Monte Carlo Simulation in Environmental Risk Assessment — Science, Policy And Legal Issues*

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Introduction

Monte Carlo simulations have become increasingly common in environmental health and safety risk assessments. They have been promoted as part of a larger movement to incorporate "quantitative uncertainty analysis" into risk estimates that form the basis of environmental health and safety standards.[1] This trend is likely to be furthered because the Environmental Protection Agency (EPA) recently adopted a policy,[2] approving this and other probabilistic analytical tools and is gearing up to implement the expected increase in use.[3]

The EPA[4] and the National Academy of Sciences,[5] have recognized Monte Carlo methods as means of quantifying variability

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* Adapted from Monte Carlo Simulation and Judicial Review — An Uncertain Future, presented at a Risk Assessment and Policy Association meeting in Alexandria, Virginia, Mar. 1997. The author thanks David Burmaster of Alceon Corporation, for suggesting readings on Monte Carlo methods, Professor John P. Simons, Department of Chemistry, University of Utah, for consulting on Monte Carlo simulation, and Professors Vern R. Walker, Jonathon B. Wiener, and Robert Adler for comments on earlier drafts. This work was supported by the University of Utah College of Law Research Fund.

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1 Several risk bills considered in the 104th Congress would have required quantitative uncertainty analysis as a component of regulatory rulemaking. *See, e.g.*, H.R. 415(1)(B), 104th Cong., 1st Sess. (1995).

2 Environmental Protection Agency (EPA), Policy for Use of Probabilistic Analysis in Risk Assessment at the U.S. Environmental Protection Agency (1997) (hereafter Probabilistic Analysis Policy).

3 *See* Senior EPA Science Group Approves Probabilistic Analysis Policy, Inside EPA's Risk Policy Report 6, 6-7 (Feb. 21, 1997) (hereafter Inside EPA).

4 *See, e.g.*, EPA, Guidelines for Exposure Assessment, 57 F.R. 22,888, 22,899, 22,922, 22,927 (1992).

5 National Research Council, Science and Judgment in Risk Assessment (1994).

and uncertainty in risk assessments. The regulated community has responded favorably to at least some uses, partly because it can avoid, or at least illuminate, the degree of conservatism that results from the compounding of conservative assumptions employed in typical deterministic risk assessments.[6]

To date, there has been little discussion of Monte Carlo simulations in court opinions[7] — perhaps not surprising given the technical nature of this computational technique and courts' inclinations to defer to agency expertise. There are, however, a number of policy issues regarding the use of Monte Carlo techniques that agencies deciding whether and how to implement them will have to address. Eventually, reviewing courts will be called upon to address those policies, including whether Monte Carlo simulations were appropriate or even required in particular cases, or whether they were properly done. Monte Carlo analysis also may indirectly impact review of risk-based standards, by making uncertainties and underlying policy choices more apparent or, conversely, more opaque.[8] This article will identify some of the more significant policy questions regarding the use of Monte Carlo techniques in environmental risk assessment and possible administrative and judicial responses to them.

Monte Carlo Simulations in Environmental Risk Assessment

Monte Carlo simulation is a widely used computational method for generating probability distributions of variables that depend on other variables or parameters represented as probability distributions.[9] Although Monte Carlo simulation has been used since the 1940s, more powerful desktop computers have made it accessible and attractive for

6 *See, e.g.*, Risk Assessment, A Flexible Approach to Problem Solving 22-24 (Chem. Mfrs. Assn. 1996).

7 For an interesting discussion of a Monte Carlo simulation in a context unrelated to risk assessment, *see* U.S. v. Shonubi, 895 F. Supp. 460 (E.D.N.Y. 1995), *vacated and remanded*, 103 F.3d 1085 (2d Cir. 1997), on remand, 962 F. Supp. 370 (E.D.N.Y. 1997).

8 Ultimately, agencies' use of Monte Carlo methods could cool some of the impetus for statutorily mandated quantitative uncertainty analysis, but no such dampening of enthusiasm is apparent to date. The Levin-Thompson Regulatory Improvement Act of 1997, S. 981, continues to require explication of the uncertainties and variabilities in risk assessments. *See* 143 Cong. Rec. S6728, S6742 (1997) (section 624 of S. 981).

9 Robert H. Harris & David E. Burmaster, *Restoring Science to Superfund Risk Assessment*, Toxics L. Rep. (BNA) 1318, 1322 (1992).

many new applications. That availability has coincided with increasing dissatisfaction with the deterministic or point estimate calculations typically used in quantitative risk assessment; as a result, Monte Carlo simulation is rapidly gaining currency as the preferred method of generating probability distributions of exposure and risk.

To date the technique has been used primarily in exposure assessments, a practice that EPA plans to continue in human health risk assessment,[10] but Monte Carlo techniques can be applied to other parameters in a risk assessment, such as the sampling and curve fitting uncertainty in dose-response modeling from animal bioassays.[11]

Monte Carlo methods are to be contrasted with the deterministic methods used to generate specific single number or point estimates of risk.[12] An example involving children's exposure to a nonvolatile carcinogenic soil contaminant through ingestion will illustrate the difference. The intake or ingestion rate of the contaminant is the product of its soil concentration and the amount of soil consumed within a time frame.[13] It is evident that both parameters will vary — soil concentrations of the contaminant at various locations at the site and children in how much contaminated dirt they ingest in a given period.[14] Further, the actual distribution of values for each of these factors may be uncertain.[15]

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10 *See* Probabilistic Analysis Policy, *supra* note 2, at 2.

