design or the execution of the study lead erroneously to a more strongly positive association between an agent and disease than, in fact, exists. An example of positive bias in a case control study would be more nearly complete ascertainment of exposure to the agent in the cases studied than in the controls. An example of positive bias in a cohort study would be nearly complete detection of cancer in individuals exposed to the agent than in individuals not exposed to the agent.

44. Confounding refers to the extraneous influence of factors, other than the one sought to be measured, in the association with the risk of disease. Positive confounding refers to the situation in which the association between the agent and the disease is rendered more strongly positive than it really is, as a result of an association between the agent and another agent which either causes or prevents the disease.

8. There may be a strong, statistically significant association, but the data may not show a dose-response relationship.⁴⁵

In addition to problems associated with epidemiologic studies in general, there are also problems associated with "case-control" (retrospective) and "cohort" (prospective) studies. In case-control studies,⁴⁶ for example, the subject's recall of earlier events may be distorted by knowledge of the disease; controls may be poorly selected; there may be a lack of information, either by lack of recall or loss of records.⁴⁷

In light of these problems with epidemiology, many scientists have advocated the use of laboratory animals as a way to test substances for their hazardous qualities. These scientists point to the very long experience with testing noncarcinogenic chemicals on animals. They also note that, with respect to cancer, a very large percentage of chemicals that are said to be human carcinogens also cause cancer in some species of laboratory animals. In addition, laboratory animal experiments are performed on genetically similar animals, under standardized conditions, with environmental factors controlled, and with the only difference between animal groups being the actual exposure to the agent being tested.⁴⁸ According to its supporters, animal testing provides reasonably precise and reproducible information about the toxicity of a particular substance.⁴⁹ Indeed some scientists even argue that since humans are genetically diverse, with susceptible, as well as resistant, individuals and are exposed

45. David Schottenfeld & Joanne F. Haas, *Carcinogens in the Workplace*, CA - CANCER J. FOR CLINICIANS, May-June 1979, at 144; Identification, Classification and Regulation of Potential Occupational Carcinogens, 29 C.F.R. pt. 1990 (1980).

46. A case-control study is one in which the disease of interest is identified and a population with that disease is selected and matched with another population which is similar, in as many ways as possible, to the study population, except that the control population members do not have the disease.

47. Schottenfeld & Haas, *supra* note 45, at 148. See generally Junius C. McElveen, Jr. and Pamela S. Eddy, *Cancer and Toxic Substances: The Problem of Causation and the Use of Epidemiology*, 33 CLEV. ST. L. REV. 29 (1984-85) (generally discussing epidemiology and the problems of causation, in the legal sense).

48. The inference that humans and animals (mammals) are similar, on average, in intrinsic susceptibility to toxic chemicals and that data from animals can, in many cases, be used as a surrogate for data from animals is the basic premise of modern toxicology. RAGS, *supra* note 5, at 7-5.

49. 1 DRINKING WATER AND HEALTH, *supra* note 41, at 30; see also SAFE DRINKING WATER COMM., NAT'L ACADEMY OF SCIENCES, 6 DRINKING WATER AND HEALTH 4 (1986)[hereinafter 6 DRINKING WATER AND HEALTH] (stating, "[i]n the absence of data on humans, therefore, convincing demonstration that a substance is neurotoxic in a test animal can be regarded as evidence that the agent may be neurotoxic in humans").

to a wide variety of environmental conditions and substances, animal testing probably understates the effects of particular toxic substances.⁵⁰ Furthermore, since large animals have so many more cells, a disease such as cancer, which might be produced infrequently by a chemical in a laboratory animal, would be likely to occur far more frequently in humans.⁵¹

There are also a wide variety of arguments, however, that are advanced for not extrapolating the results of animal experiments to man, or, if they are extrapolated, for assuming that the incidence of disease in the animals is much higher than that which would be expected to occur in humans. As one treatise points out:

When a mouse or man is exposed to a chemical, a number of events can occur that can greatly influence the final reaction, which may appear as the observed toxic effect. These events include absorption, distribution and storage; metabolism, excretion and reabsorption; arrival at the site of action; reaction with the biological receptor; and interaction with other constituents of the environment Anatomical, biochemical, physiological, pharmacological, and pathological differences and similarities can and have been identified ⁵²

Thus, some have argued that the doses given to these animals, which are usually the maximum tolerated dose⁵³ (MTD), are so high that they overwhelm the animals' normal mechanisms for handling such substances. The MTDs are also said to represent quantities of the test substance that are so high that humans could never be exposed to such concentrations. Saccharin is a frequent example of excessive concentrations. It is said that, in order to consume as much saccharin as is needed to produce tumors in animals, humans would be required to drink hundreds of diet soft drinks a day.

There are obviously other differences between lab animals and humans. As the National Academy of Sciences once noted: "a mouse is not the equivalent of a very small man; nor is a man

50. 1 DRINKING WATER AND HEALTH, *supra* note 41, at 31.

51. *Id.*

52. *Id.* at 29.

53. The Maximum Tolerated Dose is usually defined as the maximum dose the animals can tolerate, over the course of the experiment, without having an increased incidence of death from causes other than the endpoint being investigated. That dose is justified on the basis that the difference in lifespans between men and lab animals necessitates the use of these very high doses for the lifetime of the animals, in order to try to simulate the much longer human lifespan experience.

the equivalent of a very large mouse."⁵⁴ These differences range from those that are solely due to size, such as the fact that blood circulates twenty times as rapidly in a mouse than in a man and that the cell division rate is much greater in a man than in a mouse,⁵⁵ to differences in anatomy and metabolism. Some of these differences, which need to be considered in determining whether a human health hazard exists, are summarized below:

Environmental differences - nutritional differences and the physical environment can affect the response to certain substances.

Absorption - the ratio of surface area to volume in the gastrointestinal tract, and the transit time through it, often differ among and within species. These factors affect absorption. Also affecting absorption is pH, whether the animal or person is a newborn, and whether there are particular types of bacteria in the gut.

Distribution and storage - there can be differences among species with respect to the nature and extent to which foreign substances bind to components of the blood, for transport, and to tissues distant from the site of entry into the body.

Metabolic differences - there are numerous interspecies differences in the ways the liver, lung and kidneys (the major metabolic organs) metabolize various chemicals.

Excretion and reabsorption - there are differences among species in the rate of excretion and the organs used for excretion.

Differences on receptor sites - anatomical differences, differences in active-transport mechanisms, and differences in the cellular and intercellular membranes among species may affect the site of action of some of these chemicals.⁵⁶

Procedural recommendations for animal testing also play a significant role in the results obtained: (1) the route and type of human exposure should be duplicated as closely as possible; (2) more than one species of laboratory animal should be used; (3) doses should be selected so that acute toxic effects are not produced, and little or no weight loss or life shortening of the animals occurs as the result of the dose; (4) design considerations, such as the number of animals used, the species and strain selected, the number and distribution of doses, all affect the

54. 1 DRINKING WATER AND HEALTH, *supra* note 41, at 31.

55. *Id.*

56. *Id.* at 32-34; see also 6 DRINKING WATER AND HEALTH, *supra* note 49, at 264-66.

quality of the experiments; and (5) statistical considerations are also important, such as whether, in cancer experiments, benign tumors should be counted in determining if a statistically significant difference exists between control and test animals.⁵⁷

The authors of the 1977 National Academy of Sciences Report on Drinking Water and Health felt that, despite the problems with extrapolation of animal data to humans, such extrapolation can, and should, be done. The report also indicates that small animals, which are routinely used for toxicity testing, are often more resistant to toxic compounds than man. The implication is thus that small animal's systems are likely to produce a good many "false negative"⁵⁸ results, which means that conservative assumptions should be made when extrapolating animal data to humans.⁵⁹ The arguments made in favor of laboratory animals being more likely to show an effect than humans include: (1) the greater residence time of substances in human tissues than in laboratory animal tissues, due to the more rapid movement of blood in lab animals (some drugs have been shown to have a greater effect, per unit dose, on a weight basis, in humans than in test animals); (2) the larger number of cell divisions in man than in lab animals; (3) the genetic diversity of man, and the concept of the "highly sensitive individual," whose study necessarily includes the discipline of "pharmacokinetics," the study of the way substances, including toxins, are metabolized and how that differs among individuals; (4) the wide variety of environmental conditions to which man is exposed, including actions by other toxins, which may reduce the immune response, or multiply the effect of the agent in question;⁶⁰ (5) other sources of variation within a species, such as gender, age, pregnancy status, and disease.⁶¹

Despite the NAS's position, however, there continues to be a raging debate over the usefulness of positive results in animals as predictors of some human diseases, such as cancer. For example, Bruce Ames and his colleagues have recently written

57. 1 DRINKING WATER AND HEALTH, *supra* note 41, at 31.

58. The term "false negative" means that a test did not find a positive result, but if, for example, more test animals, or higher doses, were used, a positive result would occur (i.e., no effect was found, but one exists).

59. SAFE DRINKING WATER COMM., NAT'L ACADEMY OF SCIENCES, 3 DRINKING WATER AND HEALTH 27 (1980) [hereinafter 3 DRINKING WATER AND HEALTH].

60. Obviously, there is also the possibility that certain agents act antagonistically, nullifying the effect of each other.

61. 1 DRINKING WATER AND HEALTH, *supra* note 41, at 31-32, 35-36.

that the "near toxic doses" of test chemicals administered to animals cause cancer by virtue of the cell proliferation resulting from the effort of the body to repair the chemically induced damage and cell death.⁶² In other words, mitogenesis (cell proliferation) increases the chance for mutagenesis (DNA damage), which is a necessary step in the progress of most cancers. Needless to say, this opinion is not universally shared.

Despite the shortcomings of epidemiology and toxicology, other efforts to classify chemicals, such as reliance on mutagenic changes or similarities between chemical structures, are even less successful. Therefore, it is primarily on the basis of those two disciplines that regulators determine whether a substance is likely to present a human health hazard.

