FOOD SAFETY

Specialty Section | Society of Toxicology | Summer 2022

IN THIS ISSUE

CURRENT FS3 OFFICERS

Logeswari Ponnusamy, President
logeswari.ponnusamy@zoetis.com
David Szabo, Vice President
dszabo@ppg.com
Amy Roe, Vice President Elect
roe.al@pg.com
Sachin Bhusari, Past President
sbhusari@coca-cola.com
Britney Geter, Secretary/Treasurer
Britney_Geter@cargill.com
Lois Haighton, Sr Councilor
lois.haighton@intertek.com
Fleur de Mooij, Sr Councilor
fleur.de-mooij@danone.com
Alison Franzen, Jr Councilor
afranzen@toxstrategies.com
René Viñas, Jr Councilor
rene.vinas@gmail.com
Olawande C. Olagoke, Postdoctoral Rep
oolagoke@bidmc.harvard.edu
Rebecca Kim, Sr Graduate Student Rep
rk1672@nyu.edu
Lauren Payne, Jr Graduate Student Rep
paynela2@msu.edu

Letter from the President

Greetings!

After a gap of two years, it was great seeing some of you in person at the SOT meeting in San Diego!

The Food Safety Specialty Section (FS3) endorsed and sponsored various scientific sessions at the Annual Meeting, all of which were very well attended. Big Thank You to our diligent officers, generous sponsors, and all of you who attended the FS3 events. Our FS3 mentoring event, annual business meeting and reception was a remarkable success with standing room only audience! At the reception on March 28 evening, we presented the FS3 business report, financial report, announced the newly elected officers; and presented our prestigious awards, the Frank Lu Student Endowment Award and Elsevier Postdoctoral award to our award winners. A mentoring event was organized earlier the same evening for undergraduate, graduate students and postdoctoral fellows and the event was well attended. Overall, the FS3 events were a remarkable success and it was nice to see many of our colleagues and friends after a long time. It was a great networking opportunity for students, early career scientists, and for everyone who attended!

A big THANK YOU to our outgoing officers for serving on the FS3 leadership team, and their great contributions to the success of FS3, Drs. Chester Rodriguez (Past President), Sumira Phatak (Postdoc Rep), Alexandra Lobach (Councilor), and Daniele Wikoff (Councilor), and Benjamin Kistinger (Sr. Graduate Student Rep). Welcome to the newly elected officers: Drs. Amy Roe (VP-elect), Alison Franzen (Councilor), René Viñas (Councilor), Olawande C. Olagoke (Postdoc Rep) and Ms. Lauren Payne (Jr. Graduate Student Rep). Together with our current officers and the new slate of incoming officers, we have a strong team for the year 2022-2023, and we will continue to make our specialty section a strong scientific community to better serve your needs. We encourage members from academia, government and industry to consider nominating yourself or others for officers! To prepare for the 2023 SOT Annual Meeting, the FS3 leadership team is currently reviewing scientific proposals seeking sponsorship from FS3. The proposals received are of great interest to food safety and represent state-of-the-art in Toxicology. Stay tuned for our fall newsletter with a list of food safety sponsored sessions in Nashville in 2023! If you have any thoughts and suggestions or would like to share your scientific and career achievements, please do not hesitate to contact me, any of the current officers, or directly email to sotfoodsafety@gmail.com.

Sincerely yours,

Sachin Bhusari, DVM, PhD, DABT, ERT President of FS3

Incoming FS3 officers

Vice President-Elect: Amy L. Roe, PhD, DABT, ATS

Dr. Roe has 22+ years of experience as a practicing toxicologist in government, pharmaceutical and consumer product industries, through positions at both the FDA and The Procter & Gamble Company. Her professional experience is in general, descriptive, and regulatory toxicology as well as specialized expertise in drug/xenobiotic metabolism and pharmacokinetics. Her industry experience is quite broad and includes toxicology support of drugs, medical devices, herbal/dietary supplements, foods, and water filtration devices. As a project leader, she has led multi-disciplinary drug development teams. Dr. Roe is a board-certified toxicologist (DABT) and a Fellow of the Academy of Toxicological Sciences (ATS). She is well-recognized externally in her field as evidenced by her service on a number of professional boards and committees including USP Dietary Supplement Admission Evaluation & Labeling Expert Committees and Probiotic Expert Panel, SOT Regulatory & Safety Evaluation Specialty Section (Past President), Food Safety Specialty Section (Vice President- Elect) and an NIH/NCCIH Expert Advisory Panel related to natural product-drug interactions. Dr. Roe is currently serving as co-chair of the hepatotoxicity/ADME sub-committee of the HESI Botanical Safety Consortium. She also serves on the Editorial Board of Applied In Vitro Toxicology.

