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Conservative versus Mean Risk Assessments: Implications for Superfund Policies*

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This paper explores how a shift to more central estimates of risk would affect EPA decisions to remediate hazardous waste sites in the Superfund program. Analysis of 141 sites indicates that the EPA's use of conservative parameter values results in risk estimates that are 27 times greater than those based on mean values. Over 40% of sites requiring remediation would shift into the discretionary cleanup range if mean parameters were used. Though this paper examines the effect of using mean parameters for contaminant concentrations, exposure duration, and ingestion rates, additional adjustments for other conservative parameters might increase this effect. © 1997 Academic Press

I. INTRODUCTION

To regulate hazards from toxic substances rationally, regulators must have some sense of whether the risks are consequential. Quantitative risk assessment has become an increasingly important tool for determining whether a source of risk is significant enough to warrant regulatory attention, how stringently to design regulation, and how to allocate limited regulatory resources. Risk assessments are, however, subject to great uncertainty and variability. Risk estimates have typically treated such uncertainties conservatively through the assumptions and default positions mandated by policymakers. However, some analysts have suggested that mean risk assessments would produce a more realistic measure of expected policy consequences. In response to these and other concerns, Congress has considered

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but has not yet enacted legislation that would change the nature of risk assessment in many federal agencies, calling for ‘‘realistic’’ and ‘‘central’’ estimates of risk to be used in evaluating regulatory alternatives.[1]

The context for our analysis of these risk assessment practices is the U.S. Environmental Protection Agency's (EPA) Superfund program. This effort is well suited to examining risk assessments because of the extensive data generated by site investigation and decision documents. We use data on risk assessments from 141 Superfund sites and examine the risk management implications of alternatives based on the use of mean parameter values instead of the conservative default values presently employed by the agency. If mean parameters are employed, over 40% of the sites that now require remediation under conservative guidelines are shifted downward into the range of risks where EPA managers have greater discretion over whether to remediate or not.

The paper is structured in the following manner. Section II presents an overview of conservatism in assessment. We relate these concerns to specific aspects of Superfund risk regulation in Section III. We present data and methodology in Section IV, results in Section V, and conclusions in Section VI.

II. CONSERVATISM AND RISK ASSESSMENT[2]

The desire for caution or prudence in risk management, which we call conservatism, may arise directly from political considerations [21] as well as from concerns regarding uncertainty and variability about the nature and magnitude of the hazard. Uncertainty reflects a lack of knowledge of the system and can be reduced through further measurement, at least in principle. Biases toward regulation (conservative choices) in the face of uncertainty reflect a ‘‘better safe than sorry’’ approach to risk management. This may reflect a greater loss from not regulating when it is warranted than from regulating when it is not warranted.[3] Variability refers to the inherent heterogeneity in human behaviors and characteristics. Conservatism based on variability is consistent with policy that is based on protecting individuals suffering the greatest potential risk and has been characterized as a determination of ‘‘who's safe and who's sorry.’’[4] If risk is monotonically increasing in the relevant variable, then this might be better phrased as ‘‘how many safe and how many sorry.’’

Potential difficulties may arise if policymakers use conservative risk assessment values. If, for example, the 1000 residents near a Superfund site face a 0.5 chance that the risk of cancer is 1/1000 and a 0.5 chance that it is 3/1000, the conservative approach would assess the cancer risk as 3 cases rather than the 2 expected cases of cancer. Protecting society through conservative risk assessments that guard against false negatives consequently overstates the expected benefits of

[1] Bills of the 104th Congress with such provisions included HR690, HR2500, S291, S343, and S1285.

[2] Reviews of risk assessment practices and conservatism appear in Graham *et al.* [11], Latin [16], and Lave *et al.* [17].

[3] This is essentially the distinction between Type II and Type I errors drawn in statistics and econometrics. See Krier [15] and NRC/NAS [19] among others. It has been argued that these false negatives may be catastrophic so policy should therefore be biased in favor of false positives [22].

[4] We thank an anonymous referee for noting this distinction.

regulation by overestimating mean risks. An alternative mechanism for being ‘‘conservative’’ and protective is to use a higher implicit value of life associated with the lives saved or attach a higher value to the environmental benefits.

Conservatism in risk regulation is analogous to ambiguity aversion bias, which is one form of irrationality of choice under uncertainty. In situations involving lotteries to win a prize, the well-known Ellsberg Paradox has documented the predilection of individuals to prefer precisely understood chances of winning a prize to less precise and more uncertain chances of winning a prize. An analogous form of irrationality affects individual decisions involving the potential for environmental losses [36] which creates situations of ambiguity aversion. In situations in which people are exposed to environmental risks, they tend to prefer policies that reduce uncertain risks to policies that reduce a more precisely understood risk, for any given mean value of risk. Other aspects of risk perception and behavior under uncertainty also seem consistent with conservative risk regulation.[5]

Advocates of the conservatism approach might suggest that conservatism is needed because of the presence of a variety of other complicating uncertainties, such as synergistic effects. If, however, one wished to adjust for other potential risk factors, one should do so explicitly. There is no reason to believe that such influences are always systematically correlated with the degree of uncertainty in the parameters in the analysis of the chemicals at the site. This more explicit adjustment procedure also would give a role to such influences in contexts in which the site risk assessments are quite precise. There would be no role for a conservatism bias, but there nevertheless would be a mechanism for recognizing synergistic effects.

Recent legislative proposals included requirements that risk characterizations make apparent the distinction between data and policy assumptions,[6] and that preference be given to model assumptions and input parameters that represent the most plausible or realistic inference from scientific data.[7] Some proposals would have required that quantitative risk assessments be calculated using the ‘‘best estimate for each input parameter.’’[8] Superfund, under consideration for reauthorization at the time of this writing, may be subject to similar requirements, including the provision of unbiased and scientifically objective risk assessments[9] and the estimation of central estimates of risk.[10]

III. SUPERFUND AND RISK REGULATION

EPA guidelines known as the Risk Assessment Guidance for Superfund [28] govern estimates of individual cancer risks at Superfund sites. Risks arise through different pathways, which depend upon the route of exposure from site contamination to human populations. Evaluation of a pathway involves assessing many factors either explicitly or implicitly. Included among these factors are: (1) the

[5]See Noll and Krier [21] for a review. There is some evidence that EPA resource allocation is more aligned with the public’s perceptions of risk rather than with expert opinions [27].

