Welcome to November *Insights*. Inside this edition: Call for Proposals, New EI Subcommittee, and more!

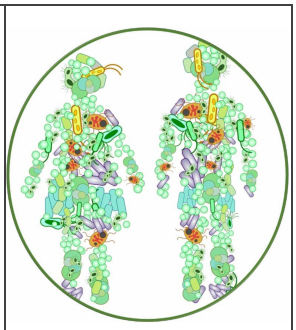
November Insights

Submit Your Idea to HESI Today!

Each year HESI seeks new project proposals as part of our Emerging Issues Process. The call for proposals went out in September and proposals are due **9 December 2016**. Read more about the process as well as answers to frequently asked questions here. The Emerging Issues Committee is looking for new ideas for projects that are well suited to public-private collaboration. The initial proposal should be succinct and should reflect applied, not basic, science. **Ready to submit?** Complete the proposal form (or access it here), and return it to Cyndi Nobles by Friday, 9 December 2016. Questions? Contact Jennifer Pierson to learn more

Microbiome Approved as New Emerging Issues Project

The microbiome proposal, which was presented at the June 2016 Annual Meeting (available here), was unanimously approved to move forward as a new Emerging Issues subcommittee for 2017. The subcommittee will be addressing whether metabolites of microbiota can be used as predictive and translational signals of toxicity and disease. The new subcommittee will convene the first kick-off call in early 2017. If you are interested in helping launch this new subcommittee, please contact Jennifer Pierson or Connie Chen.



CT-TRACS Presentation at the Cell & Gene Meeting on the Mesa

The HESI Emerging Issues subcommittee on cell therapies safety, CT-TRACS (Cell Therapy – TRAcking, Circulation and Safety), presented its first poster on 7 October 2016 at the Cell & Gene Meeting on the Mesa in La Jolla, California. The meeting was organized by the Alliance for Regenerative Medicine and the Sanford Consortium on Regenerative Medicine. The poster, entitled "Cell Therapy – TRAcking, Circulation and Safety (CT-TRACS): The Health and Environmental Sciences Institute (HESI)'s New Collaborative Effort to Address the Challenges of Cell Therapies Translation," can be viewed online here. An abstract is also available on the meeting website (poster 14). For more information about the HESI CT-TRACs subcommittee, contact Lucilia Mouriès.

Highlights From the 2016 HESI PATC Workshop

In October 2016, the HESI Protein Allergenicity Technical Committee (PATC) held a workshop on “Non-IgE Mediated Immune Reactions to Foods” in Rome, Italy, as a satellite meeting of the 4th Food Allergy and Anaphylaxis Meeting (FAAM) of the European Academy of Allergy and Clinical Immunology (EAACI). This workshop provided a great opportunity for PATC members, external academic and clinical allergy experts, and regulators and representatives of the agrobiotech and food industry to connect and share recent scientific advances in the understanding of non-IgE mediated allergic reactions to foods and celiac disease in particular. An interactive discussion provided a better understanding of the science behind the new proposed European Food Safety Authority (EFSA) guidance document (available here) on the risk assessment of newly expressed proteins concerning non-IgE mediated immune responses, currently under public consultation, while also providing valuable input to regulators on the industry processes involved in the selection of candidate new proteins. A summary report and PDF copies of the speakers’ presentations will be available soon on the event website. Full proceedings from the workshop will also be developed for publication in a peer-reviewed journal. For further details about the event, please contact Lucilia Mouries.

(Left to Right) TNO participants Dr. Kitty Verhoeckx and Dr. Jolanda van Bilsen (rapporteur), PATC co-chairs Dr. Greg Ladics (Dupont-Pioneer) and Dr. Scott McClain (Syngenta), and COMPARE Allergen Database steering team member Dr. Laurent Beuf (Limagrain).

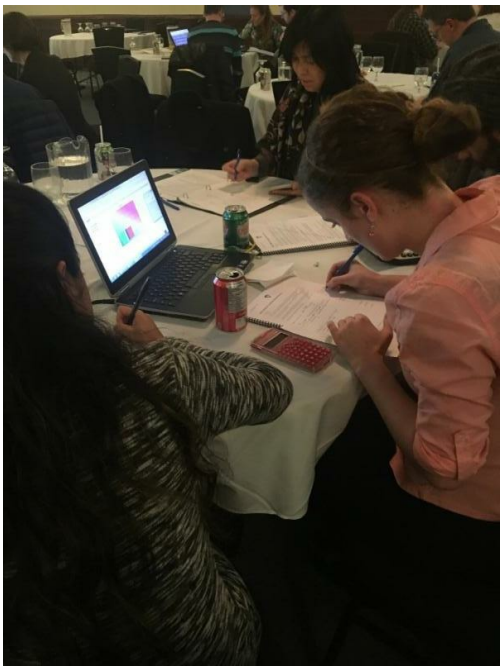
(Left to Right) TNO participants Dr. Kitty Verhoeckx and Dr. Jolanda van Bilsen (rapporteur), PATC co-chair Dr. Greg Ladics, HESI Scientific Program Manager Dr. Lucilia Mouriès, and COMPARE Allergen Database steering team member Dr. Laurent Beuf.