11 *See, e.g.*, Dennis J. Paustenbach, *Retrospective on U.S. Health Risk Assessment: How Others Can Benefit*, 6 Risk 283, 302 (1995)(suggesting Monte Carlo techniques should be applied to dose-response assessment).

12 Monte Carlo simulations are a computationally efficient method, but not the only one, for generating probability distributions that incorporate the uncertainty and variability of the underlying independent variables.

13 It is an understatement to say that this example is greatly simplified. Thompson, et al., give a "simplified" treatment of a risk assessment for dermal contact with contaminated soil that utilizes 17 parameters; distributions, rather than single point values, were used for 12 parameters. Kimberly M. Thompson, David E. Burmaster & Edmund A.C. Crouch, *Monte Carlo Techniques for Quantitative Uncertainty Analysis in Public Health Risk Assessments*, 12 Risk Anal. 153, 55-56 (1992).

14 Children would also vary in the duration and frequency of contact. These factors are omitted from the discussion for simplicity.

15 For example, the actual probability distribution for a variable may be poorly characterized. *See* William J. Brattin, Timothy M. Barry & Nancy Chiu, *Monte Carlo Modeling with Uncertain Probability Density Functions*, 2 Hum. & Ecol. Risk Assess. 820, 821-22 (1996). The carcinogenic potency is also subject to uncertainty: there is sampling and curve-fitting uncertainty, which depends on the size of the study populations and number of data points, which can be propagated through the dose

Monte Carlo simulation would involve many calculations of the intake rate rather than a single calculation; for each calculation, the computation would use a value for each input parameter randomly selected from the probability density function for that variable. Over multiple calculations, the simulation uses a range of values for the input parameters that reflects the probability density function of each input parameter. Thus, the repetitive calculations take many randomly selected combinations of the amount of soil consumed and soil contamination levels into account, generating a probability density function or cumulative density function for the output. Based on the distribution of the output, a risk level representing the high end (e.g., 95th percentile), central tendency (median or mean), or any other desired level of probability can be identified.

This simple example suggests a Monte Carlo simulation in which variability and uncertainty are not treated separately — the probability density function for each input parameter would reflect both the inherent parameter heterogeneity and uncertainty about the accuracy of measurements.[16] Thus, the output probability distribution similarly would reflect both undifferentiated variability and uncertainty. However, it may be important for some purposes to disaggregate the effects of variability and uncertainty on the output which can be achieved through second order Monte Carlo simulation.[17]

When Monte Carlo Methods Make A Difference

Advantages of Monte Carlo methods in environmental risk assessment flow from the fact that their outputs provide more

extrapolation model. *See, e.g.*, Thompson, et al., *supra* note 13, at 57-58. There also is uncertainty about the appropriate mathematical models for the high-dose/low-dose and interspecies extrapolations. The appropriate treatment of model uncertainty is discussed *infra* at notes 52-62.

16 As used herein, parameter uncertainty is to be distinguished from model uncertainty, which reflects lack of knowledge about the relationship between the variables in the underlying mathematical equation and the physical phenomenon being modeled. *See* David E. Burmaster & Andrew M. Wilson, *An Introduction to Second-Order Random Variables in Human Health Risk Assessments*, 2 Hum. & Ecol. Risk Assess. 892 (1996).

17 For an example separately accounting for variability and uncertainty in ecological risk assessment, *see* David L. MacIntosh, Glenn W. Suter II, & F. Owen Hoffman, *Uses of Probabilistic Exposure Models in Ecological Risk Assessments of Contaminated Sites*, 14 Risk Anal. 405 (1994).

information than deterministic point estimate calculations.[18] Distribution functions for the exposure or risk estimate display the range of exposure or risk and the probability associated with each value of exposure or risk.[19] A point estimate does not provide this information. For example, a point estimate of the central tendency of exposure of risk does not indicate the uncertainty of the estimate. It may be important to know both the high end of the range of risk as well as the central tendency, if the goal is to avoid an unacceptable outcome, such as a core meltdown of a nuclear reactor. Similarly, a high-end point estimate may be much higher than the central tendency; the point estimate does not indicate how much higher it is than the median or mean of the exposure or risk. Both kinds of information are useful to risk managers.[20]

The probability distributions created by Monte Carlo methods display the location of any particular risk estimate within the range of risk. Thus it is possible to determine that a particular risk or exposure level represents the 50th, 90th, 95th percentile or any other percentile level of risk, or conversely, to select a level of exposure or risk that corresponds to the desired level of protection. If variability and uncertainty are treated separately, it is possible to use the output of a Monte Carlo simulation to select both the segment of the population to be protected and the degree of confidence that the desired level of protection will be achieved.[21]

The second advantage is related to the first: because the methods provide probability distributions of exposure or risk, they avoid the problems of compounding conservative values of input variables.[22] For

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18 *See* David E. Burmaster, *Benefits and Costs of Using Probabilistic Techniques in Human Health Risk Assessments — With an Emphasis on Site-Specific Risk Assessments*, 2 Hum. & Ecol. Risk Assess. 35 (1996); Brent Finley & Dennis Paustenbach, *The Benefits of Probabilistic Exposure Assessment: Three Case Studies Involving Contaminated Air, Water, and Soil,* 14 Risk Anal. 53, 54-57 (1994).

19 The output is, however, limited by the information about the input variables and the physical processes represented by the model, as well as choices about the way the simulation is run.

20 Uncertainties in risk assessment can be very large; recent calls for regulatory reform have included quantification of uncertainty as a key element of the proposed changes. *See supra* note 1.