[6]Both major cost−benefit bills call for this (HR690, S343 of the 104th Congress).

[7]S343, 104th Congress.

[8]S343, Section 633(a)(3), 104th Congress, as reported in the Senate.

[9]See HR2500 and S1285 of the 104th Congress.

[10]S1285, Section 403, 104th Congress.

mechanism of exposure (i.e., ingestion, inhalation, or dermal contact), (2) the medium of contact (i.e., contaminated groundwater, soils, or air), (3) the exposure frequency, (4) the exposure duration, (5) the exposed population (i.e., residents, workers, recreational users, or trespassers), (6) the age of that population (i.e., adult or child), (7) the location of contact (i.e., on-site or off-site), and (8) the time frame of the exposure scenario (i.e., current or future). A given site may have many pathways of exposure based on particular permutations of the factors above.

EPA has established agency-wide methodologies and default assumptions for evaluating the first two stages of risk assessment, hazard identification and the dose–response function. These default assumptions generally produce conservative estimates of toxicity. Superfund uses the toxicity estimates that result from these procedures in conjunction with exposure assessments specific to the program. The EPA uses the term reasonable maximum exposure (RME) to describe the Superfund approach to exposure assessment and provides the following information in guidance documents:

> For Superfund exposure assessments, intake variable values . . . should be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure for that pathway. As defined previously, the reasonable maximum exposure (RME) is the maximum exposure that is reasonably expected to occur at a site. Under this approach, some intake variables may be at their individual maximum values, but when in combination with other variables will result in estimates of the RME.[11]

The RME therefore is clearly not meant to be a "worst case" scenario, but to be toward the upper end of plausible risk estimates. The EPA states it this way: "The intent of the RME is to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures."[12] While the EPA does not explicitly provide a percentile goal for the RME risk estimate, the agency describes a "reasonable worst case" of exposures in the 90–95th percentile range.[13]

Superfund risk managers use these estimates to select the appropriate site remediation strategy in accordance with agency guidelines. The emphasis on individual risk in Superfund relegates cost-effectiveness considerations to "primary balancing" criteria. The principal "threshold" criteria that must be satisfied by the selected remedial alternative are overall protection of human health and the environment. Cleanups must also comply with applicable or relevant and appropriate requirements (ARARs) from other environmental programs, but these can be waived under certain situations.[14]

Superfund risk managers rely upon action thresholds—levels of risk that guide remediation policy at the site. Superfund incorporates what may best be termed a

[11] Page 6-19, USEPA [28].

[12] USEPA [28].

[13] Appendix 2, USEPA [29]. Proposed legislation in Congress suggested the use of the 90th percentile as a goal for probabilistic risk estimates (HR 2500).

[14] For the list of criteria in evaluating remedial actions, see 40 C. F. R. 300.430 (e)(9)(iii). In terms of binding cleanup goals established at Superfund sites, we have found that goals based on state environmental standards result in lower residual risks targeted to remain after cleanups [12]. See also USGAO [32].

fuzzy threshold. Risks greater than 1×10^{-4} generally mandate remediation, risks less than 1×10^{-6} are generally considered acceptable, and risks between these two figures may or may not require action depending on the circumstances and the judgment of the manager [30].

While the goal of Superfund risk assessment is to provide a plausibly conservative estimate of risk, a number of studies suggest that RME estimates may greatly exceed this target.[15] Our own research [6] indicates that the risk estimates in the Superfund program are frequently greater than the 99th percentile of the estimated risk distribution. The compounding of conservative assumptions in the individual parameter estimates can generate risk estimates that may be considerably larger than expected through the use of upper bound, or even ''plausible upper bound,'' parameter values.[16] This effect is known as compounding or ''cascading'' conservatism and is illustrated in the following example from Burmaster and Harris [2]. Suppose that risk is estimated as the product of several independent and identically distributed (i.i.d.) lognormal parameters. If there are three such variables, each valued at its 95th percentile, the risk estimate will fall at the 99.78th percentile of the resulting distribution. The resulting estimate will be at the 99.95th percentile if there are four such parameters. This example is illustrative, but one should recognize the limitations of its stylized nature. These various distributions may in practice not be independent or identically distributed.

The difficulty for managers is that the degree of conservatism embodied in current risk assessment practices is uncertain. Do such estimates represent the 90th, 95th, or 99th percentile value? The extent of conservatism also varies according to the type of risk and site, but the degree to which conservatism is compounded is unknown, even to the analyst generating the risk estimate.

IV. METHODS AND DATA

To assess how Superfund cleanups might be affected by a change to central estimates of risk, we recalculate RME estimates using mean parameter assumptions and evaluate these according to the Superfund policy guidelines. Consistent with the EPA policy approach, we limit ourselves to how these risk estimates compare across sites and to program thresholds. EPA does not apply them to population data and estimate expected cancer cases and we will not do so here. Since we focus on cancer risks from ingestion, we first present the lifetime excess cancer risk (LECR) equation for ingestion risks and then discuss the associated

[15] For example, Michigan Manufacturers Association [18] found that interim exposure values using EPA risk assessment are significantly greater than the 95th percentile of a distribution generated by Monte Carlo simulation. A similar result was obtained by Chemical Manufacturers Association [4]. Cullen [5] cites several examples in which similar conservative point estimates are greater than the 99th percentile of a simulated distribution. Using a slightly different RME, Finley and Paustenbach [9] estimate the RME in the 99th percentile for the case of groundwater contamination, and in the 99.9th percentile for risks arising from dioxin emissions in the food chain. In contrast, Smith [25], in an example using Monte Carlo simulation to estimate potential risks from a Superfund site, finds RME risks to be between the 90th and 95th percentile.

