Perceived Problems in the Application of Risk Assessment Analysis

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INTRODUCTION

In examining the controversy in the hypothetical Town of Middleburgh used for this symposium,[1] two elements struck me as appropriate points of departure for my presentation. The first is the assertion, attributed to the Coalition of Middleburgh Citizens (the Coalition), that risk assessment oversimplifies the problems it addresses, providing clarity at the expense of accuracy. In fact, the Coalition explicitly challenges the usefulness of the risk assessment process. The second is that a thirty-fold difference in the level of cancer risk projected by the two risk assessments (one performed on behalf of Super Clean and the other by the Coalition) suggests that the risk assessment process is inherently flawed.

I. IS RISK ASSESSMENT AN OVERSIMPLIFICATION?

With respect to the first element of concern, the question raised is straightforward and fundamental: should we use risk assessment analysis as a component of public policy decisionmaking? Several lines of evidence suggest that in the past, instead of trying to assess risks from exposure, we developed two rather different approaches to regulating the use and discharge into the environment of carcinogenic chemicals.

The first approach is typified by the EPA's response to findings that pesticides like Aldrin, Dieldrin, Chlordane, and Heptachlor are carcinogenic. The decision in the 1970s was to ban these products from the marketplace. This decision was based largely on evidence of carcinogenicity, rather than on an evaluation of

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1. For a detailed discussion of the hypothetical used at this symposium, *see* DelBello, *The Politics of Garbage*, this volume.

the level of carcinogenic risk that might result from a given exposure condition; any level of risk was unacceptable. The sale of products other than pesticides were also banned or curtailed due to evidence of carcinogenicity.

The second approach to regulating the use and discharge of carcinogenic chemicals into the environment is to use best available technology to control the emission of those pollutants into the environment, or to govern the extent of cleanup of pollutants that have already been released to the environment. There is a law unique to the State of New Jersey, which requires evaluation and remediation of soils and groundwater at many industrial manufacturing facilities prior to sale.[2] When there is evidence of discharges of petroleum and chemical products to soils, sediments, surface water or groundwater, the issue becomes the extent of cleanup necessary.

One approach that has been suggested by experts is to clean up the site through the application of the best available cleanup technology. This is similar to the use of the "BAT" (best available technology), proposed in the 1970s to control effluent discharges into rivers and streams.[3] In both cases, the extent of the response is governed by what is technologically feasible.

An alternative to these approaches is the application of risk analysis to assess the risk of contaminants in the environment and the use of engineering practices to achieve sufficient control of contaminants to protect human health and the environment.

There is much debate over the appropriateness of the use of risk assessment. However, I would like to suggest that, properly used, risk assessment has a place in the regulatory and judicial decisionmaking process. Without it, we have no way of quantifying the human health and environmental risks from exposures that may occur if materials are released into or are not removed from the environment.

II. CAN RISK ASSESSMENT GIVE ANY GUIDANCE?

The second item of concern to me in the hypothetical was that a thirty-fold difference in the cancer risk projected by two different risk assessments was construed to suggest inherent flaws in the

2. Environmental Cleanup Responsibility Act, N.J. Stat. Ann., § 13:1K-6 *et. seq.* c. 1330 (West 1983).

3. Federal Water Pollution Control Act, 33 U.S.C. § 1251 *et. seq.* (1982 & Supp. V 1987).

risk assessment process. It is interesting that such a difference is seen as significant because given the uncertainties in the risk assessment process, one might expect to find much greater differences in the outcomes of risk analyses. Quite frankly, if I could come up with numbers from different approaches which were as close as 9×10^{-7} and 2×10^{-6}, I would be very pleased.

Why, then, do these differences seem significant? One reason is that we are not talking about the science of risk assessment *per se*, but rather about the use of its results in regulatory arenas and courtrooms. There is a need in such settings for a definitive statement regarding risk. When I have testified in toxic tort suits, or on behalf of parties either attempting to site incinerators or trying to oppose them, the decisionmaker hearing the arguments has felt a need to "know" the level of existing or potential risk. The risk level presented takes on such a significance that anything slightly above or below this level is perceived to be vastly different.

I think the same kind of certainty is often sought in regulatory proceedings. This probably derives in part from the early uses of risk assessment to establish levels of acceptable and unacceptable risk. One of the first uses of risk assessment by a regulatory agency was in the Food and Drug Administration's (FDA) regulation of animal feed additives.[4] The Delaney Clause had precluded the direct use of carcinogens in the food supply, and a question was raised whether carcinogens might be used to stimulate growth in raising animals. Congress' answer was "yes," if no residues of the growth stimulants were left in tissues when an animal went to the marketplace. The question then became, "What is meant by no residue?" As analytical techniques for finding residues improve, do you first approve the use of a material in the marketplace, and later disapprove it when residues are found by a more sensitive technique?