21 *See* Kimberly M. Thompson & John D. Graham, *Going Beyond the Single Number: Using Probabilistic Risk Assessment to Improve Risk Management*, 4 Hum. & Ecol. Risk Assess. 1008, 1025 (1996).

many environmental risk assessments, the goal of determining an upper bound of risk has dictated the selection of values from the upper end of the ranges for some of the variables.[23] The resulting point estimate of exposure rate is thus deliberately calculated as a conservative or high-end estimate, but it may be far above any realistic estimate.[24] EPA exposure and risk estimate protocols tend to produce point estimates that exceed the 95th percentile of the Monte Carlo probability distribution, sometimes by orders of magnitude. Such unrealistically high point estimate calculations result from the multiplication of high-end values for input parameters.[25] The larger the number of multiplied variables for which high-end values are selected, the higher the resulting exposure estimate is likely to be in relation to the overall distribution of the exposure or risk.[26] Thus, while point estimates obtained from the mean values of input parameters tend to fall close to the mean of the probability density function of the output,[27] it is not uncommon for point estimates obtained from high-end values of the input variables to exceed the 95th percentile of the output probability density function, sometimes by a factor of a hundred or more.

Where risk assessment drives standard setting, Monte Carlo simulation can make a large difference in regulatory and cleanup

22 *See* David E. Burmaster & Robert H. Harris, *The Magnitude of Compounding Conservatism in Superfund Risk Assessments*, 13 Risk Anal. 131, 133-134 (1993); Finley & Paustenbach, *supra* note 18, at 69-70.

23 *See* Russell E. Keenan, Brent L. Finley & Paul S. Price, *Exposure Assessment: Then, Now, and Quantum Leaps in the Future*, 14 Risk Anal. 225, 226-27 (1994). For example, in calculating the intake rate used as an example above, the risk assessor might select the highest or the upper 95th percent confidence level of the arithmetic mean for contaminant soil concentration, and a similar high end or conservative estimate of the amount of soil consumed by children in calculating the intake rate. Median or mean values may be used for other variables, such as body weight and lifespan.

24 In the examples of intake rate calculation, *supra* notes 13-15, point estimates calculated using high-end estimates of soil consumption rate and contaminant levels represent an unlikely scenario because the children who ingest the largest amounts of soil are unlikely to ingest only the most contaminated soil, and the most contaminated areas are unlikely to be visited only by children who eat the most soil.

25 *See, e.g.*, Kenneth T. Bogen, *A Note on Compounded Conservatism*, 14 Risk Anal. 379 (1994).

26 *See* Alison C. Cullen, Measures of Compounding Conservatism in Probabilistic Risk Assessment, 14 Risk Anal. 389 (1994).

27 *See* G. Mark Richardson, *Deterministic Versus Probabilistic Risk Assessment: Strengths and Weaknesses in a Regulatory Context*, 2 Hum. & Ecol. Risk Assess. 44, 46 (1996).

standards.[28] For example, Burmaster and Harris report that the New Jersey Department of Environmental Protection's choice of upper bound values for three exposure factors in a soil ingestion risk assessment for chloroform result in a risk estimate of 8.3×10^{-6}; a Monte Carlo simulation, in contrast, results in a 95th percentile risk of 9.5×10^{-7}, almost a factor of ten lower.[29]

Additional advantages flow from information provided by Monte Carlo simulation.[30] Results are conducive to sensitivity analysis, permitting the risk assessor to determine where additional data will be most useful in reducing uncertainty. The need to select a single value for the input parameters is avoided, which can be a contentious exercise in itself. Even so, one can envision contentious disagreements over the adequacy of data, the appropriate form of the distribution function fitted to a parameter, and the uncertainty assigned to the probability density function, so the result may be to shift the argument to a new issue, rather than to avoid it altogether. However, where those issues can be resolved, probabilistic methods permit a conservative or health protective risk management decision, but one that is made in recognition of the degree of conservatism or risk involved in the decision, and the degree of uncertainty about the actual risk distribution.

The proponents recognize that Monte Carlo methods have some disadvantages as well as advantages. They require more data; otherwise, uncertainties in the input parameters may result in large uncertainties in the resulting risk estimates. Clearly, they require a greater level of mathematical and computer sophistication than point estimate calculations, a matter recognized in the new EPA policy.[31] Checking the accuracy of Monte Carlo simulations is difficult; in contrast, results of point estimate calculations can to some degree be checked with a hand calculator.

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28 Roy F. Smith, *Use of Monte Carlo Simulation for Human Exposure Assessment at a Superfund Site*, 14 Risk Anal. 433 (1994). Smith found that point estimates produced in accordance with EPA Superfund guidance were close to the 95th percentile values produced by Monte Carlo simulations using probability density functions for exposure variables.

29 Burmaster & Harris, *supra* note 22, at 133.

30 Burmaster, *supra* note 18, at 38; Finley & Paustenbach, *supra* note 18, at 55-57.

31 *See supra* note 2, at 4.

A second set of disadvantages is also related to the greater complexity of Monte Carlo simulations as compared to point estimate calculations. The amount of information required for the calculations and generated as output may obscure the underlying assumptions of the calculation. In its most straightforward form, Monte Carlo simulation usually assumes that input parameters are independent;[32] if they are not, some adjustment may be necessary. As with any use of a mathematical model, the results are only as good as the assumptions, and the choice of assumptions, particularly simplifying ones, requires professional judgment. The greater complexity also presents challenges to effective risk communication and public participation in regulatory proceedings, a concern that is discussed more fully below.