(Left to Right) Prof. Lars Poulsen (Copenhagen University Hospital Gentofte), Dr. John Kough (EPA) (rapporteur), and PATC working group member Dr. Jean-Baptiste Rascle (Bayer).

RISK21 Training Workshop Held in Ottawa, Canada

HESI held a successful training workshop and seminar on "RISK21: A Practical Framework for Risk Assessment in the 21st Century” on 2–3 November 2016 in Ottawa, Canada. Over 100 attendees from Health Canada participated in the interactive 1.5-day session that covered the principles of RISK21 followed by

hands-on case studies for more practical, illustrative real-world applications of the RISK21 approach and visualization matrix. We thank Peter Chan (Health Canada) and colleagues for coordinating the large event and we also thank the RISK21 trainers Prof. Alan Boobis, (Imperial College London), Dr. Samuel Cohen (University of Nebraska Medical Center), Dr. Timothy Pastoor (PSC, LLC), and Dr. Douglas Wolf (Syngenta Crop Protection), along with HESI staff members Ms. Syril Pettit and Dr. Jennifer Tanir! If you are interested in learning more about RISK21 or becoming engaged in the committee's future work, please contact Michelle Embry or Jennifer Tanir.



RISK21 training in action.

Upcoming Events

ITC Webinar

The ITC Clinical and Translational Immunotoxicology Working Group is hosting a webinar on "A Risk Assessment Framework for Evaluating the Impact of Host Cell Protein(s) in Biotechnology-Derived Products" on **1 December 2016** from 12:00 pm to 1:00 pm (EST). For more information or to register, click here or contact Stan Parish.

CiPA Update Meeting Sponsored by CSRC and HESI: Room Block Closes 21 November!

The next CiPA Update Meeting with be held on **6 December 2016** in Rockville, Maryland, at the Hilton Washington, DC/Rockville Hotel and Executive Meeting Center (click here to reserve your room by 21 November 2016). The meeting will feature an update from all CiPA work groups as well as panel discussions and the opportunity to discuss the scientific progress. The final agenda is available online. Click here to register today or contact Jennifer Pierson to learn more.

Rethinking Developmental Toxicity: Evolution or Revolution

The thalidomide tragedy galvanized regulatory agencies into action to develop a testing scheme to identify the potential teratogenicity of new drugs. The outcome was the three-segment testing scheme that covered the reproductive cycle, including the Segment II protocol. Although there have been some modifications to the protocol over time, it is largely the same method that was developed in 1965. What if we were responding to the thalidomide tragedy today instead of 50 years ago, with 21st century science and technology available to us? Would we design the same protocol? If not, would it be radically different, or just an updated version of the 1965 design? This workshop (previously known as "The Blank Page") will be held **19–20 April 2017** and is intended to address that question. We will consider new strategies to identify developmental hazards taking into account the current state of science which may include alternative possibilities or improvements to the current Segment II design. For additional information, visit the workshop's website or contact Connie Chen.

Recent Publications

Theunissen PT Beken S, Beyer B, Breslin WJ, Cappon GD, Chen CL, Chmielewski G, de Schaepdrijver L, Enright B, Foreman JE, Harrouk W, Hew KW, Hoberman AM, Y Hui J, Knudsen TB, Laffan SB, Makris SL, Martin M, McNerney ME, Siezen CL, Stanislaus DJ, Stewart J, Thompson KE, Tornesi B, Van der Laan JW, Weinbauer GF, Wood S, Piersma AH (2016) Comparison of rat and rabbit embryo–fetal developmental toxicity data for 379 pharmaceuticals: on the nature and severity of developmental effects. *Critical Reviews in Toxicology.* Published ahead of print 21 October 2016. Available through open access here.

FROM THE PRESIDENT

Hello from Singapore! I have had the good fortune of being invited to participate in a meetingof the Asia Pacific Association of Medical Toxicologists in this beautifulcity. The conference is titled "AToxicologist's Rendezvous – Meeting of the Disciplines", highlighting the nexusbetween toxicologists and physicians. Iam struck by the wonderfully broad swath of nationalities and cultures in thiscity and meeting, while at the same time realizing similar concerns for issuesin human health and the environment. Thephysicians I've met are seeking ways to collaborate and are eager to seeksolutions. In each presentation and conversation, I hear ideas that echo the importantwork that HESI does: sustainability, cardiac biomarkers, new approaches to riskassessment, and many other topics. Butfew of the participants know what HESI does or how it works. When I describe the "convening" part of ourstrategic plan and point out HESI's ongoing committee work, they get excitedabout the opportunity to work together on commonly held concerns. Perhaps I take it for granted that HESI issuch a great place to get things done and that everyone knows about us. Spending time in Singapore reemphasized theimportant role that HESI plays and how we need to reach globally to convene theexperts and leaders who are seeking solutions to issues that have no boarders.

Tim Pastoor, HESI President

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