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Editorial

RISK ASSESSMENT: LESSONS LEARNED

As the Society of Environmental Toxicology and Chemistry (SETAC) has evolved over the last quarter century, we have changed from a small group of toxicologists and chemists discussing how chemicals interact with natural systems to a global society engaged in conversations about risk analysis for multiple stressors acting on complex ecosystems within particular socioeconomic constraints. We have learned many lessons during this journey, including how to build upon accrued knowledge to make more accurate risk predictions. This is the essence of the scientific principle: past information is used to frame new hypotheses and studies are conducted to develop a greater depth of understanding. As a learned society with a diverse membership from the regulatory, academic, and business communities, SETAC provides the necessary forum to objectively debate scientific principles underlying risk analysis, with the goal of providing risk managers tools that can be used to balance societal benefits and environmental risk. SETAC scientists also are learning to embrace a broader range of disciplines, incorporating ecological principles and socioeconomics into risk analysis. If we continue to apply the scientific method, include nontraditional disciplines, and learn from the past, I believe that quantitative risk analysis will result in a low probability of occurrence of large-scale, unintended consequences as a result of future ecological risk management decisions.

Over the past 15 years, two events have occurred that remind us of the meaning of low-probability, high consequence risks. Specifically, these events are the Chernobyl accident on April 26, 1986 and the terrorist attacks in the U.S. on September 11, 2001. Prior to the occurrence of either of these events, a quantitative risk analysis would have suggested very low risk as the likelihood of occurrence was quite small, with the risk of a nuclear power plant accident somewhat greater than the risk from planes simultaneously crashing into both towers of the New York World Trade Center and the Pentagon. In retrospect, analysis of what we should have known about the likelihood of occurrence of both these incidents suggests that our risk assessments were wrong. With the benefit of hindsight, we are able to see that certain safety procedures were not followed correctly at Chernobyl and that the U.S. intelligence community may not have acted as propitiously as possible on available information. Given this new information, we would be able to revise our risk estimates to show a greater likelihood and hence a greater risk of these types of events recurring. Obviously, operational changes have been made in response to these events with the intent of lowering the risk below the original estimates. Lessons learned from these events have allowed risk estimates of other nuclear accidents or terrorist attacks to be substantially revised as well.

These events are, I believe, a good object lesson in how we live with risk in our daily lives, how society responds to unwanted consequences of risky actions, and how we learn from such events to continually upgrade risk estimates. These same behaviors occur in environmental analyses, albeit with less catastrophic and immediate consequences. Initial estimates of risks from the use of DDT and other organochlorine pesticides, for example, suggested that human health risks were relatively low and that the benefits of mosquito control (and subsequent reduction of malaria) far outweighed the potential effects from overexposure to DDT. Environmental consequences due to food chain bioaccumulation were not even considered; no one knew enough to ask. In hindsight, it is easy to say that ''we should have known'' that organochlorines would accumulate, given their high K_{OW}, and to hold responsible the chemical companies who made the product and the government officials who encouraged its use. Further examples of new knowledge that has led to a reassessment of risk and revised management decisions are compiled in a report from the European Environment Agency [1]. It is notable that the editors of this document stated that they attempted without success to find similar examples of ''success stories,'' that is, where a risk analysis was done and environmental harm was avoided through the decision not to use a product. This is not surprising, as many such decisions are internal to a company's decisionmaking process and are never brought forward for review. Those that are brought forward and do not pass the government mandated risk analysis also are not generally known. Regardless, it is important that we make judgments about the adequacy of historic risk assessment (and subsequent risk management decisions) within the context of what was known at the time, not what we know now. However, it is equally important that we learn from the past and incorporate information from our failures to predict unwanted consequences into the current process for risk assessment and environmental management.

We know now how to conduct risk assessments for predicting the likelihood and consequences of the use and release of chemicals in the environment. If we are aware of missing pieces of information (i.e., we know what we don't know), we can fill data gaps through further testing and investigation. In fact, when building our risk analyses, we use a framework that helps guide us through the thought process required to cover all the areas we know may contribute to the risk from the proposed action, and to find out which data are missing and therefore limiting our capability to make a reasonable risk estimate. We rely on peer review, stakeholder input, and other technical contributions to highlight areas of knowledge that have been missed. Precedence also is used, both in the risk analysis and in subsequent management decisions, to provide a decision framework that is consistent and avoids the appearance of being arbitrary and capricious. But despite our best efforts, we simply do not have sufficient knowledge in some areas to make a reasonable risk estimate. For example, the response of populations and ecosystem dynamics of open-ocean communities to chemical input remains largely unknown. It is not possible within the time and budget constraints of most risk management questions to develop the knowledge required to provide a quantitative risk assessment for open-ocean systems with acceptable uncertainty bounds. Nevertheless, we know where the data gaps are, and we hope we can direct longer-term research in this area that will eventually provide the needed information. This is the kind of problem that is very amenable to traditional scientific approaches that have been discussed by SETAC members for many years. What is of more immediate concern are those areas where we do not know what we don't know, i.e., where we don't even know enough to ask the right questions or even that we should be asking any questions at all.

