Characterizing Risks for Sound Risk Management

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Abstract

Neglected relative to other parts of risk assessment in the past, risk characterization is taking on new prominence. The National Research Council report on risk characterization (1996), the Presidential/Congressional Committee on Risk Assessment and Risk Management (1997) and recent EPA guidance (U.S. EPA, 1995) all highlight the importance of risk characterization for risk assessment and risk management. New uses of risk assessment, involving comparisons of different risks, make improvements in risk characterization crucial. Comparative risk, substitution analysis, risk-based priority setting, and benefit/cost analysis are all part of the new risk management strategy. Improved risk characterization must make better use of science, quantify uncertainty and variability, and make choices and assumptions clear to ensure that false precision, false consistency, and hidden choices in do not distort risk management.

1. Introduction

Risk analysis has helped inform environmental, health and safety regulation for the last twenty years. It has been used to set drinking water standards, occupational radiation exposure standards and pesticide residue levels on food, to name but a few uses. The growing acceptance of the principles of risk analysis has led to its use expanding beyond simple regulatory standard setting. The new uses of risk assessment involve making comparisons of health risks to inform risk management. In the United States, comparative risk projects have been undertaken to help states, localities, and even regulatory agencies rank sources of risk to citizens. Risk-based priority setting uses the results of risk ranking efforts to allocate resources for protecting health, attacking the worst problems first. Risk communication benefits from comparison between different types of risks to life so the public can understand the relative size of the risks of accidents, diseases, and environmental threats. Industry is beginning to compare different pollution prevention alternatives to find which generate the greatest reduction in risk. Finally, there is a growing emphasis, both nationally internationally, on comparisons of the costs and the benefits (in terms of risk reduction) of environmental, health and safety regulations.

Comparative risk, substitution analysis, risk-based priority setting, and benefit/cost analysis are all part of the new risk management strategy. The ability to meaningfully compare and rank environmental risks is critical to sound risk management, helping

people identify and prioritize the actions they can take to safeguard their health. To realize the promise that risk comparisons have to offer, we must avoid three common pitfalls of risk characterization to better serve risk managers and citizens.

2. Common Pitfalls in Risk Characterization

The development of risk assessment for radiation and chemicals as a tool for setting standards led to the use of conservative assumptions in estimating risk. Whenever there was scientific uncertainty, risk assessors generally assumed the worst. Conservative risk assessment has been defended on several grounds. For example, given the scientific uncertainty in risk assessment, it is better to assume the worst rather than potentially expose people to a significant risk. In addition, some are concerned that although some conservative assumptions are made, the fact that factors such as variability in response among humans or exposure from many sources of pollution are not always explicitly accounted for means that analyses could produce risk estimates that may not be very conservative at all. In general it can be said that the use of conservative methods of risk assessment has been justified on the grounds of "better safe than sorry." Although not without controversy, the use of conservative estimates of risk for standard setting has generally been supported by the idea that even if we are exaggerating the risks we can be sure that standards protect health.

Risk comparisons are distorted by conservative risk assessment methods. Important scientific information is ignored and risks are characterized with false precision. Consequential differences between substances are ignored with uniform approaches that promise a false consistency. Hidden assumptions and choices may differ between risk assessments, yet their influence is not clear to anyone comparing risks. This paper examines the case for better risk characterization to combat false precision, false consistency, and hidden choices in risk assessment using specific examples. The underling motivation is concern about the potential for misleading comparisons by risk managers.

2.1 False Precision

In the United States, standard procedures for carcinogen risk assessment are designed to generate what the Agency describes as a "plausible upper bound on risk" (U.S. EPA, 1986). When hard data are lacking, "default" assumptions are made in the risk assessment process that are designed to be conservative -- minimizing the chances of underestimating the risk. Many risk characterizations simply report this single estimate of risk.