How Extensively Should Probabilistic Methods Be Used

The mathematical nature of Monte Carlo techniques tends to restrict focus on its use to questions that appear to be technical and scientific. Proponents have characterized it as restoring science to risk assessment and facilitating the separation of risk assessment and risk management.[33] These seem to be valid assertions insofar as they refer to the ability of Monte Carlo techniques to incorporate the full range of available data for input variables and avoid the need for policy decisions about the best single value of each, as is required for single point estimates of risk. Monte Carlo techniques in and of themselves do not dictate any particular degree of protectiveness or conservatism, they provide more information for implementation of such policy choices.

The use of Monte Carlo simulation to propagate uncertainty in the values of input variables to the output is also relatively straightforward and may be valuable to the consumer of the information, particularly if such techniques are combined with sensitivity analysis to determine the major and perhaps reducible sources of uncertainty in risk estimates. Some kinds of uncertainty, such as sampling and measurement uncertainty, can be estimated with a reasonable degree of confidence, and thus, their incorporation in probabilistic calculation seems relatively

32 *See* David E. Burmaster & Paul D. Anderson, *Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Assessments*, 14 Risk Anal. 477, 479 (1994).

33 *See, e.g.,* Burmaster, *supra* note 18, at 39.

uncontroversial. Monte Carlo simulation using probability distributions for the input variables can give a measure of the overall uncertainty in the output that is attributable to the uncertainties in the input parameters. Yet, despite these advantages, there are policy issues concerning whether and how to use Monte Carlo simulations that cannot be resolved simply as a matter of adopting "good science."

Since these techniques are more demanding of data and therefore more costly, a threshold question is how widely they should be used. Opponents of increased emphasis on quantitative risk assessment are unlikely to favor the additional resources that probabilistic methods will surely require.[34] Paradoxically, since quantitative risk assessment can only address risks that have to some degree been anticipated and investigated, increased focus on the quantitative aspects of risk assessment may further obscure the fact that for many substances there are little or no hazard data and quantitative risk assessment is currently therefore infeasible.[35] Others have questioned the value of routine numerical uncertainty analysis as introducing confusion and complexity into an already complex process, wasting time and resources.[36] The resource demands are being evaluated by EPA, and will be dealt with through identification of aspects of risk assessment where probabilistic methods will be most useful.[37]

34 *See, e.g.,* Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment,* 5 Yale J. Reg. 89 (1988); David A. Wirth & Ellen K. Silbergeld, *Risky Reform,* 95 Colum. L.Rev. 185 (1995).

35 In a recent rulemaking lowering the permissible exposure levels for methylene chloride, the Occupational Safety and Health Administration (OSHA) referenced a study that used Monte Carlo simulation of parameter uncertainty in a physiologically-based pharmacokinetic (PBPK) risk assessment. One commenter asserted that the uncertainty associated with PBPK risk assessments is lower than that of risk assessments that do not consider them. OSHA, Occupational Exposure to Methylene Chloride, 62 F.R. 1494, 1540 (1997). OSHA responded:

> Quantification of uncertainty does not equate with reducing uncertainty in an analysis. In fact, at a different level, the assumptions made… may serve to underestimate the uncertainty inherent in the PBPK-based risk assessment if the underlying assumptions are wrong.

Id.

36 Bernard D. Goldstein, *Risk Management Will Not Be Improved by Mandating Numerical Uncertainty Analysis for Risk Assessment*, 63 U. Cinn. L.Rev. 1599 (1995). Dr. Goldstein's critique was directed to proposals in various risk bills in the 104th Congress, not to "the itemization and discussion of crucial uncertainties that underlie any risk assessment and, in certain circumstances, the different risk estimates that result." *Id.* at 1601.

37 Inside EPA, *supra* note 3, at 7.

The most serious concern about the use of probabilistic risk assessments is that they will present a large barrier, in some instances perhaps an insurmountable one, to public participation in risk assessment and decisions based on risk assessment. The results of probabilistic risk assessment will be stated as ranges or as a series of values modified by confidence levels or percentiles, rather than as single values. Understanding and interpreting the output requires more sophistication than the public is usually credited with, given that most public discourse about health and safety issues focuses on whether something is or is not "safe."

A related problem is the difficulty the lay public is likely to have comprehending the process by which probabilistic risk estimates are produced. An understanding of the underlying assumptions and their impact on the risk estimate is essential to meaningful input and commentary on the risk assessment. EPA guidance requiring that the bases of risk calculations be provided will be helpful to those who have the time and expertise to examine them.[38] However, industry representatives are far more likely to have such resources than environmental organizations or community groups near Superfund sites. Technical Assistance Grants provided for in CERCLA may prove to be useful, but they are limited to $50,000.[39] Meaningful public participation will require further consideration as the use of probabilistic techniques increases.

To What Should Probabilistic Methods Be Applied

To date, EPA has used Monte Carlo techniques primarily for exposure analysis, but they can be applied to other aspects of risk estimation, including the sampling and curve-fitting uncertainties in the calculation of carcinogenic potency factors.[40] Some commentators

38 *See* EPA, Guiding Principles for Monte Carlo Analysis at 11-21, (1997) (hereafter Guiding Principles) <http://www.epa.gov/ncea/monteabs.htm> (WordPerfect version).