Thus, with respect to potential carcinogens, EPA and other agencies have developed hierarchical systems for ranking substances in accordance with these studies. EPA's ranking system, known as the "weight-of-evidence rating," is a classification system for characterizing the evidence which supports the designation of a substance as a human carcinogen. Under the weight of evidence rating: Group A substances are considered to be definite human carcinogens; Group B1 substances are considered probable human carcinogens, based on some evidence of carcinogenicity in humans; Group B2 substances are considered probable human carcinogens, based on sufficient evidence of carcinogenicity in animals; Group C substances are considered possible human carcinogens, based on limited evidence of carcinogenicity in animals.⁶³

C. Dose-Response Relationships

1. Introduction

Once it is determined that a substance is a potential human health hazard, an effort is made to determine the dose that is likely to produce a hazardous effect. In order to understand the general approach taken in this area, it is necessary to divide potential hazards into three categories. First, there are substances that produce effects which disappear after exposure ends (*i.e.*, reversible effects). Second, there are substances that pro-

62. Bruce W. Ames & Lois S. Gold, *Too Many Rodent Carcinogens: Mitogenesis Increases Mutagenesis*, 249 *SCIENCE* 970 (1990).

63. EPA, *Guidelines for Carcinogen Risk Assessment*, 51 Fed. Reg. 33,992, 33,996 (1986).

duce irreversible effects, but the effect does not progress after exposure ceases (e.g., cell killing effects). Third, there are substances that produce irreversible effects which may progress after exposure ceases (e.g., cancer).⁶⁴ The first two of these groups have traditionally been thought to have thresholds below which adverse effects would not occur. The third group has been assumed not to have a threshold (i.e., there is no dose below which an effect could not occur).⁶⁵

2. Threshold Substances

With respect to substances that cause reversible effects, and, historically, with respect to substances that caused irreversible, noncancerous effects, the assumption has been that there is a threshold below which adverse effects will not occur. As the National Academy of Sciences said in 1977:

Many effects have thresholds The curves are sigmoid, and below a particular dose there is zero probability of producing the effect, because it requires many independent occurrences and will not occur until the number of such events exceeds some critical value.⁶⁶

In other words, a diagnosable injury will not occur unless and until the number of cells killed exceed the number of cells critical to the functioning of the organ or tissue. The dose that kills less than that number of cells has traditionally been considered a "safe" dose.⁶⁷ Thus, even if taking one hundred aspirin tablets were to result in a one hundred percent mortality rate, taking one aspirin does not result in a one percent chance of dying.⁶⁸

The approach of regulators has been to try to demonstrate the threshold for the adverse effect. This was generally done by determining the highest dose at which no adverse effect was noted. Once the "no observed adverse effect level" (NOAEL)⁶⁹ had been demonstrated, certain "safety factors" were applied to that dose level depending on the adequacy of the data, so that an adequate "margin of safety" could be said to exist. As a rule, if human epidemiology were available to establish the NOAEL, no "safety factors" would be applied because, presumably, the dose

64. 1 DRINKING WATER AND HEALTH, *supra* note 41, at 26.

65. 6 DRINKING WATER AND HEALTH, *supra* note 49, at 282.

66. 1 DRINKING WATER AND HEALTH, *supra* note 41, at 37.

67. *Id.*

68. *Id.*

69. *Id.* at 24; see also 6 DRINKING WATER AND HEALTH, *supra* note 49, at 258.

at which no adverse effects would occur in humans was known. If animal test results were used to establish the NOAEL, several "safety factors" might be considered for use. First, a factor of ten would generally be applied for the extrapolation from animals to humans, on the theory that animals might be more resistant to the toxic effects of the chemical than humans. Second, another factor of ten would generally be applied to account for differential sensitivities in the human population.⁷⁰ This one-hundred fold "safety factor" would be applied to the highest NOAEL dose measured in animal studies. The first regulatory area in which this approach was used was that of food additives. Thus, the term that came to be used for the acceptable dose was the Acceptable Daily Intake (ADI).⁷¹ In more recent years, ADI has been replaced by the term Reference Dose (RfD). However, the way of calculating it has remained the same.

Before discussing carcinogens, a word needs to be said about substances which produce irreversible effects that do not progress after exposure ceases. The traditional approach to regulation of these substances has been the "threshold" approach. In recent years, however, as biochemical research has increased, some have argued that increasingly lower doses of these substances are producing unacceptable effects. They argue that chemicals producing irreversible changes, such as cell death or enzyme inhibition, should be presumed to be "non-threshold" occurrences. This presumption should hold unless the mechanism of injury is understood, and a clear threshold can be established.⁷² Lead is a good example of this change in thinking. Traditionally, lead had been considered a "threshold" substance; however, although this is still an area of heated debate in the scientific community, EPA has recently announced that it will consider lead to be a substance for which no threshold exists.⁷³

70. 3 DRINKING WATER AND HEALTH, *supra* note 59, at 28, 30.

71. *Id.* at 30.

72. C. S. Weil, *Statistics vs. Safety Features and Scientific Judgement in the Evaluation of Safety for Man*, 21 TOXICOLOGY AND APPLIED PHARMACOLOGY 454-63 (1972).

73. See 55 FED. REG. 26,460, 26,467 (1991) (to be codified at 40 C.F.R. pts. 141, 142). Lead is a little unusual, in that, at very high doses, it is reported to cause cancer in laboratory animals. However, it is generally agreed that the neurological effects of lead occur at lower doses than would cause cancer. Therefore, the noncancer effects of lead always drive the risk assessments.

3. Non-Threshold Substances

This brings us to substances that pose the risk of causing cancer. The issue of whether a "threshold" exists for carcinogenesis is a controversial one. Those who argue for a threshold say it is inconceivable that very small concentrations can cause cancer. They argue that the body's defenses are capable of protecting against cancer; the substance might be detoxified, DNA repair might occur, or the mutated molecules might be destroyed by the body's immunological defenses.⁷⁴ Those who argue against a threshold say that, if a change produced in a single molecule by a single unit of exposure is capable of beginning carcinogenesis, the substance in question cannot have a threshold, no matter how unlikely it is that the single hit will produce the effect. Furthermore, it is suspected that cancer is a process that involves mutations of DNA in some way, and it is known that DNA mutations can occur after a single hit from a carcinogen, such as ionizing radiation.⁷⁵ Indeed, studies show that people who have a decreased ability to repair DNA have a much higher risk of some cancers than other groups of people. Therefore, in the absence of an understanding of the mechanism of cancer, it is prudent to treat substances that may cause cancer as if they have no threshold⁷⁶ or as if there is no level of exposure below which cancer cannot occur. "This means," as the National Academy of Sciences has said,

that there can be no totally "safe" level of exposure to a particular carcinogen, nor can the term "margin of safety" have any meaning. Any dose of a carcinogen must be considered to be associated with a risk, and even if the risk is vanishingly small, it must be estimated.⁷⁷

Therefore, using the nonthreshold approach, if the dose-response curve is visualized as a curve on a graph, with the x-axis representing dose and the y-axis representing effect, the

74. *Indus. Union Dept., AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 636 n.41 (1980).

75. 1 *DRINKING WATER AND HEALTH*, *supra* note 41, at 37. ("So far as is known, any dose of ionizing radiation, no matter how small, might give rise to cancer or to a genetic effect in future generations"); *see also*, *RAGS*, *supra* note 5, at 10-30.

The Supreme Court noted in the benzene decision, as this case has become popularly known, "there are a number of scientists and public health specialists who subscribe to [the] view . . . that a susceptible person may contract cancer from the absorption of even one molecule of a carcinogen like benzene." *Industrial Union Dept.*, 448 U.S. at 636.

76. 6 *DRINKING WATER AND HEALTH*, *supra* note 49, at 282.

77. 1 *DRINKING WATER AND HEALTH*, *supra* note 41, at 39.

curve will extend from the highest doses all the way through zero dose, because there is no dose below which an effect will not occur. This conclusion, however, provides only part of the answer. Another major issue remains. That issue, the extrapolation of data obtained at high doses, to the potential low dose effect, affects the shape of the curve, though not its existence. It can also have profound effects on risk assessments.⁷⁸

Where epidemiological studies show an association between an exposure and the occurrence of a particular cancer, the exposure dose is usually quite high. Similarly, animal experiments often produce tumors only at very high doses. Therefore, in order to estimate the probability of cancers occurring at lower doses, it is necessary to make some assumptions about what the shape of the dose-response curve will be at lower doses.⁷⁹ There have been a large number of suggestions about what the curve should look like, based on various theories of how cancer is caused. However, in the absence of any generally accepted understanding of the mechanisms of carcinogenesis by the scientific community, along with a lack of understanding of factors such as sensitive subpopulations and the effect of interactions with other materials, the assumption has been made for risk assessment purposes that the most likely (maximum likelihood) estimate of low dose effects is linear.

Obviously, however, even if a dose-response curve for a substance is linear, the steepness of the slope of the line has a lot to do with how risky the substance is perceived to be. If the slope of the line is very steep, that signifies that the effect is much greater than the effect of a substance with a much more shallow slope. Once the slope of this line has been calculated, the incrementally increased response can be predicted. This incremental increase in response is what EPA calls the slope factor, or the Cancer Potency Factor, and that factor is used by the Agency to assess the relative potency of suspect carcinogens.⁸⁰

One more point needs to be made about dose-response curves. Even if a line exists that purports to be the "maximum likelihood" estimate of what the dose-response curve looks like

78. Another factor, the effect of the fractionation of dose, can also affect the shape of the curve, but that factor is not frequently examined in risk assessments.

79. 1 DRINKING WATER AND HEALTH, *supra* note 41, at 283.

80. Once again, it should be emphasized that these effects are not actually demonstrable. They are just what risk assessors predict should occur, if all the assumptions about low dose effect are true.

at low doses, there is a range of values within the ninety-five percent confidence limits of the "maximum likelihood" estimate. Thus, if you want to be ninety-five percent sure that the dose-response curve is accurately reflected, it is necessary to encompass a range of values within which the estimate could fall. The upper ninety-five percent confidence level (*i.e.*, the level below which, even with the vagaries of random sampling, ninety-five percent of the population are statistically sure to fall in their response to a given dose) is the level some risk assessors believe is appropriate to use as the risk level against which people should be protected.⁸¹

The slope created by this upper ninety-five percent confidence level is used by EPA as its Cancer Potency Factor. This, of course, results in extremely conservative risk estimates.

