Toxicology Excellence For Risk Assessment (TERA)

contents

Mission/Vision/Core Values

Toxicology Excellence for Risk Assessment (TERA) is a non-profit and tax-exempt organization designed for scientific and educational purposes.

Mission

To support the protection of public health by developing, reviewing and communicating risk assessment values and analyses; improving risk methods through research; and, educating risk assessors, managers, and the public on risk assessment issues.

Vision

TERA was founded on the belief that an independent non-profit organization can provide a unique function to protect human health by conducting scientific research and development on risk issues in a transparent and collaborative fashion, and communicating these results widely.

Core Values

TERA is an independent non-profit and as such we embrace our core principles and values in all our activities. These core principles guide day-to-day TERA operations - from our consideration of new projects and sponsors, to our scientific evaluations and communication of results.

- Honesty and integrity
- Independence
- Transparency
- Collaboration

Board of Directors

DATE INDICATES YEAR OF CURRENT ENDING TERM

Michael Dourson, PhD
President Toxicology Excellence for Risk Assessment
(1/1/2015 – 8/1/2015)

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Interim President Toxicology Excellence for Risk Assessment

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Department of Physician Assistant Studies

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CHAIR

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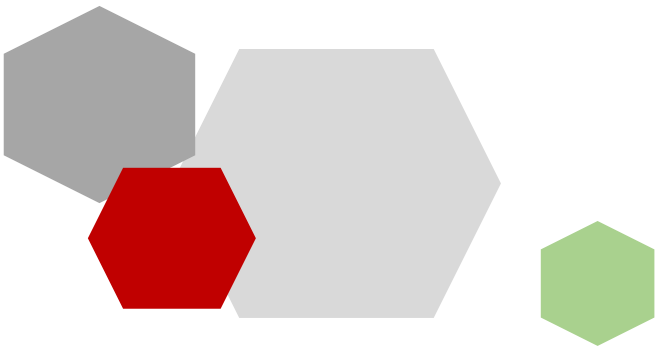


News from TERA's President and Board of Directors

TERA Joins the University of Cincinnati

Toxicology Excellence for Risk Assessment joined the Department of Environmental Health, at the University of Cincinnati's (UC), College of Medicine on July 6, 2015. TERA will be known as the Toxicology Excellence for Risk Assessment Center (or TERA Center).

TERA was organized in 1995 as a nonprofit with a mission to support the protection of public health through the best use of toxicity data. Now as a Center with the Department of Environmental Health at the University of Cincinnati's College of Medicine, we continue to accomplish this mission through independent evaluation of toxicity data and by interpreting and communicating risk assessment information through assessments and websites, organizing peer reviews and consultations, improving risk methods through research, and educating risk managers, assessors, and the public on risk assessment issues. TERA has a strong history of enhancing the use of chemical-specific data to increase the rigor and transparency of evaluations aimed at the prevention of potential human health risks.

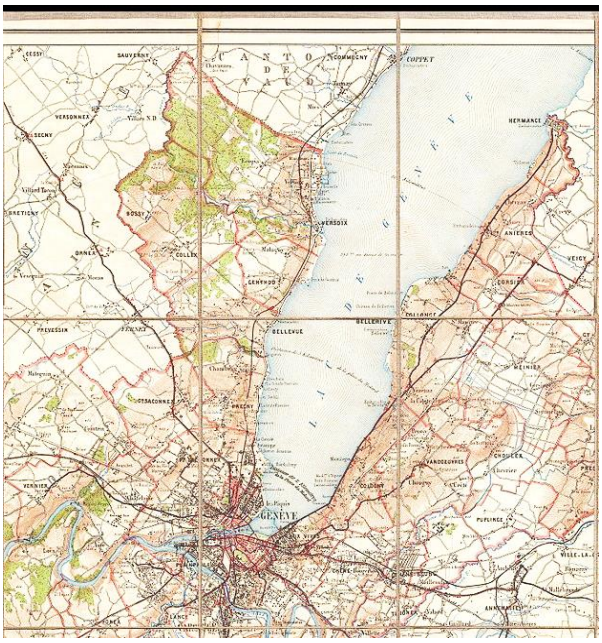
The TERA Center will maintain this rigor and transparency, but will also mesh its work with the research findings of UC investigators in order to develop the next generation of risk assessment methods based on Toxicology 21 principles.