For a while, FDA dealt with this issue by establishing a one part per million limit. Any residue below the limit was considered no residue. But this did not deal properly with the toxicity differences of various residual constituents. The agency finally proposed the use of risk assessment analysis and established that any residue that would not produce a cancer risk greater than one in a

4. Sponsored Compounds in Food-Producing Animals: Criteria and Procedures for Evaluating the Safety of Carcinogenic Residues, 50 Fed. Reg. 45,530 (1985).

million would be considered no residue. Meat complying with this standard could go to market. That standard of one in a million became a critical guideline, even outside the FDA arena, in determining what was and was not acceptable risk.

In the judicial and regulatory arenas, the uncertainties and variables that can yield different risk assessment results are often unstated or overlooked. What are some of the uncertainties? They may be categorized into two different groups: (1) inherent uncertainties attributable to the current state of knowledge or lack of knowledge; and (2) uncertainties resulting from data deficiency.

A. *Inherent Uncertainties in the Process*

Inherent uncertainties are difficult, at times impossible, to ameliorate. There is certainly a willingness to do further research and to increase understanding, but current knowledge is limited. An example of this type of uncertainty is the extrapolation of toxicity data from animals to humans. Our current understanding is limited in terms of the significance of differences in frequency and durations of exposure. So we make our best judgments based on our current state of knowledge and we can do no better.

Similarly, estimating risks of exposure to multiple agents is limited by our current understanding of the mechanisms by which chemicals exert their toxicity. When dealing with incinerator siting, a classic problem is the lack of data on the multiple materials that will be released and as to which exposure may occur, as well as the biological interactions that could be expected from combined exposures. How will we account for those multiple exposures without a better knowledge base? We make the best judgments we can today, but we are constrained by our current state of knowledge.

B. *Uncertainties Due to Data Deficiency*

Uncertainties that result from data deficiency can be improved upon. One example of a data deficiency is lack of specific knowledge regarding the nature of the exposed population. In most cases we evaluate risk to a "typical" family. Sometimes we add a sensitive family member, a "pica" child afflicted with a disease that causes ingestion of non-nutritious material such as dirt.[5] But

5. A Pica child is defined as a child who has an eating disorder involving the eating of non-nutritive substances such as ice, dirt, gravel, paint, plaster, etc. "[I]t is a rare mental

we do not necessarily look at a specific population to do our risk assessment. If necessary, we could go out and obtain population-specific data.

In some cases we are not sure of the magnitude of ambient exposure to the materials of concern. We do a lot of risk assessments evaluating the health risks from exposure to heavy metals. We know that there can be tremendous differences in the background levels of exposure to a number of these substances. We often use available general data on background exposures; but, if appropriate, we could obtain site-specific information pertinent to the population under study.

In other cases, data on the frequency and duration of an exposure is lacking. If there is contaminated soil in the backyard of a home and we want to assess the risk posed to a child playing in that backyard, we frequently assume that the child plays there a certain number of hours per day and a certain number of days per year, in order to perform calculations. That understanding can be improved upon, if necessary, with time and money, and information can be gathered on actual patterns of exposure.

Uncertainties in toxicological data are often caused by the incomplete state of our knowledge. When we evaluate information on exposed populations, however, we often start with standard assumptions. Nevertheless, we can improve on these assumptions as the need arises.

III. Perceived Problems in the Application of Risk Assessment

There is a perception among citizen and consumer groups that certain problems exist in regard to the application of risk assessment. These criticisms are that risk assessments are easily manipulated, that all materials to which people may potentially be exposed to are not being taken into account, that the risk is being considered in an incremental, segmented manner, and that, on the whole, there are too many uncertainties with the entire process.

One of the reasons people view the process as subject to manipulation is because risk assessment is often done in a staged

disorder with onset typically in the second year of life; it usually remits in childhood but may persist into adulthood." Dorland's Illustrated Medical Dictionary 1293 (27th ed. 1988).

approach. Scientists take certain steps to estimate risk and if a scientist doing an assessment determines that there is no unacceptable level of risk, the assessment will be curtailed right there. This eliminates the need for intricate, time-consuming, costly analyses.

If these same initial steps indicate that a potential risk exists, we frequently go back and try to refine the process. This is often perceived as tinkering by those who are going to be asked to accept the results of the risk analysis. Their perception is that if scientists do not get the right answer the first time, they keep going back until they reach their goal; in the case of the hypothetical incinerator, that goal is a risk factor of 1×10^{-6}. This perception of tinkering is an inherent problem, because it is logical to look at the process and assume that the paid consultant is simply re-doing the assessment until it yields the "right" result. On the other hand, the party paying to conduct the risk assessment legitimately is unwilling to invest the time and money for a more complex analysis unless a real need for it is demonstrated.