D. Exposures

1. Introduction

The third step in the risk-assessment process consists of determining the types of exposures that could put humans or environments in contact with potentially hazardous materials. Although an increasing amount of attention is being paid to the effect of pollutants on natural resources, the bulk of exposure assessment has dealt with human health hazards. Thus, that will be the main focus of this discussion.

The major exposure pathways for hazardous substances are inhalation, ingestion, and dermal contact. Thus, most risk assessments first look at the potential contamination of air, water, food, and soil or dust. Obviously, once the sources of potential exposure have been identified, a second question must be answered: What percentage of the substance is apt to get into the body and cause problems? The first of these questions is generally addressed by performing a contaminant release analysis, which examines the various ways that contaminants can be released from their sources into the air, water, food, or soil. The second question is answered by performance of a two-step evaluation: (1) a contaminant fate analysis is performed, which considers questions of transport, transformation, and ultimate fate of the contaminants; and (2) identification and characterization

81. 1 DRINKING WATER AND HEALTH, *supra* note 41, at 48; see also 6 DRINKING WATER AND HEALTH, *supra* note 49, at 267.

of potentially exposed populations is performed.⁸²

2. Air

a. Contaminant Release

Obviously, since very few sites have air sampling locations built in, either sampling must be done or assumptions have to be made. In addition, when assessing potential future contamination, researchers must replace measurements of actual concentrations with models of possible results. Although these models may use some measurements, they also rely on several assumptions. Thus, for example, the potential for air contamination depends mainly on the emissions of fugitive soils or dusts and the volatilization of contaminants. Emissions of soils depend on wind speed, the roughness and cloddiness of the surface, the moisture content of the surface soil, the kind and amount of surface vegetative cover, the amount of soil surface, and the lay of the land.⁸³ To the extent measurements of each of these parameters does not occur, assumptions must be made about them. For example, the soil moisture content might be estimated, using something called the Thornthwaite Precipitation-Evaporation Index, and estimates of soil properties may need to be obtained from general information about area soils.⁸⁴ Releases of volatiles depends on chemical properties, the depth and type of soil cover, and the amount of exposed area.⁸⁵

b. Contaminant Fate

The dose of a substance people actually receive depends on the substance, how much is absorbed, and the extent of their potential exposure. Potential exposure depends on the dispersion patterns of airborne materials and the concentration of contaminants in the airborne mixture.⁸⁶ The concentration depends, in part, on whether materials are transferred out of air or are transformed. Transformation may occur, due to photolysis (breakdown because of reactions with solar energy) and oxidation (breakdown because of reactions with oxidants, like

82. U.S. EPA, SUPERFUND EXPOSURE ASSESSMENT MANUAL, OSWER DIRECTIVE 9285.5-1 1 (1988) [hereinafter SEAM].

83. *Id.* at 12-13.

84. *Id.* at 13, tbl. 2-2.

85. *Id.* at 23.

86. *Id.* at 42, 45.

ozone, in the atmosphere).⁸⁷ Computer models are available to analyze the atmospheric fate of many substances.

c. Populations

Risk assessors are also interested in the size and characteristics of the population potentially affected. The risk presented by a substance at a site is diminished if very few people are potentially exposed. Therefore, population data must be gathered. Assumptions must also be made about inhalation rates, contaminant concentrations, and the length of time exposure continues.⁸⁸

3. Water

Evaluation of potential exposure to contaminants that may be waterborne generally considers two types of potential contamination: groundwater and surface water. Similar types of inquiries that are made about air are also made regarding water. The questions "what likelihood is there that substances will get into the water?" and "what likelihood is there that substances will get into the body?" are significant. That likelihood is determined by measurements, where possible, and by assumptions, where measurements are not possible.

a. Contaminant Releases

i. Surface Water

Some of the factors that are considered in attempting to determine if a substance can get into surface water include: The potential for soil to erode, the leachability of the material through the soil, and the speed with which that movement occurs. Those determinations are, in turn, dependent on a variety of factors having to do with the permeability of the soil and the extent to which the hazardous substance can bind to materials moving through that soil.

For example, soil erosion is dependent on something called the soil erodibility factor obtained from the Soil Conservation Service, the length and steepness of the slope of the ground, the type and extent of soil cover, and storm runoff volume and flow rates.⁸⁹ The degree of soil/water partitioning expected for given

87. *Id.* at 56.

88. *Id.* at 118, 122.

89. *Id.* at 22-23.

compounds is also calculated, using a variety of assumptions, including the partition coefficient, the density of the soil, the quantity of material, the water capacity, and other factors.⁹⁰

ii. Groundwater

For groundwater, factors affecting contaminant release include rainfall, percolation rate of the soil, the solubility of the chemicals being studied, and the area being evaluated.⁹¹

b. *Contaminant Fate*

i. Surface Water

The fate of contaminants in surface water depends on several factors. The first factor to be considered is the type of waterbody, since flowing waterbodies, such as rivers and streams, are viewed much differently than nonmoving waterbodies, such as lakes and estuaries.⁹² Second, the fate of contaminants depends on dilution potential. That potential, in turn, is dependent on mixing zone characteristics, the nature and extent of decay and removal processes, stream flow, and contaminant release.⁹³

ii. Groundwater

The fate of contaminants in groundwater also depends on a number of factors. The first step in groundwater contamination modeling is to determine the nature, depth, extent, direction, and velocity of flow of aquifers in the area of the contaminants. This is not easy, and well logs, characterizations by the U.S. Geologic Survey, and other sources of information need to be consulted.

Next, the direction and velocity of contaminant migration need to be determined, along with the contaminant concentration and volume.⁹⁴ It should be recalled that groundwater contamination results when solid contaminants are liquified or leached by rain or other precipitation. The liquid contaminants then percolate into an aquifer, contaminating the groundwater. The viscosity and density of liquid contaminants affect the rate

90. *Id.* at 25.

91. *Id.* at 30.

92. *Id.* at 53.

93. *Id.* at 53-54.

94. *Id.* at 63.

of migration. Finally, the migration rate is affected by the permeability of the soil through which the contaminant must move to reach the aquifer.⁹⁵ In addition, as has been noted for other contaminants, transformation and retardation can occur, which affect migration rate by either preventing the substances from reaching the aquifer or postponing that arrival for a very long time.⁹⁶

c. Populations

i. Surface Water

The potentially exposed populations include all those who are served by a water supply that draws water from a contaminated water source, and those who may be exposed through potential ingestion or dermal contact. Those who may be exposed (through ingestion or dermally) in recreational activities, such as swimming or fishing, must also be considered.⁹⁷

ii. Groundwater

As in the case of surface water, if contaminated groundwater is a supply of drinking water, the population using that supply is potentially exposed. To the extent that occurs, all populations identified as potentially exposed to surface or drinking water contamination should be included in the population analysis.⁹⁸

4. Soil/Dust

Soil and dust are rarely ingested deliberately. They are ingested inadvertently, however, particularly by children who are at play, crawl around, or put their toys in their mouths. Therefore, the presence of hazardous substances in soil and dust is one which must be addressed in risk assessments. Here, issues include the measurement of contaminant levels to determine how substances might be transported to the soil or dust. Interestingly, some risk assessment guidance, such as the Superfund Exposure Assessment Manual, do not permit the estimation by modeling of soil contamination. Instead, soil sampling and anal-

95. *Id.* at 68, 69.

96. *Id.* at 66, 67.

97. *Id.* at 2, 66, 68, 72, 75.

98. *Id.*

ysis are mandated.⁹⁹

On the issue of the dose which actually reaches target organs, the questions include: How much soil or dust is actually ingested, how much of the contaminant in the soil or dust gets out of its matrix in the digestive tract, and how much crosses the gut barrier. In addition, the size of the exposed populations and the amount of time they are exposed to the contaminant need to be considered.¹⁰⁰

5. Food

There are a number of ways that risk assessors assume hazardous substances can get into food. In looking at this issue, foods are generally divided into leaf crops (lettuce), root crops (potatoes), fruit crops (tomatoes), and animal life (fish, poultry, or livestock).

First, the substances may be deposited on the surface of the food. This can be accomplished by air deposition, for leaf or fruit crops, or by soil deposition, for a root crop. Second, contamination might be absorbed by the food item. One such example of absorption is the buildup of the pesticide DDT (a water-insoluble solid, used as an insecticide) in fish and other marine organisms.¹⁰¹ Harm, such as the potential danger to birds and other wildlife from eating contaminated fish, small animals, grasses, leaves or fruit, is often considered in this portion of the risk assessment as well.

E. Risk Characterization

Risk characterization is the process of estimating the occurrence of particular health effects resulting from the various exposure pathways discussed in the previous section. It is performed by combining the exposure and the dose-response assessments. As the expression of the risk derived at this step will be used by the regulators when weighing the risks and the benefits of the hazardous substance, it is particularly important. At this step, it is necessary to summarize the uncertainties which have attended the process. Issues to consider include statistical uncertainties, biologic uncertainties, which dose-response and exposure assessments should be used and why, and which population groups

99. *Id.* at 31.

100. *Id.* at 120.

101. *Id.* at 93-94, 119.

should be evaluated and why.¹⁰²

IV. THE HAZARD RANKING SYSTEM FOR SUPERFUND SITES

A. *Introduction*

To put some of these risk assessment concepts into perspective, it might be helpful to consider a rather simple approach to risk assessment recently promulgated by EPA: The revised Hazard Ranking System (HRS). This is a simplified risk assessment approach because it is designed only to provide relative rankings of hazardous waste sites that are being considered for inclusion on the National Priorities List (NPL) of Superfund sites, under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA). The HRS is designed to be sort of a "quick and dirty" approach to the assessment of the potential risks of a site. Thus, the relative ranking can be accomplished in fairly short order and those sites that do present substantial potential hazards can then begin to be subject to a more thorough risk assessment process. As has been noted above, the essence of risk assessment is determining the potency of a substance and the possible levels of exposure.¹⁰³ This is basically what the revised HRS seeks to do. As will be seen, the HRS tends to de-emphasize the characterization of hazards and the dose-response calculations, by referring the user to already developed EPA guidelines and regulations on permissible levels of exposure to various chemicals. Generally, it only considers, for evaluation purposes, the most hazardous chemical in a pathway, and it strongly emphasizes the possible exposures which may occur at the sites.