[16] Nichols and Zeckhauser [20], Bogen [1], and Burmaster and Harris [2] among others critique this approach. Some, however, question whether ''conservative'' risk estimates are really excessively conservative. See Finkel [7], for example. Other observers simply note that it is unclear exactly what the RME is [14].

effect of conservatism. The LECR from contaminant i in pathway j is given by

$$\mathrm{LECR}_{ij} = \left(\frac{\mathrm{ED}_j \times \mathrm{EF}_j \times \mathrm{IR}_j}{\mathrm{BW}_j \times \mathrm{AT}} \right) \times \mathrm{CC}_{ij} \times \mathrm{Tox}_{ij}, \tag{1}$$

where LECR is the lifetime excess cancer risk, ED is exposure duration, EF is exposure frequency, IR is ingestion rate, BW is body weight, AT is averaging time, CC is contaminant concentration, and Tox is toxicity.

EPA estimates the risks associated with each chemical from soil and groundwater ingestion by calculating what is termed the ‘‘human intake factor (HIF)’’ (the first expression in Eq. (1)), which is a function of ingestion rate, exposure frequency, exposure duration, body weight, and averaging time. EPA then multiplies the human intake factor by an estimate of the concentration of the contaminant and a measure of the chemical’s toxicity to determine the lifetime excess cancer risk arising from ingestion of the chemical.[17] Finally, EPA sums the risks from the chemicals in a pathway to determine the pathway risk from soil or groundwater ingestion at the site.[18] This summation yields Eq. (2), which we use to calculate pathway risk:

$$\mathrm{LECR}_j = \sum_i \mathrm{LECR}_{ij}. \tag{2}$$

In effect, the lifetime excess cancer risk is a function of five components in the numerator (ingestion rate, exposure frequency, exposure duration, concentration, and toxicity), and two components in the denominator (body weight and averaging time). Agency guidelines do not advocate that either of the denominator values be estimated conservatively. Instead, each takes on average values. However, four of the five numerator components are subject to conservative adjustments, with the possible exception being exposure frequency.[19] These adjustments primarily reflect variability about the parameters (except for contaminant concentration, which primarily reflects uncertainty). As we recalculate risks in order to obtain more central estimates, the only one of these conservatively estimated parameter values that will not be adjusted is the toxicity value. Our analysis will consequently not adjust for the conservatism bias in estimates of the potency of the chemicals. Doing so requires reevaluation of EPA’s interpretation of the scientific literature on a chemical-by-chemical basis

[17] The linear equation is a simplification of the underlying model. For risks greater than .01 EPA Risk Assessment Guidelines recommend the use of what is called a ‘‘one-hit’’ equation that better estimates risks from relatively high doses. Slightly different from the linear form, the risk from any given contaminant calculated using the equation: $\mathrm{LECR}_{ij} = 1 - \exp(-\mathrm{HIF}_j \times \mathrm{CC}_{ij} \times \mathrm{Tox}_{ij})$. These contaminant level risks are then summed to get the risk for a given pathway. We use each equation where appropriate.

[18] Treating the pathway risk as a summation of individual contaminant risks ignores synergistic effects of chemical mixtures and so this equation may be interpreted to be less conservative than it would be otherwise [7]. Of course, the relationship between contaminants might be antagonistic so that summation would overestimate health effects. See Seed *et al.* [24] for a review of risk assessment and chemical mixtures. The fact that not every possible contaminant is included in risk estimates will also tend to reduce potential conservatism.

[19] Even exposure frequency could be viewed as an upper bound. The number of days per year a resident is assumed to be exposed to ingestion risks is typically 350 to 365. Due to the lack of reliable data for this variable, we do not change this value.

The standard values for many components of the pathway LECR given in EPA guidance documents appear in Table I. The values listed pertain to ingestion rates by adults and children for both soil and groundwater as well as the exposure duration. As indicated in the final column of Table I, the contaminant concentration is based on information in the site documents for the reasonable maximum exposure (RME).

The typical assumption used in EPA risk assessments is the EPA default value shown in the top row of the table. The EPA default assumption for exposure duration, for example, is 30 years. The second row of information provides the EPA mean estimates for each of these values as drawn from Superfund guidance documents. In the case of exposure duration this amount is 9 years. The subsequent rows in the table provide information on different percentiles based on other information in the literature indicated in the sources for Table I. The relationship of the EPA default values to the different percentiles varies depending on the parameter. In the case of exposure duration, the EPA default value is almost as high as the 95th percentile, whereas the adult water ingestion rate is just below the 90th percentile and the adult soil ingestion rate is between the mean and the 90th percentile. The extent of the conservatism of risk assessments consequently varies across the different parameters.

A note about the values used in this analysis is in order. EPA mean values were drawn from a review of the guidelines that governed the Superfund risk assessments in our sample. We derived alternative mean values from the literature on risk assessment, and much of this work is more recent than the Superfund

TABLE I

Parameter Values Used for Risk Sensitivity Analysis

	Adult soil ingestion rate (mg/day)	Child soil ingestion rate (mg/day)	Adult water ingestion rate (L/day)	Child water ingestion rate (L/day)	Exposure duration (years)	Contaminant Concentration (mg/kg or μg/1)
EPA default	100	200	2.0[a]	1	30[a]	RME[b]
EPA mean	50	200	1.4	1	9	Site Documents
Alternative mean	46.6	75	1.3	0.7 (ages 0–10) 0.9 (ages 11–18)	11	—
Alternative 90th percentile	176	1190	2.1	1.2 (ages 0–10) 1.6 (ages 11–18)	26	—
Alternative 95th percentile	196	1751	2.5	1.4 (ages 0–10) 1.9 (ages 11–18)	33	—
Alternative 99th percentile	211	—	3.5	2.0 (ages 0–10) 2.7 (ages 11–18)	47	—
Source of EPA values	[29, 28]	[29, 28]	[29, 28]	Most frequently used in assessments	[29, 28]	Site Documents
Source of alternative values	[3]	[26]	[23]	[23]	[31]	—

[a] Value is approximately the 90th percentile.

