As my term as President of the Risk Assessment Specialty Section (RASS) comes to an end, I again want to thank the members of RASS for the honor to serve as your President and to extend my sincerest thanks to the strong support from our team of 2011-2012 officers. I also extend our sincerest thanks to Annie Jarabek as she continues to organize and host our popular teleconference series, and John Christopher who continues to serve this specialty section.

As I mentioned in my previous message, we wanted to focus our work this year on ways to increase students’ involvement in RASS. We have revised our by-laws this year to formalize the terms of involvement for graduate and postdoctoral students. We have applied this new process and added a graduate and a postdoctoral position to the nomination and voting process this year, which allowed our members to play a larger role in the identification of students interested in playing a more active role in RASS. We also will continue to provide awards for our student members and are extremely grateful to our continued sponsors and endowment funds that allow RASS to sustain these awards.

Another priority for 2011-2012 is to increase RASS’ collaboration with other specialty sections and societies, in turn increasing the interaction among scientists involved in various aspects of risk assessment. I encourage all of our members to attend a workshop at the annual meeting that was supported by RASS and developed in collaboration with the SETAC Human Health Risk

You Are Invited to the Annual SOT RASS Reception

The annual SOT meeting is just around the corner and the RASS Council looks forward to welcoming you to the Risk Assessment Specialty Section Reception. The RASS reception will take place from 6:00 to 7:30 pm on Tuesday March 13th with the following schedule of events:

- 6:00 pm -- Annual RASS awards and business meeting
- 6:20 pm – Science Forum: Perspectives on the Future of the EPA IRIS Program.
- 7:00 pm— Networking and socializing.

See detailed announcement, Page 3
Risk assessment is absolutely central to what we do as toxicologists, whether directly or indirectly—the goal of our discipline is to apply research knowledge towards assessing and characterizing the potential for adverse chemical effects for protecting human and ecological health. However, as students and postdocs, many of us do not receive formal training on the topic as we focus on what could be characterized as more theoretical benchtop research efforts, and the steps involved in performing risk assessments can be overwhelming and confusing. Some of the confusion involves a lack of familiarity with the concepts and methods of risk assessment and the related regulatory aspects that ultimately control how risk assessments are conducted and interpreted. While the scientific research we perform for our academic degrees or further postdoctoral training covers an essential part of toxicology, students and postdocs often do not have the opportunity to apply their research in the risk assessment process. As the student and postdoctoral representatives of RASS, we thought that a crash course in the steps of the risk assessment paradigm may be helpful to other students and postdocs who are interested in careers in this exciting and dynamic arena.

Depending on who is conducting the risk assessment, the process can differ in methodology and the steps used to obtain the final product. The U.S. National Research Council (NRC) report, “Risk Assessment in the Federal Government: Managing the Process”, more commonly known as the “Red Book” (NRC, 1983) has been widely accepted and endorsed by several federal and private agencies. This risk assessment process consists of four steps: hazard identification, dose response assessment, exposure assessment, and risk characterization.

1. Hazard identification. This is the process of determining whether a chemical exposure causes an increased incidence of an adverse health effect (such as reproductive effects, cancer, etc). This is the first step in the risk assessment process; if exposure to the chemical doesn’t cause any adverse effects (or if the regulatory agency conducting the assessment chooses to take action without further analysis), the assessment stops here. Use of available human data for the hazard ID is ideal (biomonitoring data, occupational data, etc); however, for many substances, epidemiological data is not available or the evidence for an association between exposure and adverse health effects is not convincing (small number of study subjects, limited time period, etc.). Thus, we often have to rely on data from controlled animal studies demonstrating an association between exposure to the chemical and an adverse effect. Reliance on animal data introduces uncertainties around human relevance, human sensitivities, mode-of-action, and other issues that make risk assessment challenging.

2. Exposure assessment. This is where human exposure to the agent is measured or estimated based on theoretical input factors such as how much drinking water is consumed, how much soil is ingested, bioavailability, etc. The duration, frequency, amount to which people are exposed, sources from which they are exposed, and the route of exposure must all be considered (i.e., is the exposure acute or chronic? Are people exposed occupationally, environmentally, through food, or drinking water? Are...
Assessment Advisory Group. The goal of this workshop, entitled Concepts Critical to the Next Generation of Human Health and Ecological Risk Assessment, is to highlight challenges currently facing the next generation of risk assessors. With the release of the recent National Academy of Sciences Silver Book, risk assessors are faced with the challenge of integrating innovative data (e.g., genomics) into the current risk assessment paradigms and with the development of new paradigms or methods to address changing issues in risk assessment. In considering all the biological changes and scientific information, many of these new methods attempt to incorporate all of the available scientific information for a compound or even for mixtures. This type of integration can be used to better inform both human health and ecological risk assessments. The Workshop will be held on Monday, March 12, 2012, from 2:00 to 4:45 pm in Room 309 of the Moscone Convention Center.