Supporting Missions

TERA Center: To support the protection of public health by developing, reviewing and communicating risk assessment values and analyses; improving risk methods through research; and educating risk assessors, managers, and the public on risk assessment issues.

UC-DEH: To improve the quality of life by identifying the mechanisms of disease and injury due to environmental exposures and genetic factors, and by developing effective methods of preventions and interventions.

Global impact



Geneva

9/14/2015 – 9/25/2015

Dr. Michael Dourson served on the 2015 Joint Meeting of the Pesticide Review panel to determine the appropriate acceptable daily intakes and exposures for up to 20 pesticides.

The meeting was highly interactive and impactful.

A report is available at the World Health Organization website.

Philippines

8/25/2015-8/31/2015

Dr. Michael Dourson served as a US delegate to the Asian Pacific Economic Conference held in Cebu, Philippines, where he gave several lectures on metal toxicity, and led a small study group on methyl mercury contamination of fish.

This organization meets periodically to share technology among member states.

A busy year...

TERA brings RISK ASSESSMENT PERSPECTIVE *to* Nutrition Science

In a novel approach

to addressing the effect of consumption of a macronutrient, TERA has conducted an evaluation of the relationship between the intake of trans fatty acids (TFAs), particularly industrially-produced TFAs (iTFAs), and changes in plasma low density lipoprotein cholesterol (LDL-C), particularly in the low intake region.

A key issue was evaluating the shape of the dose-response curve in the low-dose region. TERA took a two-pronged approach to address the issue. First, the mode of action (MOA) for the impact of TFA on plasma LDL-C was evaluated. Second, TERA conducted a meta-regression of the controlled clinical trial data on iTFAs, using (MCMC) modeling, in collaboration with Bruce Allen for the modeling, and DeAnn Liska of Biofortis for the nutritional perspective.

This approach was unique in nutritional literature, in rigorously considering a variety of flexible curves, including both linear and nonlinear models. The MOA analysis concluded that, although there are several data gaps precluding a rigorous application of the evolved Hill Criteria for evaluation of MOA, the feedback loops and homeostatic controls responsible for maintaining homeostasis of cholesterol and triglyceride levels result in a less than linear relationship between TFA and LDL-C. Consistent with the MOA evaluation, the meta-regression found that an S-shaped curve fit by the Hill model is clearly better than linear model, and linear model is not acceptable.

This novel analysis has generated much interest in the nutrition and risk assessment communities. It has been presented at several venues, including the ToxForum, and SOT-FDA Joint Colloquium; publications are in preparation.

This work was sponsored by the ILSI North America PHO Task Force.

Ozone NAAQS Science and Policy Workshop Report Now Available

Working with the Texas Commission on Environmental Quality (TCEQ) and others, TERA organized a public workshop in April 2015 to provide an independent evaluation and synthesis of key considerations for EPA's November 2014 proposal to lower the primary National Ambient Air Quality Standard (NAAQS) for ozone. A diverse group of well-known and respected science and policy experts engaged in robust discussions on key issues, so that TCEQ and other attendees could gain a better understanding of the issues and implications. This multi-disciplinary group of science and policy experts deliberated on the nexus between scientific findings and implications for public health. The focus was on science related to the level (concentration) of the primary NAAQS and an independent evaluation and synthesis of key policy and other considerations for approaching the difficult and important ozone NAAQS decision.

Presentations, background materials and a summary report are available at http://www.tera.org/Peer/ozone/index.html.

Framework for Addressing Less-than-Chronic and Intermittent Exposures

How does one identify an exposure limit (toxicity reference value, or TRV) for an intermittent exposure (e.g., one day/month for 40 years)? Should one use an acute or a chronic limit for this sort of scenario? How does one decide?

Intermittent exposures such as these are common in many sectors, including manufacturing, waste site cleanup, food safety, and consumer product exposures. Led by Lynne Haber and in collaboration with Bette Meek and Health Canada scientists, the TERA team developed a framework for addressing such scenarios. The framework presents an integrated, tiered approach that assists the user in identifying when existing TRVs can be applied directly, and the adaptations needed to assess the acceptability of short-duration or intermittent exposure scenarios. A manuscript based on the framework is nearing publication, and Dr. Haber shared the framework in a Risk Assessment Specialty Section webinar.

See http://www.toxicology.org/groups/ss/RASS/downloads.asp.

