Dear Colleagues,

Thanks so much for being part of our Specialty Section, one of the largest in the Society of Toxicology. Your dedication and daily striving to integrate toxicology findings into risk assessment and regulatory positions are both important. Such efforts need to be not only scientifically-based, but peer reviewed, honorable to diverse stakeholders, easily communicated, and protective of public health and the planet on which we all live. This is not an easy task by any one of us, but working together can yield surprising results. For example, during this year together we have or have started to:

- Investigate the seeming plethora of poorly conceived and described toxicology literature, under the leadership of Marie Fortin with a small ad hoc committee whose members are: Frank Dost, Lynn Pottenger, Mike Kamrin, Jaya Chilakapati;
- Develop a process to showcase some of our best publications, under the leadership of Suzanne Fitzpatrick;
- Continued the process of developing webinars and non-SOT meetings, under the leadership of Ed Ohanian and April Lake;
- Broker the invitation of a highly regarded regulator from the South Pacific to our next SOT speaker’s breakfast, under the leadership of Suzanne Fitzpatrick and Amy Roe;
- Explore methods for a risk assessment certification process, under the leadership of Suzanne Fitzpatrick and Michael Dourson;
- Offered toxicology, risk assessment and regulatory principles to the Society of Environmental Journalist at their annual meeting; and
- Successfully implemented a stunning program at the 2017 SOT Annual Meeting under the leadership of Elizabeth (Liz) Vancza with a small and very dedicated standing committee composed of Mark Powley, Robert (Bob) Budinsky, John Ko zlosky, Mary Ellen Cosenza, and David Allen.

(Continued on page 2)

President’s Message

by Michael Dourson
PhD, DABT

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In short, our work as a Specialty Section embodies SOT’s mission to create a safer and healthier world by advancing the science and increasing the impact of toxicology. As always, if you want to participate more fully in this collective work of RSESS, please feel free to contact any of the officers and councilors.

Enjoy your holiday season.

Michael

Global Regulatory Breakfast about Regulatory Landscape in China at SOT Annual Meeting in New Orleans

Speaker: Dr. Jianxun (Jack) Xie, Head of Toxicology at Pharmaceutical Sciences, Roche Innovation Center, Shanghai, China

At the 55th Society of Toxicology (SOT) Annual Meeting in New Orleans on March 15th 2016, Dr Jianxun (Jack) Xie, presented an overview of the CTA/NDA Regulatory Landscape in China on behalf of the China FDA (CFDA). He kindly stepped in on behalf of Dr. Qingli Wang, Deputy Director of Pharmacology and Toxicology at the CFDA’s Center for Drug Evaluation, who could not travel to SOT on short notice.

The lecture, which was organized by Amy L. Roe and Annette Körner current RSESS councilors and treasurer received an overwhelmingly positive feedback. During the well-attended early morning session, Dr Xie shared a comprehensive overview of the Chinese Health Authority structure, an update on the changes and progress in pharmaceutical regulations, as well as an illuminating comparison between US/EU regulations. Colleagues from around the globe actively engaged in an ensuing discussion and were eager to better understand the regulatory processes in China. All SOT RSESS Board members, including the president, Suzy Fitzpatrick from the US FDA, and Dr. Lijie Fu, Vice President of Chinese SOT (CSOT), attended the entire session.

You can find the entire presentation on our RSESS website. For next year the RSESS council is currently considering potential speakers from various regulatory agencies from the South Pacific to once again bring deep insights into global regulation to our membership.
On September 21, 2016, the United States Environmental Protection Agency (EPA) released the final document, “Technologies for Legionella Control in Premise Plumbing Systems: Scientific Literature Review.” The document, which is posted on EPA’s website, can be found here.

The document summarizes scientific literature on effective strategies for controlling Legionella growth in plumbing found in buildings and facilities. With this information, states, facility owners/operator, and others can make more informed risk management decisions that prevent or mitigate Legionella growth in premise plumbing. EPA produced this document based on requests from states and the Veterans Health Administration for EPA to provide information on effective strategies for controlling Legionella in buildings. State drinking water program representatives participated in the preparation of the document and experts from the United States Centers for Disease Control and Prevention provided feedback on several sections of the document. EPA also obtained input from the public and external experts.

The document does not recommend any particular technology nor the installation of treatment. It does not apply to households but rather to commercial and institutional facilities. Please feel free to contact César Cordero (technical lead) at cordero.cesar@epa.gov if you have any questions.

Now Announcing the 2017 RSESS Student Travel Award!

Are you, or do you know, a student or postdoctoral scholar who will be presenting a poster or making a presentation at the 2017 SOT Annual Meeting in Baltimore, Maryland? If so, you should know that the RSESS plans to continue its successful practice of providing travel awards to trainees who have presentations that are broadly applicable to regulatory toxicology or safety evaluation.

In 2016, 6 awardees were each given $1,500 by the RSESS to defray travel costs to the SOT Annual Meeting in New Orleans, Louisiana. For 2017, we intend to again offer awards of $1,500 each to selected awardees. Please note that undergraduate and graduate students as well as postdocs are eligible.