[b] Reasonable Maximum Exposure is the maximum detected or 95th upper confidence limit on the mean, whichever is lower.

guidelines. However, since the EPA risk values are also based on the scientific literature, it is not surprising that EPA estimates often coincide with independent published estimates. There is, for example, little difference between these two sets of mean values except for the case of child soil ingestion. Recent work by Calabrese *et al.* [3], Stanek and Calabrese [26], and the review by Finley *et al.* [8] provide parameter distributions. Our choices are consistent with these studies.[20]

Consider the case of groundwater consumption. The EPA default value for adults is 2 liters per day, while the mean value determined by the EPA is 1.4 liters per day. We use the EPA's mean value to recalculate pathway risks, and we also use an alternative mean value of 1.3 liters per day, drawn from the literature. Similarly, we estimate the risks using different assumptions detailed in Table I for groundwater ingestion rates for children and for the soil ingestion rates for adults and children.

In the case of the contaminant concentration at a site, EPA guidance directs risk assessors to use the upper end of the 95% confidence limit on the estimate of the mean concentration at the site or the maximum detected concentration, whichever is lower. This value, termed the RME concentration, is presented in baseline risk assessments in the equations used to estimate lifetime excess cancer risks. This value may be only mildly conservative as it is an adjustment of the mean value to incorporate the uncertainty from samples. However, the variance is so large for some samples that the maximum concentration is used instead.[21] Some risk assessors also provide information on the average concentrations of individual chemicals at a site. We thus vary contaminant concentration as the third variable in the assessment to see how the risk estimates change when values other than those directed by EPA guidance are used. This variation is on a chemical-by-chemical basis using information reported in the site documents.

The empirical analysis relies upon an original data set developed by the authors. These data utilize information from the Record of Decision (ROD) and the Risk Assessment and Remedial Investigation/Feasibility Study (RI/FS) generated for each Superfund site. Each ROD details the site history, risks, and selected remedial action taken at a particular site. The Risk Assessment and RI/FS provide further detail on the specific nature of risks and the remedy selection. Using these documents we have compiled a detailed database pertaining to the costs and the risks at Superfund sites. Our sample of sites is limited to those 266 non-federal sites with RODs signed in 1991 and 1992. The risk data focus on a sub-sample of 141 sites for which risk assessments were sufficiently documented. The sample distribution across ten EPA regions mirrors that of the universe of all non-federal Superfund sites.

The analysis focuses on a total of 719 pathways for soil and groundwater ingestion by residents for 141 sites. An example of such a pathway is adult water ingestion risks for off-site residents. There are several reasons for limiting our-

[20] In particular, our choice for exposure duration is recommended by Finley *et al.* [8], and our choice for groundwater ingestion rates is derived from the recommended source. Child soil ingestion data come from a more recent study by Stanek and Calabrese [3]. There is relatively little data on adult residential soil ingestion rates and no recommendation is made for this value. Our choice is based on the best available data.

[21] It is difficult to determine how often this is the case for Superfund sites because assessments often report that exposure concentration is the RME value without specifying if this is the sample maximum or the 95th UCL on the mean estimate.

selves to pathways of this type. Soil and groundwater ingestion pathways account for 40% of the total pathways for these sites, and they are often the pathways of highest risk. Also, the relatively simple LECR equation has made these pathways the most consistent in terms of parameter values used at each site. For each change in assumptions, we estimate the distribution of risks based on the information in the site documents and compare these estimates with the distribution of pathway risks using alternative assumptions.[22]

For the subsequent comparison of the risk estimates, we present the original EPA risk estimates in the site documents alongside the recalculated risks using alternative parameter values since the particular number of pathways used to estimate the risk will vary by scenario. The parameters for exposure duration are varied only for adult pathways since child pathways always assume that the exposure duration equals the number of years that a child is in a particular age group. These age groups varied substantially across Superfund sites, from as little as 2 years to over 15. As a consequence, the pathways for children drop out of the analysis when exposure duration is varied. Similarly, the number of pathways analyzed declines when the concentration value is varied since the average concentration parameter is not available for all sites. As a final note, no adjustment has been made for hypothetical versus actually occurring pathways; we have taken as given the EPA assumption that pathways based upon changes in land use receive weight equal to those based on current land use.

V. RESULTS

To explore the effect of the conservative assumptions, we present the EPA risk estimates for the different pathway types and compare these estimates to those obtained using mean parameter values. Table II presents estimates in which these mean values are based on those estimated by EPA, and Table III utilizes mean values derived from the literature. In each case, the analysis distinguishes the risks associated with soil ingestion, groundwater ingestion, and the combined influence of both of these, where these exposure mechanisms constitute the three major row categories in Tables II and III. The additional subdivision of the rows indicates the parameters varied. After first presenting estimates based on the site documents, we also present estimates in which we vary the EPA parameter assumptions for the ingestion rate (IR), exposure duration (ED), and contaminant concentration (CC). We then present the combined influence of the variation and uncertainty of each of these parameters.

The columns in Table II indicate the different risk ranges. The first set of three columns indicates the percentage of pathways in each of the risk policy categories based on EPA guidance documents [30]. As noted above, risks greater than 1×10^{-4} generally warrant policy action, risks in the 1×10^{-4} to 1×10^{-6} range

[22] Note that it is possible that the site document numbers that are calculated with the parameter estimates may diverge from EPA default values, but a careful comparison of the two sets of estimates indicates that most of the site risk assessments are consistent with the use of default EPA values. The average of the figures reported in the site documents was $1.3 \text{x} 10^{-2}$. When we reestimated these risks using EPA recommended guidelines, the average of these conservative risks was 1.1×10^{-2}. A test of equality of the means yields a t statistic of 0.38, which implies that risks reported in site documents were calculated using EPA's stated conservative guidelines.

