President’s Message

By: Edward V. Ohanian, PhD

Dear Colleagues,

Greetings and welcome to the SOT’s Regulatory and Safety Evaluation Specialty Section (RSESS) Winter Newsletter. I am taking this opportunity to share with you some of RSESS’ past accomplishments/success stories while introducing some new activities of interest to you as we are preparing for the SOT 57th Annual Meeting and ToxExpo in San Antonio, Texas.

At our RSESS Meeting and Reception on Monday, March 12th at 6:00 – 7:30 PM, the RSESS Awards Ceremony will include: “RSESS Graduate Student Excellence Award”, “RSESS Postdoctoral Excellence Award” and “Best Published Paper Award.” For more details on requirements and deadlines related to these awards, please visit this RSESS website’s “Awards” section and/or contact any of the members of RSESS’ Executive Committee. Following the Awards Ceremony, we will have our favorite “Great Debate,” this year entitled “Relevance and Predictability of Animal Toxicity Studies to Human Toxicity.” The debater on the Pro side – Dr. David Herr, USEPA and on the Con side, Dr. Michael DeVito, NIEHS.

Our popular Breakfast Seminar is scheduled for Wednesday, March 14th at 6:30 AM. We are very fortunate to have Dr. Scott Jordan, Associate Director, Marketed Biologicals, Biotechnology and Natural Health Products Bureau, Marketed Health Products Directorate, Health Canada, as our distinguished speaker. We are also delighted to introduce a brand new initiative which will encourage networking and mentoring of young professionals by experienced toxicologists. The goal of this “Lunch and Learn Mentoring Event” on Wednesday, March 14th at 11:30 AM is to provide mentees with an opportunity to learn about careers in regulatory and safety evaluation through small group discussions with a toxicologist experienced in this field. More specifics related to these events can be found within this Newsletter.

Inside this issue:

<table>
<thead>
<tr>
<th>President’s Message</th>
<th>1-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSESS-sponsored meetings at SOT</td>
<td>2</td>
</tr>
<tr>
<td>Hot Topics</td>
<td>3-5</td>
</tr>
<tr>
<td>RSESS-sponsored Mentoring Event</td>
<td>5</td>
</tr>
<tr>
<td>Annual SOT RSESS Meeting Reception—Awards, Great Debate</td>
<td>6</td>
</tr>
<tr>
<td>SOT RSESS Breakfast Seminar</td>
<td>7</td>
</tr>
<tr>
<td>Recap of RSESS-sponsored Webinar—GLP Regulations</td>
<td>7</td>
</tr>
<tr>
<td>GSLC and RSESS Collaboration on Webinar—Careers in Regulatory Toxicology</td>
<td>8</td>
</tr>
<tr>
<td>Graduate Student Training Funds</td>
<td>9</td>
</tr>
</tbody>
</table>
As far as some key past events from 2017, on Friday, September 29, 2017 at 11:30 AM, the RSESS Executive Committee (EC) hosted a webinar on “Updates to FDA’s GLP Regulations”, by Dr. Mark Seaton, Ph.D., US FDA. The webinar focused on the Good Laboratory Practice regulations (GLPs; CFR Title 21, Part 58) for nonclinical laboratory studies which were established by the FDA in 1978. GLPs provide a framework to ensure the quality and integrity of data generated from nonclinical laboratory studies.

On October 31, 2017 at 1:00 PM, RSESS in conjunction with the Graduate Student Leadership Committee (GSLC) conducted a very timely webinar on “Finding Your Dream Job in Regulatory Toxicology.” Additional details related to this event, including a link to presentations can be found elsewhere in this newsletter.

Please don’t hesitate to participate in RSESS activities and feel free to contact any of our officers and councilors with your thoughts, suggestions, and/or recommendations. The members of the Executive Committee are as follows: Marie Fortin (Vice President), Anne Loccisano (Vice President Elect), Amy Roe (Secretary-Treasurer), Norman Kim (Councilor), Monique Williams (Graduate Student Representative) and Gregory Smith (Post-Doc Representative). RSESS needs you!

See you in Antonio Texas in March 2018

Be well!

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(Continued from page 1)

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2018 SOT Annual Meeting Important Dates!

- 57th Annual SOT Meeting and ToxExpo, San Antonio, TX March 11-15, 2018
- RSESS Meeting and Reception, Monday, March 12th, 6:00—7:30 PM (includes Awards presentations and the Great Debate)
- RSESS-sponsored Breakfast Seminar, Wednesday, March 14th, 6:30—8:00 AM
- RSESS Executive Committee Meeting, Monday, March 12th, 6:30—8:00 AM
- RSESS-sponsored Mentoring Event, Wednesday, March 14th, 11:30 AM

Refer to the Annual Meeting Program, Mobile Event App, or Online Planner for up-to-date details on meeting locations.
EPA launches cross-agency effort to address PFAS

Per- and polyfluoroalkyl substances (PFAS) can make products stain-resistant, waterproof, and nonstick. These chemicals, known as PFAS, do not break down easily in the environment and can build up over time in exposed organisms like fish and wildlife. EPA has launched a cross-agency effort to help communities across the country address these chemicals in their environment.