TERA Scientists Assist With Harmonization Effort in Pharmaceutical Industry

Like other industries, the pharmaceutical industry has to manage chemical safety issues—both for workers and consumers. The TERA Center has been working with toxicologists and risk assessment scientists from pharmaceutical industries, consulting groups and academia to discuss current practices for exposure limits, evaluate inconsistencies across guidance documents, identify key areas for harmonization, and document best practices for risk assessment of pharmaceuticals.

"Harmonization doesn't necessarily mean standardization," says Andrew Maier, PhD, an associate professor in the Department of Environmental Health and TERA Center co-director. "It's more a matter of understanding the basis for safety so that we enable savvy users of the risk assessment materials.

Maier and Alison Pecquet were key organizers and facilitators for an October 2014 workshop that was convened in New Brunswick, New Jersey, to identify and address further opportunities for advancing harmonization and best practices in deriving and applying acceptable daily exposures (ADE) in pharmaceutical manufacturing operations. The workshop effort was spurred from a benchmarking assessment to compare current methods in risk assessment for pharmaceuticals.

> "During our benchmarking work, we found that the international guidance documents and methods being used were clearly not harmonized in a number of areas," Pecquet says. "The workshop, which involved most of the top global pharmaceutical companies, was an effort to discuss some of the ways that we could harmonize efforts across agencies so that all of these health-based limits for pharmaceuticals are based on consistent methodologies."

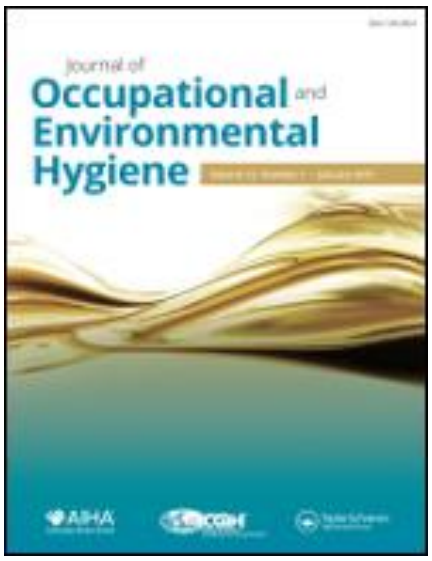
Following the workshop, an article summarizing key workshop findings was published in the September 2015 issue of Contract Pharma, a trade magazine.

The article concluded that a "harmonized set of recognized scientific principles is needed to inform individual efforts in calculating, interpreting, and implementing pharmaceutical risk assessments."

"We are currently working on a series of 10 articles associated with each workshop topic that will appear in a Special Issue of Regulatory Toxicology and Pharmacology in early 2016," Pecquet says. "Our goal is for these reports to shed light on inconsistencies and data needs, lead to further research of the knowledge gaps and contribute to informing decision making among risk assessors in the pharmaceutical industry by providing a 'guide to best practices.'"

"Ultimately, we aim to have one publication that summarizes key issues in this area to help users harmonize and use best practices, all in one place."

SPECIAL ISSUE: State of the Science of Occupational Exposure Limit (OEL) Methods and Guidance