Another perceived problem has become evident in risk assessments we have done for incinerator siting. There the question raised by the public is, "What are we really being exposed to?" The risk assessments often select a subset of heavy metals or incomplete combustion products, such as dioxins or furans. But there are many materials to which the population may be exposed and which are not strictly accounted for in the risk assessment. How can the public be sure that the risk has been fully evaluated?

This problem also arises in connection with Superfund site cleanups. For one site we analyzed recently, 290 chemicals were detected in groundwater. Should a risk assessment evaluate all of these chemicals? Should we set priorities and consider only a subset of chemicals? If we do, is the analysis legitimate? What about compounds that are present, but unidentifiable? The public again raises the question, "To what are we being exposed, and of what have you evaluated the risk?"

I mentioned earlier the issue of chemical mixtures. Most risk assessments handle mixtures of chemical carcinogens by adding the risks of the individual constituents. We know that the presence of multiple contaminants may cause an increase or decrease in the effect of any single constituent. Yet, without specific knowledge of the effects, we are subject to the criticism that we have not evaluated risk adequately.

Another common criticism of the risk assessment process is that most analyses consider only the incremental risk created by a particular situation without taking into account background levels of exposure. Citizens will complain that plans call for eight incinerators in an area, but the analysis looks at each incinerator separately in an isolated format rather than at the impact of all eight incinerators operating simultaneously. Furthermore, exposure to carcinogens is probably already occurring without the operation of any of the proposed incinerators and this is not taken into consideration in the risk analysis.

Additional uncertainties exist in estimating exposure when emission rates for incinerators are involved. We are frequently given emission rates to work with for an existing facility; but these are often derived from a test burn in an isolated circumstance, rather than from continuous smoke stack monitoring data. We are often asked to do assessments before a facility is even licensed, sited, or built. In these cases we use our best "guesstimate" of what emission rates will be. We can do elaborate toxicological workups or transport modeling, but if the emission estimate is varied then the picture of the risk can change dramatically. What rate of emission is really correct?

A final criticism that comes to mind relates to exposure routes. Some of the early risk assessments were limited to one or two direct pathways. Now we also try to account for indirect pathways as well, such as the potential contamination of meat, milk, or mother's milk. We are doing an assessment in an agricultural area in Canada, and have been asked to look at the impact of a particular industrial activity on chickens, pigs, and fruit trees. Each is a legitimate route of exposure. If the assessment neglects to account for or somehow evaluate these routes, it fails to provide to the public a complete understanding of the risk that may exist.

We must understand all of the uncertainties in the process to use risk assessment successfully in regulatory, judicial, or other forums. In the regulatory or judicial arena, there will be pressure to quantify risk levels confidently and to de-emphasize the discussion of uncertainties so that a decisionmaker can be comfortable in the decision he or she must make.

We can take steps to deal with some of the uncertainties. For example, in an incinerator risk assessment, continued risk analysis can be performed after a facility is built, including monitoring in

the general community to determine what levels of contaminants are actually present, taken up by plants, in the water supply, and the like. These analyses will reflect any differences between predicted risks and actual risks.

A number of uncertainties in the exposure portion of the assessment process could be addressed and clarified through research. I made reference earlier to a "pica" child. The debate rages as to how much dirt or non-nutritious material a pica child really eats. Estimates range from several hundred milligrams to 10 grams per day. The figure employed has a dramatic effect on the level of risk. A similar situation arises in the determination of risk caused by exposure to dust during construction. How much dust does a construction worker actually inhale or ingest during the construction of a building? In choosing to undertake construction at a site where contamination is known to exist, worker safety must be considered before proceeding. Even a thorough toxicological understanding of a soil contaminant is insufficient without an accurate modeling of potential occupational exposure. Each of these uncertainties could be reduced with proper research and study.

The uncertainty continues beyond the exposure point. For example, what is the true bioavailability of ingested metals? We generally use 100 percent as a default value, even though limited studies have indicated that this is an overestimate for many constituents. So we are aware that our assumption is incorrect, but existing data are insufficient to yield more conclusive assumptions. Further research will be necessary.

IV. CONCLUSION

I would like to emphasize the need to use risk assessment analysis, to understand its limitations, and to appreciate its uncertainties. We in the field should recognize the concerns of those who are asked to accept the results of risk assessments, and we should continue to conduct research to limit or eliminate some of these uncertainties. Let me point out that even though it has limitations and can be misused, it is the best tool we have at our disposal today to evaluate risks and to help guide our efforts to protect populations from the adverse health effects of exposure to toxic substances.