B. *History of the HRS*

CERCLA provided, in Section 105,¹⁰⁴ that the President was to identify the four hundred hazardous waste sites in the United States that warranted the highest priority for remedial action. CERCLA also furnished some guidance on the factors to be considered in prioritizing the sites. First, by requiring that priorities be based on the relative risk to public health, welfare, or the environment; and second, by mandating that certain factors be considered, as follows:

102. NAS, *supra* note 4, at 20, 28, 33, 36.

103. Paustenbach, *supra* note 2, at 29.

104. 42 U.S.C. § 9605(a)(8)(B).

The population at risk, the hazard potential of the hazardous substances at such facilities, the potential of contamination of drinking water supplies, the potential for direct human contact, [and] the potential for destruction of sensitive ecosystems
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EPA, to whom the President had delegated the duty to identify those sites, obviously had to devise a way to rank sites by the degree of hazard they presented. Therefore, in July of 1982, the Agency promulgated a scoring system designed to assess the actual threat of a release, or a potential release, of hazardous substances from waste sites.¹⁰⁶ That system was called the Hazard Ranking System. The HRS was published as Appendix A to the National Contingency Plan (NCP),¹⁰⁷ and it was to be used to evaluate "the relative potential of uncontrolled hazardous substance facilities to cause human health or safety problems, or ecological or environmental damage."¹⁰⁸

The 1982 HRS assigned a score to a facility, based on three "hazard pathways": (1) migration of hazardous substances away from the facility by groundwater, (2) migration of those substances by surface water, or (3) transfer of the substances off-site by air.¹⁰⁹ While the threat of fire or explosion of hazardous substances and direct contact with hazardous substances at the facility were also evaluated to determine a need for emergency action, those evaluations did not enter into the decision to place the site on the NPL.¹¹⁰

The score for each of these "hazard pathways" was obtained by evaluating and assigning numerical values to a set of factors characterizing the potential of the facility to cause harm by that pathway. These factors included such things as characteristics of the site, attributes of the waste, and people or resources actually or potentially exposed. Those factor values

105. 42 U.S.C. § 9605(a)(8)(A).

106. National Oil and Hazardous Substances Contingency Plan, 47 Fed. Reg. 31,180, 31,187 (1982) (codified at 40 C.F.R. pt. 300).

107. 40 C.F.R. pt. 300. The National Contingency Plan is a regulation, originally promulgated pursuant to the Federal Water Pollution Control Act of 1972 (Clean Water Act), which sets out guidelines and procedures for responding to releases and potential releases of oil and hazardous substances.

108. 40 C.F.R. pt. 300, app. A, § 1.0.

109. *Id.*

110. Hazard Ranking System For Uncontrolled Hazardous Substances Releases; Appendix A of the National Oil and Hazardous Substances Contingency Plan; Proposed Rule, 53 Fed. Reg. 51,962, 52,000 (1988) (codified at 40 C.F.R. pt. 300) [hereinafter HRS, Proposed Rule].

were then combined within three factor categories: "likelihood of release," "waste characteristics," and "targets;" after the values within a pathway were combined, they were then divided by the maximum possible score for that pathway and multiplied by one hundred.¹¹¹ This formula put all scores on a zero to one hundred scale. The final HRS score was obtained by squaring each of the pathway scores, dividing by the number of pathways, and taking the square root of that value.¹¹² This "root mean square" calculation served to emphasize the highest scoring pathway. If a facility scored higher than 28.50, it was listed on the NPL; according to EPA, this was not because such a cutoff represented any unacceptable risk, but because it was, originally, the score above which there were at least four hundred sites.¹¹³

In 1986, CERCLA was amended by the Superfund Amendment and Reauthorization Act of 1986 (SARA Amendments).¹¹⁴ These Amendments directed EPA to revise the HRS, to "assure to the maximum extent feasible, that the hazard ranking system accurately assesses the relative degree of risk to human health and the environment posed by sites and facilities subject to review"¹¹⁵ In furtherance of the goal, Congress directed EPA to consider several additional factors in its ranking of hazards. Those factors included:

1. Assessment of the human health risks associated with contamination or possible contamination of surface waters (directly, or as the result of runoff). Recreational values and possible migration to downstream drinking water sources should also be considered.
2. Assessment of potential damage to natural resources that might affect the food chain.
3. Assessment of potential contamination of the ambient air.¹¹⁶

In addition to the SARA Amendments providing that sites already scored under the old HRS would not be rescored according to the new HRS, required revisions of the HRS to address sites that contained substantial amounts of certain types of wastes regulated under the Resource Conservation and Recov-

111. 40 C.F.R. pt. 300, app. A, § 1.0.

112. *Id.*

113. HRS, Proposed Rule, 53 Fed. Reg. at 51,965.

114. Superfund Amendments and Reauthorization Act of 1986, Pub. L. No. 99-499, 100 Stat. 1613 (codified at 42 U.S.C. §§ 9601-75).

115. 42 U.S.C. § 9605 (c)(1).

116. 42 U.S.C. §§ 9605(a)(8)(A), (c)(2).

ery Act, such as fly ash, bottom ash, slag wastes, and flue gas emission control wastes.¹¹⁷

EPA published a notice of proposed rulemaking for HRS revisions on December 23, 1988.¹¹⁸ After considering comments, EPA published the revised HRS on December 14, 1990.¹¹⁹ The effective date of the new HRS was March 14, 1991. The revised HRS evaluates four pathways: groundwater migration, surface water migration, air migration, and exposure to soil. The groundwater and air pathways use single threat evaluations: people exposed or potentially exposed to contamination migrating from the site by those pathways. The soil exposure pathway evaluates two threats: resident population and nearby population. The surface water pathway evaluates three threats: drinking water, human food chain, and environmental. Those three threats are each evaluated for two separate migration possibilities: overland, flood migration and groundwater to surface water migration.¹²⁰

Each pathway score is still based on combining the three factor categories of the original HRS: "observed release" or "likelihood of release," "waste characteristics," and "targets." Each pathway score is the product of these three factor categories, divided by 82,500. The overall site score is still calculated by computing the root mean square of all the pathways.¹²¹

With a few exceptions, evaluations of the "waste characteristics" and "targets" categories are common to all pathways. These two categories each consist of a "potency" factor and a "potential for exposure" factor. The "release" or "likelihood of release" factors, which deal only with the "potential for exposure" aspect of risk assessment, are evaluated for each pathway. However, the criteria for an "observed release" are quite uniform throughout all pathways.

117. 42 U.S.C. §§ 9605(c)(3), 9618, 9625.

118. HRS, Proposed Rule, 53 Fed. Reg. 51,962.

119. Hazard Ranking System, Final Rule, 55 Fed. Reg. 51,532 (1990) (to be codified at 40 C.F.R. pt. 300) [hereinafter HRS, Final Rule].

120. *Id.* at 51,587, § 2.1.

121. *Id.* § 2.1.1.

C. *Waste Characteristics - A Combination of Hazard Identification, Dose-Response Assessment and Potential Exposure Factors*

1. Toxicity/Persistence/Bioaccumulation

As has been noted, the first step of any risk assessment is the identification of substances that may be potentially hazardous. In the new HRS, that task is simplified for the risk assessor because "hazardous substances" are defined to include only those substances identified in CERCLA as hazardous,¹²² and only those to which the potential for exposure exists.¹²³

One of the ways the HRS shortcuts more traditional risk assessment approaches is that, for each exposure pathway, only the potentially most hazardous substance in that pathway is evaluated for scoring purposes.¹²⁴ To determine what the potentially most hazardous substance is for a pathway, a value called the "toxicity-factor-value" is obtained.

The toxicity factor represents the potential for a substance to cause adverse health effects. It is basically a combination of hazard information and some dose-response data:

1. For cancer, Cancer Potency Factors (slope factors) are combined with the weight-of-evidence ratings for the carcinogenicity of the substance. This determination, accomplished by the use of a table in the Rule, results, as would be expected, in a very high score being given to a substance which is both potent (*i.e.*, has a high cancer potency factor), and is a probable human carcinogen. If a cancer potency factor is not available, the rule directs that an estimate be made, using the ED₁₀ for the substance. (The ED₁₀ is the estimated dose associated with a 10% increase in an endpoint — here, cancer — between test

122. CERCLA hazardous substances are those which are defined in Section 101(14) of CERCLA, 42 U.S.C. § 9601(14), and include a very broad range of substances, including those designated or listed as hazardous pursuant to several provisions of the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, CERCLA itself, and the Toxic Substances Control Act.

123. The potential for exposure exists if, for any pathway (groundwater, surface water, air, or soil) either an observed release has occurred or the source has a containment factor greater than zero (*i.e.*, there is some potential for the substance to escape). HRS, Final Rule, 55 Fed. Reg., at 51,588.

124. The use of only the single most hazardous substance in a pathway to score toxicity was criticized by a number of commenters to the rule, as being too conservative. However, EPA indicated that any other approach would be too complicated for a screening system. However, it did do some analyses and conclude that the use of the single substance approach usually resulted in an assigned value within one order of magnitude of what would have been assigned if more chemicals were considered. *Id.* at 51,543.

animals and control animals.)¹²⁵

2. For noncancer chronic toxicity, reference dose (RfD) values are used, again, with very low reference doses resulting in the highest score.

