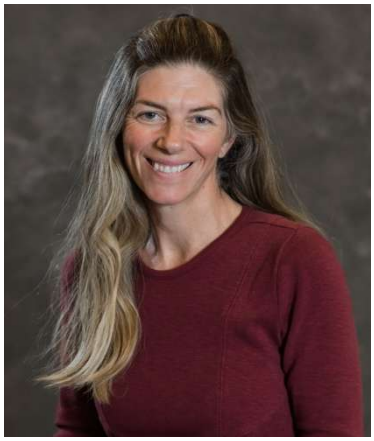
SOT | Society of Toxicology

Creating a Safer and Healthier World by Advancing the Science and Increasing the Impact of Toxicology

REGULATORY & SAFETY EVALUATION Specialty Section

Spring 2026 Newsletter



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President's Message

Dear RSESS Members,

It's an exciting time for RSESS! Your Board of Officers has been hard at work planning a dynamic lineup of activities designed to celebrate excellence, strengthen connections, and ultimately advance regulatory and safety evaluation science. The months ahead are full of opportunity, and we can't wait to share them with you.

We are especially energized as we prepare for the SOT Annual Meeting in March in San Diego. RSESS will host our Member Reception, where we will proudly showcase our award winners and display their posters for viewing. This is always a highlight of the meeting—an opportunity to recognize outstanding science while reconnecting with colleagues and making new connections. And this year, we're adding a little extra fun with Tox Trivia to keep the energy high and the competition friendly!

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Our celebration of excellence continues at the private RSESS Awards Luncheon during the Annual Meeting, where we will formally honor our award recipients. Recognizing the remarkable achievements of our members—from trainees to seasoned leaders—is central to our mission and a powerful reminder of the impact our community has on regulatory science worldwide.

Collaboration is another key theme this year. At the Annual Meeting, RSESS and other Component Groups are partnering with the CAMAN (Career Advancement, Mentoring and Network) Committee to host a NetworX Night event. This promises to be an engaging evening where toxicologists can come together to share experiences, exchange ideas, and expand their professional networks. Whether you are just starting out or are well established in your career, this event is designed to foster meaningful connections across sectors and disciplines.

Our momentum extends beyond San Diego. On February 19, we hosted an important webinar titled "Basic Concepts of Regulatory Toxicology and Risk Assessment Methodologies." Our speaker was George Kass, a highly seasoned Toxicologist who was previously a Lead Expert in the European Food Safety Authority. It was highly attended and a was a great opportunity to broaden perspectives, share insights, and strengthen international dialogue.

Looking ahead, we are also planning a dedicated webinar to spotlight our award winners and their work. This session will feature presentations from our Best Paper, Graduate Student, Postdoctoral, Three-Minute Thesis, and Outstanding Contribution to Regulatory and Safety Evaluation awardees. It will be an inspiring opportunity to hear directly from these talented scientists and learn more about the innovative work shaping our field.

Finally, I encourage you to explore the impressive work of our Guidance Subcommittee. Their thoughtful articles—some of which are included in this newsletter—provide valuable, concise summaries on recent developments in regulatory toxicology across multiple sectors, and reflect RSESS's commitment to leadership and practical insight in rapidly evolving landscapes.

A huge Thank You to you, our members for your engagement, your expertise, and your commitment to advancing regulatory and safety evaluation science. I look forward to seeing many of you in San Diego.

With appreciation and enthusiasm,

Claire Neilan, PhD, DABT
President, RSESS

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Specialty Section

New Officer Introduction:

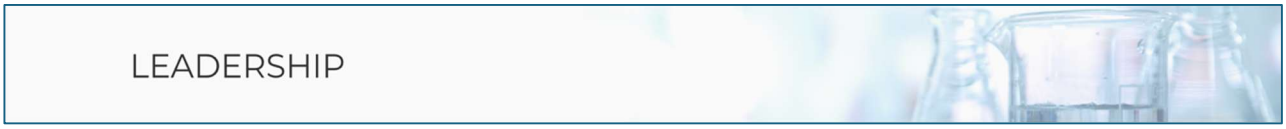
RSESS is excited to welcome and introduce the new RSESS officers!

William (Bill) D. Klaren – Vice President-Elect

Dr. William Klaren is a board-certified toxicologist at ToxStrategies. As a consultant with ToxStrategies, he assists clients in systematic reviews and consumer product risk assessments specializing in pesticides, microbials, food ingredients, and cosmetic products. He received his doctorate in Human Toxicology from the University of Iowa and was a Postdoctoral Research Fellow at Texas A&M University. Before joining ToxStrategies, Dr. Klaren was a toxicologist at the consumer goods company, S.C. Johnson and Son, Inc., where he performed consumer goods risk assessments and supported pesticidal product registrations. For the past three years, he has served as the RSESS Secretary/Treasurer.