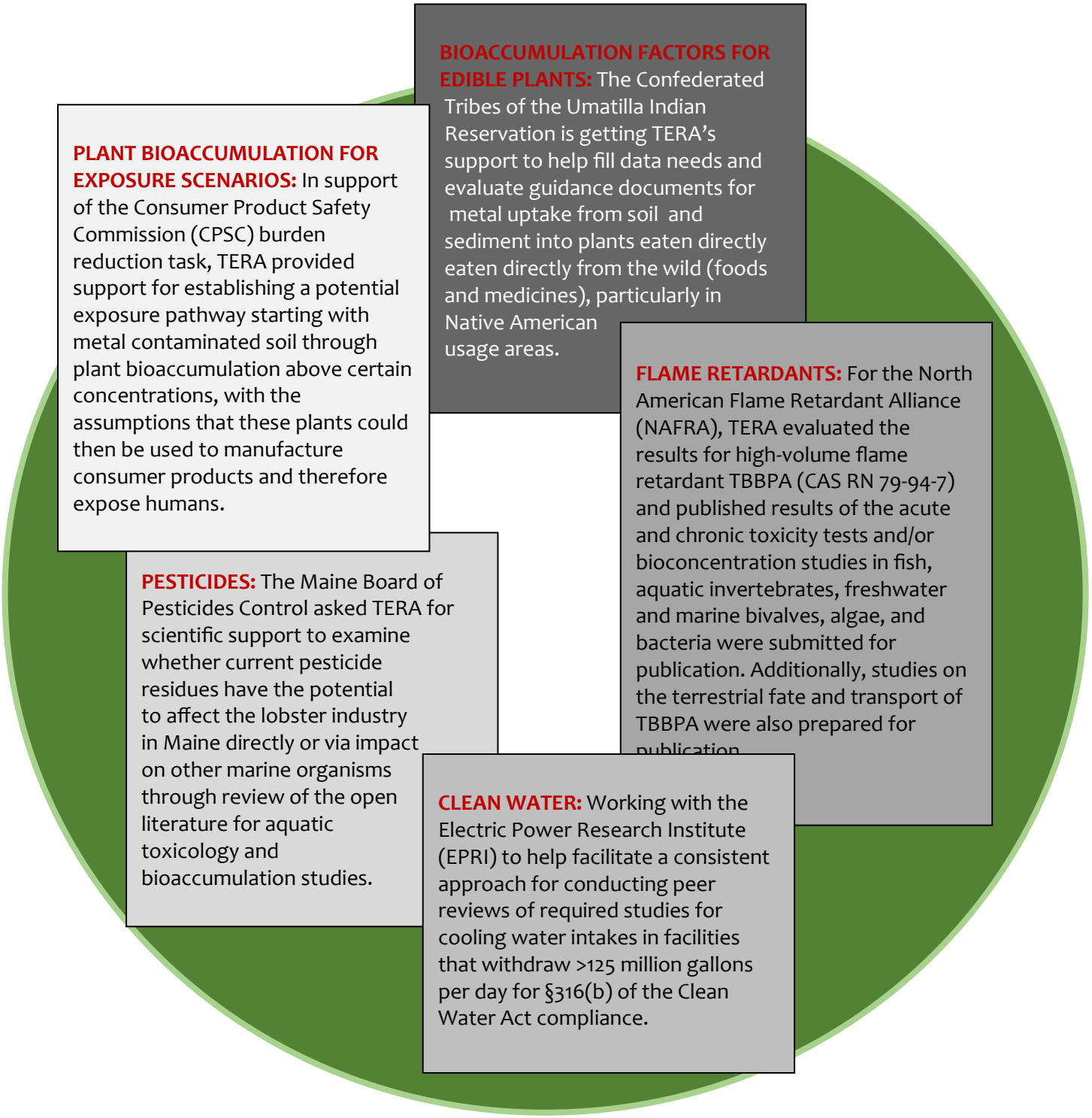
The National Institute for Occupational Safety and Health (NIOSH) conducted an effort to identify and characterize leading issues pertaining to OELs and their development through research, which culminated in a collection of articles focused on each key issue. Those articles and the key issues they explore comprise a Special Issue of the *Journal of Occupational and Environmental Hygiene*. The goal of this effort is to describe the issues related to education and communication of science principles and to understand how they can be incorporated into (and thereby impact) the practices of OEL development and interpretation. Focusing specifically on the state-of-the-science in the fields of exposure science, occupational hygiene, risk assessment, and toxicology this effort sought to provide a clear description of how advances in these research areas can contribute to the practice of OEL setting—by reviewing the methods used for most OELs that are currently available as well as new methods that are actively being incorporated in the OEL process. An essential topic included within the set of complementary and interrelated articles dedicated to this pursuit is the consideration and interpretation of OELs in the context of evolving risk management practices. The articles are intended to serve as a current critical review of occupational risk assessment methods that will enable occupational hygiene professionals to have a clear understanding of the science methods incorporated in the OELs they develop or use.

The ten articles in the supplement resulted from collaborations among scientists at NIOSH, Toxicology Excellence for Risk Assessment (TERA) Center (Dr. Andrew Maier, Dr. Lynne Haber, Dr. Michael Dourson, Dr. Bernard Gadagbui), and other organizations.

While the list of topics for OELs covered in this supplement is in no way exhaustive, it does represent some of the most relevant, promising, and readily applicable scientific advances that can be integrated into risk assessment and management of occupational hazards. The purpose of this collection of article is to inform the practitioner, stimulate the researcher, and provide a basis for more protective and scientifically sound guidance and policy.

TERA's Eco Risk Assessment portfolio is growing!

