Controlling Costs in Multipathway Health Risk Assessment

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INTRODUCTION

Federal agency estimates tell us 88.5% of Superfund hazardous waste sites pose no current or potential risk to human health or the environment, yet it is estimated it will cost $700 billion dollars to remediate these sites. To prove a cement kiln operating at 3,000° can destroy organic waste costs upwards of a half a million dollars, following current federal and state guidance for conducting risk assessment to prove risks are insignificant enough to warrant a permit. According to published reports, complying with recent wood preservative rules will cost something equivalent to the gross domestic product.

What is happening with risk assessment that the sky no longer seems the limit? Is is a useful tool that has been misused, like the captured spy that former EPA Administrator Ruckleshaus said if you torture enough, will tell you anything? Or is it the wrong approach for trying to explain what potential health risks are associated with environmental hazards?

This paper briefly reviews some of the basis of risk assessment, identifies ways in which the process can be improved, and suggests alternatives. The paper focuses on the issue of multipathway risk assessment as applied to combustion facilities, as this is the focus of much of the current EPA effort to develop guidance for multipathway risk assessment.

WHAT IS INDIRECT HEALTH RISK ASSESSMENT?

The U.S. EPA divides exposure to a source into two categories: direct and indirect exposure. For a source of emissions to air, such as a stack, the "direct" source of exposure is via inhaling air containing emissions from that stack. Historically, this "direct" exposure to emissions via inhalation of ambient air has been the primary interest to the regulatory community.

In recent months, however, interest has been growing in "indirect" routes of exposure, such as eating vegetables, beef and diary products, fish, water, etc., that have been exposed to facility emissions and thereby become indirect sources of exposure (i.e., not via direct inhalation). Thus interest has grown from straightforward interest in direct inhalation, to the inclusion of several additional pathways of exposure. The combination of direct and indirect health risk assessment is termed "multipathway" health risk assessment, with direct inhalation now constituting one of several factors to be addressed in the overall assessment.

ARE WE STILL SEEING THE FOREST FOR THE TREES?

A more comprehensive look at a facility's risks is to be welcomed as a means of better characterizing risks of facility operations to local populations, provided of course the same level of rigor is applied to all sources. (This is not generally the case. For example, landfills, which do not have to meet such stringent risk assessment criteria, are generally shown to pose greater risk once the same criteria are applied). Indeed, when properly quantified, risk assessment is an important tool in increasing our overall understanding of the risks of high-temperature combustion relative to other waste management options.

However, it appears that with increasing levels of complexity in the risk assessment process, the overall understanding of facility risks is being lost. Although we have better tools to characterize risk and more information about these facilities than ever before, this increased complexity appears to distort the issue and further the notion of increased facility risk, rather than help us put risk in proper context.

This notion of perceived risk has manifested itself in the concern expressed in the Combustion Strategy over the need to conduct indirect risk assessments, based on the belief that somehow this "major" source of risk, the non-inhalation pathways, has been overlooked in the past and that the combustion units must therefore be far greater sources of risk than formerly believed.

This misperception is further enhanced through reports of several risk assessments based on models, not actual offsite measurements, which have concluded that up to 97% of a facility's risk is due to these indirect routes of exposure, and that direct inhalation accounts for only 3% (in this example). If true, this is very alarming, as it means combustion devices may be two orders of magnitude greater risk than formerly believed, looking at inhalation only.

But how certain are we of the numbers in an indirect risk assessment? Not very. Environmental chemists are continually researching how chemicals move through the environment and the food chain, but there simply haven't been enough studies done to know how chemicals move between every species of plants and animals or even the different environmental media. In these cases, educated "worst-case" estimates are used. In order not to underestimate risk, these guesses incorporate uncertainty factors from 10 to 100,000 or more, multiplied through each step of the process. As one can imagine, multiplying these large values through the multiple steps of a risk assessment can result in some rather large values, often incorporating a large degree of uncertainty in the resulting estimates.