Madelyn (Mimi) Huang – Junior Councilor

Dr. Madelyn "Mimi" Huang is a Senior Toxicologist at Premier Research. At Premier, she provides input on nonclinical aspects of therapeutic product development for biotech and specialty pharma companies, ranging from small molecules, biologics, cell and gene therapies, as well as marketing applications via the US FDA's 505(b)(2) pathway. She obtained a PhD in Toxicology at the University of North Carolina at Chapel Hill and did postdoctoral training at the National Toxicology Program. Dr. Huang has been an active member of the Society of Toxicology since 2012, from volunteering for continuing education courses, planning webinars, submitting and chairing multiple sessions over the years. She has a passion for helping trainees develop transferable skills and professional networks in industry and has coordinated or supported numerous career development events locally and nationally. Dr. Huang currently serves RSESS as the Chair of the Endowment Committee and the steward for the RSESS endowment fund and supports the administration of the awards made possible through the fund. She is excited to be able to continue supporting the RSESS community in the Junior Councilor position.



2025–2026 RSESS Leadership:

President:
Claire Neilan
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William D. Klaren
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Senior Councilor:
Dahea You
(dhyou21@gmail.com)

Vice President:
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Junior Councilor:
Timothy McGovern
(timmcgovern7@gmail.com)

Grad Student Rep.:
Olivia Lampe
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Appointed Officers:

Program Committee Chair:
Nikolaos Georgiadis
(nikolaos.georgiadis@echa.europa.eu)

Endowment Committee Chair
Madelyn Huang
(madelyn.huang@premierconsulting.com)

Announcement of Blog/Blogposts:

This year, we're launching a career development series highlighting various aspects of working as a toxicologist in regulatory and safety evaluation. Our first post explores important considerations when assessing a position at a consulting firm, such as billable hours and business development responsibilities. Check it out here and on ToXchange.

https://www.linkedin.com/posts/sot-rsess_happy-new-year-rsess-members-this-year-activity-7422338329519661058-9QXG?utm_source=share&utm_medium=member_desktop&rcm=ACoAAAYVZ_8BAOFUVr5f4yte0ciPCujtJ3svwU

Follow RSESS on LinkedIn to stay up to date on these posts and to join the conversation. Let us know what kind of topics you want to see!

Announcement of Recent RSESS Webinars:

RSESS recently hosted a webinar on February 19 at which there were 354 attendees! George Kass, formerly of the European Food Safety Authority, gave a presentation titled "Basic Concepts of Regulatory Toxicology and Risk Assessment." Our aim is to bring you timely and recent topics with a focus on building an understanding of the similarities and differences in toxicology practice and regulatory expectations between different regions of the world. The abstract of the presentation and George's bio can be found below:

Webinar Abstract: Regulatory toxicology is defined as the process whereby information relevant to assessing and evaluating the toxicity of agents, which may be biological or chemical in nature, is obtained and evaluated by or on behalf of governmental or international organizations. There are two fundamental components to this process. The first one is the consideration of the legal framework under which the biological or chemical agent will be used. The second component is the nature and type of information required under that regulation. This presentation will focus on the types of information typically requested, and how risk assessors use this information to either classify the properties of a substance or develop a full risk characterization. The

different approaches used to generate the data and how to come to a regulatory decision will be discussed.

George E. N. Kass, PhD, ERT
European Food Safety Authority (retired), Parma, Italy, and
University of Galway, Galway, Ireland

Georges Kass was trained as a biochemist and a toxicologist. He received his PhD in biochemical toxicology from the Karolinska Institute in Stockholm in 1990. After completing a postdoc at the Swiss Federal Institute of Technology in Zurich, he returned to the Karolinska Institute as an Assistant Professor. In 1994, he moved to the University of Surrey in the UK where he became Professor of Toxicology. Fifteen years later, in 2009, he moved to the European Food Safety Authority in Parma, IT, where he was Lead Expert in toxicology until his retirement in 2025. He continues his activities as a European Registered Toxicologist (ERT) and expert in food safety, and as Adjunct Professor at the University of Galway in Ireland.

Georges Kass was awarded a DSc from both the Karolinska Institute and the University of Turku in Finland. He holds or has held several visiting posts in the UK, Ireland, France and Italy. Georges Kass has published over 160 papers in the field of toxicology and chemical risk assessment. A substantial part of his research has focused on the molecular mechanisms of drug toxicity and on liver injury. He serves as the Associate Editor of *Toxicology and Applied Pharmacology* and the Chief Editor of *Frontiers in Toxicology.* In 2020, he was elected to the Académie d'Agriculture de France. He is also Honorary Member of EUROTOX and a Fellow of the US Academy of Toxicological Sciences (ATS).