Junior Councilor: Alison Franzen

Dr. Allison Franzen is a Senior Scientist in the Health Practice at ToxStrategies, where she has 10+ years of experience as a human health risk assessor. Her areas of expertise include risk assessment of flavors and food additives and unknown or variable complex chemical mixtures of biological origin (UVCBs) in food products. Over the past few years, she has focused on the European Food Safety Authority (EFSA) and the United Kingdom's Food Safety Authority (FSA) risk assessment frameworks for flavors and food additives. She has stayed up to-date on training and implementation of the EU Transparency regulation (implemented March 2021) as it impacts flavors and food additives. Dr. Franzen also frequently participates in EFSA and European Commission (EC) led scientific webinars, and reviews of updated scientific guidance as it relates to EFSA's evaluation and approval of safety of flavors, food additives and food contact materials. In addition, she has experience in a variety of risk assessment methodologies, including the development of adverse outcome pathways (AOPs) and the application and/or conduct of systematic reviews, weight-of-evidence analysis, quantitative risk assessments, globally harmonized exposure assessments, physiologically based pharmacokinetic (PBPK) and benchmark dose modeling. Dr. Franzen received a doctorate in Toxicology & Pharmacology from the University of Louisiana at Monroe in 2017. She is the author of 11 publications, including peer-reviewed articles and a book chapter including "*A global Human Health Risk Assessment for Decamethylcyclopentasiloxane (D_5)*." This publication was a large effort that included a globally harmonized oral and inhalation risk assessment of D_5 found in both indoor and outdoor air, a multitude of consumer products (i.e., deodorant, hair care, skin care products, bakeware) and from the consumption of water, fish, vegetables, meat, milk, soil and breast milk. She has been a member of SOT since 2011 and has served the SOT as graduate student representative for the Risk Assessment Specialty Section (2013-2015) and as chair for the Graduate and Student Leadership Committee (2015-2017). She is currently a volunteer for the Women in Toxicology awards committee and newsletter, as well as the RASS awards committee.

Junior Councilor: René Viñas

Dr. René Viñas is currently Regulatory Affairs Toxicologist at UPSIDE Foods, a food technology company dedicated to providing consumers with humane and sustainable versions of their favorite foods. At UPSIDE, Dr. Viñas provides functional toxicology expertise that supports and enables new research initiatives.

Previously, Dr. Viñas held diverse safety and regulatory roles while working for The Coca-Cola Company and at the Grocery Manufacturers Association. Before venturing into a career in industry, Dr. Viñas was an ORISE Fellow at U.S. FDA's Center for Devices and Radiological Health (CDRH) where his work centered on the development of risk assessment approaches for nanomaterials associated with medical devices, including nanomaterial characterization, nanoparticle exposure assessment, and toxicological characterization of nanoparticles.

Dr. Viñas earned his PhD in Pharmacology & Toxicology from The University of Texas – Medical Branch where his research focused on the endocrine disrupting potential of novel chemical replacements for bisphenol-a (BPA). He is also an active member of the Society of Toxicology and associated Specialty Sections and Special Interests Groups.

Postdoctoral representative: Olawande Olagoke

Dr Olawande Olagoke is a Gastroenterology Research Fellow at BIDMC, Harvard Medical School, where he is using a systems biology approach that incorporates clinical metadata, metabolomics, lipidomics and microbiome measurement to enhance predictive models.

His experience spans more than seven years of teaching and research as a lecturer of Human Physiology at Kampala International University Uganda, and as a postgraduate fellow of The World Academy of Science at the Biochemical Toxicology program of Universidade Federal de Santa Maria, Brasil. He is an author/co-author of over ten peer-reviewed articles.

Olawande is a member of several professional bodies, including the Society of Toxicology where he has served on the Graduate Student Leadership Committee, Continuing Education Committee, and Professional Development Subcommittee, while currently volunteering as the postdoc rep of the SOT Food Safety Speciality Section.

Junior Graduate Student Representative: Lauren Payne

Ms. Lauren Payne is a graduate student at Michigan State University in Pharmacology and Toxicology, with a concentration in Toxicology. Her coursework in food safety includes mycotoxins, inorganic food contaminants, natural toxins in plant foodstuff, biotechnology-derived novel foods, seafood toxins, and food packaging.

