Consultancy Companies: Intertox

1. Introduction

Intertox Inc (www.intertox.com) is a scientific consulting and research firm whose mission is to achieve long-term solutions to enhance public health and manage risk. Headquartered in Seattle, Washington, **Intertox** is comprised of scientists with expertise in risk assessment, decision analysis, toxicology, epidemiology, industrial hygiene, occupational medicine, ecology, and regulatory policy who work with local, national, and international clients.

Intertox strives to develop sound *science* strategies that clients use to protect health, minimize risks associated with products that they use or produce and ultimately improve product manufacturing process efficiency. The firm has national and international experience in situations where scientific data are limited or non-existent and where regulatory policy is pressing – both highly relevant to emerging threats. Work products and scientific opinions developed by Intertox are used by the National Academy of Sciences, U.S. EPA and U.S. DOD to develop regulatory standards and to establish policy directions in several EHS areas, including nanotechnology.

Risk assessment and decision analysis go hand-in-hand in Intertox's offerings. Intertox is one of a few companies who is combining the best of the two disciplines to support client's needs. Details about our unique approach and projects are provided below

2. Areas of Specialization

2.1. Integration of Risk Assessment and Decision Analysis

Multi Criteria Decision Analysis (MCDA) and risk assessment are often used to support decision making. Nevertheless, the decisions are often made with an arbitrary process that may or may not be based on risk analysis. Risk analysis (RA) may be just one factor to consider, in addition to stakeholder input, costs, etc., but no guidance exists on how to integrate these. In the process of risk analysis, people do make decisions, but these are often not explicitly documented. While each discipline operates within its own set of methods and tools, some decisions may benefit from the fusion of the two disciplines. Decision makers operating in a risk analysis setting may benefit from the structure provided by decision analysis (DA) when, for example, tradeoffs must be made between risks, alternatives need to be clarified and selected, and when there is some dynamic possibility of resolving uncertainty. A combined RA/DA differs from pure decision analysis because much of risk analysis is mandated, certain information is present that may not be obtained in standard DA, and there is generally a high budget for analysis. Risk analysis may have explicit requirements about who must be involved, what must be modeled and how, as well as rules about what must be done given the findings of the risk analysis study. T he way the budget is determined for risk-analysis based decisions is different from a standalone decision analysis. In this situation, various stakeholders' preferences for tradeoffs of money vs. mitigation depend on whose money is involved. All this could make DA fail. Intertox scientists have successfully integrated DA techniques as effective tools to augment the formal RA process, and furthermore help accommodating these approaches in order to allow federal agencies to make better decisions.

2.2. Risk Communication and Training

Risk communication is a critical part of overall risk management. While risk assessment produces estimates of potential risks, risk communication puts the risks into perspective, including making complex scientific principles understandable to lay audiences. When used effectively, risk communication provides a basis for discussing the relative importance of risk assessment information, encourages positive community and government involvement, and involves all parties in solving problems in a constructive manner.

In large organizations, business development leaders, managers, and scientists are likely to be involved in operations in which they must be interdependent with the cultures of organizational units, including scientists of different disciplines, governmental agencies, industrial partners, and customers. Exposure of personnel to different groups and units within the organization may be limited. Today's competitive business environment requires cognitive skills from managers who must deal with social, cultural, and technological challenges. Interox's projects frequently include front-end analysis to determine the components of shared mental models of organization members' understanding of cultural differences among the organizational units and professional disciplines, as well as operational capabilities and situations where these issues are especially important. Based on this analysis, Intertox is developing a computer-mediated training tool that can rapidly enhance the cognitive leadership skills required for personnel to be effective in a wide range of research and development activities.

2.3 Environmental Risk Assessment

Risk assessment is an important tool used to quantitatively estimate the potential for adverse health effects from chemical or microbial exposures. Intertox specializes in preparing risk assessments for a variety of situations where chemical or microbial exposure is a concern, including industrial activities, accidental releases, and consumer exposures. The primary objective of the risk assessment process is to develop a clear understanding of potential risks, including identifying chemicals of interest, characterizing potential routes of exposure, and identifying potentially sensitive population groups in order to support informed decision-making. Risk assessments provide valuable information that may be used to respond to citizen action groups concerned over potential impacts to the community, quantify the risks associated with site development or proposed action (such as a contaminated site cleanup), or develop adequate protective standards for human health and ecological impacts.