The recording of this webinar is available for viewing on ToXchange.

Graduate Student and Postdoc Update:

Hi everyone! SOT is right around the corner, and we would like to extend a warm welcome to new and veteran RSESS trainees. We always have a ton of amazing trainees who receive RSESS awards which will be highlighted at the annual reception, and we always encourage you to apply for awards if you are planning to submit an abstract at SOT next year. Please come and say hi at SOT's graduate student and postdoc mixer or the RSESS annual reception!

Happy Spring!

Olivia Lampe
RSESS Graduate Student Representative

Taylor Carter, PhD
RSESS Postdoctoral Representative

Regulatory Guidance Subcommittee Update:

Chair: Dahea You, PharmD, PhD, DABT
Co-Chairs: Stephene Ford, BS, MBM; Erik K. Pacyniak, PhD, DABT

The regulatory guidance subcommittee was formed in the fall of 2022 to alert RSESS membership of new and updated guidances as well as impactful articles in the field of regulatory and safety evaluation.

Please contact Stephene Ford (sford@montoxllc.com) if you are interested in helping the Regulatory Guidance Committee.

Folders have been created on ToXchange in which new and recently updated guidance and articles of interest are stored.

Recent additions include:

- *US FDA/CDER/OND Experience with New Approach Methodologies (NAMs)*
  The US Food and Drug Administration (US FDA), Center for Drug Evaluation and Research (CDER), and Office of New Drugs (OND) has continuously encouraged the submission of nonclinical tests utilizing New Approach Methodologies (NAMs) supporting the safety and efficacy of new drugs, with previous publications on perspectives about nonclinical testing strategies, opportunities and challenges of using NAMs to replace, reduce, and refine animal testing in drug development, and gaps and challenges underserved by existing nonclinical testing approaches.

  This report describes how US FDA/CDER incorporated NAMs into standard nonclinical assessments, and how specific tests were validated and internationally adopted as alternatives to animal testing for regulatory decisions. This report also presents a CDER/OND Pharmacology/Toxicology reviewer's perspective on NAMs submitted in support of new drug development, providing greater transparency and insight into their evaluation, and outlining key considerations for refining NAM submissions. Furthermore, it provides a forward-looking perspective on NAM incorporation into nonclinical development programs as scientific technology continues to evolve.

  Ultimately, the objectives of this report are to 1) illustrate the US FDA/CDER/OND scientific approach to evaluating NAM submissions, (2) reiterate US FDA/CDER's commitment to the 3Rs (replace, reduce, refine), and (3) foster confidence in their continued efforts to encourage submission of NAMs data (even in parallel with animal studies) to support regulatory decision-making through improved assessments and/or predictivity while maintaining their mission to protect public health and patients from unintended harm. The US FDA is developing new formal guidance pertaining to the use of NAMs.

- *Monoclonal Antibodies: Streamlined Nonclinical Safety Studies (US FDA Draft Guidance for Industry)*
  The US FDA published a draft guidance for industry entitled "Monoclonal Antibodies: Streamlined Nonclinical Safety Studies," which provides recommendations to streamline long-term safety assessment of monoclonal antibodies that recognize a single molecular target. The goal of this guidance is to assist Sponsors in avoiding unnecessary use of animals, particularly non-human primates, in furtherance of the 3Rs. The guidance emphasizes that for monospecific antibodies, clinically relevant toxicities are primarily due to exaggerated pharmacological effects rather than off-target issues. Instead of traditional extensive packages, it advocates for refining the general toxicology studies through: (1) performing Weight-of-Evidence (WoE) risk assessment to determine the need for a chronic toxicology study and reproductive assessment; (2) focusing on pharmacologically relevant species in the toxicology studies; and (3) integrating New Approach Methodologies (NAMs) to replace, reduce and refine animal usage.

  By implementing these streamlined pathways, the US FDA aims to facilitate greater efficiencies in product development while maintaining rigorous safety standards.

- *ICH Q3E Extractables and Leachables*
  The draft ICH Q3E guideline (August 2025) broadens the traditional guidelines on extractables and leachables (E&L), shifting from a narrow analytical focus to a holistic, risk-based approach that integrates science, toxicology, and product quality. It encourages teams to consider manufacturing processes, formulation behavior, patient use and lifecycle interactions, providing a science-driven roadmap for managing E&L risks across diverse products—from conventional injectables to advanced cell and gene therapies.