Last year, Congress passed a bill to reform the Toxic Substances Control Act (TSCA), which helps EPA protect American families from the potential health effects of chemicals. To make sure TSCA is enforced effectively, EPA requires the best scientific data on chemical safety. EPA researchers are developing and improving tools to provide chemical data and help implement TSCA.

EPA recently announced a cross-agency effort to address PFAS. The agency’s water and research offices will lead the effort, and regional offices will help to enhance cooperation with partners at the state and local levels and to provide on-the-ground knowledge about specific issues – and address PFAS nationwide.

As part of the agency’s work, EPA will:

- Identify a set of near-term actions EPA will take to help support local communities.
- Enhance coordination with states, tribes, and federal partners to provide communities with critical information and tools to address PFAS.
- Increase ongoing research efforts to identify new methods for measuring PFAS and filling data gaps.
- Expand proactive communications efforts with states, tribes, partners, and the American public about PFAS and their health effects

visit the PFAS in Your Environment web page for more information.

Safeguarding Science to Protect Human Health and the Environment*

Science is the backbone of our informed decision-making. Our ability to pursue our mission to protect human health and the environment depends upon the integrity of the science on which we rely. The environmental policies, decisions, guidance, and regulations that impact the lives of all Americans every day must be grounded, at a most fundamental level, in sound, high quality science. It is our key responsibility to conduct, utilize, and communicate science with honesty, integrity, and transparency. As an example, this article will focus on the implementation of the Environmental Protection Agency’s (EPA) Scientific Integrity Policy (https://www.epa.gov/osa/policy-epa-scientific-integrity).

This policy provides a framework intended to ensure scientific integrity throughout the Agency and
promote scientific and ethical standards, including quality standards; communications with the public; the use of peer review and advisory committees; and professional development. It also describes the scope and role of a standing committee of Agency-wide scientific integrity officials to implement this policy.

This Scientific Integrity Policy builds upon existing Agency and government-wide policies and guidance documents, enhancing the EPA’s overall commitment to scientific integrity. This commitment is evidenced by the Agency’s adherence to the 2002 Office of Management and Budget (OMB) Information Quality Guidelines(1), the 2005 OMB Information Quality Bulletin for Peer Review (2), the EPA’s Quality Policy (3) for assuring the collection and use of sound scientific data and information, the EPA’s Peer Review Handbook (4) for internal and external review of scientific products, and the EPA’s Information Quality Guidelines (5) for establishing the transparency, integrity, and utility of information published on the Agency’s websites.

The Agency has appointed a Scientific Integrity Official to champion scientific integrity throughout the Agency. The Scientific Integrity Official chairs a standing committee of Deputy Scientific Integrity Officials representing each EPA Program Office and Region. These senior level employees provide oversight for the implementation of the Scientific Integrity Policy at the EPA, act as liaisons for their respective Programs and Regions, and are available to address any questions or concerns regarding this policy.

As of the effective date, all Agency employees, including scientists, managers, and political appointees, are required to follow this policy when engaging in, supervising, managing, or influencing scientific activities; communicating information in an official capacity about Agency scientific activities; and utilizing scientific information in making Agency policy or management decisions. In addition, all contractors, grantees, collaborators and student volunteers of the Agency who engage in scientific activities are expected to uphold the standards established by this policy and may be required to do so as part of their respective agreements with the EPA.

This policy is created against a complicated regulatory backdrop; it is intended to guide Agency activities in an area that is already subject to a number of rules and policies for various purposes. When there is overlap with other applicable rules and guidance, this policy is not intended to preempt other authorities, but instead to work in conjunction with and supplement them. This policy is intended to improve the internal management and operation of the Agency. It does not create any obligation, right or benefit for any member of the public, substantive or procedural, enforceable by law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees or agents, or any other person.

Consistent with the EPA’s Principles of Scientific Integrity, the Agency’s Scientific Integrity Policy reaffirms the expectation that all Agency employees, including scientists, managers, and political appointees, regardless of grade level, position, or duties:
HOT TOPICS (continued)

Edward V. Ohanian, Ph.D.
President, RSESS

References:


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**RSESS First Mentoring Lunch and Learn!**

2018 SOT Annual Meeting

The RSESS is sponsoring a new initiative this year to provide trainees (e.g. students and post-docs) with an opportunity to learn about careers in regulatory and safety evaluation through small group discussion with a toxicologist experienced in this field. This networking event will foster the development of lasting professional relationships that will benefit both the mentors and mentees. The activity will be held in a restaurant near the Convention Center as a “Lunch and Learn Mentoring Event” on Wednesday, March 14th at 11:30 AM. **A few seats remain available for mentees.** If you are interested, please send an email to mentoring.rsess@gmail.com and provide your name, status, institution, and submit a question regarding careers in safety evaluation and regulatory toxicology.