TABLE II[a]

Risk Estimates with Parameter Values Replaced with EPA Means

Pathway type	Permutation (parameter varied)	Percentage no action[b]	Percentage discretionary	Percentage take action	Mean	Median[c]	t statistic for means	Count
Soil ingestion	Site documents	1.5	81.3	17.2	1.4×10^{-3}	1.5×10^{-5}	2.5	268
	IR only	5.2	79.9	14.9	1.2×10^{-3}	1.1×10^{-5}		
	Site documents	1.2	85.9	12.9	9.2×10^{-4}	1.3×10^{-5}	2.3	162
	ED only	11.7	83.3	5.0	2.8×10^{-4}	3.9×10^{-6}		
	Site documents	0.7	78.9	20.4	2.5×10^{-3}	1.6×10^{-5}	2.7	147
	CC only	8.8	83.0	8.2	1.5×10^{-3}	7.5×10^{-6}		
	Site documents	1.5	83.8	14.7	2.1×10^{-3}	1.1×10^{-5}	2.2	68
	All (IR, ED, CC)	57.4	41.2	1.4	1.8×10^{-4}	7.2×10^{-7}		
Groundwater ingestion	Site documents	0.9	35.9	63.2	1.7×10^{-2}	3.1×10^{-4}	3.9	451
	IR only	2.4	36.6	61.0	1.3×10^{-2}	2.3×10^{-4}		
	Site documents	1.2	30.4	68.4	2.1×10^{-2}	5.3×10^{-4}	3.7	332
	ED only	7.8	39.5	52.7	4.6×10^{-3}	1.2×10^{-4}		
	Site documents	0.7	39.1	60.2	1.3×10^{-2}	3.3×10^{-4}	2.7	294
	CC only	2.0	48.3	49.7	3.6×10^{-3}	1.0×10^{-4}		
	Site documents	0.9	33.2	65.9	1.7×10^{-2}	6.0×10^{-4}	2.9	214
	All (IR, ED, CC)	10.7	56.1	33.9	5.6×10^{-4}	2.9×10^{-5}		
Soil and groundwater ingestion	Site documents	1.1	52.9	46.0	1.1×10^{-2}	7.1×10^{-5}	3.9	719
	IR only	3.5	52.7	43.8	8.6×10^{-3}	5.2×10^{-5}		
	Site documents	1.2	48.6	50.2	1.5×10^{-2}	1.0×10^{-4}	3.8	494
	ED only	9.1	53.8	37.1	3.2×10^{-3}	3.0×10^{-5}		
	Site documents	0.6	52.4	47.0	9.7×10^{-3}	8.4×10^{-5}	2.8	441
	CC only	4.3	59.9	35.8	2.9×10^{-3}	3.4×10^{-5}		
	Site documents	1.1	45.3	53.6	1.3×10^{-2}	2.0×10^{-4}	3.0	282
	All (IR, ED, CC)	22.0	52.5	25.5	4.7×10^{-4}	1.1×10^{-5}		

[a] In this table IR denotes ingestion rate, ED denotes exposure duration, and CC denotes contaminant concentration.

[b] According to EPA guidance, risks less than 1×10^{-6} require no remedial action in the Superfund program. Risks from 1×10^{-6} to 1×10^{-4} allow the site manager to use discretion with an explanation given if remedial action is taken. Risks greater than 1×10^{-4} are deemed unacceptable and require remedial action.

[c] All median pairs are significantly different according to the sign test for equality of medians.

TABLE III[a]

Risk Estimates with Parameter Values Replaced with Means from Literature

Pathway type	Permutation (parameter varied)	Percentage no action[b]	Percentage discretionary	Percentage take action	Mean	Median[c]	t statistic for mean	Count
Soil ingestion	Site documents	1.5	81.3	17.2	1.4×10^{-3}	1.5×10^{-5}	2.5	268
	IR only	7.8	82.1	10.1	5.4×10^{-4}	5.9×10^{-6}		
	Site documents	1.2	85.9	12.9	9.2×10^{-4}	1.3×10^{-5}	2.3	162
	ED only	10.5	83.3	6.2	3.4×10^{-4}	4.8×10^{-6}		
	Site documents	0.7	78.9	20.4	2.5×10^{-3}	1.6×10^{-5}	2.7	147
	CC only	8.8	83.0	8.2	1.5×10^{-3}	7.5×10^{-6}		
	Site documents	1.5	83.8	14.7	2.1×10^{-3}	1.1×10^{-5}	2.2	68
	All (IR, ED, CC)	55.9	42.6	1.5	2.0×10^{-4}	8.2×10^{-7}		
Groundwater ingestion	Site documents	0.9	35.9	63.2	1.7×10^{-2}	3.1×10^{-4}	3.8	451
	IR only	2.4	37.9	59.7	1.1×10^{-2}	2.1×10^{-4}		
	Site documents	1.2	30.4	68.4	2.1×10^{-2}	5.3×10^{-4}	3.7	332
	ED only	6.6	37.7	55.7	5.6×10^{-3}	1.4×10^{-4}		
	Site documents	0.7	39.1	60.2	1.3×10^{-2}	3.3×10^{-4}	2.7	294
	CC only	2.0	48.3	49.7	3.6×10^{-3}	1.0×10^{-4}		
	Site documents	0.9	33.2	65.9	1.7×10^{-2}	6.0×10^{-4}	2.9	214
	All (IR, ED, CC)	10.3	55.6	34.1	6.2×10^{-4}	3.2×10^{-5}		
Soil and groundwater ingestion	Site documents	1.1	52.9	46.0	1.1×10^{-2}	7.1×10^{-5}	4.1	719
	IR only	4.5	54.4	41.1	7.4×10^{-3}	3.9×10^{-5}		
	Site documents	1.2	48.6	50.2	1.5×10^{-2}	1.0×10^{-4}	3.8	494
	ED only	7.9	52.6	39.5	3.9×10^{-3}	3.6×10^{-5}		
	Site documents	0.6	52.4	47.0	9.7×10^{-3}	8.4×10^{-5}	2.8	441
	CC only	4.3	59.9	35.8	2.9×10^{-3}	3.4×10^{-5}		
	Site documents	1.1	45.3	53.6	1.3×10^{-2}	2.0×10^{-4}	3.0	282
	All (IR, ED, CC)	21.3	52.5	26.2	5.2×10^{-4}	1.2×10^{-5}		

[a] In this table IR denotes ingestion rate, ED denotes exposure duration, and CC denotes contaminant concentration.

[b] According to EPA guidance, risks less than 1×10^{-6} require no remedial action in the Superfund program. Risks from 1×10^{-6} to 1×10^{-4} allow the site manager to use discretion with an explanation given if remedial action is taken. Risks greater than 1×10^{-4} are deemed unacceptable and require remedial action.