So how do we account for the unknown and unknowable? Frequently, we use safety factors (also known as assessment factors) that reflect our degree of risk aversion [2]. More recently, the Precautionary Principle has been invoked as a way of reducing risks in the face of large uncertainties. This management philosophy calls for delaying implementation of new technologies or reducing current activities until sufficient information is available to make an informed decision [3]. It does not, however, consider the relative risks of inaction or the risk of maintaining current behaviors with the risk of implementing new technologies. Furthermore, because individuals, institutions, and governments all have different degrees of risk aversion, the amount of knowledge required to be ''sufficient'' for informed decision making varies greatly, thus engendering controversy and intense debate. This is, perhaps, most apparent when dealing with emerging technologies. The application of biotechnology to genetic modification of crops and livestock is the most visible of such recent problems. Analysis of long-term ecological effects of transfer of novel genetic material, for example, insertion of transgenes from one phylum or kingdom of organisms to another such as insertion of *Bacillus thuringiensis* (Bt) toxin into a plant, is only now emerging as a technical area for risk assessment. Questions have not yet been clearly defined, and there is great trepidation that we simply do not know enough to even know the right questions to ask. The fear is that we are at the same place scientifically in regard to ecological damage from transgenes that we were 50 years ago in regard to ecological effects from organochlorine pesticides. A significant difference is that we now know enough to realize that unintended ecological consequences can result from our actions and that we must be prudent in the use of new technologies. Two extreme approaches have grown out of this risk management need for caution: (1) simply ban the use of the new technology or (2) test everything. The former approach eliminates the potential for society as a whole to benefit from the new technology. One example would be the insertion of betacarotene, a Vitamin A precursor, into rice to create ''golden rice'' that helps eliminate malnourishment in many countries. The latter is a costly approach that will generate unused data and delay implementation. The middle ground is to require targeted testing based on sound science and to allow the application of a new technology, but only under conditions of appropriate monitoring and continual reassessment. This is known as adaptive management [4] and has been used successfully in many large-scale environmental assessments, for example, assessment of environmental consequences from building the Glen Canyon Dam on the Colorado River in Arizona. It enables new information to be brought forward and risk reassessed under a predetermined, formal timetable; if the new risk estimate shows a higher likelihood of the occurrence of adverse effects than was initially calculated, management controls can be put into place to reduce the risk. This is precisely what is being done in the United States in response to the events of Sepember 11, 2001 as the risk estimates for future terrorist activities here are revised and additional preventive measures put in place.

It is with a certain amount of hubris, but also with a solid record of accomplishment, that I offer SETAC as a forum for entering into discussions of how to balance the desires of people everywhere to lead lives free of risks from externalities while enjoying the rewards of scientific advancements and emerging technologies. People are willing to take some risks in their daily lives, but only those for which they perceive some level of control and for which direct benefits accrued outweigh the risk involved [5]. They rely on governments to provide appropriate controls on companies or individuals that conduct business that may result in undesirable consequences, using nongovernmental organizations as an additional influence on both government and industry actions [6]. But because of the subjectivity of many of the attributes and terminology used to define ''risk,'' ''undesirable,'' ''adequate protection,'' and other similar metrics of risk management, it is easy to lose sight of the distinction between what we know, what we think we know, and what we do not even know enough to consider. SETAC provides an opportunity through a variety of formats (large or small meetings, workshops, publications, website, etc.) to parse the risk perception, risk analysis, and risk management components of environmental decisionmaking into their various parts. This will allow a rational discussion of the role that personal, religious, or institutional beliefs play in the process, what information traditional or alternative science brings to the table, and how compromise and cost/benefit analyses contribute to decisionmaking. Because SETAC is aware that these and many other factors determine environmental quality, SETAC's mission statement includes a specific promise to ''provide the central scientific arena'' to ''propagate and facilitate the translation of environmental science into policy making.'' It is my hope that the globalization of SETAC will facilitate cross-cultural discussions of all the components in risk analysis. It is important that we have a place to come together for objective discussion, where personal agendas can be set aside and all sides of an argument are thoroughly examined. Scientific principles should be applied not only to the natural and biological sciences involved in ecological assessments, but also to the social and economic issues. Social sciences have the potential to illuminate the underlying basis of many seemingly intractable differences in opinion about how to deal with uncertainties that are, and always will be, inherent in risk analysis, as well as the differences in degree of risk aversion that lead to many seemingly irreconcilable differences. SETAC has begun to embrace this larger arena of scientific discourse, through the current discussion of publishing a new journal, by hosting Pellston workshops on topics related to human and environmental health interactions, and at sessions during annual conferences. I hope to continue this trend toward embracing a more diverse membership, all of whom can contribute to a science-based, objective discussion of risk analysis and mitigation. Many lessons can be learned from the successes and failures of our past decisions, not the least of which is that it is now time to open the conversation to a wider variety of disciplines.

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