

## **“Risk, Science, and Regulation: Bridging the Divide”**

The Monday Plenary Session—“Risk, Science, and Regulation: Bridging the Divide”—moderated by Gail Charnley (HealthRisk Strategies) included Keynote Speaker Paul Gilman, PhD (Assistant Administrator, Office of Research and Development, Science Advisor, US Environmental Protection Agency) and Respondents Bernie Goldstein (University of Pittsburgh), Leslie Hushka (ExxonMobil Chemical Company), and Paul Locke (Johns Hopkins University, Bloomberg School of Public Health).

### **“Risk, Science, and Regulation: Bridging the Divide”**

*Paul Gilman*

In risk assessment, we attempt to elucidate the connection between exposure of some stressor to its potential adverse outcome in humans (for example, disease). As a leader in the development of risk assessment approaches for regulatory decision making, the US Environmental Protection Agency (EPA) uses to its fullest extent the relevant and available chemical- and/or site-specific data and information in characterizing risk. In addition, we encourage the development of the specific data necessary to more accurately assess potential risks, including mode-of-action data.

In many instances, there are data gaps in the underlying science and we must use default assumptions to bridge the gap in order to complete the assessment in a timely manner. Taking into account the uncertainty and variability of the data, information, and methodologies available to EPA, we tend to make science and science policy judgments to ensure we do not underestimate risk. We must continually look for opportunities to increase our certainty and confidence in the defaults and assumptions we use, that is, encourage the derivation of more data-derived defaults.

EPA has taken the lead in developing policies and guidances for the conduct of risk assessment (for example, Risk Assessment Guidelines for different endpoints, Risk Characterization Policy, Peer Review Handbook). Further, EPA is working on many efforts to improve our risk assessment practice and build up the body of credible science for use in assessments and the derivation of default assumptions. Efforts including activities such as research in the Office of Research and Development, the updating of the Cancer Risk Assessment Guidelines, EPA’s Computational Toxicology initiative, improvements to the Integrated Risk Information System, and constant vigilance to peer review all contribute to increased understanding and use of sound science in informing regulations.

### **“Bridging International Divides: Does the Developing World Need Risk Analysis?”**

The Tuesday Plenary Session—“Bridging International Divides: Does the Developing World Need Risk Analysis?”—was presented by Moderator Christopher Schonwalder (Senior Environmental Health Advisor to the Director, Fogarty International Center, National Institutes of Health) and Panelists Rosana Moraes, PhD (Golder Associates Brazil, Rio de Janeiro), Jamal Hisham Hashim, PhD (Professor of Environmental Health at the Department of Community Health, Faculty of Medicine at the National University of Malaysia), and Kuku Voyi, PhD (Associate Professor, School of Health Systems and Public Health University of Pretoria).

## **Introduction**

*Christopher Schonwalder*

Risk analysis really is where the rubber meets the road and the ultimate goal is risk management. Why support risk analysis in the developing world? (1) Because you can get some good science and very good information through associations and collaborations with the developing world. (2) It is good foreign policy to help countries in the developing world by training them to set standards.

Further sessions were held during the rest of the meeting to discuss SRA's role in supporting risk analysis in the developing world and SRA members were asked to participate and share information concerning SRA's role.

## **“Improving Decision Making Based Upon Risk Assessment in South America: Lessons Learned from Two Recent Projects”**

*Rosana Moraes*

Science is an essential foundation for effective environmental assessment, but we must recognize that it is only one element in the decision-making process. Despite our efforts to develop new tools for risk assessment, they alone will not solve environmental problems in developing countries, even if these tools are well adapted to the conditions of these countries. Problems will remain as long as existing environmental regulations are not implemented, institutional issues are disregarded, and decision makers are not aware of the applicability of tools such as risk assessment.

During this talk the major difficulties regarding project planning, data collection, implementation of the study, as well as the interaction with stakeholders and risk managers which were faced during two large environmental risk assessment projects—one in Brazil and another in Bolivia—were presented. Based on the experiences gathered during those studies, the panelists and audience were invited to think about and discuss how to improve the decision making based on risk assessment, not only in South America, but in other developing regions.

## **“Risk Analysis in Prioritizing Health Issues in Developing Countries”**

*Jamal Hisham Hashim*

There are similarities and differences between the developed and developing countries in the approach that should be used in the practice of risk analysis. In both worlds, risk analysis is a useful methodology for assessing existing and future environmental and health hazards. It can also be an effective tool for assisting countries in making sound decisions on setting standards, guidelines, and allowable exposures to environmental hazards. However, inherent differences between the two worlds in terms of science, politics, and societal value systems must be strategically addressed. There is a communication gap between the scientific community and the policy makers in both worlds, and risk analysis can be used as a bridging tool between the two. This gap is however more apparent in the developing world where policy makers are normally the dominant decision makers.

It is critical that when we conduct risk analysis in the developing world, we should not lose sight of the most important sociopolitical issues, namely poverty, low education, poor health, government inefficiency, human rights abuse, and exploitation of

labor. Risk analysis must help improve on these issues and not cause more problems than it intends to solve.