  Along with the guideline, ICH published Class 3 leachable monographs that illustrate how acceptable exposure limits are derived using toxicology data, read-across, and *in silico* tools. Altogether, Q3E and the monographs signal a shift toward modern, flexible, and globally aligned E&L practices, reinforcing the growing importance of mechanistic toxicology and exposure-based decision-making in ensuring patient safety.

- *US EPA's Weight-of-Evidence-Based Cancer Assessment*
  On January 6, 2026, the United States Environmental Protection Agency (US EPA's) Office of Pollution Prevention and Toxics (OPPT) published final risk assessments for five phthalates (91 Fed. Reg. 373), including the use of a weight-of-evidence framework for carcinogenicity assessment. This approach, adapted from the international Rethinking Carcinogenicity Assessment of Agrochemicals Project (ReCAAP) initiative and developed jointly by regulatory agencies across the globe, industry, academic experts, and the PETA Science Consortium, provides a structured framework for evaluating carcinogenicity when traditional

in vivo bioassay data are unavailable. Its application marks the first regulatory use of ReCAAP for industrial chemicals in the US, supported by prior publications in *Regulatory Toxicology and Pharmacology* (Hilton, 2022) and *Frontiers in Toxicology* (Goetz, 2024), and the Organisation for Economic Co-operation and Development (OECD, 2024).

- *US EPA's Decision Framework for Hazard Identification of Skin Irritation and Corrosion Skin Irritation*
  The US Environmental Protection Agency's (US EPA's) Office of Pollution Prevention and Toxics (OPPT) issued a new decision framework advocating for the use of human cell–based and other non-animal approaches to characterize the severity of skin irritants from corrosive to non- or minimally irritating substances. The decision framework intent is to provide transparency and consistency to the data submission and review process as well as increasing confidence for the use of non-animal data. The new framework aligns with the concepts described in the 2025 paper, titled "Human relevance of *in vivo* and *in vitro* skin irritation tests for hazard classification of pesticides", which was co-authored by the US EPA, toxicity testing experts, industry, and others. The article provided evidence that non-animal based tests are considered better clinical predictors of human responses.

  The US EPA, the Science Consortium, and the Institute for In Vitro Sciences will co-present a poster describing the framework at the upcoming Society of Toxicology Annual Meeting on Monday, March 23, 2026, in San Diego. The framework follows the 2024 framework for eye irritation testing that stated a preference for the use of non-animal, human cell–based methods, reflecting a global trend towards the use of more modern, reliable, and human-relevant toxicity tests to best protect human health.

- *US EPA's Recommitment to Phasing out Animal Testing*
  On January 22, 2026, the US EPA reaffirmed its commitment to phasing out animal testing (https://www.epa.gov/system/files/documents/2026-01/recommitment-to-reducing-animal-testing-memo-1.22.26.pdf), emphasizing that New Approach Methodologies (NAMs) are suitable for regulatory use when scientifically appropriate. The agency outlined steps to support this transition, including identifying NAMs that can replace traditional animal testing, reviewing guidance and regulations to provide flexibility in data requirements, and encouraging researchers to adopt NAMs and seek waivers to reduce animal use.

As a reminder, all RSESS members must be logged into ToXchange to view guidances and articles.

RSESS would like to thank the 8 subcommittee members across several sectors and areas of the globe for their contributions over the last year!!

Dahea You (Chair)

Stephene Ford (Co-Chair)

Erik Pacyniak (Co-Chair)

Jossie Garthoff

Gina Hilton

Min-Sik Kim

Miao Li

Pramila Singh








The GRAS Framework at a Crossroads: Current Regulations and Impending Reform

What Is GRAS?

Generally Recognized as Safe (GRAS) is a legal designation established under the Federal Food, Drug, and Cosmetic Act (FDCA) for substances intentionally added to food that are considered safe under their intended use conditions.

The GRAS classification was codified by Congress in 1958 as part of the Food Additives Amendment, which exempted GRAS substances from the otherwise mandatory premarket approval required of food additives. The determination of a substance's GRAS status was based on either having "(1) their safety... established by a long history of use in food; or (2) by virtue of their nature of the substances, their conditions of use, and the information generally available to scientists."[1] While basing a GRAS determination on a long history use in food is an available option, compiling the necessary evidence to demonstrate this history can be challenging. The later approach termed "scientific procedures" is more common and is based on the "…generation and evaluation of publicly available scientific and toxicological data to establish safety."[2]

The basis of GRAS is a prepared dossier that must include a comprehensive safety evaluation characterizing the substance (e.g., identity, specifications, manufacturing process, processing aids, production consistency, stability, etc.). The dossier must also include the ingredient's intended use, which can inform exposure, dietary intake, and an understanding of estimated daily intake (EDI), as well as a review of relevant toxicological and clinical data. Finally, the dossier must present a conclusion that the available evidence supports a finding of reasonable certainty that the substance is not harmful under the intended use conditions. Importantly, the key or pivotal studies used in the dossier to support the GRAS conclusion must be "generally recognized" and "generally available" to scientists via readily available peer-reviewed publications.