39 Comprehensive Environmental Response, Compensation, and Liability Act § 103(e), 42 U.S.C. § 9617(e) (1997).

40 Current EPA guidance calls for extrapolation from the lower 95% confidence limit on a dose that produces a 10% response, in essence another upper bound estimate, given the sampling uncertainty. *See* EPA, Proposed Guidelines for Carcinogen Risk Assessment, 61 F.R. 17,960, 17,962 (1996). The dose-response uncertainty can be propagated through a Monte Carlo simulation, however, which

have recognized or even advocated the extension of Monte Carlo simulation to carcinogenic potency factors, with the expectation that the resulting risk distributions would diverge even more markedly from point estimate calculations.[41] Probabilistic methods have also been proposed for noncancer risk estimation.[42]

Development of Guidance for Application of Monte Carlo Methods

EPA and other agencies have not resolved the extent to which specific guidance will cabin the application of probabilistic techniques. Some commentators have identified the absence of regulatory guidance as a barrier to use of probabilistic methods in risk assessment.[43] Although Monte Carlo techniques avoid some of the problems of deterministic calculations, some science policy issues remain. For example, there will be many instances when the data or theories called for in the risk assessment are not available and must either be supplied through surrogates or assumptions.[44] Elicitation of expert opinion, both informally and formally, is being used to fill some of these gaps.[45] Some limits on professional discretion and judgment seem inevitable, and indeed, EPA's probabilistic risk assessment policy specifies eight conditions that must be met when a Monte Carlo analysis is used in a risk assessment, largely directed toward requiring full explanations of the underlying data, assumptions and methods.[46]

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would tend to produce still lower risk estimates than current practices produce. This issue appears to be under consideration at EPA. *See* Probabilistic Analysis Policy, *supra* note 2, at 7; OSHA, Occupational Exposure to Methylene Chloride, Final Rule, 62 F.R. 1494, 1540 (1997) (discussing Monte Carlo simulation of uncertainty in parameters of physiologically-based pharmacokinetic modeling).

41 *See* Paustenbach, *supra* note 11, at 302.

42 *See* Sandra J. S. Baird, et al., *Noncancer Risk Assessment: A Probabilistic Alternative to Current Practice,* 2 Hum. & Ecol. Risk Assess. 79 (1996).

43 Kimberly M. Thompson & John D. Graham, *Going Beyond the Single Number: Using Probabilistic Risk Assessment to Improve Risk Management*, 4 Hum. & Ecol. Risk Assess. 1008, 1025 (1996).

44 Some instances where gap-filling assumptions will remain controversial are assumptions about contaminant distributions and contaminant concentrations below the analytical detection limits. *See* Keenan, Finley & Price, *supra* note 23, at 227-228.

45 *See* John S. Evans, et al., *A Distributional Approach to Characterizing Low-Dose Cancer Risk*, 14 Risk Anal. 25, 31 (1992).

46 These conditions bear more than a little resemblance to recommendations found in David E. Burmaster & Paul D. Anderson, *Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Assessments,* 14

EPA has also just issued a guidance document,[47] in connection with the adoption of its new policy on probabilistic risk assessment and is reportedly developing case studies illustrating the application of Monte Carlo analysis.[48] On the other hand, it is unlikely that any guidance document can anticipate all issues likely to arise in connection with Monte Carlo analysis or other probabilistic methods, and it would be unfortunate if overly specific and rigidly applied guidelines undermine the potential for these techniques to provide risk assessments carefully tailored to the situation at issue.

Guidance on Policy Issues

Guidance is appropriate, however, on the fundamental policy questions that are implicated in Monte Carlo analysis. Monte Carlo techniques, like uncertainty analysis generally, do not obviate the hard policy choices, such as which groups deserve protection and at what levels. Some of these issues will affect the design of the input probability distributions, some will affect the manner in which the Monte Carlo analysis is designed and conducted, and some will affect how the output is interpreted.

Should, for example, standards be designed to protect the randomly selected individual to a maximum one-in-a-million risk at a 95% confidence level, or to protect all but the most susceptible 5% of the population to a one-in-a-million risk at a 95% confidence level? The choice will dictate whether variability and uncertainty must be disaggregated in the Monte Carlo simulation.[49]

What is the appropriate duration of residence for the Most Exposed Individual (MEI) for the purposes of the residual risk regulation under the hazardous air pollutant provisions of the Clean Air Act? What percentile of risk represents the MEI? These issues affect both the input distribution, with respect to assumptions about the duration of residence near the site,[50] and the interpretation of the output with

Risk Anal. 477 (1994). The guidance accompanying the Probabilistic Analysis Policy, *supra* note 2, contains a more extensive set of principles, on which the eight conditions listed in the policy are based. Guiding Principles, *supra* note 38.

47 Guiding Principles, *supra* note 38.

48 *See* Probabilistic Analysis Policy, *supra* note 2, at 7.

49 *See* Thompson & Graham, *supra* note 43, at 1013-15.

respect to what percentile of the risk distribution must be protected at the specified risk level.[51]

Should risk assessments at Superfund cleanup sites assume possible uses that appear unlikely, such as residential development, or should a more likely scenario of industrial or commercial use be the basis of the assessment? The assumptions about future use affect various inputs, such as whether the risk assessment should address the risks of children playing outdoors at the site or adult workers visiting the site primarily during working hours. Requirements to clean up to levels suitable for onsite residential occupancy may be particularly demanding and tend to drive cleanup requirements. This issue is particularly important in connection with redevelopment of old industrial sites.

A significant policy issue concerns how to deal with model uncertainty, such as the uncertainty about the proper dose-extrapolation model for carcinogenicity assessment.[52] Monte Carlo and other probabilistic analytical techniques are relatively straightforward as applied to parameter variability, the natural heterogeneity of a system, and parameter uncertainty, the uncertainty about the true value of the parameter in question. On the other hand, model uncertainty represents a lack of knowledge about the way that variables are related to each other and thus constitutes uncertainty about whether a model approximates a real-world process or relationship.[53]

50 If the MEI is treated as an individual who will reside next to a facility for her entire lifetime, it would be improper to use a probability distribution of residence duration as a the input variable. *See* Paul S. Price, James Sample & Robert Stricter, *Determination of Less-Than-Lifetime Exposures to Point Source Emissions,* 12 Risk Anal. 367, 380 (1992).