Ms. Alison Pecquet, M.Sc. and Dr. Charles Pittinger, TERA Fellow, along with additional TERA staff and external collaborators are working to provide support for environmental risk-related services.



BIOACCUMULATION FACTORS FOR EDIBLE PLANTS: The Confederated Tribes of the Umatilla Indian Reservation is getting TERA's support to help fill data needs and evaluate guidance documents for metal uptake from soil and sediment into plants eaten directly eaten directly from the wild (foods and medicines), particularly in Native American usage areas.

PLANT BIOACCUMULATION FOR EXPOSURE SCENARIOS: In support of the Consumer Product Safety Commission (CPSC) burden reduction task, TERA provided support for establishing a potential exposure pathway starting with metal contaminated soil through plant bioaccumulation above certain concentrations, with the assumptions that these plants could then be used to manufacture consumer products and therefore expose humans.

FLAME RETARDANTS: For the North American Flame Retardant Alliance (NAFRA), TERA evaluated the results for high-volume flame retardant TBBPA (CAS RN 79-94-7) and published results of the acute and chronic toxicity tests and/or bioconcentration studies in fish, aquatic invertebrates, freshwater and marine bivalves, algae, and bacteria were submitted for publication. Additionally, studies on the terrestrial fate and transport of TBBPA were also prepared for publication.

PESTICIDES: The Maine Board of Pesticides Control asked TERA for scientific support to examine whether current pesticide residues have the potential to affect the lobster industry in Maine directly or via impact on other marine organisms through review of the open literature for aquatic toxicology and bioaccumulation studies.

CLEAN WATER: Working with the Electric Power Research Institute (EPRI) to help facilitate a consistent approach for conducting peer reviews of required studies for cooling water intakes in facilities that withdraw >125 million gallons per day for §316(b) of the Clean Water Act compliance.

Partnerships

A collaborative effort to organize the world's risk data

Through the Alliance for Risk Assessment, a group of organizations have come together to build the world's premiere database of human health risk values. Building from TERA's *International Toxicity Estimates for Risk (ITER)*, this effort has been dubbed *ITER+* and seeks to first expand the database offerings to include the European Union's Derived No Effect Levels (DNELS), and then additional values to be determined. *ITER* is currently available via the National Library of Medicine, and includes risk values from EPA, ATSDR, IARC, IPCS, and more. The *ITER+* Advisory Committee is responsible for prioritizing the addition of risk values from new sources.

Situation: Exposure analysis requires the use of reference values to qualitatively understand exposure data. Currently, these values are developed by a number of researchers and/or authoritative bodies and reside in a variety of locations. Searching for these values can be time-intensive, values identified can be of varying scientific quality, and often additional expertise is needed to conduct a screening level exposure assessment.

Proposal: Build upon the existing data housed within the International Toxicity Estimates for Risk Assessment (*ITER*) database to include additional values needed for exposure and risk assessment. *ITER* includes peer-reviewed human-health risk values and is searchable using the Toxicology Data Network (TOXNET) on the National Library of Medicine's website (**http://toxnet.nlm.nih.gov/newtoxnet/iter.htm**).

The Alliance for Risk Assessment is organizing a collaborative public/private partnership for the systematic addition of credible values to *ITER+*. The new additions will include the health basis of the value and any assessment or uncertainty factors needed for the lack of key data. These additions will be for chemical ingredients that are known to be used or are found in consumer products. As the initial start for a systematically-phased project, REACH data for derived no effect levels (DNEL) for about 600 chemicals will be added, followed by derived minimal effect levels (DMEL), and the values for the 100 most commonly found

chemical ingredients in consumer products. This focus could encourage analysts to use *ITER+* as their initial 'go to library' site prior to undertaking a full literature search.

Value: Centralizing authoritative reference values from global organizations in a curated database will streamline the risk assessment process, and foster the consideration of exposure for consumer products by removing one of the current barriers to the use of screening level exposure analysis.

The Alliance welcomes additional partners interested in helping to build ITER+, whether through financial or in-kind support. Additional information can be found at www.allianceforrisk.org.

Turning Big Data to Knowledge (BD2K): A discussion of the NIH BD2K initiative and how it might advance the practice of Toxicology and Risk Assessment: The fields of toxicology, pharmacology and risk assessment are undergoing a revolution in the use of pathway-based approaches to evaluate the biological effects of chemicals. These fields would benefit from accessible tools that make big data convenient and intuitive to integrate, analyze, query and visualize. The aim of this ancillary meeting is to reach out to toxicological scientists and introduce them to the NIH big data programs. A panel of researchers provided short overviews of the BD2K and LINCS initiative and thoughts on how big data can be leveraged for protection of people and the environment.