Ms. Payne is also a Scientist II at ToxStrategies, a scientific consulting firm, where her professional experience includes assessing safety of novel or naturally occurring ingredients, dietary supplement formulations, and GRAS ingredients. She has co-authored peer-reviewed publications that include the safety of low-calorie sweeteners. As a Scientist II, her role is often to support food safety assessments by developing syntax for conducting literature searches, screening relevant articles and identifying ADIs from regulatory agencies.

FS3 Treasury, Sponsorship, and Membership Report

Treasury

Feb 2022 - Net assets $43,017

Membership report

2021-2022 FS3 membership with 245 members

FS3 Sponsors

A very big THANK YOU to our tremendous Sponsors for your continuing support of our Specialty Section efforts.

Join the FS3 LinkedIn!

- Enter the group name in the LinkedIn search bar ("SOT Food Safety Specialty Section")
- Click on the group
- Click on the blue 'Request to join' button
- A group manager will approve your request

SOT ANNUAL MEETING REPORT SAN DIEGO

Awards recipients

Congratulations to **Dr. Saroj Amar** for winning the **Elsevier Post Doc Award** with his research titled *'Effects of Inhalation of Neat and Ethyl Parathion Incorporated Soil on Plasma Acetylcholinesterase Activity and Dopamine Levels in a Rat Model'.*

Congratulations to **Lauren Heine** for winning this years Frank C. Lu Graduate Student Award with her research on '*Dietary Omega-Fatty Acid Prevents Silica-Triggered Autoimmune Disease in Adult Lupus-Prone Mice'.*

FS3 Mentoring Event

With the SOT meeting in person there was also the opportunity to host the FS3 mentoring event again. Students had the opportunity to interact with several mentors from academia and industry. There was a great turnout of students and due to the round-robin style session everyone got to meet several of the mentors which made it a very interactive and engaged session. We therefore want to warmly thank all the mentors and mentees for this great session!

FS3 Reception

Following the mentoring event, the annual FS3 reception with the FS3 business meeting was convened. It was great to see a full house of members again after two years of online meeting. The agenda covered the financials, membership, communication, webinars, and the FS3 award ceremony! The business meeting was finished with a hot topic session on PFAS followed by food and drinks.

It was great to see everyone again in person and we hope to see you again in Nashville next year!

Summary of FS3 endorsed symposia and workshops

Safety Challenges and Development Strategies Unique to Biotechnology-Derived Products Across Industries
Chairs Tod Harper & René Viñas

The workshop "Safety Challenges and Development Strategies Unique to Biotechnology-Derived Products Across Industries" illustrated challenges and strategies unique to biotechnology-derived products by bringing together experts across several different industries. The speakers addressed issues common to biotechnology and highlighted unique challenges within their specific industries. The first speaker introduced the field of biotechnology and provided an overview of unique applications and societal impact that biotechnology has had on the global population. The second speaker representing the crop agriculture industry, described the robust risk assessment process associated with the development and approval of genetically modified (GM) crops utilizing different technologies. The third speaker representing the "cultivated foods" industry provided an overview of cell-cultured meat and seafood and the safety assessment needed to market these biotechnology-derived foods compared to traditional animal-based food. Potential food safety risks

presented by this new application of cell-culture technology to food and proposed safety assessment frameworks and FDA/USDA regulatory pathways were discussed. The final speaker representing the biopharmaceutical industry, highlighted challenges associated with the safety assessment and development of biotechnology-derived therapeutics. Questions such as what happens when there is no pharmacologically relevant species, or when immunogenicity in animals greatly reduces drug exposure were discussed. Additionally, a comparison between ICH S6(R1) guideline for biotechnology-derived drugs and ICH M3(R2) guideline for pharmaceuticals were reviewed.