A single estimate of carcinogenic risk, however, fails to communicate important scientific information about the hazards of a chemical. Because people focus on the numbers, key information about the nature of a chemical's carcinogenic potential and the origins of the risk estimate is frequently overlooked by regulators, reporters, and the public (Gray and Graham, 1991). Qualitative descriptions, usually communicated as text or in carcinogen classification, are frequently neglected. No quantitative adjustment, or estimate of uncertainty, is attached to a risk estimate to distinguish known human carcinogens from compounds with very weak evidence for human carcinogenicity.

For instance, an EPA risk assessment estimated the nationwide risk from outdoor exposure to radon and vinylidene chloride at 10 deaths per year each (U.S. EPA,

1989). Although the different carcinogen classification for each chemical was reported, from these numbers the two chemicals would appear to be similar risks. Indeed, EPA simply added these numbers together in deriving a summary number of cancers. But radon is a known human carcinogen and the risk estimate is based on data from uranium miners exposed to radon on the job. Vinylidene chloride, on the other hand, has no human data and has been tested in eighteen rodent bioassays, of varying quality, and found positive in only one. The dose-response relationship that generates the risk estimate is even taken from one of the negative studies! Clearly a single estimate of risk, 10 deaths per year, does not tell the whole story and does not allow meaningful comparison.

2.2 False Consistency

The biggest problem with current risk characterization, from a scientific perspective, is that the default assumptions and methods are more scientifically plausible for some chemicals than for others. This means that "plausible upper bounds" of carcinogenic potency may be reasonable estimates for some compounds and wild overestimates for others.

The default, conservative, methods of risk assessment used by EPA assume a dose-response function that is linear in the low-dose region and has no threshold. There is evidence that some agents, like certain types of radiation and directly mutagenic chemicals, may indeed have this type of dose-response relationship. However, many scientists believe the linear, no-threshold, approach to risk estimation is inappropriate for many other chemicals, such as some that are not direct mutagens (Upton, 1988).

This means that when EPA applies standard procedures to all chemicals, regardless of how appropriate they might be for a given substance, the amount of conservatism in a risk estimate varies greatly. A risk estimate for a powerful direct mutagen may be quite close to the calculated "plausible upper bound" while for a nonmutagenic compound the estimate may be an extreme overestimate of plausible risk. Two "plausible upper bound" risk estimates that are generated through consistent procedures may have very different levels of scientific plausibility.

The same risk assessment of outdoor exposure to air toxics (U.S. EPA, 1989) reported annual cancer deaths of 115 from chloroform and 68 from ethylene dibromide. This would make chloroform appear to be the much greater public health problem. But ethylene dibromide is a compound for which the linear no-threshold model of risk may be scientifically quite appropriate while chloroform risk is generally believed to be very nonlinear, perhaps even with a threshold. A risk assessment process that made better use of all available scientific information would very likely reveal that ethylene dibromide poses a much greater risk than does chloroform although the reported numbers appear otherwise.

2.3 Hidden Choices

Conduct of risk assessment involves many choices and assumptions because of incomplete theory and gaps in knowledge, or data. Different choices can have very large influences on estimates of risk. If these choices differ between assessments, and the influence of the choices is hidden, the results will be difficult to compare. Let us look at pesticides as an example.

When estimating exposure to pesticides for the general public EPA would like to know, in effect, the dose of pesticides "on the dinner plate." However, risk assessors