3. For noncancer acute toxicity, acute toxicity parameters, such as LD₅₀ or LC₅₀ are used.¹²⁶

If both a slope factor and an RfD are available, the values for each from the appropriate table should be assigned, and the higher one selected. If either a slope factor or an RfD is available, the value for that parameter should be assigned. If neither is available, the value for acute toxicity should be assigned. If no values are available, another hazardous substance must be selected.¹²⁷

There are six possible toxicity factor values: 10,000, 1,000, 100, 10, 1, and 0. If all substances at the site are assigned zero for a particular pathway because insufficient toxicity data are available for all the substances, a default value of one hundred must be assigned. If hazardous substances have usable toxicity data for multiple exposure routes (e.g., inhalation and ingestion), all exposure routes must be considered. After all the routes are considered, the highest assigned value must be assigned as the toxicity factor value, regardless of exposure route.¹²⁸

For HRS purposes, asbestos and all compounds of lead must be assigned a toxicity factor value of 10,000.¹²⁹ For radionuclides, a slightly different human toxicity factor approach applies:

1. All radionuclides are to be evaluated only on the basis of carcinogenicity, and all are to be assigned to weight-of-evidence Group A.
2. The human toxicity factor must be assigned on the basis of the Cancer Potency Factor (slope factor).
 - a. For each radionuclide the higher of the inhalation or ingestion slope factors is to be used.
 - b. If only one slope factor is available, it is to be used.
 - c. If no slope factor is available, the radionuclide should

125. *Id.* at 51,589, tbl. 2-4.

126. The original HRS had essentially considered only the potential acute effects of hazardous substances and had utilized the National Fire Protection Association rating scheme and the toxicity ratings developed by N.I. Sax., 40 C.F.R. pt. 300, app. A. The new HRS focuses much more on chronic effects, both cancer and noncancer. Only if evidence on chronic effects is not available are acute effects data used.

127. HRS, Final Rule, 55 Fed. Reg. at 51,589 tbls. 6, 7.

128. *Id.*

129. *Id.*

be assigned a zero, and another radionuclide should be used.

d. If all radionuclides have a value of zero, a default value of 1,000 is to be assigned.

3. If a site contains mixed radioactive and other hazardous wastes, the toxicity factor must be evaluated separately for each, even if they are physically or chemically combined.¹³⁰

Once toxicity-factor value has been determined, the HRS makes an effort to combine that value with some indication of how likely exposure is to occur by looking at factors that affect the longevity and mobility of the substance. These factors that affect those aspects vary according to the pathway, so a very brief description of each will be given below.

a. Groundwater

The major issue considered for groundwater is potential mobility. In order to understand the potential for substances to move to, and through, groundwater, a great many factors come into play. Among them are information about the concentrations of anions, cations, dissolved organics, pH, redox potential (Eh) and absorption characteristics of the geologic material. However, it is not feasible to get all that information at the HRS stage.¹³¹

Therefore, in the HRS, mobility is simplified. Mobility is evaluated for all hazardous substances capable of migrating to groundwater and moving in the aqueous phase. Any substance that is part of an observed release would be assigned the maximum value because its presence is an indication that it is sufficiently mobile. For substances not a part of an observed release, a mobility factor based on water solubility of the substance and the distribution coefficient, which is the measure of the extent of partitioning of a substance between geological materials and water, and referred to as K_d , is assigned. If the substance is present as a liquid, the water solubility is determined by that fact. For metals or metalloids, the overall range of water solubilities for all compounds of the substance, not just those present at the site, are determined and the geometric mean of the lowest and highest solubilities are calculated and used as the water solubility. For other hazardous substances, their actual

130. *Id.* at 51,664.

131. *Id.* at 51,566.

water solubilities are used.¹³²

Groundwater mobility is never assigned a value of zero.¹³³ The purpose of this is to prevent the understatement of the risk at sites that have a large volume of highly toxic hazardous substances with low mobility.

b. Surface Water

i. The Drinking Water Threat

For surface water used for drinking, the measure of longevity is persistence, or how long the contamination is apt to last. In both the proposed rule and the final rule, the measure for the tenacity of the contamination is "half-life."¹³⁴

The HRS persistence factor contains four decay processes: biodegradation, hydrolysis, photolysis, and volatilization. Once the half-life of the substance has been determined, the persistence value is assigned, based on the half-life of the substance and the type of surface water, which together represent the time the hazardous substance would take to travel through the water.

In addition, a sediment absorption factor has been added to account for contaminants sticking to sediment as the water travels away from the site.¹³⁵ Like groundwater mobility, surface water persistence is never assigned a value of zero. Since persistence is now multiplied by toxicity and quantity, a value of zero could understate the risk posed by a site with a large quantity of highly toxic hazardous substances with low persistence.

ii. The Human Food Chain Threat

Threats to the human food chain, toxicity and persistence of hazardous substances are calculated as previously described, with one exception. The water category used to assign the persistence factor is based on the type of water between the probable point of entry of contamination into the water and the nearest fishery, which is the HRS's one-step effort to approximate the human food chain.¹³⁶ In addition, for this threat the

132. *Id.* at 51,601-02.

133. *Id.*

134. Half-life is a concept most people are familiar with in the context of radioactivity. It means the length of time which must elapse, assuming natural radioactive decay, before half of the amount of the element (e.g., uranium) has decayed away. However, half-life can also be applied to other biological processes.

135. HRS, 55 Fed. Reg. at 51,612.

136. *Id.* at 51,617.

additional factor of bioaccumulation is added.

The data used to determine bioaccumulation potential is, in order of preference: bioconcentration factor (BCF) data for aquatic human food chain organisms, the logarithm of the octanol-water partition coefficient, and water solubility. Bioconcentration value assignments are made based on either Water Quality Criteria documents or on peer-reviewed literature. Whether the water body is fresh water or salt water is also an important factor when assigning bioconcentration values. If data on bioconcentration are not available, the log octanol-water partition coefficient has been shown to have a statistically significant linear correlation to the log of the bioconcentration factor for organic chemical compounds. Water solubility also has a statistically significant correlation with bioconcentration factors for organics.¹³⁷

iii. The Environmental Threat

For this threat, persistence is evaluated based on the type of water between the probable point of entry of contamination and the nearest sensitive environment. Bioaccumulation potential is evaluated in accordance with the method used for the human food chain threat, except: (1) BCF data should be used for all aquatic organisms, not just human food chain organisms, and (2) BCF data should be used that corresponds to the types of water bodies in which the sensitive environment, not fisheries, are located.¹³⁸

c. Air

For air, the potential exposure parameter again returns to simple mobility. Mobility is calculated differently for gases and particulates, as follows: (1) For gases: (a) a mobility factor of one is assigned to gases that meet the criteria for an observed release, (b) a mobility factor from a table is assigned, based on vapor pressure, if gaseous hazardous substances do not meet the criteria for an observed release; (2) for particulate substances: (a) a mobility factor of 0.02 is assigned to particulate hazardous substances that meet the criteria for an observed release, (b) a mobility factor is assigned from a figure and based on the site's location, for each particulate hazardous substance that does not

137. *Id.*

138. *Id.* at 51,622.

meet the criteria for an observed release, (c) for sites near the boundaries of the locations on the map, and for locations not on the map, a formula is used, based on mean average wind speed and the Thornthwaite P-E Index.¹³⁹

d. Soil

There is no mobility or longevity factor in the soil exposure pathway because the assumption is that soil doesn't have to go anywhere in order for exposure to occur.

2. Hazardous Waste Quantity - Another Way of Estimating Potential Exposure

Once the toxicities and mobilities/bioaccumulation attributes of various chemicals have been determined, the HRS directs that a hazardous waste quantity factor must be calculated for each of the three migration pathways - air, water, and soil. The quantity factor reflects the amount and duration of potential hazardous substance releases from the site.

The revised HRS provides that hazardous waste constituent concentration may be used to determine quantity, if that information is available. Otherwise, hazardous wastestream quantity, volume, or surface area of the site must be used, in that order.¹⁴⁰ The hazardous constituent concentration represents the actual quantity of hazardous substances deposited, which amounts to the total mass of all CERCLA hazardous substances in, and releases from the source or area of observed contamination for the soil exposure.¹⁴¹

The wastestream quantity factor represents the quantity of hazardous substances potentially deposited, based on available information about the nature and quantity of wastes that actually were deposited on the site. This factor consists of the mass of hazardous wastestreams plus the mass of any additional CERCLA pollutants and contaminants, either allocated to the source or released from the source or area of observed contamination.¹⁴² The volume of the source or, if that cannot be determined, the area of the source represents the quantity of hazardous substances potentially deposited on the site based on available information about the amount of hazardous substances

139. *Id.* at 51,655.

140. *Id.* at 51,590.

141. *Id.* at 51,990-92.

142. *Id.* at 51,591.

the site could have received.¹⁴³

For each of the sources in a pathway, values for the concentration, wastestream, volume, or area are assigned based on formulas set out in the rule. Once that has been done, the highest value assigned to the source or area of observed contamination is assigned as the source hazardous waste quantity value. These values, for all the sources in the pathway, are then added together. Based on that number, a hazardous waste quantity factor value is selected from Table 2-6 in the Rule. If sources contain both radioactive and non-radioactive substances, quantity factors for both must be calculated and they must be summed. The HRS Final Rule assigns the maximum value to hazardous substance quantities in excess of 1,000,000 pounds.¹⁴⁴

For all but two pathways or threats, the waste-characteristics-factor-category value will be the product of the toxicity value and the hazardous-waste-quantity-factor value, subject to a maximum of 1×10^8 . For the surface water human food chain threat and the surface water environmental threat, the maximum product is 1×10^{12} , due to bioaccumulation potential.¹⁴⁵ Thus, in a sense, the waste characteristics score is a mini-risk assessment combining factors of potency (*i.e.*, toxicity) and potential for exposure (*i.e.*, waste quantity and mobility/bioaccumulation).

