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Risk in Perspective

Complete Risk Characterization

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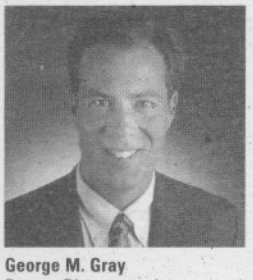

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Risk characterization is the final part of the risk assessment process, combining information from hazard identification, dose-response evaluation, and exposure assessment. It is used to communicate with risk managers, legislators, journalists, and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

continued

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 amount 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 residue concentration (TMRC), (2) farm gate data, and (3) residue monitoring. The TMRC method assumes that every acre of a particular crop has the highest 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.

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, rarely are risk estimates comparable. 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.

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 seen as 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, EPA Assistant Administrator for Prevention, Pesticides, and Toxic Substances Dr. Lynn Goldman was recently quoted as saying "Before I make a decision [to phase out a pesticide] I'd like to know what are the substitutes... and are those substitutes going to be more or less risky than what I'm phasing out?" But does current risk characterization give Dr. Goldman the information she needs to make these comparisons?

Comparison and prioritization of the many public health risks facing our country 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.

Complete Risk Characterization

Current methods of risk characterization hide much important information from a risk manager. By embedding policy choices and value decisions, current practice takes the decision-making power out of the hands of the risk manager and gives it to the technical people responsible for risk assessment.

Complete risk characterization means presenting risk estimates characterized by alternative assumptions and methods. But all estimates are not equal. Therefore, these estimates should be accompanied by a description of the scientific principles behind the number — a sort of checklist of what one has to believe about the science in order to put faith in a particular estimate. In order to help risk managers, all risk assessments should contain a narrative description of the scientific facts on the hazards of a chemical. This should contain information to allow risk managers, and other users of a risk assessment, to make judgments about which assumptions and models, and consequently which risk estimates, have the most scientific support. EPA has proposed hazard assessment narratives as part of the risk assessment process. These narratives should be of sufficient detail to allow the assumptions and choices in different risk estimates to be evaluated for scientific plausibility. Probalistic expert judgments may also help in assessing the scientific plausibility of different risk estimates.

Presentation of multiple estimates of risk will help to avoid the trap of false precision. It can also help combat false consistency. Choices will no longer be hidden, either, because risk estimates will be presented using all plausible choices, not picking and choosing just one. Much of the risk assessment process is subject to scientific uncertainty and disagreement, and this is exactly what risk characterization should convey.

Complete risk characterization will have many beneficial consequences. It will lead to a better appreciation of the strengths and limitations of the risk assessment process by regulators, legislators, journalists, and the public. It will improve our ability to compare and rank health risks, from chemicals and from other sources. It may improve the scientific credibility of the risk assessment process as scientists see more of their data and judgements used to evaluate environmental hazards. Presentation of the range of risk estimates and their scientific validity will also allow risk managers to do what they are paid to do — make policy decisions. It is time that risk assessors begin a policy of "full disclosure" by conducting complete risk characterizations.

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Further Reading:
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