I look forward to seeing you all at the 2012 SOT Annual Meeting in San Francisco, CA and hope you will plan to attend the reception on Tuesday night from 6:00-7:30 pm in Golden Gate Ballroom A at the Marriott Marquis for our annual awards and a Forum on the future of the USEPA IRIS program. In addition, I hope you will plan to attend the SOT Contemporary Concepts in Toxicology Workshop, “Building for Better Decisions: Multi-Scale Integration of Human Health and Environmental Data” of which RASS is a sponsor. This workshop will be held in RTP, NC, May 8-11 and offers a unique opportunity for scientists from all aspects of both human health and ecological risk assessment to come together with software developers and data analysts to advance application of toxicological data in risk assessment.

Thanks again and see you in San Francisco!

Robinan Gentry, Ph.D., DABT

**************************************************

2012 RASS Reception
Tuesday, March 13, 2012, 6:00-7:30 pm

Reception Forum: Perspectives on the Future of the EPA IRIS Program

Following the presentation of the Annual RASS awards and business meeting at 6:00 pm, a brief Forum will be held at the RASS annual reception. The Forum topic will consist of comments and questions surrounding the USEPA Integrated Risk Information System (IRIS) program. Three invited panelists/presenters will initiate the discussion with the presentation of brief perspectives from both government and industry on the current utility of the IRIS program and the changes recommended. The panelists/presenters will include:

- Dr. Vince Cogliano, USEPA
- Dr. Richard Becker, American Chemistry Council
- Dr. Ivan Rusyn, Committee member from the recent National Academy of Science review of the Draft IRIS Toxicological Profile for Formaldehyde.

Each Panel member will provide an initial 5 minute perspective that addresses the following questions:

- What is the current use and function of the IRIS program?
- What are the benefits/shortcomings of current processes and use of data?
- What are the proposed areas for improvement?

Following the presentation from each Panel Member, the floor will be opened for 20 minutes to the RASS members at the reception for questions/comments/rebuttal. Closing remarks will be provided by Robinan Gentry, RASS President. The remaining reception time will be available for RASS members to network.

“...a priority for 2011-2012 is to increase RASS’ collaboration with other specialty sections and societies, in turn increasing the interaction among scientists...”
they inhaling the substance, is it dermally absorbed? At what concentrations is the chemical present in air, dust, or drinking water?). Sensitive subpopulations should also be considered. The fetus and infant can be exposed through the placenta or breast milk, or other individuals may be more susceptible to the toxic effects of a chemical due to a preexisting health condition.

3. Dose-response assessment. This is the task of defining a relationship between the administered dose (or if you’re lucky, the internal dose) and the incidence of adverse health effects in exposed individuals, and then quantifiably estimating the incidence of adverse effects as a function of human exposure to the agent. Rarely do epidemiologic data allow for a dose-response relationship to be defined directly from observations in humans. Thus, a dose-response assessment usually requires extrapolation from animals to humans and from high to low doses, both of which introduce uncertainties in the risk estimates. Variability in age, sex, susceptibility, and differences in exposure patterns must also be taken into account to obtain risk estimates for the entire population. The use of a physiologically-based pharmacokinetic (PBPK) model is a very useful tool to define a relationship between the administered dose and internal dose, for extrapolation across dose routes and species, and to evaluate population variability.

4. Risk characterization. This is the process of estimating the resulting adverse health effects that are expected to occur under various exposure scenarios in the exposed population. This is done by integrating the data from the exposure assessment and dose-response assessment steps. The uncertainties also carry over and are considered in this step. This information is usually presented in different ways for cancer and noncancer effects.

a. Cancer Effects. Cancer risk is usually expressed as the maximum number of new cases of cancer expected to occur in a population of 1 million people from exposure to the chemical over a life time of 70 years. In other words, a cancer risk of 1 in 1 million for a substance means that in a given population of 1 million people, not more than 1 person would be expected to develop cancer as a result of exposure to the substance. Cancer risk assessment is a controversial topic. Thresholds and margin of exposures (MOE) approaches are generally accepted in countries outside the US. In the US, linearity is assumed in most cases of cancer risk assessment, meaning that there is no threshold dose (i.e., any exposure is considered to present an increased cancer risk).
b. **Noncancer Effects.** Noncancer risk is usually determined by comparing the actual human level of exposure to a chemical with the calculated level of exposure that is not expected to cause any adverse effects. Calculated levels are generally based on the results of animal studies (using LOAELs and NOAELs and benchmark dose modeling to provide points of departure), and various uncertainty factors are then applied (intraspecies uncertainty for human variability, animal to human extrapolation, subchronic to chronic uncertainty, etc). The application of uncertainty factors to the point of departure result in the reference dose (RfD) or reference concentration (RfC), which can be much lower than the levels that were found to have no adverse effects in the animal study.