As a result, the orders of magnitude of uncertainty and the several conservative default assumptions associated with the many steps in calculating the risks of several non-inhalation pathways are collectively so high that they distort the overall risk. This is particularly true in comparison to calculations of risk of direct inhalation, which is better understood and about which risk estimates we have much more confidence. (For a diagram of multipathway risk assessment to help visualize this, see Foigure 1 of the paper contained elsewhere in this proceedings on comparing US and European methods of deriving site cleanup levels.)

Therefore, the level of confidence in calculating indirect risk is so low relative to the better-known inhalation risk that the results of the two assessments almost cannot be compared. Rather than developing two risk estimates with different levels of confidence, which might be more informative, the current procedure is to compare the numbers side-by-side and present them as a fraction of 100% risk without any indication of the vastly different levels of uncertainty associated with direct vs. indirect exposure.

Monte Carlo simulation is one means of helping to address this problem. Monte Carlo is a software-based statistical analysis of the range of uncertainty inherent in the input parameters in the risk assessment calculations, of which there may be hundreds. The results indicate the level of confidence that may be applied to a given risk estimate (i.e., there is 99% confidence the risk is 10^{-8} or less; 95% confidence that the risk is below 10^{-7}; 90% that the risk is below 10^{-6}, etc.). Monte Carlo will also indicate the major "drivers" of the risk, normally those variables that incorporate the widest range of uncertainty in their values and therefore tend to help drive risk estimates higher.

WHAT IS THE SCIENTIFIC OR OTHER BASIS FOR THE CURRENT RISK GUIDANCE?

There is some debate as to the basis for much of the current risk guidance, particularly relative to the costs required to achieve these levels. For example, the current risk-based offsite concentrations in the BIF rules equate to a cost of $280 million per case of cancer avoided to achieve these levels, as calculated by the U.S. Office of Management and Budget. Because of this perceived imbalance between costs and benefits, OMB did not allow EPA to implement the BIF levels as regulations for incinerators.

Upon having its request declined to have the BIF risk-based levels be implemented for incinerators, the EPA issued a memo to its regional offices directing the permit writers to use the levels anyway under the Omnibus Authority. The Omnibus Authority is an unusual feature of the Resource Conservation and Recovery Act, which allows permit writers virtually unlimited discretion in the requirements imposed on the permit applicants. The current risk assessment guidance, as well as the BIF limits being applied to incinerators, is being implemented under that authority.

In addition, there is growing debate over the basis of many common risk criteria, such as the venerable "10^{-6}" or one-in-a-million chance of developing cancer. There are efforts underway in states such as New York and New Jersey, as well as at EPA, to revisit the scientific and economic basis of risk assessment and improve the process. Nonetheless, risk assessment remains our best tool for assessing the potential for adverse effects to human health and environment from exposure to chemical compounds. Ongoing refinements to the process are further improving the overall usefulness and predictive value of risk assessment.

THE PROTOCOL IS KEY TO PROJECT SUCCESS

A well-written and thorough workplan or protocol to conduct the risk assessment is of key importance to the success of the risk assessment process. Where the risk assessment guidance does not offer specific enough information, the workplan provides an opportunity to use site-specific information in the development of the protocol for each site's risk assessment. Indeed, most state agencies now encourage the use of as many site-specific variables as possible, provided the proponent can justify the use of those alternate figures through documentation or other means. This justification is best included as part of the protocol to the state, so that the state has ample time to review and comment on the basis for taking an alternate approach.

Often submitted to the permitting agency for their review too early in the project, the importance of the protocol to the success of the project tends to be overlooked. This would be a mistake. By some agency estimates, 80% of the work of the risk assessment should be done by the time the protocol is turned in. Indeed, a thoughtfully prepared protocol should describe the basis for every input parameter used in the risk assessment, particularly those parameters for which the proponent would like to use site-specific information in lieu of agency default parameters, which are meant to apply from small boilers to large cement kilns from Alaska to Puerto Rico. Without this specific information, the protocol becomes little more than a regurgitation of agency guidance, and a basis for extensive future negotiations over every variable not discussed in detail in the protocol.