Looking forward to making new connections! Your hosts, Monique Williams and Marie Fortin
Don’t Miss This Year’s Great Debate at the 2018 SOT Annual RSESS Reception

The 2018 RSESS Recession is on Monday, March 12 at 6:00 – 7:30 PM.

The title of this year’s debate is “Relevance and Predictability of Animal Toxicity Studies to Human Toxicity”. We are very fortunate to have 2 outstanding experts in the field to address this timely topic:

Pro – Dr. David Herr, USEPA  
Con—Dr. Michael DeVito, NIEHS

Refer to the Annual Meeting Program, Mobile Event App, or Online Planner for up-to-date details on meeting locations.

RSESS Graduate and Post-doctoral Student Awards
&
Best Published Paper Award!

The RSESS will present Excellence Awards for both graduate and post-doctoral students and a Best Published Paper Award. The winners of these awards will be announced at the RSESS Reception at the SOT Annual Meeting.
2018 SOT Annual Meeting Breakfast Seminar

Dr. Scott Jordan, Health Canada, will provide the annual RSESS Breakfast Seminar on Wednesday, March 14th, at 6:30—8:00 AM.

Dr. Jordan is Associate Director of the Marketed Biologicals, Biotechnology and Natural Health Products Bureau of Health Canada. He will provide an overview of how OTC drugs and dietary supplements are regulated through Health Canada, challenges in the assessment of their safety, and an update on any recent changes in regulations related to this category of products.

Dr. Jordan joined Health Canada’s Food Directorate in 1992, where he conducted toxicological assessments on a wide variety of food-related chemicals (both natural and synthetic) and food contaminants. He became increasingly interested in the safety of herbal products used in food or as medicinal ingredients. Since 1998, he has been involved in risk assessment pertaining to natural health products (dietary supplements). Dr. Jordan took part in the discussion leading up to the formation of the Canadian Office of Natural Health Products (now the Natural Health Products Directorate of Health Canada), and contributed to the review of regulations for natural health products in Canada, which came into force in 2004.

Dr. Jordan joined the Marketed Biologicals, Biotechnology and Natural Health Products Bureau of the Marketed Health Products Directorate of Health Canada in 2003, as a senior reviewer. Since that time, he has been involved in the risk assessment of marketed natural health products from the post-market (pharmacovigilance) perspective, as both an evaluator and manager.

RSESS Webinar on Updates to FDA’s GLP Regulations

RSESS sponsored a webinar titled “Updates to FDA’s GLP Regulations” on September 29, 2017. Captain Mark Seaton, Ph.D., DABT, who is the Regulatory Officer in the Office of Study Integrity and Surveillance at the FDA, was the presenter of the webinar.

The Good Laboratory Practice regulations (GLPs; CFR Title 21, Part 58) for nonclinical laboratory studies were established by the FDA in 1978. GLPs provide a framework to ensure the quality and integrity of data generated from nonclinical laboratory studies. As a continued modernization process in pharmaceutical evaluation and development, the FDA has recently proposed updates to the GLP regulations. The webinar provided a brief history of GLP regulations, background for Notice of Proposed Rulemaking (NPRM), and highlighted the proposed changes of the current GLP regulations. The webinar was well attended with over 800 registered. Recording and slides of the webinar are available on the SOT’s RSESS website:

http://www.toxicology.org/groups/ss/rsess/events.asp

We would like to specially thank the SOT, in particular SOT staff members, Raul Suarez and Ashley Black, for making this webinar possible.
Graduate Student Leadership Council and RSESS Collaborate

On October 31st, 2017, the Graduate Student Leadership Council (GSCLC) and the RSESS held a joint webinar entitled, “Careers in Regulatory Toxicology.” The webinar was organized by GSLC members, Lauren Walker (GSLC Professional Development Subcommittee Secretary), and Krystin Carlson (GSLC Professional Development Subcommittee Chair).

Many graduate students and postdoctoral scholars have expressed interest in pursuing Regulatory Toxicology and/or Risk Assessment careers, and they are looking for information on how to prepare for pursuing occupations in these fields. To address this interest, the GSLC and RESESS developed a webinar designed to answer the pressing career questions students and postdocs have for scientists currently working in Regulatory Toxicology and Risk Assessment. Topics included discussion of experience required for launching into such a career path, what working in these areas is like on a daily basis, as well as important advice to potential job seekers.

Dr. Ed Ohanian (EPA), Dr. Amy L. Roe (Procter & Gamble), and Dr. Anne Loccisano (Exponent) provided perspectives on careers in regulatory toxicology across government, industry, and consultant firms.

SOT Graduate Student Leadership Committee (Baltimore, MD 2017)
ATTENTION GRADUATE STUDENTS! (or their mentors)

Supplemental Training for Education Program (STEP)- Next Deadline: May 1

Doctoral students are encouraged to apply with a strong application that proposes participation in a workshop or event that enables professional or scientific training needed to achieve career goals, but that is outside the scope of their graduate program.

For more info: http://www.toxicology.org/education/st/step.asp