



Risk in Perspective

Complete Risk Characterization

"Complete risk characterization means presenting risk estimates characterized by alternative assumptions and methods."

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Risk characterization is the final part of the risk assessment process, combining information from hazard identification, dose-response evaluation, and exposure assessment. It is used to communicate with risk managers, legislators, journalists, and the public.

Neglected relative to other parts of risk assessment in the past, risk characterization is taking on new prominence. For instance, the National Research Council has recently convened a new committee devoted exclusively to risk characterization.

There is widespread dissatisfaction with the current risk assessment process, and a primary reason is the way numerical estimates of risk have been characterized. Procedures designed to develop upper bounds on risk are routinely treated as generating best estimates, and rarely are key assumptions and uncertainties in risk assessment fully acknowledged. The important role of choice of data and extrapolation model, for example, is rarely made clear. Thus, a risk manager cannot know the scientific plausibility of the reported estimate of risk.

This issue of RISK IN PERSPECTIVE examines the case for better risk characterization to combat false precision, false consistency, and hidden choices in risk assessment. The underlying motivation is concern about the potential for misleading comparisons by risk managers.

False Precision

Standard EPA procedures for risk assessment are designed to generate what the Agency describes as a "plausible upper bound on risk." 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.

Any single estimate of risk 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.

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. Although the different carcinogen classification for each chemical was reported, from these numbers the two chemicals would appear to pose 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 18 rodent bioassays, of varying quality, and found positive in only 1. 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.

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.

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.

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