Regulatory decisions, such as setting drinking water standards or cleaning up hazardous waste sites, rely on human health and environmental risk assessments. Risk management, which is the process of evaluating alternative regulatory options and selecting a course of action from among them, may be informed by the scientific information coming from the risk assessment of a chemical, and thus, the risk assessment may be one of the bases of risk management. Risk management decisions are focused on the protection of public health, but economic, social, and political implications must also be considered when making decisions (risks vs. benefits). For example, if regulatory requirements are set at the most conservative level, the cost of removing a chemical from a community water supply could be prohibitively expensive for customers or the loss of employment due to the closing of a manufacturing facility could have a devastating effect on a particular community. The scientific information from the risk assessment can thus aid in weighing the benefits vs. the risks for reducing chemical exposure. While it would be ideal to completely eliminate all exposure to hazardous substances, it is not possible to remove all of it once it has been released to the environment. The goal is to reduce the human health and environmental risks resulting from exposure to the chemical to negligibly low levels.

We hope that this short outline of the risk assessment process is helpful and that you can see how your respective research projects can contribute to this process and protection of human and public health.
**RASS Sponsorship Guidelines**

Two times per year the Risk Assessment Specialty Section will review of proposals for supporting activities of interest to our members.

Proposal ideas should be submitted by Jan. 1 and June 1 for consideration. Based on our budget projections, we anticipate that we can support one to two activities at approximately $1,000 to $2000 each. Priority will be assigned based on the following criteria:

- Impact student and fellow participation in RA
- Potential for making a difference in our field
- Potential for benefiting a large sector of our members

All recipients of these awards will be asked to submit a report to the RASS that will include the following information.

1. Identify the impact of the conference – list both your methods and enclose any reports generated from the event
2. Attach electronic copy of course/workshop presentation materials
3. Attach the attendance list from the event. Identify the RASS members who attended by sector i.e., Government, Industry, Consulting or Academic. Specifically identify student or postdoctoral fellow members.

---

**In Memory of Randall Oliver Manning**

After a six-year struggle with cancer, Dr. Randall Oliver Manning died peacefully at his home on Monday, January 16th. Randy was a rare individual with intelligence, kindness, compassion and grace to spare. The scientists who worked with him and the students he taught all loved him for his optimism, his sense of humor and his energy. He was the consummate professional with the perfect combination of technical aptitude, charm, and the sense that science was indeed fun. He was a much-sought and valued collaborator.

Randy received his doctorate from the College of Agriculture at the University of Georgia. In 1990, he became the state toxicologist for the Environmental Protection Division at the Georgia Department of Natural Resources. He was a pioneer in the area of fish consumption advisories and provided these for the state of Georgia. He was a full member of the Society of Toxicology and Chemistry. He was also a member and served as Chapter President of the Southeastern Regional Chapter of the Society and was a member of the Risk Assessment Specialty Section. He served on the Board of Directors with the Toxicology Excellence for Risk Assessment and was a consultant to the U.S. Environmental Protection Agency and the ATSDR/Centers for Disease Control.

Randy was an avid gardener of both flowers and vegetables. He was a voracious reader and enjoyed traveling. He is survived by his wife, Rita.
Announcement

Building for Better Decisions: Multi-scale Integration of Human Health and Environmental Data

WHY: Toxicologists and other environmental scientists now face the challenge of integrating increasingly complex data to translate our work and predict adverse outcomes in various applications.

WHAT: An SOT Contemporary Concepts in Toxicology Workshop, an open, international conference featuring breakout groups related to exposure, dose-response, ecosystem impacts, life cycle/cost-benefit, and information technology that provide an opportunity for scientific discussion and debate. In addition, abstracts can be submitted for poster presentations to facilitate discussions and develop recommendations.

WHO: Sponsored by the SOT and US EPA with:
DOD ACE
DOE PNNL
NRC
USDA
US FDA
USGS

SETAC
SRA
ISES
iEMS

American Chemistry Council
Environ Corp.
OGC
OpenMI
TERA

WHEN: May 8 – 11, 2012

WHERE: US EPA, RTP Campus, NC

For complete information (Agenda, Abstract submission, Registration, etc) go to: https://www.toxicology.org/ai/meet/cct_b4bd.asp
Deadline for Abstract Submission is March 23, 2012