Current Pathways to GRAS Determination

Under existing regulations, manufacturers have two distinct routes to establish GRAS status for a food substance:

1. US FDA Notification (Voluntary).

A manufacturer may voluntarily submit a GRAS notice to the Food and Drug Administration (US FDA) for its review. Often this submission follows a preliminary consultation with the US FDA, during which a manufacturer presents the data on the subject food ingredient, and the US FDA provides input and answers or asks questions. Once the notification is submitted and the US FDA issues a filing number, the statutory 180-day review period begins, with a potential 90-day extension, for the US FDA to complete its

[1] Gaynor PM, Bonnette R, Garcia Jr. E, Kahl LS, Valerio Jr. LG. 2018. FDA's Approach to the GRAS Provision: A History of Processes. January 4, 2018. Retrieved February 19, 2026 from: https://www.fda.gov/food/generally-recognized-safe-gras/fdas-approach-gras-provision-history-processes.

[2] Henderson RG, Nguyen H. 2022. Pathways to the US supplement market: New dietary ingredient notification and Generally Recognized as Safe determination. Chapter 19 in: Ruthsatz M, Wong AW (Eds.), *Nutrition, Health, and Disease: Regulatory Policy Matters. Regulatory Affairs Professional Society.* pp. 183-196.

review. During this time, the US FDA may request additional data or ask for clarification on the subject dossier. Notably, these are historic timeframes, and more recent timelines can exceed two years for review. Once the US FDA has completed its review and has no further questions, the agency issues a "no questions" letter signaling that it has no objection to using the substance as proposed in the dossier. Notified GRAS substances are then catalogued in US FDA's publicly available GRAS inventory.

2. Self-GRAS Determination (Independent Expert Panel).

Introduced informally in the late 1990s to address a substantial backlog of notifications, the self-GRAS pathway allows manufacturers to convene an independent panel of experts (at least three) who evaluate all available safety data and render a conclusion that the substance meets the GRAS standard. Under this model, the manufacturer retains the supporting documentation internally (i.e., dossier with the same information as the notified GRAS, and signed expert panel consensus statement), and the substance may legally enter interstate commerce without any US FDA involvement. However, the US FDA does have the authority to request any needed information, including the dossier, or to challenge the conclusion itself at any point. Critics have long characterized this pathway as a regulatory loophole, arguing that it allows potentially unsafe food chemicals to enter the food supply without independent governmental review.

Importantly, the GRAS dossiers, either for US FDA Notification or Self-GRAS, are specific for a chemical and a use. If new food categories or increased use is desired, a GRAS supplement is required which addresses the changes to the use parameters.

Proposed Regulatory Overhaul: 2025–2026 Developments

The GRAS framework is facing its most significant potential overhaul since US FDA's 2016 Final Rule. Two primary parallel reform efforts—one regulatory and one legislative—that have been gaining the most attention are advancing simultaneously.

US FDA Proposed Rulemaking. On March 10, 2025, Secretary of Health and Human Services (HHS) Robert F. Kennedy Jr., citing the "Make America Healthy Again" (MAHA) initiative, directed US FDA to explore potential rulemaking to eliminate the self-GRAS pathway.

HHS/US FDA subsequently published its intent in the Spring 2025 Unified Regulatory Agenda (RIN: 0910-AJ02) and, on December 1, 2025, transmitted a proposed rule to the White House for review. The proposed rule is expected to amend 21 CFR Parts 170 and 570 to: (1) "require the mandatory submission of GRAS notices for the use of human and animal food substances that are purported to be GRAS," with exemptions for ingredients with "no questions" letters and those established as GRAS by regulation; (2) require the US FDA to "maintain and update the a public-facing GRAS notice inventory for all substances that are the subject of mandatory GRAS notice for its conditions of intended us;" and (3) "clarify the process under which US FDA would determine that a substance

is not GRAS."[3] Following the current rule review period, a formal Notice of Proposed Rulemaking (NPRM) is expected to be published in the *Federal Register* no earlier than mid-2026, followed by public comment period before formalization.