SOT Roundtable Session - Are Animal Studies Still the "Gold Standard" for Validating New Approach Methods?
Chairs Suzanne Fitzpatrick, US FDA & A. Wallace Hayes, University of South Florida College of Public Health

Over the last decade, there has been an explosion in the development of new approach methods (NAMs) that could serve as meaningful alternatives to many types of animal testing. The first (and most critical) step is to determine how to assess the relevance of NAMs data to humans. Experimental data from animal studies are currently thought to be needed to validate the physiological relevance of *in vitro* results; however, recent advances in new technologies can mimic human physiology and responses with equivalent or better accuracy than some animal models. The following questions need to be addressed for any NAM to be used for regulatory assessment: (1) What endpoints are being measured? (2) Are they predictive of *in vivo* effects? (3) Are they translatable and relevant to humans? At this session, the panel debated if animal studies should continue to be considered the "gold standard" for addressing these questions. Dr. Bailey argued that the answer is yes, that animal data are essential to show concordance to any new NAMs data, and that without animal data, it is impossible to rely on NAMs data for a credible risk assessment. Drs. Casey and Baran, on the other hand, suggested that for some NAMs data, animal studies may no longer be needed to demonstrate their relevance to humans. For example, organoids and organs-on-a-chip have demonstrated their ability to recapitulate human physiology and disease states. Thus, from both a scientific and an ethical viewpoint, animal studies should no longer be considered the gold standard, and animal data should no longer have any role in 21st-century validation and risk assessment. Because no single NAM has been developed to replace *in vivo* animal observations, the debate hinged on whether animals will remain or can be replaced as the standard, a critical issue that continues to prevent the adoption of NAMs for regulatory use.

Call for expert volunteers

SOT FS3 is seeking nominations for experienced speakers in the Food safety field to be part of the SOT Speaker directory. Up to five expert members from FS3 membership will be nominated. Please nominate yourself or someone you know who would be willing to serve as a potential speaker and be listed in the SOT directory. Nominations can be sent to fs3.proposals@gmail.com

Member Spotlight: Dr. Samuel Cohen

Food and Safety Specialty Section student representatives Rebecca Kim and Ben Kitsinger sat down with Dr. Samuel Cohen (Department of Pathology and Microbiology in the University of Nebraska Medical Center), the 2020 recipient of the Mildred S. Christian Career Achievement Award, for a conversation about career, mentorship, and current trends in food safety science.

Q: In your recent autobiography, you mention some of the teachers and mentors that influenced your career path and encouraged your development and pursuit of your academic interests. How have these individuals influenced your view of mentorship in science? What advice would you give to graduate students and early career toxicologists on finding and working with a mentor?

Finding a mentor is almost accidental. I just happened to have people involved with my life that turned out to be outstanding mentors. There has been a lot of work done over the last 20-30 years to develop better mentorship between students and faculty. I don't know the magic answer but basically it is a chemistry that happens to develop between student and mentor, where you can have trust in that individual and trust that they are looking out for you. The student also needs to be willing to take their guidance as well. To summarize- it takes trust, guidance, time, and effort.

Q: How have you been able to develop your professional network over the years, and do you have any advice for graduate students on how to build a network?

You never know what opportunities will arise, so go to the meetings that you can and don't be afraid to talk to people. Meet as many people as you can. When doing research, you can't do everything on your own. It's important to identify what needs to get done and who you need to associate with to get the task done. Don't be afraid to ask people who or what they recommend to solve a problem. Additionally, follow the research where it takes you. Don't become too wedded to any specific technology because that changes. As an early career scientist, your network will expand and it is important for it to do so.

Q: What makes an MD, PhD different from getting a PhD or MD separately? Is it harder? Any benefits?

There are significant differences between an MD/PhD and an individual MD or PhD degree program. For an MD/PhD program, time is tight! You take coursework, and then essentially have two full time jobs. Although they are both doctorates, they are very different. With medicine, you take coursework and move on to training residency to work with patients. It is all laid out for you to follow. In many ways this is "instant gratification."

Research is not. There is no clear guidance on what to do. You can map your project out with your advisors and professors over a few years, and then hope that you get results. Even then, you don't get results over a matter of days, it happens over a few years. Research is not linear, and you figure out a lot of it as you go.
There is a gap between MD's and PhD's. MD's don't know research approaches, and PhD's don't know the nuances of patient care in medicine. When you learn about a disease from a textbook, you don't get a feel for the enormous variability and biology in practice. You need to learn to deal with that uncertainty in making decisions that involve peoples' lives.

In both fields, one thing I am being increasingly concerned about is that people have really become enamored with new technology. But, tech is just the tool to try and solve a problem. It's important to focus on the problem and not the technology. You must understand the meaning in the totality of the situation, and in appropriate context. Make sure the model you are using is truly representative of the question you are trying to address. As statistician George Box said, "all models are wrong, but some are useful." Think, "how does what you are doing in research fit into what happens in the patient?"

An MD/PhD helps bridge the chasm between MD's and PhD's. I can bring medical insight into my research problems and I can bring my research approach into my medical world. Best of both worlds.