Developing countries undoubtedly need risk analysis, especially when their pace of development is sometimes more rapid than what was experienced in the developed countries. However, simpler but more comprehensive tools are needed because expertise is limited, and a broader social concern is at stake than merely environmental protection. There are many ways by which risk analysts from the developed countries can assist, but they first need to understand the sociopolitical scenarios in the developing countries. Lastly, it should be emphasized that developing countries are a heterogeneous grouping and stereotyping them would be a mistake.

### **“Crossing Boundaries in Human Health Risk Assessment for Southern Africa”**

*Kuku Vuyi*

The development in Southern Africa varies greatly among countries. It is important for state and nongovernment agencies to work together across Southern African Development Community (SADC) to ensure that health issues are central to development. Currently South Africa does have health risk assessment in some countries, however, there is little focus on health risk. The South African Department of Health is drafting environmental health impact assessment guidelines which will be used in conjunction with the Environmental Impact Assessment guidelines.

A question to ask is can the standards and guidelines of developed countries be adapted to the local needs of these developing countries without training and guidance to the users?

It is necessary to consider who needs the training and what type of training should be given (it will not be one size fits all), who should develop the training, who determines the suitability of the skills, where the training is going to take place (if people are trained outside of SADC they should be required to then return to build capacity and apply their knowledge to the benefit of the region). In addition, what are the funding sources and what institutions will participate in the program.

The proposed model for risk assessment presented in this talk would include collaboration, joint funding, use of the best practices in the developing world, and a Web site as a center of information for all those involved in the assessment.

### **“Building Bridges to the Future: Lessons Learned from Anthrax, 2001”**

The Wednesday Plenary Session—“Building Bridges to the Future: Lessons Learned from Anthrax, 2001”—was presented by Moderator Caron Chess (2004 SRA President) and Panelists Thomas Day (Vice President Engineering, US Postal Service), Monica Schoch-Spana (Senior Fellow, Center for Biosecurity of the University of Pittsburgh Medical Center), and Ivan Walks (CEO, Ivan Walks & Associates).

#### **Introduction**

*Caron Chess*

This plenary session presents not only information about lessons learned about anthrax—discussion and study of the anthrax event also provides lessons to risk analysts in dealing with many risk events that have tremendous uncertainty.

## **“USPS Response to Anthrax Events”**

*Thomas Day*

In September and October 2001, seven letters (four known and three suspect) postmarked out of Trenton, New Jersey, resulted in 22 fully confirmed cases of anthrax infection, including five deaths.

When the US Postal Service (USPS) realized this was not only an event with specific targets, but that a postal service facility also became contaminated, it started an employee personal protection program with the help of an expert panel with knowledge and experience of postal systems and processes and knowledge of specific agents and threats.

The overall strategy of the USPS if there is a threat to the system is to detect it (biohazard detection system), contain it (ventilation/filtration system), neutralize it (decontamination), and offer a level of deterrence to discourage further attacks.

In order to continue to protect postal employees and customers and safeguard the mail from future attacks, the USPS will use many technologies working together to provide near real-time detection at the entry unit; limit potential exposure to employees; ensure that mail does not leave the facility, eliminating cross-facility contamination; implement a controlled shutdown of the facility; and reduce the decontamination effort needed.

## **“Responding to Bioterrorism in the Information Age: Public Reflections on Anthrax”**

*Monica Schoch-Spana*

Findings of a national study to advise government and public health leaders on the communication requirements of bioterrorism response, based upon experiences during the 2001 anthrax attacks and challenges anticipated during a smallpox attack, were discussed. Twenty-three focus groups were conducted July 2002 to June 2003 among three priority subject groups: (1) official responders (for example, local political leaders, health officials, emergency managers, safety officials, physicians, nurses, journalists, Red Cross), (2) people potentially at increased risk of anthrax exposure (for example, mail handlers, congressional staff, media organization staff, others in anthrax epicenters), and (3) grassroots leaders from a broad variety of organizations and neighborhoods. Research sites were selected for their proximity to or distance from the 2001 terrorist events and to represent diverse regions of the country as well as cities of varying size and density.

Key findings include (1) Communication in the information age: Modern outbreaks involve a diffuse public without immediate epidemiological or physical involvement. We must deal with this contemporary condition of epidemics through effective communications. (2) Uncertainty amidst expectations of scientific precision: Public expectations of instantaneous knowledge by government experts regarding the scope and nature of a public health crisis and possible solutions are high; we need to recalibrate. (3) Public health in a world of have and have not: Bioterrorist crises map onto existing social and economic fault lines (for example, race/ethnicity, labor/management).

## **“Lessons Learned”**

*Ivan Walks*

There is a big difference between telling people what you know and what you tell people to do. How do you get to a point where you communicate that?

There are divides present that need to be crossed: social/economic, historic, cultural, health status, health history, and health literacy. The challenge is in communication and credibility—you must have credible folks giving a clear message to get everyone to respond.

Among the many lessons learned from the anthrax attacks are (1) you need a subject-matter expert available, (2) you need to be a listener as well as a teacher at all times, (3) the job you have to do is more important than you the individual, (4) most of the folks who show up for treatment aren't physically injured—we have to look at psychological aspects also, and (5) relationships made in time of crisis can help a lot post-crisis, for example, in dealing with immunizing school children, obesity, and asthma.

When you are in an unfamiliar situation and don't have all the facts, you need “imaginative leadership” to develop creative solutions. As risk communicators, we must be able to tell people what we know and what we don't know and when we will know more. We need to continue to be honest with people.