To submit an application, email the following information before December 15, 2016 to Dr. Edward V. Ohanian, Vice President, RSESS, ohanian.edward@epa.gov

- Application forms are available at RSESS website;
- The abstract of the work that you will be presenting at the 2017 SOT meeting; and
- A recommendation by the student or postdoc’s advisor.

Awardees will be notified by February 15, 2017.
We are looking forward to your applications!!!
The Lautenberg Chemical Safety Act Update (TSCA Reform)
By Sol Bobst MBA PhD DABT, ToxSci Advisors

On June 22nd, President Obama signed the Frank R. Lautenberg Chemical Safety Act for the 21st Century. The effort represents several years of bi-partisan negotiation to amend and reform the Toxic Substance Control Act from the late 1970s. The new law has major impacts on how the government will review not just new, but existing inventory chemicals, as well as how industry and non-governmental organizations will interact. The EPA has set up a website for the program and updates here.

The new law will require the EPA to systematically review the safety of commercial chemicals, excluding those regulated as food, drugs, or pesticides. The goal is to ensure that no chemical in commerce poses an unreasonable risk the human health or the environment. The agency has had little real regulatory action directly on commercial substances since 1991 when a federal appeals court denied the EPA to ban asbestos products as cancerous. The agency also was limited to reviewing new chemicals versus the existing inventory for practical purposes after the 1991 decision. The agency will start conducting its new work by conducting risk reviews of at least 10 chemicals from a priority list of 90 chemicals.

Another major change in the law is in how trade secrets are managed. The Lautenberg act requires chemical manufacturers / importers to provide evidence to support the need or justify a confidential claim (not otherwise in commerce, proprietary). Claims will expire after ten years unless re-asserted. Under the old law, Confidential Business Information claims would never expire.

On the testing side, the new law also aims to reduce the use of laboratory animal testing. The mandate is that the EPA must opt, whenever practical and justified, to use alternatives to animal testing on chemical toxicity for studies done with vertebrates. EPA will have to identify these methods that it will consider reliable and relevant enough to replace animal tests to make regulatory and risk assessment decisions.

The last but not least important update is how the new federal law manages chemical regulations by the states, a topic which stalled passage of the bill until acceptable compromise was reached. Under the compromise agreement, states that had bans on chemicals in commerce are allowed to retain any bans based on legislation that was passed by April 22nd, 2016 of this date. If any future actions of the EPA determine that the chemical does not pose unreasonable risk to human or environmental health, then the EPA forbids the states to act on that law (hence pre-emption, or federal over state power). However, it is expected that the EPA will take a long time to review the existing or priority chemicals in the inventory, and states are free to pass legislation on any chemical that has not been reviewed at the EPA or released a determination on its risk to human and environmental health.

In summary, regulatory stakeholders should expect a lot of planning, rulemaking, and implementation of the new law at the EPA, new chemical legislation at state level, and new chemical testing in the industry consortia in order to deal with the new regulatory frameworks of the Lautenberg act. For detailed information: the text of the new law can be read here: link. Contact Sol Bobst at 281-686-6363 or sol@toxsciadvisors.com for any questions.
Implications of Brexit for the Science of Toxicology

By Marie Fortin, PhD, DABT

An interview with Prof Heather Wallace¹, University of Aberdeen, UK; Immediate Past President of the British Toxicological Society and President-Elect of EUROTOX.

M: Hi Prof Wallace, thank you for being willing to participate to this interview.

In the United States, we have heard quite a bit of buzz about Brexit. However most of it surrounded the fact that it would be horrible for science. Needless to say that as scientists we are all a little bit perplexed by what this means for the science of toxicology. From safety and regulatory toxicology in the chemical and pharmaceutical industries, to fundamental research in academia, we look forward to understanding what this means.

First, can you tell us more about what is “Brexit” exactly? When will it come in full effect?

H: Brexit is short hand for “British exit” which entails Britain leaving the European Union. This historic vote took place on 23rd June 2016 and the result was 51.9% in favour of leaving the EU. This involves disentangling all aspects of government of the UK from the EU and will be a very complex and involved process. At the moment the UK government is preparing for Brexit but the leaving date has not yet been agreed. The UK has to trigger Article 50 of the Treaty of Lisbon which became law in 2009. Essentially once Article 50 has been invoked then the clock will start ticking for the full exit of the UK from the EU. The whole process of exiting is predicted to be 2 years although it may be longer.

M: Let’s try to understand the regulatory implications… the EU has been leading the front on so many fields of chemical legislation:

First, REACH has been a game changer in toxicology and safety evaluation of chemicals by requiring data and democratizing the accessibility to the data. What are your thoughts with respect to chemical regulation?

H: REACH is a major issue. Any exports from the UK to the EU will still be governed by REACH. Under the regulations there is a legal entity responsible for REACH registration or re-registration of chemicals known as an Only Representative (OR). Anyone out with the EU must have an appointed OR. Currently an OR has to be within the European Economic Area (EEA). When the UK withdraws from the EU, smaller companies and consultants in the UK will no longer be able to undertake REACH registration for exports from a UK based company. This will clearly create many problems and undoubtedly increase the costs for smaller businesses.