However, it is unlikely that a large quantity of relatively hazardous material may be released or, if it is, that it would affect many people. Therefore, since use of a multiplicative relationship between hazardous waste quantity, toxicity, and other waste characteristics could produce a disproportionately large influence of the waste characteristics category relative to the likelihood of release and the target categories, EPA generally limits the values assigned to waste characteristics to one hundred, to limit its effect on pathway scores. The exception to this is that the characteristic score can go to one thousand in the human food chain threat and in the environmental threat of the surface water pathway, so as to account for bioaccumulation.¹⁴⁶

143. *Id.*

144. *Id.* at 51,591-92 tbl. 2-6.

145. *Id.* at 51,592 tbl. 2-7.

146. *Id.* at 51,542.

D. Targets - Another Effort to Combine Hazard Identification, Dose-Response Assessment and Exposure

As is the case with the waste characteristics category, the targets category combines features of hazard identification, dose-response assessment, and exposure evaluation. Each of these features will be discussed below.

1. Hazard Identification

The hazards to be evaluated vary depending on the pathway of potential exposure. The hazards are as follows:

a. For the Air Pathway:

- i. Substances for which National Ambient Air Quality Standards (NAAQSs) have been set, under sections 108 and 109 of the Clean Air Act.
- ii. Substances for which National Emissions Standards for Hazardous Air Pollutants (NESHAPs) have been set, under section 112 of the Clean Air Act.
- iii. Substances that are potential carcinogens by inhalation.
- iv. Substances for which an inhalation RfD has been established.

b. For the Groundwater Pathway:

- i. Substances for which Maximum Contaminant Levels (MCLs) or Maximum Contaminant Levels Goals (MCLGs) have been set, under section 1412 of the Safe Drinking Water Act.
- ii. Substances that are potential carcinogens, by ingestion.
- iii. Substances for which an oral RfD has been established.¹⁴⁷

c. For the Soil Pathway:

- i. Substances regulated under the Uranium Mill Tailings Radiation Control Act.
- ii. Substances that are potential carcinogens by ingestion.¹⁴⁸

147. *Id.* at 51,593.

148. For radionuclides, two measurements are made. One is for ingestion, the other is for gamma ray exposure through the skin. *Id.* at 51,663-64.

iii. Substances for which an oral RfD has been established.

d. For the Surface Water Pathway:

i. Drinking water threat:

- (a) Substances for which MCLs and MCLGs have been set.
- (b) Substances that are potential carcinogens by ingestion.
- (c) Substances for which an oral RfD has been established.

ii. Human food chain threat:

- (a) FDA Administrative Action Levels (FDAALs) for fish or shellfish.
- (b) Substances that are potential carcinogens by ingestion.
- (c) Substances for which an oral RfD has been established.

iii. Environmental threat:

- (a) Ambient Water Quality Criteria (AWQC) for protection of aquatic life, set under Section 304 (a)(1) of the Clean Water Act.
- (b) Ambient Aquatic Life Advisory Concentrations (AALAC) for acute or chronic toxicity to aquatic organisms.¹⁴⁹

2. Dose-Response Assessment

The dose-response assessment has already been performed in the HRS in the sense that levels of exposure have been established for the various hazards, and the score for each pathway is determined by reference to where the concentrations of hazardous substances fall, with respect to those levels. These levels are known as "benchmarks," and they are, as follows:

- a. MCLs and MCLGs (greater than zero).
- b. FDA Administrative Action Levels.
- c. Ambient Water Quality Criteria levels.
- d. Ambient Aquatic Life Advisory Concentrations.
- e. National Ambient Air Quality Standards (NAAQS).
- f. National Emission Standards for Hazardous Air Pollutants (NESHAP).
- g. Uranium Mill Tailings Radiation Control Act (UMTRCA) standards.
- h. The concentration that corresponds to the 1^{-6} individual cancer risk for inhalation exposures (air migration pathway) or oral exposures (groundwater migration pathway).

149. *Id.* at 51,593.

drinking water and human food chain threats in the surface water migration pathway, and the soil exposure pathway).

i. Screening concentrations for noncancer toxicological responses corresponding to the RfD for inhalation exposures (air migration pathway) or for oral exposures (groundwater migration pathway, drinking water and human food chain threats in surface water migration pathway, and soil exposure pathway).¹⁵⁰

3. Exposure Evaluation

Regardless of the pathway, there are four types of targets evaluated by the HRS. All targets have some evaluations in common, but there are some pathway-specific-target issues. The commonalities will be discussed first. Then, each pathway will be reviewed, briefly, for specific issues.

a. Common Features

For all pathways, four types of targets are examined:

- Potentially Maximally Exposed Individuals. The name of the factor varies by pathway and threat, (e.g., nearest drinking water well, nearest surface water intake, nearest fishery).
- Human populations.
- Resources, which vary by pathway and threat.
- Sensitive environments, which exist for all pathways except groundwater migration.¹⁵¹

The value assigned to each type of target depends on whether the target is subject to actual or potential contamination, and whether the actual contamination is Level I or Level II, as the HRS defines those terms.

Actual contamination is established by direct observation or sampling that meets the criteria for an "observed release," as defined.¹⁵² Level I concentrations for contaminants are those

150. *Id.*

151. *Id.* at 51,592.

152. A release may be "observed" by direct observation (*i.e.*, material from the site must be seen entering the medium being evaluated or that material must be known to have entered the medium through direct deposition, and that material must contain one or more hazardous substances including, where applicable, radionuclides). A release may also be "observed" by indirect observation. Such a release is established when a hazardous substance sample measurement equals or exceeds the sample quantitation limit (SQL) for that substance and is at least three times the background level for that substance (The SQL is the quantity of a substance that can be reasonably detected, given the limits of detection

concentrations that are above the specific benchmark values. Level II concentrations are levels below benchmark values but above the level for an "observed release."¹⁵³

Though the approach varies slightly, according to the various pathways, for the Maximally Exposed Individual, the following factor values are assigned: (1) Fifty points are assigned if any individual is exposed to Level I concentrations, (2) forty-five points are assigned if any individual is exposed to Level II concentrations, and (3) a maximum of twenty points is assigned if any individual is subject to potential contamination. The value assigned is then multiplied by the distance or dilution weight appropriate to the pathway.¹⁵⁴

For populations and sensitive environments, the following factor values are assigned:

1. Level I targets are summed and multiplied by ten. Level I is not used for sensitive environments in soil exposure and air migration pathways.
2. Level II targets are summed.¹⁵⁵
3. Potential targets are multiplied by distance or dilution values, summed, and then divided by ten.
4. The values for the three levels of exposure are summed.

For resources, resource value points are assigned within all pathways for welfare-related impacts (e.g., impacts to agricultural land) but do not depend on whether there is actual or potential contamination.

for the method of analysis and sample characteristics which may affect quantitation: for example, dilution or concentration). The available information must also support the attribution of some portion of the increase to the site. The background sample should be chosen to reflect the concentration of the hazardous substance in the medium exclusive of the contribution of any possible releases from the site.

If no background concentration is detected (i.e., the background level is below the analytical detection limits), an observed release occurs when the sample measurement equals or exceeds the SQL. If the sample quantitation limit is not known, EPA's contract-required quantitation limit (CRQL) or the detection limit may be used. Radionuclides are treated somewhat differently, depending on whether they occur naturally or are ubiquitous in the environment, are man-made and not ubiquitous, or (for the soil exposure pathway), are gamma-ray emitters. Evaluations of the potential for radioactivity to be released from a site are based on the physical and chemical properties of the radionuclides, not their level of radioactivity. *Id.* at 51,589, 51,563.

153. *Id.* at 51,592.

154. *See, e.g., id.* at 51,602-03, 51,613.

155. *Id.* at 51,603, 51,614.

*b. Pathway-Specific Features**i. The Groundwater Pathway*

The groundwater-target-factors category reflects the human population and resources potentially at risk from the actual or potential release of hazardous substances to an aquifer. The 1982 HRS evaluated two factors: a use factor and a factor that combined distance to the nearest well with the population served by the groundwater. Under the 1982 Rule, the use factor considered four uses for the water drawn from the aquifer within a three mile radius of the site: (1) drinking water with no unthreatened alternate source; (2) drinking water with alternate sources, and commercial, industrial, or irrigation uses without alternatives; (3) commercial, industrial, or irrigation uses with alternatives, or without, used but usable water; and (4) unusable water; the groundwater use with the highest factor was used to assign the value to that factor.¹⁵⁶

The revised rule considers the four factors: "Population," "nearest well," "resources," and "wellhead protection area."¹⁵⁷ In addition, the Rule establishes a "target distance limit," for determining which targets are to be included; that limit is either four miles from the site or the distance of the farthest well containing contamination attributable to the site, whichever is farther.¹⁵⁸

The "population" factor is an indicator of the number of people actually or potentially at risk from exposure to hazardous substances in drinking water. The original HRS gave equal weighting to all the people who lived within three miles of the site, combining that population with distance to the nearest well, in assigning a factor value. As noted, the new rule expands this area to four miles.

When determining the size of the population, residents, students, and workers who regularly use the water are to be considered. If population estimates are made based on the number of residences, each residence must be multiplied by the average number of persons per residence for that county. If water from wells in the target area is blended with water from other sources, the populations are to be apportioned, in accordance with

156. 40 C.F.R. pt. 300, app. A., § 3.5 (1990).

157. HRS, Final Rule, 55 Fed. Reg. at 51,551.

158. *Id.* at 51,595.

requirements set out in the rule.¹⁵⁹ The population served by water from each point of withdrawal is evaluated using either the Level I or II, or potential contamination concentrations, as discussed above.