2.4 Litigation Support

Intertox has an established practice providing toxicological and risk assessment expertise for clients involved in litigation. The firm has provided expert witness services, toxicological data review, and independent toxicological research for both plaintiff and defense attorneys in a wide variety of cases. The firm's toxic tort experience includes large-scale class action cases as well as small cases involving individual health claims due to chemical and biological exposures. Intertox works closely with attorneys and other technical experts retained by the client to develop strategies for managing the scientific aspects of each case. The firm is particularly skilled at critically evaluating opponent's scientific information and developing scientifically sound support for clients. The scientists advise on the technical merit of lawsuits or threatened lawsuits and testify on behalf of clients when necessary. Intertox's multi-disciplinary team is skilled at uncovering the factual scientific basis of complex issues, which are sometimes contrary to public perception. The firm's team approach supports the uncovering of new information that can aid the legal process, allowing clients to examine their case from different angles. Intertox scientists have conducted a full range of research and risk assessments required to gain a thorough understanding of whether the suspected chemical or biological agents of concern have or can cause the alleged health effect. Intertox and its associates have testified as experts in depositions, arbitration matters, and trials. Intertox scientists adhere to objective examination of the evidence, and rely upon sound science to deliver this service.

3. Principal Scientists

Intertox is comprised of a multidisciplinary team of risk assessors, toxicologists, industrial hygienists, and regulatory policy experts working together to solve complex human health and environmental issues with innovative, cost-effective, and resourceful approaches based on sound scientific methodology.

3.1 Igor Linkov – Risk Assessor and Decision Analyst

Dr. Igor Linkov is a Managing Scientist with Intertox Inc. in Brookline, MA, and Adjunct Professor of Engineering and Public Policy at Carnegie Mellon University in Pittsburgh, PA. Dr. Linkov's skills include decision analysis, environmental security, risk assessment for emerging threats, multiple criteria toxicology, radiation health and safety, guidance development, risk communication, policy analysis, and biostatistics.

Dr. Linkov's research in the area of emergency response, portfolio management and homeland security has been supported by the North Atlantic Treaty Organization as well as the US Department of Defense. One focus of his current research is integrating risk assessment and multi-criteria decision analysis tools in military and environmental management. He is currently developing decision support tools to prioritize resource allocation and technology gaps in several military programs as well as in other areas (such as algal bloom management and nanotechnology). He managed the radiation safety program for the US Army Soldiers' Systems Command and helped in developing the Army Risk Assessment Modeling System (ARAMS). He is developing cognitive leadership training materials for the US Army Research Institute.

Dr. Linkov has organized more than a dozen national and international conferences and continuing education workshops on risk assessment, decision analysis, risk communication and modeling and participated in organizing many others. For NATO, he organized several international workshops including: Role of Risk Assessment in Addressing Environmental Security Needs (2004); Integrating Human Effectiveness and Risk Characterization of Non-Lethal Weapons into Antiterrorism Civil Science Programs (2003); Environmental Security in Harbors and Coastal Areas (2005); and Ports Security and Critical infrastructure (2006). As a Member of the Organizing Committee for the 2003, 2004, 2005 and 2006 annual meetings of the Society for Risk Analysis (SRA), Dr. Linkov was responsible for the military and terrorism-related track, and he organized several symposia and special sessions on military applications and emergency response. He has also organized SRA continuing education workshops on Risk Communication: Application and Case Studies in Military and Emergency Settings, and he is currently organizing one on the Use of Risk Assessment and Decision Analysis in Military Applications. Dr. Linkov has published widely on policy, environmental modeling, and risk analysis, including eight books and over 80 peer-reviewed papers and book chapters.

Dr. Linkov serves as a Scientific Advisor to the Toxic Use Reduction Institute, a position that requires nomination by the Governor of Massachusetts. Dr. Linkov is the Founding Chair of the SRA Decision Analysis and Risk Specialty Group and is Past President for the Society for Risk Analysis-New England. He is also Past Chair of the SRA Ecological Risk Assessment Specialty Group and participates in several SRA and Society of Environmental Toxicology and Chemistry (SETAC) Committees. Dr. Linkov is the recipient of the 2005 SRA Chauncey Starr Award for exceptional contribution to Risk Analysis.

3.2 Richard Pleus – Risk Communicator and Toxicologist

Dr. Pleus, Intertox Director, is a toxicologist with over 25 years experience assessing the risk to humans exposed to chemical and biological agents via food, consumer products, therapeutic agents, and the environment. He is an expert in neurological and reproductive toxicology. He has a proven ability to communicate risks of toxicants to a variety of audiences, skillfully facilitating both public forums and industry meetings, in litigation support, on expert panels, and as an expert witness. His clients include companies from the pulp and paper, utility, cement manufacturing, mining, building material, and chemical industries; law firms; citizen groups; and governmental agencies both national and international. He continues to be involved in research, publications, and education.

Dr. Pleus' research focuses on human health risk, including mode-of-action studies aimed at quantifying exposure to critical organ systems, with particular interest in human and laboratory animal nervous system development. In association with these activities, he has conducted a variety of human health risk evaluations of exposures to chemical and biological agents in air, water, food, and soil, as well as risk evaluations relating to consumer products and therapeutic agents. His work is focused on the application of academic research results to protect human health and resolve public health issues. He has presented the results of his research at national and international meetings in Australia, France, South Africa, and the Czech Republic.