rarely have this type of data so exposure must be estimated. There are three ways to estimate the public's exposure to pesticides. In order of increasing realism they are (1) theoretical maximum residues (TMRC), (2) farm gate data, and (3) residue monitoring. The TMRC method assumes that every acre of a particular crop has the highest possible allowed level (the "tolerance level") of the pesticide applied to it and this level does not decrease with time, storage or cooking. This method gives an upper bound on possible exposure to the pesticide. Farm gate, or field trial data, measure the levels of pesticide on a crop after it has been treated at the maximum allowable rate and had the minimum required preharvest time interval. These levels may be adjusted with experimentally determined processing, washing, or cooking factors to give a more realistic estimate of consumer exposure. The final type of exposure estimate, residue monitoring, is based on measurements of pesticide residues for raw and processed produce as purchased at the grocery store and normally prepared. Residue monitoring data reflects actual agricultural practices, such as different preharvest intervals, the effects of time and storage, and different pesticide application rates as well as consumer food preparation such as washing and peeling. The difference between these methods can be quite large, TMRC estimates being higher than monitoring estimates by a factor of 10, 100 or even more (Table 1). No method is inherently better, each one may be appropriate depending on the decision faced and time and resource constraints.

Table 1. Residues of Chlorothalonil on Celery (from Eilrich, 1991)

	chlorothalonil (ppm)	% of tolerance
TMRC	15.00	100.0
Field Data	4.07	27.1
Residue Monitoring	0.12	0.8

When comparing risks it is imperative that important choices in the risk assessment be well characterized. In pesticide risk assessment, because of the different ways in which exposure is estimated, risk estimates are often difficult to compare. In one case risk may be estimated with theoretical maximum residue contributions while in another it may be actual measured levels that are used. In this case then, identical risk estimates would mean very different things, in one case it would be a worst case number and for the other it would be a more realistic number, yet the distinction is likely to be lost in the current risk characterization process and will not be clear to a decision maker or the public.

3. Discussion - Misleading Comparisons?

Increasingly, policy makers and risk managers are advocating risk comparisons and risk ranking. Risk comparison evaluates different hazards to health and compares the nature and magnitudes of the risks. Risk ranking attempts to put health hazards on a scale from large to small. Both of these approaches are ways to improve the effectiveness of public health protection. It is critical that these comparisons be supported by complete risk characterization.

Comparison of substitute chemicals is also growing in importance. For instance, the Food Quality Protection Act of 1996 directs the U.S. EPA to

establish a faster registration process for “safer” substitute pesticides. Of course, this determination requires comparison of currently used and new agricultural chemicals. Given EPA’s approach, however, does current risk characterization give the agency the information needed to accurately make these comparisons?

Comparison, and prioritization, of the many public health risks for risk management actions is another reason for complete risk characterization. Since statistics for many other public health threats, such as motorcycle accidents or AIDS cases, are not deliberately inflated, environmental risk assessment must go beyond single "plausible upper bound" risk characterization to ensure meaningful comparisons.

4.0 Conclusions – We Must Improve Risk Characterization.

The key to making better use of risk assessment for risk comparisons is improved risk characterization. Risk assessment is a valuable tool, but one that is subject to significant scientific uncertainty. Consumers of risk assessments, especially those comparing risks, must have knowledge of the scientific plausibility of different estimates of risk.

Improved risk characterization means presenting risk estimates characterized by alternative assumptions and methods to prevent false precision. But all estimates are not equal. We must make use of scientists and the range of expertise and data they possess in assessing risks to address false consistency. An example of a risk assessment that relies on scientists, rather than conservative assumptions, has recently been published (Evans, *et al.*, 1994). The result is not a single estimate of risk but a range of risk estimates based on different data and assumptions but weighted by plausibility as judged by scientists. This reflects the uncertainty inherent in any attempt to estimate cancer risk from environmental exposures. The use of probabilistic techniques in exposure assessment (e.g., von Stackelberg and Burmaster, 1994; Burmaster and Anderson 1994) can present uncertainty and variability quantitatively, avoiding hidden choices and assumptions.

Better risk characterization is difficult but it will have several benefits. It should lead to a better appreciation of the strengths and limitations of the risk assessment process for informing risk comparisons. It will contribute to the scientific credibility of the risk assessment process as scientists see more of their data used in risk estimates. Finally, it will increase our confidence in our ability to compare risks and ensure sound risk management decisions.

5. References

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