The risk to the Maximally Exposed Individual of the HRS Proposed Rule was replaced in the HRS Final Rule by the "nearest well" concept. The concept, however, is essentially the same. For the "nearest well" factor, if a release is directly observed for any well within the target distance limit, that well is assigned Level II concentrations. However, if one or more samples meet the criteria for an observed release, the determination must be made as to whether Level I or Level II concentrations exist. The nearest well factor is then computed, as follows:

1. If one or more drinking water wells has Level I concentrations, the highest value fifty is assigned.
2. If one or more drinking water wells has Level II concentrations, a value almost as high as forty-five is assigned.
3. If no drinking water wells have Level I or II concentrations, but a karst aquifer underlies any part of the source, and a drinking water well draws from the karst aquifer, a value of twenty is assigned.
4. If no drinking water wells have had Level I or II concentrations, and there is no karst aquifer, the distance to the well nearest a source with a groundwater containment factor greater than zero is measured and converted to a value, using a table in the rule.¹⁶⁰

In the new rule, a "resources" factor assigns a value for certain beneficial uses that are within the target distance limit. These uses include irrigation for commercial crops, watering of commercial livestock, use as an ingredient in commercial food preparation, or supply for a water recreation area. The value is also assigned if the water in the aquifer is usable for drinking water, even if there are no wells within the target distance limit.¹⁶¹

A new HRS factor increases the target score if the source or its contamination are within a Wellhead Protection Area, designated under section 1428 of the Safe Drinking Water Act (*i.e.*, the area surrounding a well or wellfield supplying a public water system), and that source has a groundwater containment factor

159. *Id.* at 51,603.

160. *Id.* at 51,602-03.

161. *Id.* at 51,604.

value greater than zero.¹⁶²

ii. The Surface Water Pathway

a) *The Drinking Water Threat*

The new rule considers three factors: "population," "nearest intake," and "resources." The concept of the Maximally Exposed Individual is essentially incorporated into the "nearest intake" category.¹⁶³ To evaluate the "nearest intake" and "population" factors, the level of actual or potential contamination at the target surface water intakes must be determined. Contaminated sediments are evaluated using Level II concentrations. The nearest intake factor is computed like the "nearest well" factor of the groundwater pathway.¹⁶⁴

The new rule tracks the rules for groundwater in determining the population factor. The population factor is an indicator of the number of people actually or potentially at risk from exposure to hazardous substances in drinking water. To determine the population factor, residents, students, and workers are evaluated; residential population estimates must be based on population per residence for that county; if water is blended, the population can be apportioned; and the dilution-weighted population values for potential contamination are based on the type of surface water body (*i.e.*, size and flow of streams and rivers, depths of oceans and Great Lakes). Lakes, again, are treated separately.¹⁶⁵

b) *The Human Food Chain Threat*

The human-food-chain-threat category reflects the threat to people from consumption of aquatic food chain organisms. Since it is impossible to count the people who may eat fish in a potentially contaminated area, EPA initially proposed to estimate this number based on the amount of food chain products harvested from the water body and the bioaccumulation of the hazardous substance.¹⁶⁶ The Final Rule, however, took a similar approach to the groundwater and drinking water pathways, and provides for a "food chain individual" and a "food chain

162. *Id.*

163. *Id.* at 51,613.

164. *Id.*

165. *Id.* at 51,614.

166. *Id.* at 51,620.

population."¹⁶⁷

To evaluate the food chain individual and population factors, the level of actual or potential contamination at a fishery must be determined. If one or more fisheries are subject to actual food chain contamination, the determination must be made as to which parts of the fisheries are subject to Level I, Level II, and potential contamination. If the contamination is based on direct observation, it should be evaluated using Level II concentrations. However, if contamination is based on tissue samples from aquatic food chain organisms, those values should be used.¹⁶⁸ Once the determination of Level I or II fishery contamination is made, the population value factor is based on annual production by the fishery.¹⁶⁹

c) The Environmental Threat

The Final Rule expands the types of environments to be evaluated from wetlands and endangered species in the original HRS to include, among several others: National parks, wilderness areas, seashore recreational areas, national or state wildlife refuges, wild and scenic rivers, certain feeding areas and migratory pathways, and small areas important to the maintenance of unique biotic communities. Furthermore, all sensitive environments will be considered, not just the highest scoring one. Scores will differ, depending on actual or potential contamination. The Final Rule also adds a wetlands factor to the score, based on the amount of wetlands acreage contiguous to surface water bodies.

iii. The Air Pathway

In the Final Rule, the targets category is based on four factors: nearest individual, population, resources, and sensitive environments. Only those targets within four miles are to be considered, unless an observed release is established beyond the four mile limit. As in groundwater and surface water, the individual and population factors are based on whether the target populations are subject to Level I or II concentrations, or potential contamination. To determine the population factor, residents, students, and workers regularly present are considered.¹⁷⁰

167. *Id.* at 51,638.

168. *Id.*

169. *Id.* at 51,620-21.

170. *Id.* at 51,661.

Commercial agriculture or silviculture and major recreation areas are counted as resources, but they must be present within 0.5 miles of a source at the site having an air-migration-containment value greater than zero.¹⁷¹

Sensitive environments are evaluated based on either actual or potential contamination.¹⁷² As in the surface water pathway for sensitive environments, a wetland factor, based on acreage of the wetlands, is also added.¹⁷³

iv. The Soil Exposure Pathway

The Final Rule considers five factors: the resident individual, the resident population, workers, resources, and terrestrial sensitive environments.¹⁷⁴ For resident individuals, the highest score is assigned if at least one resident is in an area subject to Level I concentrations. There is a conversion table for workers.¹⁷⁵

Target populations include a "nearby-individual-factor" which is based on the population within a one-mile travel distance of the site. The nearby individual factor is based on the distance from the nearest residence or school to the source of contamination. The resident population factor is calculated by counting residents and students within the specified distances from the site. Unlike in the groundwater and surface water pathways, workers are not counted.¹⁷⁶

A value is assigned to the resources factor if commercial agriculture, silviculture, livestock production, or livestock grazing are present on an area of observed contamination at the site.¹⁷⁷ A value is assigned to the factor from a table that lists terrestrially sensitive environments if such an environment is located in an area of observed contamination.¹⁷⁸

E. Likelihood of Release

1. Introduction

The "likelihood of release" portion of the HRS is strictly a

171. *Id.*

172. *Id.* at 51,662.

173. *Id.* at 51,662 tbl. 6-18.

174. *Id.* at 51,647.

175. *Id.* at 51,647 tbl. 5-4.

176. *Id.* at 51,647-48.

177. *Id.* at 51,647.

178. *Id.* at 51,647-48.

measure of the potential for exposure. Therefore, it is appropriately considered as a part of the exposure assessment portion of the risk assessment process.

In all pathways, the "likelihood of release" category is divided into two subcategories. The first, and the one which generates the highest "likelihood of release" score in all pathways, is "observed release." The ways an observed release is to be established have already been discussed. If there is no "observed release," the HRS directs that the "potential to release" be evaluated. The factors that affect the "potential to release" are pathway specific, so each pathway will be discussed in turn.

2. The Groundwater Pathway

In the original HRS, the "potential to release" was evaluated by considering what the "route characteristics" were. Those characteristics included: (1) The depth to the aquifer of concern, (2) the net precipitation, (3) the permeability of the unsaturated zone, (4) the physical state of the materials on the site, and (5) the containment at the site.¹⁷⁹

The proposed HRS would have evaluated four factors: containment, net precipitation, depth of aquifer/hydraulic conductivity and absorptive capacity.¹⁸⁰ Although the proposed revisions to the HRS in this area were those that might be seen in a full blown risk assessment, they were really far more complicated than would have been appropriate for a screening system. For example, the proposal would have combined the "depth to aquifer" factor with the "thickness-weighted" hydraulic conductivity of all the layers of geologic material between the contaminant source and the aquifer. The purpose of this approach was to provide an indication of the relative travel time required for migration to the aquifer. Aquifer depth would be measured down to 800 feet, instead of the 1982 HRS's 150 feet, and out to a distance of two miles. The thickness weighting would not apply to karst layers of material, in which water moves through openings in the rock caused by dissolution of the rock itself, (e.g., limestones). Information regarding possible aquifer interconnections (such as literature, well logs, pump tests, and observed migration) was to be used to characterize the aquifers,

179. Protection of the Environment, 40 C.F.R. pt. 300, app. A, §§ 3.2, 3.3.

180. HRS, Proposed Rule, 53 Fed. Reg. at 51,984.

vertically and horizontally.¹⁸¹

EPA also proposed to add an absorptive capacity factor to the groundwater "potential to release" category. This factor would have measured the potential of different types of geologic materials to absorb contaminants and therefore retard their migration to aquifers. The absorptive capacity would be evaluated based on the clay and organic carbon content of the geologic materials.¹⁸²

The Final Rule is simpler. It still requires evaluation of possible aquifer interconnections. It eliminates, however, absorptive capacity altogether, makes "depth to aquifer" and "travel time to aquifer" separate categories, and eliminates the requirement to consider all geologic layers between the hazardous substance and the aquifer in determining the travel time to the aquifer.¹⁸³ The "depth to aquifer" is measured within two miles or as far out as contamination attributable to the site extends. Three depth ranges are evaluated: less than 25 feet, 25-250 feet, and greater than 250 feet. If the necessary geological information is available for multiple locations, all values must be used.¹⁸⁴ The "travel time" factor, the depth to aquifer/hydraulic conductivity factor in the proposed rule, is now based on the layer with the lowest hydraulic conductivity at least three feet in depth and greater than ten feet below the source. This value may be taken from a table in the rule or it may be measured. If more than one layer has the lowest hydraulic conductivity, they may be summed. The highest travel time factor value must be used.¹⁸⁵

Karst layers that underlie the site are still given special consideration regarding "depth to aquifer" and "travel time." When determining depth, karst layers are not considered. If all layers between a site and an aquifer are karst, the soil is considered to have no ability to retard the flow of contaminants.¹⁸⁶

In the new rule, there is a net precipitation factor value that is designed to indicate the amount of water available for infiltration to groundwater. The new rule simplifies the method used to compute precipitation. Now, net precipitation factor values can

181. *Id.*

182. *Id.* at 51,984-85.

183. HRS, Final Rule, 55 Fed. Reg. at 51,553-54.

184. *Id.* at 51,600 tbl. 3-5.

185. *Id.* at 51,600.