[c] All median pairs are significantly different according to the sign test for equality of medians.

are those for which the record of decision ‘‘must explain why remedial action is warranted.’’ For risks below 1×10^{-6} no action is warranted. The next three columns in Table II present the mean and median risk values associated with the pathway type for the given assumptions and tests for equality of mean values. Because the sample differs as we vary parameter values (not all sites provided sufficient data to vary all parameters), the mean and median risk from site documents varies accordingly. All median values were found to be significantly different according to the sign test for the difference in medians. The count of pathways associated with each of the parameter value analyses is presented in the last column. For discussion, we will sometimes refer to the ratio of the mean risk calculated using the conservative assessment to the mean risk based on the use of central parameter estimates. We will refer to this as the ratio between conservative and central risks.[23]

Changes in the ingestion rate have a fairly modest effect. In the case of soil ingestion, the ratio between conservative and central risks is 1.17, and the number of pathways that fall under the ‘‘No Action’’ heading increases by less than 4 percentage points. Similarly, in the case of groundwater ingestion, the ratio between conservative and central risks is 1.31, and the mean parameter alternative increases the percentage of sites for which no action is warranted by 1.5 percentage points.

If, however, the ingestion rate parameter is varied based on the evidence in the literature, as is the case in Table III, the ratio between conservative and central risks is 2.59 for soil ingestion and 1.55 for groundwater ingestion. This shift alone increases the percentage of no action soil ingestion risk pathways by over 6 percentage points and increases the number of no action groundwater ingestion pathways by 1.5%. The combined influence of altering the ingestion rate parameters for both soil ingestion and groundwater ingestion is intermediate between these two estimates on a percentage basis.

The exposure duration assumption appears to have a much more consequential effect on the risk estimate. This change increases the percentage of pathways for which no action is warranted by over 9 percentage points for soil ingestion and over 5 percentage points for groundwater ingestion. The effects for the mean values from the literature shown in Table III are comparable in the case of the exposure duration parameter. The net effect when the exposure duration assumption is varied for both soil and groundwater ingestion to the value from the literature is that the ratio between conservative and central risks is 3.85. The pathways for which no action is warranted increase by over 6 percentage points. Similarly, the percentage of pathways for which action is definitely warranted (risk greater than 1×10^{-4}) drops by almost 11 percentage points.

The final individual parameter varied is the contaminant concentration amount, which is varied based on the contaminant concentration estimates reported in the site documents in the case of both Tables II and III. When mean concentrations are used, the fraction of pathways for which action is warranted drops by over 10 percentage points for soil pathways, groundwater pathways, and both groundwater and soil pathways. Most of the changes in the other categories are exhibited in the

[23] We note that this ratio of expected values is not the same as the expected value of the ratio (i.e., $E(\text{conservative})/E(\text{central}) \neq E(\text{conservative}/\text{central})$).

intermediate discretionary action category. The number of soil and groundwater ingestion pathways now in the discretionary range increases by over 7 percentage points.

Although considering each of these parameter values in turn is useful to get a sense of their individual influence, the overall policy question is how altering all of the exposure parameters to reflect the mean values will affect the estimated risk. For concreteness, let us focus on the final set of results for which both soil ingestion and groundwater ingestion are combined. The overall effect of altering the three parameter values for which the biases are compounded in the analysis is considerable. In the case of the EPA mean estimates, the estimated pathway risk for soil and groundwater ingestion drops from an average of 1.3×10^{-2} to 4.7×10^{-4}, whereas in the case of the mean values from the literature the decline is to 5.2×10^{-4}. The average RME (e.g., the value used in EPA decisions) value is over 27 times greater than central estimates using the EPA mean parameter values and 25 times greater when mean parameter values from the literature are used.

These parameter changes greatly influence the actions warranted under the policy action guidelines. In the case of the EPA mean estimates in Table II, the percentage of pathways for which no action is warranted increases by 21 percentage points, the percentage of pathways for which action is discretionary and must be justified increases by 7 percentage points, and the fraction of pathways for which action is required drops by 28 percentage points. Similar declines are exhibited in the case of the mean estimates from the literature shown in Table III. The fraction of pathways for which no action is warranted increases by 20 percentage points, the percentage of pathways for which cleanup is discretionary increases by 7 percentage points, and the percentage of pathways for which cleanup action is required decreases by 27 percentage points. These implications are, of course, based solely on the residential ingestion pathways present at these sites. Other significant sources of risk may still exist, where these other risks are also assessed conservatively.

Although analysis of all adult (and some child) resident ingestion pathways at 141 sites is instructive, all of these pathways may not be equally influential in driving the policy choice. In particular, one might posit that the maximum risk pathways at sites play a more prominent policy role than smaller risk pathways. Table IV presents the maximum pathway risks from either soil or groundwater ingestion at the different sites. Thus, only the largest risk pathway associated with the site is included in this analysis. Nearly all of the sites in the sample had a maximum risk pathway that was a soil or groundwater residential risk ingestion pathway so that our focus on these classes of risk for our sensitivity analysis for the effect of mean parameter values is instructive in indicating how maximum risk pathways will be altered. Table IV A excludes sites for which no action was recommended to focus attention on the potential to shift some sites where remedial actions were selected to no action status. Table IV B provides an assessment in which the no action sites are included to provide a comprehensive analysis for the broader sample.