Neither the proponent nor the agency benefits from such a process. Indeed, most agencies will now return a protocol which is not sufficiently developed with site-specific information. It is in the facility's best interests to present its best judgment up front; once approved by the agency, the actual execution of the risk assessment becomes straightforward, and the agency is in a better position to support the results having agreed to all the assumptions that went into the risk assessment up front. Conversely, not doing so can dramatically increase the costs and time to complete the overall process through the need for extensive back-and-forth negotiations.

WHAT DOES A MULTIPATHWAY RISK ASSESSMENT COST?

Four risk assessments for cement plants were recently completed at a reported cost of US $400,000 to $600,000 each. Because they were completed before the EPA's recent guidance was issued, none of these is as comprehensive a document as the current guidelines require. At a half a million dollars apiece, the 355 incinerators and BIFs the EPA says will require a multipathway risk assessment in the next five years face a combined tab of $150 million plus -- to prove risks are acceptably low.

Computer technology is key to reducing the amount of labor needed to complete a risk assessment, which is historically the highest cost of the process. This is recognized by EPA. For example, Appendix III of EPA's current guidance document contains recommendations for long-term improvement of multimedia risk modeling. Recommendation #2 cites the need for a single, integrated model which the EPA does not believe exists but agrees would be an important improvement. The model, they suggest, should be interactive, integrated, modular, and linked to a statistical driver.

In fact, such a model does exist. Developed by Environmental Toxicology International (ETI), the ETI Risk Manager (ERM) model meets all of the above criteria of being interactive, integrated, modular, and linked to a statistical driver (see Figure 1). It also meets several other criteria, particularly reducing costs:

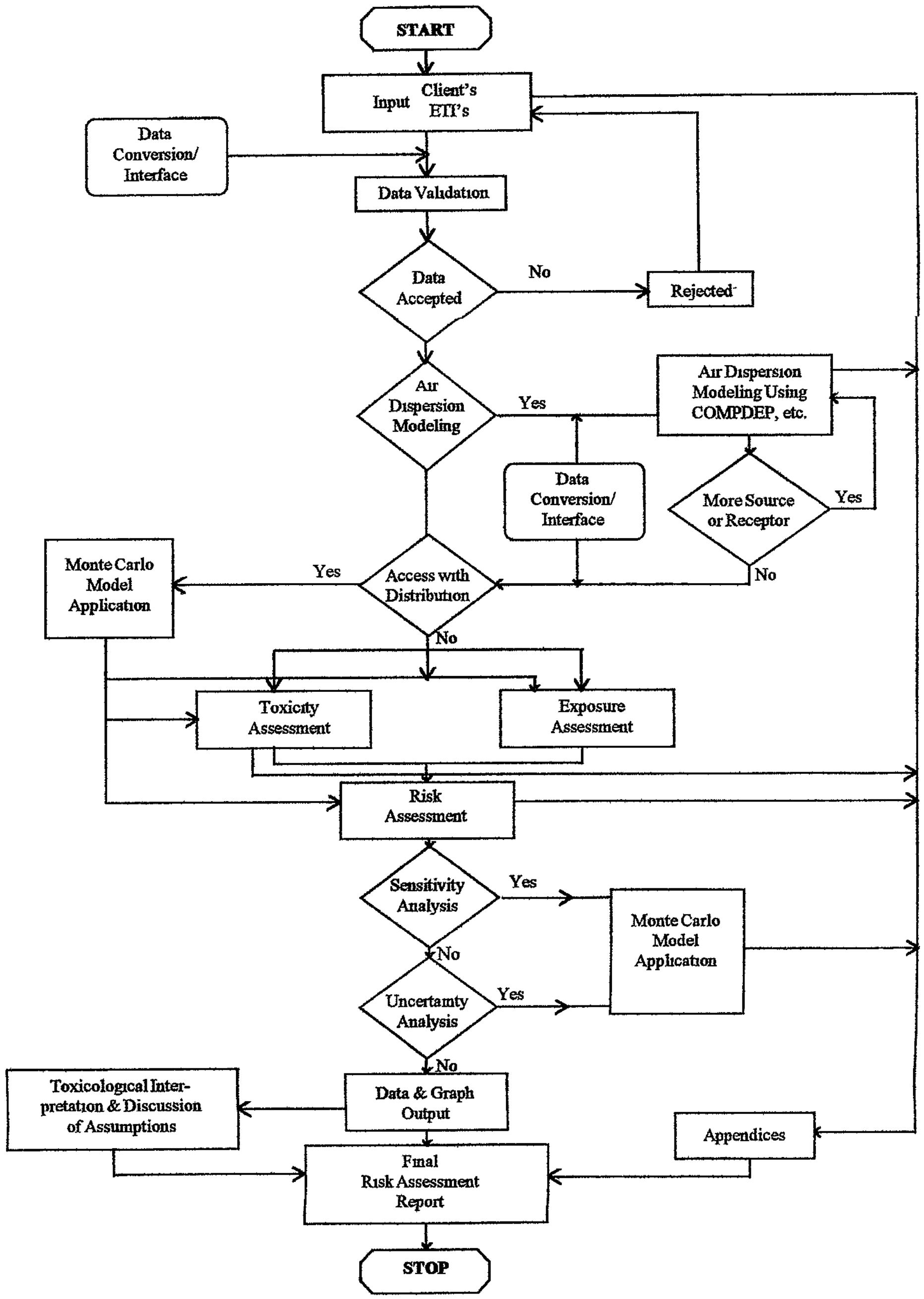
- A multipathway risk assessment involves hundreds of calculations and thousands of data points. Every time a variable is changed in one spreadsheet, several other spreadsheets need to be changed also. Through reducing labor costs by making all the risk assessment modules interactive, i.e., by coordinating the various data input, process, and post-process modules, the cost of conducting a risk assessment is significantly reduced.

  In addition, as each variable is entered once and not manually reentered into several spreadsheets, the number of manual errors is greatly reduced. Finally, an interactive model allows "what if" scenarios to be played out in a matter of minutes. ("What if we doubled our emissions of thallium -- how does that impact the risk results?" can be answered in a matter of a few minutes, not days.)

- By integrating the risk assessment information requirements, from initial data entry to final report generation, the overall accuracy of the risk assessment increases. As EPA suggests, calculated concentrations and fluxes in individual media are transferred to other media modules via common blocks or arguments, and the user can directly specify loadings to individual media.

- It also allows immediate modification of the risk assessment process according to new federal or state guidance, an increasingly important feature. This is important for facilities interested in expediting the risk assessment review process for their facility, but not inclined to pay tens of thousands of dollars each time the state or federal guidance changes.

ETI RISK MANAGER (ERM) MODEL



In short, using available software tools, the multipathway risk assessments for combustion units can now be done more comprehensively, yet far faster and with greater accuracy, than risk assessments of the past, and at far lower cost. Costs for multipathway assessments for large-scale units are now under $150,000; the costs for smaller units should be well below $50,000 due to the ability to screen out more information due to lower impacts from these facilities. Future costs are expected to reduce even further as the software to streamline the process improves, such as by more automatically integrating national databases through the shell of the program.

Why isn't this approach more widespread in the industry? Possibly due to lack of incentive among the providers of the risk assessment service. (Why offer a service for $100,000 when there are plenty of clients willing to pay $500,000?) Ultimately, the price will be driven down by facility proponents who have a vested interest in completing these studies quickly, accurately, and cost-effectively. Risk assessments currently underway by Texas Industries, Medusa, and others using this approach will be important steps in the evolution of using software to streamline the process.