Better Food Disclosure Act of 2025 (S. 3122). On November 6, 2025, Senator Roger Marshall (R-KS), with co-sponsorship by Senators Rick Scott (R-FL) and Katie Britt (R-AL), introduced S. 3122[4], which proposes to amend the FDCA to "(1) mandate notification of all GRAS substances to the US FDA (including those currently on the market); (2) require US FDA to create a public listing of GRAS substances; and (3) establish a post-market review process to assess the continued safety of food additives, color additives, and GRAS substances."[5] Under this legislation, a food substance would be deemed "adulterated" under FDCA §402(a)(2)(C) unless it is included on a new US FDA-maintained GRAS list or is actively under review for inclusion. Manufacturers of substances currently marketed under self-GRAS determinations would face a two-year compliance window to submit a formal notice. Following receipt, US FDA would have 180 days to approve or issue a preliminary denial; substances not acted upon within this period would be automatically added to the GRAS List. Additionally, this legislation includes a provision to reevaluate substances based on citizen petitions, notices from state official(s), or by US FDA itself. Following the review, the US FDA could amend, reclassify, or remove substances from the GRAS list, thereby restricting their use.

This proposed shift in policy is significant, as it reverses an almost 30-year-old agency determination. In 1997, US FDA concluded that mandatory GRAS notification would be too resource-intensive to administer effectively, and that post-market enforcement authority was sufficient to protect public health. The proposed mandatory notification framework therefore raises substantive questions about statutory authority, agency resource capacity, and implementation feasibility, particularly given that S. 3122 provides no additional US FDA funding to support the anticipated submission surge.

Implications for the Food and Ingredient Industry

If implemented, mandatory GRAS notification would represent a major shift from quasi-post-market enforcement to a de facto pre-market review model for all food ingredients. Concerns related to this shift have prompted industry stakeholders, including manufacturers currently relying on the self-GRAS pathway, to proactively inventory their ingredients, assess their supporting safety dossier robustness, and model the potential impact of mandatory US FDA submission on product development timelines and ingredient costs. While the ultimate rule that will be adopted remains uncertain at this time, the current ongoing discussions represent the most significant potential change to food ingredient safety in over a decade.

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[3] Substances Generally Recognized as Safe, RIN 0910-AJ02, UNIFIED AGENDA, Spring 2025, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202504&RIN=0910-AJ02.

[4] Better Food Disclosure Act of 2025, S. 3122, 119th Cong. (introduced Nov. 6, 2025) (sponsored by Sen. Marshall).

[5] Begley AM, Schultz MB, Petrin L. 2025. Reforming GRAS: Digesting the proposed "Better Food Disclosure Act" (S. 3122). . Nov. 21, 2025. Washington, DC: Wiley Rein LLP. Retrieved February 19, 2026 from: https://www.wiley.law/alert-Reforming-GRAS-Digesting-the-Proposed-Better-Food-Disclosure-Act-S3122.

By: William D. Klaren, PhD, DABT

2025/2026 Award Winners:

RSESS is proud to announce the winners of the 2026 RSESS awards, recognizing outstanding contributions in the fields of regulatory safety science. This year we received over 40 applications highlighting the exceptional work of researchers and scholars dedicated to advancing knowledge and practices of toxicology. These awards are made possible through generous donations to our Endowment fund, and from sponsorship from Elsevier. The RSESS is very grateful to our colleagues who have made finanical contributions in order to provide these impactful oppurtunities for fellow toxicologists.

Overview of the Awards

The RSESS awards are designed to acknowledge and reward excellence in research and innovation in regulatory safety science. The awards are categorized into five distinct areas: Best Paper, Postdoc, Graduate Student, 3MT (Three-Minute Thesis), and Outstanding Contribution.

Award Winners

Best Paper Award

Winner: Srijit Seal

- Title: Machine Learning for Toxicity Prediction Using Chemical Structures: Pillars for Success in the Real World

The Best Paper award recognizes the most impactful research paper submitted in the past year. Srijit Seal's work on utilizing machine learning for toxicity prediction stands out for its innovative approach and practical implications in real-world applications.

Postdoc Awards

1st Place: Zakiyah Henry

- Title: Roots to Neurons: Evaluating Developmental Neurotoxicity (DNT) Potential of Botanicals Using an *In Vitro* Testing Battery

2nd Place: Isha Mhatre Winters

- Title: Association of Prenatal Pesticide Exposure with Plasma Aβ-42/40 and Cognitive Function in Midlife is Modified by APOE Genotype: Evidence from the CHDS cohort

3rd Place: Chander Kant Negi

- Title: Analysis of Species-Specific Hepatocyte Function and Drug Effects in Static Monolayers, Spheroids, and a Perfused Microphysiological System

Honorable Mention: Nicole McNabb-Kelada

- Title: Integrating Inter-Individual Variability and Cellular Interactions: Transcriptomic Responses to Acrolein in a Donor-Matched Lung Co-Culture Model

The Postdoc awards celebrate the achievements of early-career researchers. The researchers presented compelling studies that contribute significantly to our understanding of mechanism of toxicity and protection of human health.