The estimates of the mean risks from the site documents are extremely large for the maximum site risks—an average of 0.036 overall. This lifetime cancer risk is almost as great as the estimated lung cancer risk from cigarette smoking and, by

TABLE IV[a]

Maximum Risk Pathways Using Alternative Mean Values

Permutation (parameter varied)	Value	Percentage no action[b]	Percentage discretionary	Percentage take action	Mean	Median[c]	t statistic for means	Count
A. Does not include "No Action" sites								
Ingestion	Database risks	0.8	12.3	86.9	3.6×10^{-2}	1.7×10^{-3}	2.9	114
rate	Alt. mean	0.8	14.9	84.3	2.4×10^{-2}	1.1×10^{-3}		
Exposure	Database risks	1.0	8.7	90.3	3.8×10^{-2}	1.8×10^{-3}	3.2	104
duration	Alt. mean	1.0	12.5	86.5	1.5×10^{-2}	8.1×10^{-4}		
Contaminant	Database risks	1.3	10.5	90.8	3.4×10^{-2}	1.7×10^{-3}	2.8	76
concentration	Alt. mean	1.3	23.7	75.0	1.0×10^{-2}	3.7×10^{-4}		
All	Database risks	1.5	4.5	94.0	3.8×10^{-2}	1.9×10^{-3}	2.2	67
(IR, ED, CC)	Alt. mean	3.0	43.3	53.7	1.9×10^{-3}	1.1×10^{-4}		
B. Includes "No Action" sites								
Ingestion	Database risks	0.8	13.6	85.6	3.3×10^{-2}	1.2×10^{-3}	2.9	125
rate	Alt. mean	0.8	16.8	82.4	2.2×10^{-2}	8.2×10^{-4}		
Exposure	Database risks	0.9	9.7	89.4	3.6×10^{-2}	1.4×10^{-3}	3.1	113
duration	Alt. mean	0.9	15.0	84.1	1.4×10^{-2}	7.2×10^{-4}		
Contaminant	Database risks	1.1	12.6	86.3	3.0×10^{-2}	1.2×10^{-3}	2.8	87
concentration	Alt. mean	1.1	28.7	70.2	9.1×10^{-3}	2.0×10^{-4}		
All	Database risks	1.3	6.6	92.1	3.4×10^{-2}	1.5×10^{-3}	2.2	76
(IR, ED, CC)	Alt. mean	5.3	46.1	48.6	1.7×10^{-3}	8.9×10^{-5}		

[a] In this table IR denotes ingestion rate, ED denotes exposure duration, and CC denotes contaminant concentration.

[b] According to EPA guidance, risks less than 1×10^{-6} require no remedial action in the Superfund program. Risks from 1×10^{-6} to 1×10^{-4} allow the site manager to use discretion with an explanation given if remedial action is taken. Risks greater than 1×10^{-4} are deemed unacceptable and require remedial action.

[c] All median pairs are significantly different according to the sign test for equality of medians.

any standard, is considerable.[24] The overall median risk is somewhat lower—1.7×10^{-3}—but is still quite large. Perhaps more striking is that conservative risk estimates for only 4 out of the 67 maximum risk pathways are less than the 1×10^{-4} remediation trigger.

Once we shift to estimates based on mean parameter values, these risk estimates drop considerably. (See the sixth and seventh columns of Table IV.) Altering the ingestion rate reduces the mean by one-third, altering the exposure duration reduces the mean by over half, and altering the contaminant concentration to the mean reduces the overall mean risk by over two-thirds. The net effect on the estimated risk for maximum risk pathways is to reduce the risk value by a factor of 20, where this value drops from 3.8×10^{-2} to 1.9×10^{-3}. The proportional effect is almost identical for maximum risk pathways in which the no action sites are included, as their mean risk value drops from 3.4×10^{-2} to 1.7×10^{-3}.

The distribution of the maximum risk estimates shifts substantially toward lower values in the case of both parts of Table IV. In A, 94% of sites had maximum risk pathways above the high risk threshold value of 1×10^{-4}, where this amount drops to 54% based on the alternative risk assessment value. An almost identical pattern is shown in B. There is a slight increase of 4 percentage points in the number of sites with a maximum pathway that falls below the ‘‘No Action’’ threshold in B. From a policy standpoint the most important shift shown in Table IV is the substantial increase in the number of sites that fall into the range of risks where there is discretion regarding the cleanup action. Shifting to the alternative mean values puts almost half the maximum risk pathways into the intermediate 1×10^{-4} and 1×10^{-6} risk range.

It is also useful to inquire how the risk values are altered once we sum all the pathway scenarios involving soil and groundwater ingestion that may affect a population group. In particular, we sum all ingestion risks from the various pathways (e.g., ingestion of soil and groundwater containing many different chemicals) for populations specified by exposure population (worker or resident), age group, population location (on or off site), and time frame (present or future). These population groups may be at risk from both contaminated soil and contaminated groundwater, a fact that this measure incorporates. Again, because of complications arising from the exposure duration variable, these risks apply only to adults. We generated cumulative risks in three steps to assess the effect of each step. We put each site into a remediation category based on the highest cumulative scenario risk we calculated at the site.

Table V presents these statistics, which reflect the cumulative scenario risks to individuals from Superfund sites. Consider the final row in Table V, which considers the combined influence of using means for these parameter values. At 80% of these sites, the cumulative EPA risk estimate was greater than 1×10^{-4}, as compared to 33.3% when mean values were used. The percentage of sites in the discretionary range jumped from 20 to 57%, while the percentage of sites requiring

[24] Lung cancer risks from cigarette smoking are estimated as ranging from 0.05 to 0.12. Overall mortality risks from cigarette smoking are somewhat larger, between 0.16 and 0.33. See Viscusi [34]. Job fatality risks, for example, are on the order of 1×10^{-4} and the risk threshold for many other federal risk policies is between 1×10^{-5} and 1×10^{-6}. See Viscusi [33].

TABLE V[a]

Cumulative Scenario Risks

Variables at mean value	Type of Estimate	Percent no action[b]	Percent discretionary	Percent take action	Mean	Median[c]	t statistic for means	Number of sites
ED and IR	Site docs.	0.0	20.0	80.0	3.7×10^{-2}	1.0×10^{-3}	3.0	135
	Mean risk	2.2	36.3	61.5	6.6×10^{-3}	2.4×10^{-4}		
CC	Site docs.	0.0	19.6	80.4	2.7×10^{-2}	1.0×10^{-3}	2.1	102
	Mean risk	0.9	32.4	66.7	8.4×10^{-3}	2.1×10^{-4}		
ED, IR, CC	Site docs.	0.0	19.8	80.2	2.8×10^{-2}	1.0×10^{-3}	2.3	96
	Mean risk	9.4	57.3	33.3	1.2×10^{-3}	4.2×10^{-5}		

[a] In this table IR denotes ingestion rate, ED denotes exposure duration, and CC denotes contaminant concentration.