WHAT DRIVES THE COST OF A RISK ASSESSMENT?

Labor: As discussed, labor has historically been the highest contributor to the cost of risk assessment. However, software tools can now reduce the cost of hours of data input and review into a far more streamlined "assembly-line" approach, which also increases the overall accuracy of the risk assessment by reducing manual errors. The assembly-line manufacture of electronic parts is perhaps a useful example; the quality of many consumer goods from computers to watches has increased at the same time the cost and time to manufacture them has decreased. The same concept applies to risk assessment and any other process for which labor costs can be reduced through automation -- in this case, by significantly improving the management of hundreds of calculations and thousands of data points.

The other main contributor to labor costs is the acquisition of very site-specific data, much of which is not readily obtainable in the literature, such as what percentage of locally-produced milk is purchased by local residents, or what is the wind velocity 10m over the largest local water body, or the sediment erosion coefficient from the local watershed. Some of this information can be obtained by national databases or survey documents; other reference materials produced by every county provide much-needed information. Ultimately, the EPA will hopefully collate much of this site-specific information and provide it through databases accessible on line.

On the other hand, several types of information requested by the risk assessment guidance are very time-consuming to produce, yet provide little overall use relative to the expenditure necessary to acquire this information. These areas are often open to negotiation with the regulatory agencies and offer important means of streamlining the risk assessment process without compromising the final results. Some of these areas include:

Assessing Too Large a Population: Population projections over wide geographic areas and/or for decades into the future are a frequent but often unnecessary feature of risk assessments. This is sometimes done in an attempt to address the concern about the results of risk assessments of facilities in areas of high population density. For example, a facility may pose a risk to an individual not exceeding an agency's threshold (such as 10^{-5}, or one chance in 100,000 of developing cancer due to lifetime exposure to the maximum offsite concentrations). If located in an area with, say, one million people in the surrounding area, the 10^{-5} individual risk can quickly become (incorrectly) reported as 10 cases of cancer in that population of a million.

What is wrong with this approach? One, as EPA points out in its guidance, assessing impacts to all areas within the air dispersion model's ability to predict concentrations (usually a 50 km radius from the plant) is "not the optimum method for defining population...not only can this procedure result in inclusion of many unexposed or negligibly exposed persons in the study population...it can result in a great deal of unnecessary work...It is important to avoid collecting information for wide geographical areas where little or no exposure occurs."

Two, the agencies (and society in general) have no defined threshold of acceptable cases of cancer in a population; partial "bodies" less than one (e.g., 0.75×10^{-5}) seem to be acceptable, but not when the risk number exceeds one. Then that one chance in 100,000 suddenly seems to take on an identity of its own, and becomes an identifiable person who may develop cancer. (This is also why those who oppose the facility tend to report that same figure as 7.5×10^{-6}.)

Three, it is not widely understood that these risk figures represent potential cases of cancer, not cancer deaths. While some may not consider that an important difference, it is nonetheless important from a risk assessment perspective; *an increase of one case of cancer in a population* of 100,000 (of which statistically about 33,000 will develop cancer from all causes) represents an increased risk due to facility emissions of 0.003%. This is less of an increase in risk than is generally believed, and is far less a contributor to overall risk than diet, automobile emissions, and other facets of daily existence.

Four, 10^{-5} risk to the most exposed individual does not equate to one case of cancer in a population of 100,000, *unless those 100,000 are located in that same point of maximum exposure* -- an obvious impossibility. The solution to population concerns appears to be ensuring the safety of a plant to nearby residents on an individual basis, no matter whether 10 or 10 million people live in the immediate vicinity of the site.