Dr. Pleus was an instructor for 10 years at the University of Minnesota where he taught human science classes for both lower and upper level undergraduate students. In addition, he taught courses in physiological psychology and psychopharmacology for Metropolitan State University. He periodically serves as a graduate level guest lecturer in toxicology at the School of Public Health at the University of Washington. He is an adjunct Associate Professor in the Department of Pharmacology at the University of Nebraska Medical Center, as well as a faculty member of the Center for Environmental Toxicology at the University of Nebraska. He is an elected member of the Delta Omega Honorary Society in Public Health.

Dr. Pleus' credentials include a B.S. with Honors from Michigan State University, an M.S. in Environmental Health, a Ph.D. in Environmental Toxicology from the University of Minnesota, and postdoctoral research in neuropharmacology at the University of Nebraska Medical Center.

4. Case Studies

Our highly trained and experienced scientists provide expert project support customized to our client's needs. We take pride in the opportunity to be called upon to evaluate some of the most challenging issues in the world. Our project experience exemplifies our valuable relationships with clients in our local community, foreign governments, and with some of the most successful companies in the world.

4.1 Human Health Risk Assessment for Large Watershed

Overview: Intertox participated in a water quality and quantity monitoring and modeling project focused on a large watershed in Washington State. This project was initiated to support a variety of potential water resource decisions for the majority of the watershed. The primary purpose was to assist wastewater capital planning, habitat conservation planning, salmon recovery, and watershed planning efforts by collecting information, developing a set of scientific tools to better understand the watershed, and use these same approaches to explore resource management options. One of the primary tools for use in these planning efforts was the assessment of potential current and future human health risks resulting from human alteration of the watershed. The risk assessment consisted of three sequential tiers of increasing refinement. Intertox completed the human health component of Tier 1, a general risk screening of all existing water, sediment, and tissue chemical data, and designed the methodology for Tier 2. Tier 1 used conservative assumptions to identify and screen out chemicals posing negligible human health risk from further evaluation. Chemicals not screened out through the Tier 1 process were retained for further evaluation in the Tier 2 evaluation. Client benefit: The screening level risk assessment allowed the client increased efficiency for the remainder of the risk assessment by being able to focus on dominant contaminants and routes of exposure.

Chemicals of concern: Contaminants of potential concern in the Tier 1 evaluation included chemical constituents such as metals and organic compounds, including polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAHs), and pesticides, as well as conventional stressors that may be of potential concern to human health (e.g., phosphates, nitrates). The biological indicators E. coli and fecal coliforms were also evaluated in Tier 1.

Approach: The chemical screening approach used in Tier 1 was based on technical guidance for selecting exposure routes and contaminants of concern by risk-based screening developed by USEPA Region III. The screening approach involved four steps: (1) data quality evaluation; (2) reducing the data set using risk-based concentration screening; (3) considering re-including eliminated chemicals and routes; and (4) makeing further specific reductions in the data set (optional). All chemicals for which water, fish tissue, and/or sediment data from the study area were available were evaluated in Tier 1 using the risk-based screening approach described above. Chemicals that did not exceed screening criteria in any one of the three environmental media (water, sediment, or fish tissue) were eliminated from further consideration.

4.2 Environmental Health Impacts from a Proposed Wastewater Treatment Facility

Overview: Intertox provided an evaluation of potential environmental health impacts from the construction and operation of a proposed wastewater treatment plant to workers at a neighboring food production facility and its customers. Specifically, Intertox determined whether these potential impacts had been adequately and consistently evaluated in an Environmental Impact Statement for the plant and if recommended mitigations were appropriate and set in a consistent manner. Sources of potential impacts included soil contaminants, hazardous constituents of buildings, raw and treated sewage, biosolids, disease vectors (e.g., birds, rodents, insects), and treatment chemicals. Because it produces food for public consumption, the potentially impacted facility presented unique business concerns that not only included health risks, but the perception of risks by customers due to potential odors from the proposed plant or the mere proximity of its presence.

Client Benefit: With our findings, the client was able to negotiate a favorable settlement in the matter.

Chemicals of Concern: Biological agents; volatile organic compounds; metals

Approach: Intertox performed a variety of investigations to support its findings. These included: evaluating the adequacy of the Environmental Impact Statement for the proposed plant; reviewing environmental site assessments for the parcels composing the site to determine historical releases to soil and hazardous building constituents; and performing literature reviews of chemical and biological agents in wastewater and biosolids and their potential releases.

4.3 Nanotechnology EHS Risk

Nanotechnology is likely to produce revolutionary materials for industry, consumers, and medicine. Companies worldwide are looking to take advantage of nanotechnology to help them improve products and gain competitive advantages. However, much work needs to be done to understand the environmental health and safety (EHS) risks of nanomaterials. In response to this need, Intertox has developed a nanotechnology team to help firms assess and minimize their exposure to nanotechnology EHS risks and promote good public health practices. Intertox promotes the use of multi-criteria decision analysis and risk assessment for nanomaterials management.