M: Similarly, in 2009, the EU cosmetic regulation prohibited animal tests for cosmetic ingredients. Do you think that the UK will return to conducting such tests and/or that it will delay progress in the development of alternatives approaches?

H: The UK is a leading voice in the regulatory field and is a strong supporter of the 3Rs – replacement, refinement and reduction of animal tests. It will continue to promote the (Continued on page 6)
development of the best approach to safety testing of all chemicals.

M: Finally, the obvious outstanding question is what will be the implications in the pharmaceutical industry? Will the UK remain aligned with the ICH guidelines / EMA regulations?

H: This is one of the areas where the scientific community will be pressing the UK government very hard to retain harmonization of the regulatory framework that already exists in the current EU. This framework has been developed carefully over time and offers best practice across Europe currently. The UK is highly regarded in terms of the quality and transparency of its regulation.

M: Now let’s address the environment:

There was a recent article in “the Guardian” stating that Brexit would adversely impact the air pollution crisis, and EU regulations have driven improvements in water quality throughout Europe. Will Brexit result in a worsening of the UK environmental standards?

H: Personally, I do not see the UK backtracking on any legislation that improves the environment. The UK has always supported improvements to the environment.

M: Last but not least, and more closely related to you, what about the impact on the toxicological research that is conducted in Academia? What will be the repercussion on funding? On progress?

H: There are 3 main areas of concern here: funding, free movement of scientists and students and retention of the current workforce. The EU through a range of funding instruments have supported scientific and clinical research for many years. The current framework is Horizon 2020. Within these instruments the UK has consistently “punched above its weight” and UK researchers been heavily involved in the programmes and indeed have led many of the framework projects. Loss of access to this funding stream is of great concern. The UK Treasury recently announced that it will underwrite funding for approved Horizon 2020 projects which is good news. However, what will happen in the future is very unclear and uncertain.

Within the UK toxicology is an international business with many EU nationals working in Universities and in the pharmaceutical, chemical and biotechnology industries. Our success depends on the free movement of these scientists and clinicians and most importantly on the nurturing of EU exchange students who are funded through a variety of schemes (ERASMUS, Marie Sklodowska-Curie) available within the EU.

Retaining our talented workforce needs to be a key goal in all the Brexit negotiations and that can only be done by creating an environment that is supportive and collaborative within our Universities and industries.
M: Any final thoughts for your colleagues from the other side of the pond?

H: All of this will be challenging and at present the biggest issue is the uncertainty around almost everything. Once Article 50 has been triggered and the negotiations start in earnest then we might have a clearer picture of what will be to come.

M: Thank you so much for taking the time to answer our questions, your insight is truly appreciated and I wish you, and all of UK’s toxicologists, the best through these uncertain times.

\(^1\)Professor Heather M Wallace PhD FRCPath FBTS FRSC FRSB FBPhS
European Registered Toxicologist
Professor of Biochemical Pharmacology and Toxicology
School of Medicine, Medical Sciences and Nutrition
University of Aberdeen

Now Announcing the New RSESS Best Published Paper Award!

The Regulatory and Safety Evaluation Specialty Section (RSESS) would like to recognize talented researchers who have recently published exceptional papers that contribute to the field of regulatory and safety evaluation in toxicology.

This award will be presented to the author(s) of the best paper published in the calendar year preceding the Annual Meeting at which the award is recognized. The author(s) need not be a member of the Society of Toxicology.

Nominations should include a one page summary of the paper’s contribution to the science of regulatory and safety evaluation and a copy of the article for which the nomination is being made.

Any member of the Society may submit one title for consideration. The recipients of this award will receive a plaque and a cash award. Please submit nominations to Dr. Suzanne Fitzpatrick by December 15, 2016.
Biosketch of Our New Councilor

April D. Lake, Ph.D.,
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As a project toxicologist in the drug safety evaluation department at Gilead Sciences, Dr. Lake supports early and late stage development of compounds for targeting inflammatory diseases and viral indications. Her roles include providing assessment and interpretation of nonclinical safety studies as well as providing early investigational research toxicology support. April received her doctorate in Pharmacology and Toxicology from the University of Arizona in 2013 for dissertation work on mechanisms of human nonalcoholic fatty liver disease in Nathan Cherrington’s laboratory. April then went on to the U.S. Environmental Protection Agency’s integrated systems toxicology division for postdoctoral studies with Charles Wood and Susan Hester. Her research at the EPA investigating early mode of action signals for phthalate-induced rodent liver tumor outcomes was supported by the University of North Carolina Chapel Hill, Curriculum of Toxicology and the Oakridge Institute for Science and Education from 2013 to 2015. Five first-author articles have resulted from April’s research and she has co-authored over a dozen peer-reviewed articles. As a member of the Society of Toxicology since 2010, April has enjoyed actively participating in presenting research, volunteering at annual meetings, serving as the elected treasurer on the Postdoctoral Assembly Board from 2014-2015, and serving as the junior councilor of RSESS from 2015-2016. April looks forward to serving the SOT community as the Regulatory and Safety Evaluation Specialty Section councilor in the year ahead.