51 Is it the $100^{[(N-1)/N]th}$ percentile where the exposed population has N individuals? Or does the 95th or 99th percentile represent an adequately protective assumption for the MEI? *See* Science and Judgment in Risk Assessment, *supra* note 5, at 205 (suggesting the first interpretation). This assumption avoids outcome manipulation by selection of the population over which exposure is estimated.

52 EPA is apparently grappling with the question of how to address dose-response issues under its new Probabilistic Analysis Policy, but has not yet taken a position on dose-response and related issues *see* Probabilistic Analysis Policy, *supra* note 2, at 2. The statistical and curve-fitting uncertainty associated with animal bioassays can be characterized as parameter uncertainty and are potential candidates for Monte Carlo simulation. *See* EPA, Proposed Guidelines for Carcinogen Risk Assessment, 61 F.R. 17,960, 17,993-96 (1996). The choice of a dose extrapolation model (e.g., linear or nonlinear) is subject to model uncertainty because without a mechanistic understanding of the processes at work for a given carcinogen, the appropriate mathematical model cannot be determined scientifically.

53 Of course, models are always inaccurate to some degree because real-world

The current approach to carcinogen dose-extrapolation uncertainty is the use of a default model, selected to err, if at all, on the side of overestimating risk.[54] Some researchers, however, have developed techniques for utilizing subjective probabilities to generate probability distributions of risk that incorporate quantitative treatment of model uncertainty.[55] The meaning of probability distributions generated through such methods is problematic, however.

Model uncertainty is not a distribution of a natural phenomenon (such as parameter variability), nor is it an uncertainty estimation that converges on a measured value or set of values (like parameter or measurement uncertainty). With respect to dose extrapolation models, a particular carcinogen probably acts through one mechanism or another and thus is more accurately represented by one model or another.[56] With mechanistic information, experts may be able to denominate one model as representing the likely mechanism of action; without mechanistic information, there may be no evidentiary basis for selecting one model over another. In the latter case, expert judgement expressed as subjective probabilities cannot be validated experimentally.

A single probability distribution that included dose extrapolation model uncertainty could be very misleading. It would tend to suggest that a risk lies somewhere in between the values predicted using the "conservative" model (such as the linearized multistage nonthreshold model) and some other model (such as a threshold model). This is a little like asking four experts whether a compass needle points north or south. If two experts indicate north and two indicate south, a simulation incorporating their subjective estimates might suggest the

phenomena are too complex to be represented by manageable mathematical expressions. Nonetheless, it still seems useful to distinguish between cases where the modeler understands the processes represented by the model even if she must use simplified expressions to represent them, and instances where there is a lack of understanding of a fundamental process, such as the mechanism of carcinogenesis for a particular substance, so that the modeler cannot choose scientifically among basic forms of modeling equations.

54 For a taxonomy of methods for dealing with model uncertainty, *see* Clark D. Carrington, *An Administrative View of Model Uncertainty in Public Health*, 8 Risk 58 (1997).

55 John S. Evans et al., *supra* note 45.

56 Some carcinogens may act through two multiple mechanisms, each of which would require its own dose extrapolation model.

compass points east, a result that obscures the dichotomous nature of the phenomenon. Evans, et al., incorporate subjective estimates of model uncertainty into a probabilistic risk assessment for formaldehyde carcinogenicity for which they report 50th and 90th percentile risk estimates which differ by a factor of 10^8.[57] Where model uncertainty spans many orders of magnitude, the high end (e.g., 95th percentile) estimate and the central tendency would likely either exceed or underestimate the true risk by orders of magnitude, depending on which model is correct.

This issue is closely related to the question of when to depart from default assumptions about dose-extrapolation models, currently under consideration in connection with the revision of EPA's Carcinogen Risk Assessment Guidelines.[58] Under the proposal, expert judgment and peer review will determine when a default assumption will be abandoned in the face of new information.[59] Most practitioners appear not to have incorporated quantitative estimates of model uncertainty into their analyses.[60]

In Science and Judgment in Risk Assessment, the NAS noted the problems with incorporation of subjective assessments of model uncertainty into probability distribution functions, suggesting that such quantitative analyses of model uncertainty be reserved for priority setting and risk trading.[61] For standard setting, residual risk determinations and risk communication, however, the NAS recommended that separate analyses of parameter uncertainty be conducted for each relevant model (rather than a single hybrid distribution), with additional reporting of the subjective probability that each model is correct.[62] That approach avoids the interpretative problems identified above and the potential for obscuring the policy choice necessitated by the absence of more definitive information.

57 John S. Evans et. al., *supra* note 45.

58 *See supra* note 52, at 17,968-970.

59 *Id.* at 17,964-966.

60 *See* Burmaster & Anderson, *supra* note 46, (including no principle on model uncertainty). Thompson & Graham, *supra* note 43, at 1028, similarly decline to address how risk assessment and risk management should deal with model uncertainty, although they also acknowledge it as an important issue.

61 *See supra* note 5 at 171-75.

62 *Id*.

Legal Challenges

The paucity of legal opinion addressing Monte Carlo techniques[63] gives one pause at suggesting that Monte Carlo simulation will ever be challenged, much less successfully, on judicial review.[64] Judges will likely be disinclined to delve into their intricacies, likely characterized as technical and scientific and subject to a longstanding judicial deference.[65] Monte Carlo simulation and other probabilistic methods will in many cases strengthen the scientific basis of a risk-based decision, since the risk assessment will involve a more comprehensive analysis of risk than alternative point estimates. In any event, directives set forth in guidance documents are usually not reviewable as such. Judicial scrutiny will have to await a challenge to the techniques in a specific application. Challenges in the Superfund context may be especially difficult to mount, since judicial review of remedy selection must usually wait until the remedy is implemented.