186. *Id.*

be taken directly from maps in the Rule or a calculation can be made of annual precipitation and converted to a net precipitation factor value by the use of a table.¹⁸⁷

There is a "containment" factor considered under both the old and the new rules. This factor measures the means taken to minimize or prevent the release of hazardous substances from a site to the groundwater. However, the new rule is more comprehensive than the original rule. It discusses surface impoundments, land treatment areas, containers, tanks and other sources. Only sources that meet the minimum size requirement (*i.e.*, that have a source hazardous waste quantity value of 0.5 or higher) are used in assigning containment factor values. This is to ensure that very small uncontained sources do not unduly influence the score.¹⁸⁸ For example, a site might have a large, but well-contained source and a very small, uncontained source. Without a minimum size requirement the "potential to release" could be assigned based on the very small source, which could overestimate the hazard posed by the site.

The potential-to-release factor value is the sum of net precipitation, depth to aquifer, and travel time, multiplied by the containment factor.

3. The Surface Water Pathway

The likelihood-of-release factors are the same for all three "threat" evaluations, under the surface water pathway (*i.e.*, drinking water, human food chain, and environmental). Under the original HRS, a release was scored if it was demonstrated that a site had released hazardous substances to surface water. Aquatic, benthic, sediment sampling, or direct observation could be used to demonstrate the release.¹⁸⁹ The old HRS calculated the potential to release by multiplying route characteristics by the containment. Route characteristics included the slope of the site; the slope of intervening terrain; the one-year, twenty-four hour rainfall; the distance to the nearest surface water; and the physical state of the waste.¹⁹⁰

The new HRS replaces the potential-to-release factors with two new ones: overland flow or potential-to-release by flood and groundwater-to-surface-water migration. With respect to both

187. *Id.* at 51,596.

188. *Id.* at 51,595-96.

189. 40 C.F.R. pt. 300, app. A, § 4.1.

190. *Id.* at § 4.2.

of these migration components, the migration "path" is defined to include both the overland segment and the in-water segment hazardous substances would take as they migrate away from sources at the site.¹⁹¹

As is the case with other pathways, an "observed release" for the surface water pathway is established by direct observation or by chemical analysis. For direct observation of overland flow, it is necessary to have seen a material that either contains one or more hazardous substances enter the surface water through migration or is known to have done so through direct deposition. For direct observation in the flood situation, it is necessary that the source area have been flooded and that hazardous substances have been in contact with the flood waters. Finally, when evidence supports the inference of a release, demonstrated adverse effects associated with that release can be used to establish an observed release.

To obtain a chemical analysis, surface water, benthic, or sediment samples may be analyzed. Samples, however, must be compared to similar types of background material. For benthic samples, comparisons should be limited to sessile organisms.¹⁹²

Overland flow is the sum of the runoff and the distance to surface water factors, multiplied by the overland containment factor.¹⁹³ A "rainfall/runoff" value would be obtained from a table comparing soil group with two-year, twenty-four hour rainfall. That number would then be compared to the drainage area value, to get the runoff factor value.¹⁹⁴

As noted, these runoff and distance-to-surface water sub-factors would be multiplied by the overland containment factor value. This factor is a measure of the means taken to minimize or prevent the release of hazardous substances to surface water and is set out in detail in Table 4-2 of the rule. If one or more sources is physically located in surface water, even if the source is a sealed container, the maximum value is assigned. Again, only sources that meet the minimum size requirement (*i.e.*, those which have a source hazardous waste quantity value of 0.5 or higher) are used in assigning containment values.¹⁹⁵

The old HRS did not score for potential-to-release by flood.

191. HRS, Final Rule, 55 Fed. Reg. at 51,605.

192. *Id.* at 51,609.

193. *Id.*

194. *Id.*

195. *Id.*

Under the new rule, each source on a site is evaluated separately for the floodplain in which it is located. The value is calculated by multiplying the flood frequency by the flood containment value. The highest value calculated is the one used for the potential-release-by-flood factor.

4. The Air Pathway

The criteria used to score an observed release are the same as those discussed for water: direct observation or chemical analysis of samples.¹⁹⁶ When evidence supports the inference of a release, demonstrated adverse effects may be used to establish an observed release.¹⁹⁷ Potential releases are scored in response to a mandate in SARA.

In the Final Rule, the potential to release is separately evaluated for a gas potential to release and a particulate potential to release for each source at the site. This is to avoid the problem of having a high score assigned to gas because of its high mobility value. The highest potential-to-release value, either gas or particulate, that has been calculated for any of the sources evaluated is the value assigned as the site potential-to-release factor category.¹⁹⁸

Gas potential to release should be considered for every source that contains gaseous hazardous substances with a vapor pressure greater than 10^{-9} torr. Three factors are to be evaluated: gas containment, gas source type, and gas migration potential.¹⁹⁹

Maximum gas containment factor values are assigned if there is evidence of a biogas release, if there is an active fire within the source, or if there is little soil cover and poor vegetation.²⁰⁰

The gas source type is assigned a value based on whether it meets the minimum size requirement. The size requirement is based on the source-hazardous-waste-quantity value. If the source has hazardous waste which is assigned a quantity value of 0.5 or more, it meets the minimum size requirement. There are a number of source types, which are also used for particulates. These include fire areas, containers or tanks, contaminated soil,

196. *Id.* at 51,651.

197. *Id.*

198. *Id.*

199. *Id.*

200. *Id.* at 51,652.

landfarms, landfills, piles of various sorts, and surface impoundments, which may have been either buried or backfilled or neither.²⁰¹

Gas migration potential is measured by the use of the vapor pressure and Henry's Constant (the meter-kilogram-second unit of inductance, equal to the inductance of a circuit in which an electromotive force of one volt is produced by a current in the circuit that varies at the rate of one ampere per second). The migration potential is derived by averaging the migration potential for the three gases having the highest migration potential.²⁰²

The gas potential-to-release value is determined by summing the gas-source-type-factor value and migration-potential-factor value and multiplying that sum by the gas-containment-factor value.²⁰³

The particulate potential-to-release value is evaluated for those sources with particulate hazardous substance (*i.e.*, those with a vapor pressure less than or equal to 10^{-1} torr). As with gases, the particulate potential to release is based on three factors: containment, source type, and migration potential.²⁰⁴

The containment factor values are set out in a table.²⁰⁵ Only sources that are completely covered either by liquid or by impermeable, regularly inspected, and maintained cover receive the lowest score. Values for particulate source types are to be assigned in the same manner as those for gas sources. Migration potential is determined by reference to a table or by calculation of a value, based on the Thornthwaite P-E Index, the mean monthly precipitation and the mean monthly temperature.²⁰⁶

The particulate potential-to-release value is calculated by adding each particulate-source-type-factor value and particulate-migration-potential-factor value and then multiplying by the particulate-containment-factor value.²⁰⁷

5. Soil Exposure Pathway

a. *The Resident Population Threat*

The resident population threat resulting from surface con-

201. *Id.* at 51,652 tbl. 6-4.

202. *Id.* at 51,652.

203. *Id.* at 51,653.

204. *Id.*

205. *Id.* at 51,653 tbl. 6-9.

206. *Id.* at 51,653-55 tbl. 6-10.

207. *Id.* at 51,655.

tamination could be documented by analytical evidence of hazardous substances. If the hazardous substance is not present on the surface, the threat could also exist if the hazardous substance is not covered with less than two feet of cover material, unless that material is essentially impenetrable. For contaminated soil, areas between contaminated sampling should also be considered to be contaminated areas, unless available evidence indicates otherwise. The soil exposure pathway need not have a release potential component, as do the other pathways, because no migration is necessary.²⁰⁸ Samples of potentially contaminated areas would be taken at specified depths below the surface. The Proposed Rule indicated that, if surrounding properties were contaminated, it may be possible to infer onsite contamination, even in the absence of soil sample contamination. The Final Rule, however, specifies that the resident population threat will be evaluated only if contamination is observed within the property boundary or within 200 feet of a residence, school, day care center, or workplace; within the boundaries of a natural resource; or "within the boundaries of a sensitive terrestrial environment."²⁰⁹

b. The Nearby Population Threat

The Final Rule includes in nearby populations only those who live or go to school within one mile of the observed contamination. It also replaces the Proposed Rule's concept of "accessibility/frequency of use" with a simpler "attractiveness/accessibility" factor measured as part of the likelihood of exposure, along with the area of contamination.²¹⁰

A designated recreation area would have the highest "attractiveness/accessibility" score, and one regularly used for recreation would have the next highest score. Only if it were physically inaccessible to the public would it be scored a zero. The nearby population likelihood-of-exposure-factor value would be a comparison of the attractiveness/accessibility-factor value and the area-of-contamination-factor value.²¹¹

208. *Id.* at 51,646.

209. *Id.*

210. *Id.* at 51,648.

211. *Id.* at 51,648 tbls. 5-6, 5-8.

V. CONCLUSION

The risk assessment process, despite its widespread use by federal agencies, remains a complex and difficult procedure. As has been shown, the lack of a consistent methodology for risk assessment among the different agencies makes it difficult for the regulated public to determine the regulatory consequences of their behavior.

Our exploration of risk assessment procedures within the framework of the Hazard Ranking System is but one approach to making the process comprehensible. It should be noted that, given the limited objective of this article, the discussion of many of the components of risk assessment was superficial. Each of the components could themselves be the focus of lengthy analysis and discussion.

By far the most problematic aspect of risk assessment methodology is that, in reaching a conclusion, agencies often pile uncertainty atop uncertainty. Critics of this procedure claim that this practice results in standards that are too conservative and subject parties to burdensome requirements that are in no way based on a realistic appraisal of the pertinent risks. Supporters of the current methodology allege that given the unknowns and the potential for irrevocable harm, it is better to err on the side of caution.

Due to the complexity of the terrain, therefore, the risk assessment process has spawned something of a scientific cottage industry, devoted exclusively to analyzing and evaluating the various choices available at every step of the process. Not surprisingly, these efforts have resulted in even more complexity. They have also served to create adversarial relationships among the government, states and localities, site and facility owners and the public, when the use of more realistic assumptions, by all sides, might have produced workable solutions. Sadly, this situation does not appear likely to change in the near future. Hopefully, this article helps to explain how risk assessment works, so that those involved in decisions that employ the process may better evaluate how best to present their position.