Q: Did you ever consider changing career paths along the way? What did you consider, and how did you make the decision to continue in the direction that you did?

I did contemplate changing careers, especially early on. Becoming an MD/PhD is very difficult and there were points in time where it was very challenging to continue. There were two things that kept me going in the same direction overall. I had a very strong wife that looked out for my best interests and felt that it was important for me to continue my involvement with both research and medicine. The other was that I really enjoyed what I was doing. One of the real strengths of research is perseverance. You have to keep going and figure out how you will get around the obstacles that you are facing. This is very important. Additionally, you always have to be on the lookout for additional opportunities. Increasingly, you won't be in one career for your whole life. At the end of the day, if you are good at what you are doing, and doing what you enjoy you will be ok.

Q: What are your thoughts on finding happiness in work?

Ask yourself if it is something you enjoy. For research, it is asking myself if what I am doing is meaningful, or if it will have an impact on how people do things. You can look back after many years and see the progress in your field, which has helped make science and society that much better. It is rewarding to know that you helped move that, and it is a longer-lasting effect. In medicine it is easy to be gratified, as it is very instant. (After doing 100 appendectomies, the 101st isn't necessarily as exciting anymore!) Of course there are emotional challenges that come with practicing medicine. You also never know the impact of what you are researching in science.

Q: You've had the privilege and experience of traveling internationally for science (from Japan to Israel). How have these experiences affected the way you view the science community and intersection of research and culture?

It gives you exposure to lots more people. More importantly, it gives you exposure to a whole different approach to culture and science. Each of these cultures have different approaches to the way they deal with science. These are all different. One isn't right and one isn't wrong, they are different approaches that have developed from thousands of years and it is the way people are influenced to do that; everything has a strength and weaknesses. Learn to approach things differently, and listen to people with different viewpoints. Learn more about why the approach is different. Both can learn from each other. I think every person should spend a few months in a different culture/country. Everyone can use more perspective, and learn more tolerance.

Q: You have served on the expert panel of the Flavor and Extract Manufacturers Association since 2002. Can you discuss the workflow for evaluating an ingredient? How has the evaluation process changed during your tenure on this panel?

Our approach is basically the same. We look at the chemical composition, manufacturing processes and how this relates to safety. Our involvement is strictly in safety (not efficacy). The evaluation approach still looks at genotoxicity, reproductive toxicity, and involves a lot of read-across. We continue to evolve our processes and some of the technology has improved, but the reality is that some of the data we have is 40-50 years old and dated.

We re-review all of the ingredients to see if it impacts our interpretation of the safety. Over the last 15-20 years we have de-GRAS'ed (FDA shorthand for Generally Recognized As Safe) between 15 and 20 chemicals. We don't ban them but we can't approve their use, safety-wise, because we need answers to these questions. It is up to industry to say they will invest to answer those questions or put it to the side.

One of the big changes is the increased emphasis on exposure analysis. We make our evaluations based on use levels. For example, we don't approve a chemical as a flavor. Instead we see it as a chemical with certain uses in specific categories of foods. We ask ourselves, how much does that actually mean for consumption? Is this an ingredient in food that is widely consumed? Or, is it consumed by only a small subset of people? We then make adjustments for that.

One of the things that has occurred over the last 20-25 years is that the industry does a poundage survey on all these ingredients to find out how much is being consumed. We make estimates when we give an approval, but the estimate by industry is more often than not an overestimate of what will be sold. Occasionally an ingredient will come out that gains widespread popularity. Its usage is much greater than we anticipated. An example of this is cooling agents such as menthols. There are some synthetic ones that have come out recently. When they first came out the poundage was low but has gotten very high over last 20 years. Accordingly, we have begun to re-analyzing these. For one of these chemicals, we let the company know that they were approaching their 100x margin. Since they were at their limit, they cannot put more of this out and must find substitutes in these foods. We give this feedback, and industry must respond.

This has been the best panel I have been on. There are world renowned experts and a diversity of expertise. There is great respect for one another and always friendly discussion which is important in scientific discussion.

Q: Since we are the food safety specialty section we like to have questions about food. What is your favorite meal to have for breakfast, lunch, and dinner, or favorite foods in general?

I like food, so I don't have favorites. The professor I had in Japan taught me a lesson about food very early. “Eat first, ask later.” I like all kinds of food (Sushi, Italian, Chinese) but draw the line at bats. Try everything! You never know.