Graduate Student Awards

1st Place: Hannah Roe

- Title: ECHA Writes Back: The Reasons for Rejection of Read-Across in Compliance Check Decisions by the European Chemicals Agency

2nd Place: Rachel Kim

- Title: Neurotoxicity Risk Modeling of Oral-Mucosal BPA Exposure from Dental Resin Composites: Implications for Reassessing the US EPA Standard

3rd Place: Hangyu Wu

- Title: Multidrug Resistance-Associated Protein 4 (MRP4) Deficiency Disrupts Hepatic Lipid Homeostasis and Exacerbates Metabolic Dysfunction-Associated Steatotic Liver Disease

The Graduate Student awards highlight the innovative research conducted by students. This research provides valuable insights into chemical safety assessments, as well as address critical issues in neurotoxicity and metabolic health.

3MT (Three-Minute Thesis) Awards (from an Elsevier donation)

1st Place: Hannah Roe

- Title: ECHA Writes Back: The Reasons for Rejection of Read-Across in Compliance Check Decisions by the European Chemicals Agency

2nd Place: Manisha Thakur

- Title: Multiwalled Carbon Nanotubes Modulate Lipid Rafts Assembly and Hippo Signaling

The 3MT competition encourages students to present their research succinctly and engagingly, enabling them to communicate complex ideas effectively, a crucial skill in the scientific community.

Outstanding Contribution Award

Winner: Bette Meek

The Outstanding Contribution award recognizes individuals who have made significant impacts in the field of regulatory and safety science. Dr. Bette Meek is an internationally recognized leader in regulatory and safety science whose four-decade career has transformed human health risk assessment through the integration of mode of action science, PBPK modeling, biomonitoring equivalents, and chemical-specific adjustment factors into regulatory practice. She pioneered science-based, biologically grounded approaches at Health Canada and through WHO/IPCS that modernized hazard identification, dose-response, and exposure assessment globally, influencing the evaluation of thousands of chemicals. She received this award in recognition of her sustained, groundbreaking impact on advancing more rigorous, transparent, and scientifically robust risk assessment worldwide. The RSESS Award Committee would like to thank Michael Dourson for the nomination.

Furthermore, RSESS is collaborating with the International Society of Regulatory Toxicology and Pharmacology (ISRTP) and the University of Arizona for additional awards.

- Hannah Roe and Chander Kant Negi were this year's ISRTP Graduate and Postgraduate award winners, respectively.

- Diksha Manhas, a postdoctoral scientist in Prof. Xinxin (X. Ding) Ding's laboratory, won this year's University of Arizona award.

  Title: PCB-11 Induces Brain CYP2B10 Expression and Activity in Mice: Implications for Neurotoxicity and Drug Interaction Potential

The RSESS executive team extends our heartfelt congratulations to all winners and nominees for their outstanding work and contributions to the field. Your dedication and passion inspire us to pursue excellence in our research endeavors. We also extend our sincere thanks to RSESS members and the volunteers, April O'Connell, Ashley Brinkman, Claire Neilan, Dahea Diana You, Jessica Sapiro, Madelyn Huang, Monica Langley, Nicholas Drury, Nikolaos Georgiadis, Olivia Lampe, Rosonald Bell, Sandeep Kondakala, Susan Laffan, Taylor Carter, Tim McGovern, William (Bill) Klaren and others who supported the award review process.

Please stay tuned for an announcement regarding an upcoming webinar where we will showcase the work of our winners!

We encourage interested candidates to prepare and apply for the 2027 RSESS Excellence Awards in Q3 2026, when the application window opens. If you are interested in volunteering for the 2027 awards review process, please contact us.

Manoj Aggarwal, DVM, PhD, DABT (RSESS Awards Committee Chair)

Announcement of RSESS sponsored sessions:

A total of 24 session proposals for the 2026 Annual Meeting were received for review and endorsement by the RSESS. Of these proposals, 14 were selected for the program. Congratulations to the organizers of the following courses and sessions that were endorsed by the RSESS and were accepted into the 2026 program:

Continuing Education Courses:

- Systematic Methods for AOP Development and Application: New Technologies and Tools. (**Sunday, March 22**, 8:15 AM – 12:00 Noon). Continuing Education Course AM06.
- Rethinking Carcinogenicity Assays in the 21st Century: Testing a Functionality Framework (**Sunday, March 22**, 1:15 PM – 5:00 PM). Continuing Education Course PM09.
- This Is Real: How AI Can Actually be Used in Hazard and Risk Assessments. (**Sunday, March 22**, 1:15 PM – 5:00 PM). Continuing Education Course PM10.