[b] According to EPA guidance, risks less than 1×10^{-6} require no remedial action in the Superfund program. Risks from 1×10^{-6} to 1×10^{-4} allow the site manager to use discretion with an explanation given if remedial action is taken. Risks greater than 1×10^{-4} are deemed unacceptable and require remedial action.

[c] All median pairs are significantly different according to the sign test for equality of medians.

TABLE VI
Correspondence of Site Rankings by Risk Level Quantile:
Fraction of Sites from Conservative Ranking Quantile in Mean Ranking Quantile

		Conservative ranking quantile				
		Highest risk **1** (n = 15)	**2** (n = 15)	**3** (n = 15)	**4** (n = 15)	Lowest risk **5** (n = 14)
Highest risk	**1** (n = 15)	0.80	0.20	0	0	0
	2 (n = 15)	0	0.47	0.53	0	0
Mean ranking quantile	**3** (n = 15)	0.07	0.13	0.33	0.47	0
	4 (n = 15)	0.07	0.13	0.07	0.40	0.33
Lowest risk	**5** (n = 14)	0.07	0.07	0.07	0.13	0.64

no remediation rose by 9%. Using only mean concentration estimates (in conjunction with conservative exposure values) similarly shifted many sites into the discretionary range.

Shifts in prioritization may arise by using conservative risk estimates rather than means. Would priorities be different if central estimates of risk are considered? In the Superfund program changes in risk estimates could affect which pathways at a site to focus on and which sites to prioritize. Because our analysis in this paper focuses only on ingestion pathways we cannot fully examine distortions across pathways. However, we can look across sites for inconsistencies. We have done this by taking the maximum EPA-assessed risk for each site and ranking the sites accordingly. We then compare this ranking to a ranking using mean estimates of risk.

Rank-order correlation measures indicate how well two different rankings tend to agree. Two measures are used here. The Spearman correlation coefficient uses squared differences in rank to measure concordance while the gamma statistic[25] relies upon the number of inversions found between the two rankings. These rankings have a significant Spearman correlation coefficient of 0.74 and a gamma statistic of 0.62, indicating that a positive correspondence is found between the two rankings. The gamma statistic lends itself to a straightforward interpretation: among untied pairs, the probability of selecting a pair with the same order is 0.62 more than doing otherwise. We can conclude that a positive relationship exists between conservative and central site priority, but the rankings are not identical.

Table VI presents these results in tabular form for a more thorough examination. The conservative rankings are measured on the horizontal axis from high (left) to low (right). The mean rankings are on the vertical axis from high (top) to low (bottom). If the rankings were perfectly consistent we would expect to see a 5×5 identity matrix, but this is not the case. Consider the data by matrix rows. If we take the conservative case to be the baseline, we see that although there is an

[25] Goodman and Krusk [10].

80% agreement in the first quantile, 3 of the 15 first-quantile sites have fallen to the third quantile or below in the rankings of mean risk. In the second conservative quantile 3 additional sites have fallen below the third mean risk quantile. Together, 7 sites fall by two or more quantiles when mean estimates of risk are used for prioritization. One of these sites fell from being the eighth riskiest site (of 74) to the sixty-first. Overall, approximately 40% of the 74 sites fall off the diagonal and into a different quantile when central risk estimates are considered. Using central risks will result in different priorities for the policymaker.

VI. CONCLUSIONS

Although there is a growing theoretical literature on conservatism in risk assessment and accompanying policy concerns, the debate over conservatism has been largely over principles. What has been missing is a firm empirical sense of the consequences of moving to a mean risk approach. This paper presents the first program-wide evidence on the magnitude and implications of limiting conservatism in accordance with various legislative proposals. Our analysis of 141 Superfund sites indicates that current EPA use of conservative risk assessment parameters instead of mean variables leads to estimated risks that are 27 times greater than the mean and 18 times greater than the median. For the maximum risk pathways at the sites in our sample, the use of conservative parameter values instead of mean values generates risks that are 20 times greater at the mean and 17 times greater at the median. The use of central estimates of risk may therefore result in fewer sites requiring remediation under agency action thresholds. More sites fall into the range where managers have the greatest discretion under a central risk approach. Results using pathways of maximum risk as an indicator suggest that over 40% of sites requiring remediation under EPA risk assessments fall below the 1×10^{-4} cutoff when mean parameters are used. Program priorities also differ when sites are ranked based on mean parameter assumptions. Because toxicity estimates are often conservative, these results would presumably be more dramatic if we varied toxicity estimates as well.

While we find that the use of central estimates of risk shifts more sites into a discretionary zone for site managers, the implications in part depend on how risk managers react to risk estimates and the efficacy of site remediations. We have found that risk estimates do affect how remediations are conducted. Most soil chemical concentration cleanup goals established at Superfund sites are derived from risk-based calculations rather than state or environmental standards [12]. Estimates of individual risk levels influence site-level decisions about individual chemical remediation targets and the ultimate cost per cancer case avoided arising from remediation expenditures [35]. While current guidelines result in few NPL sites ending up with risks in the ‘‘No Action’’ category, we have found that at the majority of sites we examined that remediations fail a benefit−cost test based on cost per cancer case averted [13]. Changes in risk assessment methodology and risk management practices that provide site decision makers with more discretion about whether and how to remediate sites would, by the metric of benefit−cost analysis, appear to be desirable. Switching to a mean parameter approach would also allow one, for a given cleanup budget, to avoid the greatest number of expected cancer cases arising from contamination.

In sum, our analysis suggests that risk assessments based on mean parameter values could affect policy judgment by substantially changing estimates of risk levels, especially for cumulative risks that mandate remediation under current guidance. Shifting to an approach based on central risk estimates would provide the risk manager with greater flexibility in addressing site hazards since many more site risks would fall within the discretionary range of 1×10^{-4} to 1×10^{-6}.[26] A mean parameter approach also results in policies that will save the greatest expected number of lives.

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[26] It should be noted that the risk manager is currently constrained by the legislation that authorizes Superfund, e.g., requirements that cleanups comply with ARARs.

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