Undue Emphasis on Organics: There are over 300 possible organics to be considered in the emissions for a high-temperature combustion facility. However, risk assessments, ambient air measurements, and emissions tests have consistently shown that metals, not organics, are the main drivers of risk at a hazardous waste incinerator or cement plant, as one would expect from the high combustion temperatures which effectively destroy organic wastes. Hence spending undue effort on characterizing and quantifying hundreds of organic emissions and their byproducts of incomplete combustion can result -- like estimating exposures to essentially non-exposed populations -- in a great deal of unnecessary work. Effort should be made to screen out organics early in the risk assessment process when it can be clearly shown that they are not major contributors to risk.

Air Dispersion Modeling: Once a key source of frustration, this is now one of the simpler steps in the risk assessment process, thanks to extensive agency development of models available at no cost from the EPA and conveniently downloaded through electronic bulletin boards. Efforts to validate these models have significantly reduced the uncertainty associated with the results of the modeling. However, if adequate meteorological data is not available nearby, the cost of obtaining onsite data for up to a year for use in the risk assessment can be an expensive delay as well as a costly undertaking.

On the other hand, it is frequently useful to offer unsolicited information in the risk assessment if that information is helpful to the agency's decisionmaking. For example, the current EPA guidance does not ask the proponent of a cement plant to conduct a "baseline" assessment of the risks of that facility without use of hazardous waste compared to subsequent risks using hazardous waste. Offering this "baseline" information is helpful to an agency which may not know, for example, that substituting hazardous waste fuels for coal to make cement generally results in a net *reduction* in risk to the community due to the usual net decrease in metals emissions, which tend to be the main drivers of risk. This is important information to an agency whose intent is to protect public health and the environment; it is very hard to argue against a facility's attempt to reduce risk to the community, no matter what the perceived risk may be.

Other key areas of risk assessment which tend to increase costs and/or risk estimates substantially include:

1. Undue focus on a hypothetical individual of high risk on paper, but who does not exist in reality (e.g., assuming subsistence fishermen live at the point of maximum exposure in an inland area of high meat consumption, when in fact no one lives at that location and if they did, their main diet is unlikely to be primarily fish they have caught themselves).

2. Unrealistic exposure assumptions (e.g., assuming 100% of substances to which residents are exposed are absorbed through the skin if actual absorption rates cannot be found).

3. Not using available criteria (e.g., insistence on assessing the transport through the environment and ultimate effect of each dioxin and furan congener, rather than using the available dioxin toxic-equivalents to streamline the process and reach the same results).

4. Assessing cumulative impacts of unknown additional sources (rather than determining what additional increment of risk is acceptable, regardless of other surrounding exposures).

5. Undue emphasis on fugitive emissions or accident analyses (largely an occupational risk, not a major source of exposure to offsite residents).

ALTERNATIVES TO MULTIPATHWAY RISK ASSESSMENT

There are an increasing number of alternatives to multipathway risk assessment which are being explored, particularly for existing facilities for which actual measurements can be taken. These include:

1. Biomonitoring. Taking actual samples of animal or vegetation tissue and analyzing it for the presence of environmental contaminants. As expected, this approach routinely results in concentrations far below that which routine risk assessment modeling would predict, with its intentionally built-in degree of conservatism and uncertainty factors. A paper on ecological risk assessment by Pascoe elsewhere in these proceedings tells how biomonitoring was used to reduce remediation costs at one site from an estimated $500 million to $2 million, plus $0.5 per year in institutional controls, without comprmising environmental protection.

2. Use of Prescribed Levels. The new prescribed levels developed for Superfund will avoid the costs of risk assessment at many sites. At some sites, the prescribed levels will also increase the overall costs of remediation if the assumptions on which the prescribed levels are based are significantly different that those at the site being evaluated, and prescribe cleanup levels much lower than site conditions warrant. Larger and/or less contaminated sites would seem to benefit most from using prescribed levels.

Further examples of cost reduction were given in the presentation; unfortunately, space does not allow presentation of all examples in the paper.