One cautionary note is suggested by the fact that Monte Carlo simulations will tend to make risk estimates appear less certain than otherwise, since they will be presented as probability distributions rather than single numbers. A court faced with a costly standard based on an admittedly uncertain risk estimate could be sympathetic to arguments that the regulation is unjustified, leading the court to require that the agency find a more robust basis for the standard.[66] In the proper case,

63 A number of decisions of the Interior Board of Land Appeals have considered challenges to fair market value determination for oil and gas leases, based on discounted cash flow modeling using Monte Carlo techniques. These decisions have generally upheld the results where the input and modeling assumptions were adequately disclosed and explained. *Compare* Southern Union Exploration Co., 97 IBLA 322 (1987)(upholding rejection of bid on oil and gas lease) *with* Suzanne Walsh, 75 IBLA 247 (1983)(vacating rejection of bid based on unexplained reference to Monte Carlo simulation).

64 Thompson & Graham posit that risk managers may be hesitant to use probabilistic methods out of concern that they may result in litigation, although they conclude that this fear is likely to be unfounded. *See* Thompson & Graham, *supra* note 43, at 1026.

65 Both the arbitrary and capricious and substantial evidence standards of proof are highly deferential. *See, e.g.,* Western Resources, Inc., v. Federal Energy Regulatory Comm'n, 9 F.3d 1568, 1574 and n.8 (D.C. Cir. 1993).

66 *See* Gulf South Insulation v. U.S. Consumer Product Safety Comm'n, 701 F.2d 1137 (5th Cir. 1983). Here the Fifth Circuit vacated the CPSC's ban on urea-formaldehyde foam insulation, finding the rule unsupported by substantial evidence. Evidence of carcinogenicity, which the court rejected as insufficient, involved a single animal study. *Id*. at 1146. The court noted that the resulting risk number, which was presented as a range from zero to 51/1,000,000, was highly uncertain, stating, "[t]o

a number of challenges might be made to the use of Monte Carlo simulation.

For environmental agencies, Monte Carlo and other probabilistic techniques will often represent a departure from prior practices and the policy choices implicit within them, which may result in heightened judicial scrutiny should their use be challenged.[67] This kind of challenge should be easily answered, provided the agency has explained the basis for implementation of probabilistic methods.

Other possible challenges to risk assessments involving Monte Carlo simulation include claims that it should or should not have been used in a particular instance.[68] An assertion that Monte Carlo simulation should have been used is evident in a recent EPA hazardous waste delisting decision, where challengers have claimed that Monte Carlo methods should have been applied to the exposure assumptions used to establish health-based levels.[69] Other commenters on EPA delisting decisions have objected to the use of Monte Carlo simulation in connection with the Composite Model for Landfills, apparently arguing for more realistic, less "conservative," site-specific point estimates.[70]

The NRC's experience with probabilistic risk assessment may be instructive. It has used probabilistic risk assessment for a number of years, culminating most recently in a 1995 Final Policy Statement.[71]

make precise estimate, precise data are required." *Id*.

67 In Citizens Awareness Network, Inc. v. U.S. Nuclear Regulatory Comm'n, 59 F.3d 284 (1st Cir. 1995), the First Circuit overturned a decision of the Nuclear Regulatory Commission changing its policy on review of decommissioning plans for nuclear power plants. *Id.* at 291-92. The court found that the Commission had not set forth a reasoned basis for its reinterpretation of its regulation.

68 *See* Edison Elec. Inst. v. EPA, 2 F.2d 438 (D.C. Cir. 1993). Here an industry petitioner contended that Monte Carlo simulation should have been used to develop a biodegradation constant for chloroform in groundwater. *Id.* at 448. The court appeared to accept EPA's explanation that it lacked the necessary data, ultimately concluding that the petitioner could not raise the issue on appeal because it was not discussed in comments during the rulemaking. *Id.*

69 *See, e.g.*, EPA, Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Exclusion, 58 F.R. 40,067 (1993) (contention EPA should have used Monte Carlo simulation, rather than point estimate, to generate high end exposure estimate).

70 EPA, Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Exclusion, 60 F.R. 31,107 (1993). The EPA used Monte Carlo simulation to generate landfill scenarios from which it derived dilution and attenuation factors (DAFs) used to evaluate the risks of landfill disposal of delisted waste.

The NRC's initial limited uses of probabilistic methods were expanded after the 1979 accident at Three Mile Island and currently are applied to design certification, reactor licensing and waste disposal.[72] Probabilistic risk assessment methods were originally challenged as faulty by opponents of nuclear plants, but their objections failed.[73]

The NRC initially focused on median values generated in probabilistic risk assessments, a practice that was criticized by one of its commissioners[74] and subsequently changed to focus on mean estimates of risk.[75] At first hearing, this may seem puzzling because one of the primary benefits of probabilistic methods is that they provide an estimate of the uncertainty of mean or median estimates, indicating whether there is a significant probability that actual risk is higher than the mean or median value. Evidently, the NRC's focus on median estimate from probabilistic analysis does not mean that the NRC ignores the remainder, especially the high ends, of the probability distributions of risk. Rather, the NRC also considers the uncertainty of any probabilisitic risk estimate, although apparently without specific numerical acceptance criteria for required confidence levels.[76]

The NRC experience also indicates that probabilistic methods are not favored only by those opposing stringent regulatory requirements. In Sierra Club vs. NRC,[77] licensing opponents relied on a probabilistic

[71] NRC, Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement, 60 F.R. 42,622 (1995). The NRC apparently uses Monte Carlo simulation in certain aspects of its risk assessments. *See, e.g.,* In the Matter of Northeast Nuclear Energy Co., 38 N.R.C. 5, 1993 NRC LEXIS 33 (July 9, 1993)(discussing Monte Carlo simulation of pool reactivity in connection with spent fuel pool design).