Informational Sessions:

- Toxicology Meets Public Policy: Lessons Learned from NAMs Advocacy in the United States. (**Tuesday, March 24**, 11:00 AM – 12:30 PM).
- Understanding the GRAS Loophole: History, Science, and Legal Challenges. (**Tuesday, March 24**, 1:00 PM – 2:30 PM).

Roundtable:

- Toward a New Paradigm: Can Mechanistic *In Vivo* Studies Replace Traditional DART Guideline Studies? (**Tuesday, March 24**, 4:30 PM – 6:00 PM).

Symposiums:

- NAM *In Vitro* Assessment of Intestinal Metabolism to Inform PBK Modeling of Bioavailability and Systemic Exposure. (**Wednesday, March 25**, 8:00 AM – 10:45 AM).
- Visionary Foresight: Pioneering Cell-Based Therapies. (**Wednesday, March 25**, 8:00 AM – 10:45 AM).

Symposium / Innovations in Applied Toxicology Session:

- Human Health Risk Assessments of Biopesticides: Evaluating Safety for Agricultural Use. (**Wednesday, March 25**, 1:30 PM – 4:15 PM).
- AI in Toxicology: Navigating Promise, Pitfalls, and Practical Implementation. (**Wednesday, March 25**, 2:00 PM – 4:45 PM).

Workshops:

- Toxicological Risk Assessment of Medical Devices Used for Neonatal and Pediatric Populations. (**Monday, March 23**, 2:00 PM – 4:45 PM).
- Reevaluating Adversity and the Maximum Tolerated Dose in the Modern Regulatory Environment. (**Monday, March 23**, 2:00 PM – 4:45 PM).
- Cardiovascular Toxicity as a Globally Harmonized System Hazard Trait: The Evidence and the Path Forward. (**Wednesday, March 25**, 8:00 AM – 10:45 AM).
- Endocrine Disruption Safety Assessment Approaches for Cosmetics. (**Wednesday, March 25**, 1:30 PM – 4:15 PM).

We are soliciting for volunteers for the Program Committee to review session proposals for the 2027 meeting. This is a very rewarding volunteer opportunity as ultimately, we are helping to shape the agenda and content of the Annual Meeting. And it is fun to get a sneak-peak into some of the topics that will be presented and discussed at the next meeting! Volunteering on this committee also provides a great networking opportunity and a learning opportunity, as you will be reviewing proposals centered around Toxicology topics that may fall outside of the sector that you currently practice in.

A huge thank you to all the RSESS Program Committee members Brent Yamamoto, Sherleen Adamson, Mimi Huang, Claire Neilan, Kevin French, Ashley Brinkman, Bill Klaren, Manoj Aggarwal, Kristin Noell, and Deirdre Dalmas-Wilk. If you have any interest in participating on this committee or if you simply have any questions, please contact Nikolaos Georgiadis (Nikolaos.GEORGIADIS@ec.europa.eu)

NetworX Night at the Annual Meeting

The CAMAN (Career Advancement, Mentoring and Networking) Committee will be hosting a NetworX Night at the Annual Meeting from 7:30-9:00pm on Monday, March 23 (immediately following the RSESS reception) in the Marriott Marquis. CAMAN has partnered with 30+ Component Groups, including RSESS, to host this speed-networking opportunity for trainees. At this event trainees can meet diverse professionals in toxicology, increase networks, and explore career paths and career-change options. Table hosts nominated by Component Groups will represent different career sectors (e.g., academic, industry, government, consulting). After a brief introduction to toxicology-related career resources, those who register will follow their assigned rotation to three tables, concluding with additional time to network freely with the table hosts. Each participant will receive a drink ticket, and a cash bar will be available.

Announcement of RSESS Annual Meeting Reception

Save the Date! The RSESS reception at the Annual Meeting in San Diego will be held at the Marriott Marquis on Monday March 23 from 6:00-7:30pm. Please join us as we listen to some live music, network with colleagues including our award winners, several of whom will have their posters on display, and (NEW this year), we will have Tox Trivia! Drinks and light bites will be available.

SOT MARCH 22-25 SAN DIEGO

REGULATORY & SAFETY EVALUATION Specialty Section