[72] *Id.* at 42,622-623.

[73] *See* Union of Concerned Scientists v. U.S. NRC, 880 F.2d 552 (D.C. Cir. 1989); Limerick Ecology Action v. U.S. NRC, 869 F.2d 719 (D.C. Cir. 1989).

[74] *See* NRC, Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants, 50 F.R. 32,138 (1985) (dissenting views of Commissioner Asselstine).

[75] NRC, Safety Goals for the Operation of Nuclear Power Plants; Policy Statement; Correction and Republication, 51 F.R. 30,028, 30,031 (1986) (hereafter 1986 policy Statement). The NRC also continues to utilize deterministic risk estimates in its decisionmaking. *See* NRC, Use of Probabilistic Risk Assessment in Nuclear Regulatory Activities; Final Policy Statement, 60 F.R. 42,622 (1995). This 1995 policy reiterates the breadth of use of probabilistic risk assessments in NRC activities. *Id.*

[76] *See* 1986 Policy Statement, *supra* note 75 at 30,031. *See also* Draft NRC Regulatory Guide, *supra* note 71 at 13-19.

risk assessment that identified a high likelihood of fire and radiation release in the event of any one of several accident scenarios. Although risk estimates for the accident scenarios were low, authors of the study noted that the estimates were "quite uncertain" and recommended certain precautions. The Ninth Circuit held that the Sierra Club should have been permitted to intervene in the license amendment proceedings.[78] A probabilistic risk assessment can indicate, as it did for the Diablo nuclear power plant, that although the expected or median value of the risk is acceptable, the upper range may not be.

Undoubtedly courts will in time be faced with contentions that a Monte Carlo simulation, although warranted, was improperly conducted. That kind of assertion could be based on factual or policy grounds. A recent article critiques the EPA's use of Monte Carlo simulation to generate a range of landfill scenarios for which it calculated dilution and attenuation factors for waste constituents that might migrate from landfills.[79] It concludes that the scenarios generated in simulation combined the soil characteristics of Phoenix, the rainfall of Seattle and the population density of Newark.[80] If correct,[81] that would represent a failure to recognize and account for the interdependency of variables — landfills are unlikely to be built in sandy soils in highly populated, high rainfall areas. There is ample judicial precedent for rejection of modeling based on assumptions not supported by, or at odds with, ascertainable facts.[82] Where various

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77 Sierra Club v. U.S. NRC, 862 F.2d 222, 226-28 (9th Cir. 1988).

78 *Id.* The Court also held that the NRC had improperly considered the merits of the Sierra Club's contention, and further declined to address the merits itself. *Id.* at 228-29.

79 *See* Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment,* 19 Harv. Envt'l L.Rev. 409, 446-450 (1995).

80 *Id.* at 461-64.

81 When EPA published its delisting methodology in connection with a delisting petition, one commentator objected to what it viewed as over-simplified, unrealistic and conservative simulation scenarios, while a second comment raised the possibility of impossible combinations. EPA, Hazardous Waste Management System: Identification and Listing of Hazardous Waste; Final Exclusion, 56 F.R. 67,197, 67,201, 67,204 (1991). Although EPA responded that the model checked for impossible combinations, *id*. at 67,204-205, Shere concludes that the simulation generated "impossible" combinations and that the agency provided inadequate explanation of any mechanism that would have prevented such combinations from being generated. Shere, *supra* note 79, at 462-64.

82 In Leather Indus. Am., Inc., v. EPA, 40 F.3d 392 (1994), the D.C. Circuit held that the EPA failed to supply a rational basis for its risk estimate for selenium, where

factual interpretations are arguable, however, a court is likely to accord the agency deference.

Policy issues, on the other hand, might be raised by a misapplication of the concept of the MEI under the residual risk provisions for hazardous air pollutants. As described earlier, the risk assessment required by the Clean Air Act requires a determination whether the MEI will be assumed to reside at the site for a lifetime, and what percentile of risk adequately represents the MEI. EPA's determination on either issue could be subject to challenge, and such a challenge would likely be characterized as one of law and policy rather than as purely factual or scientific. Policy issues are more clearly fair game for judicial intervention than are issues characterized as science,[83] but even here, administrative agencies are entitled to deference in interpreting ambiguous statutory mandates .[84]

Conclusion

Monte Carlo simulation and other methods of probabilistic risk assessment are already bringing more information and more sophisticated uncertainty analysis into risk assessment. However, these methods raise many policy and legal issues which may be obscured by the complexity of the methods. These issues are only beginning to be examined in the probabilistic framework. If Monte Carlo and other probabilistic methods are to fulfill their promise in environmental risk assessment, the discussion of those issues and the development of appropriate guidance and legal rules must grow apace.

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the exposure assessment assumed daily contact by children at sites such as highway medians, to which children would not have access. *Id*. at 404. *See also* Susan R. Poulter, *Science and Pseudo-Science: Will Daubert Make a Difference?* Proc. 40th Ann. Inst., Rocky Mountain Mineral Law Foundation, 7-1, 7-39 to 7-41 (1994).

83 Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 Colum. L.Rev. 1613, 1661-67 (1995).

84 Chevron v. NRDC, 467 US 837 (1984).