This discussion was held March 23, 2015 Society of Toxicology (SOT) Outreach Meeting in San Diego, California.

Beyond Science & Decisions: *From Problem Formation to Dose-Response Assessment*

9

Workshops
the Workshop series has now completed 9 workshops, bringing scientists of various affiliations and expertise together.

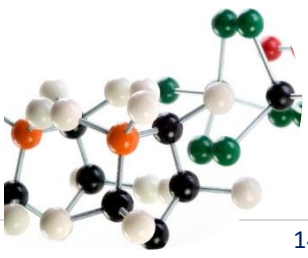
60+

Over 60 organizations
government, industry scientific societies and nonprofits— have contributed to the Workshop's mission to advance the science of risk assessment.

40+

Case Studies
the Workshop series has now reviewed over 40 case studies focusing on a range of risk topics.

Preparation for 2016 Workshop 10 is in underway.



ARA Coalition

1,4-Dioxane Reanalysis of a Regenerative Hyperplasia Mode of Action

EPA's IRIS 2012 external reviewers of the 1,4-dioxane assessment suggested that the histopathology slides from the NCI 1978 dioxane cancer bioassay in mice be reviewed to ascertain whether non cancer pathology was evident. If evident, this finding would support the conclusion that the cancer MOA is regenerative hyperplasia. TERA scientists worked with Dr. Gene McConnell and staff of the NTP to reevaluate these mouse liver slides and found extensive non cancer pathology, thus supporting the regenerative hyperplasia MOA.

This evaluation also suggested the need to re-evaluate the mouse liver slides from a series of Japanese studies on 1,4-dioxane. Five US states and TERA scientists requested the full unpublished reports (including the relevant micrographs) from the study authors. These reports have been reviewed and a draft analysis was prepared.

As described in our draft analysis, the additional information and translations are also supportive of a regenerative hyperplasia MOA but with one exception, specifically, the reported findings from the histopathology and clinical chemistry of the mouse liver in the Japanese studies are contradictory. This may be due in part to the investigators changing the criteria for liver histopathology scoring during the course of reporting their results.

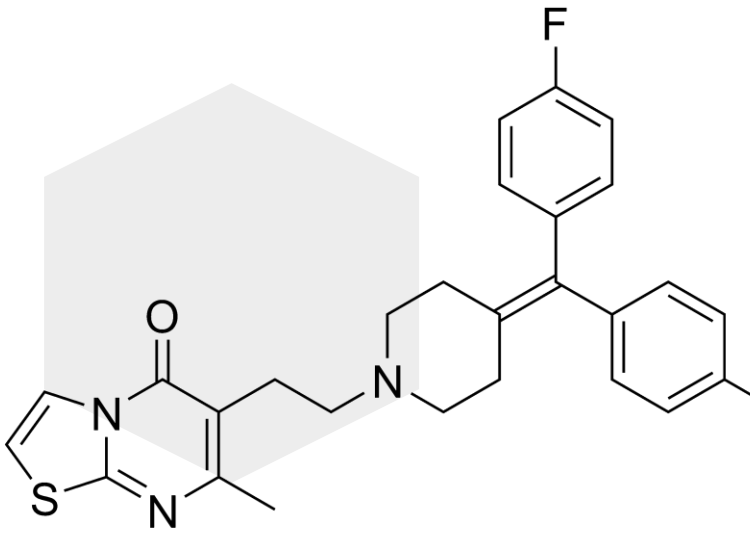
The State of Kentucky petitioned the Alliance for Risk Assessment (*ARA*) Steering Committee to obtain additional histopathology documentation from the Japanese studies to inform 1,4-dioxane's cancer Mode of Action (MOA). The intent of this project is to use this additional information, together with the earlier re-evaluations, in order to reach a conclusion regarding the hypothesized MOA for 1,4-dioxane's liver tumor formation (and potentially other tumors). The coalition includes 5 groups and others are welcomed to participate. An evaluation of the data is being done by 3 pathologists and will be used in the final publication.

More information, including a project timeline, can be found on the project website at http://allianceforrisk.org/14-dioxane-analysis/

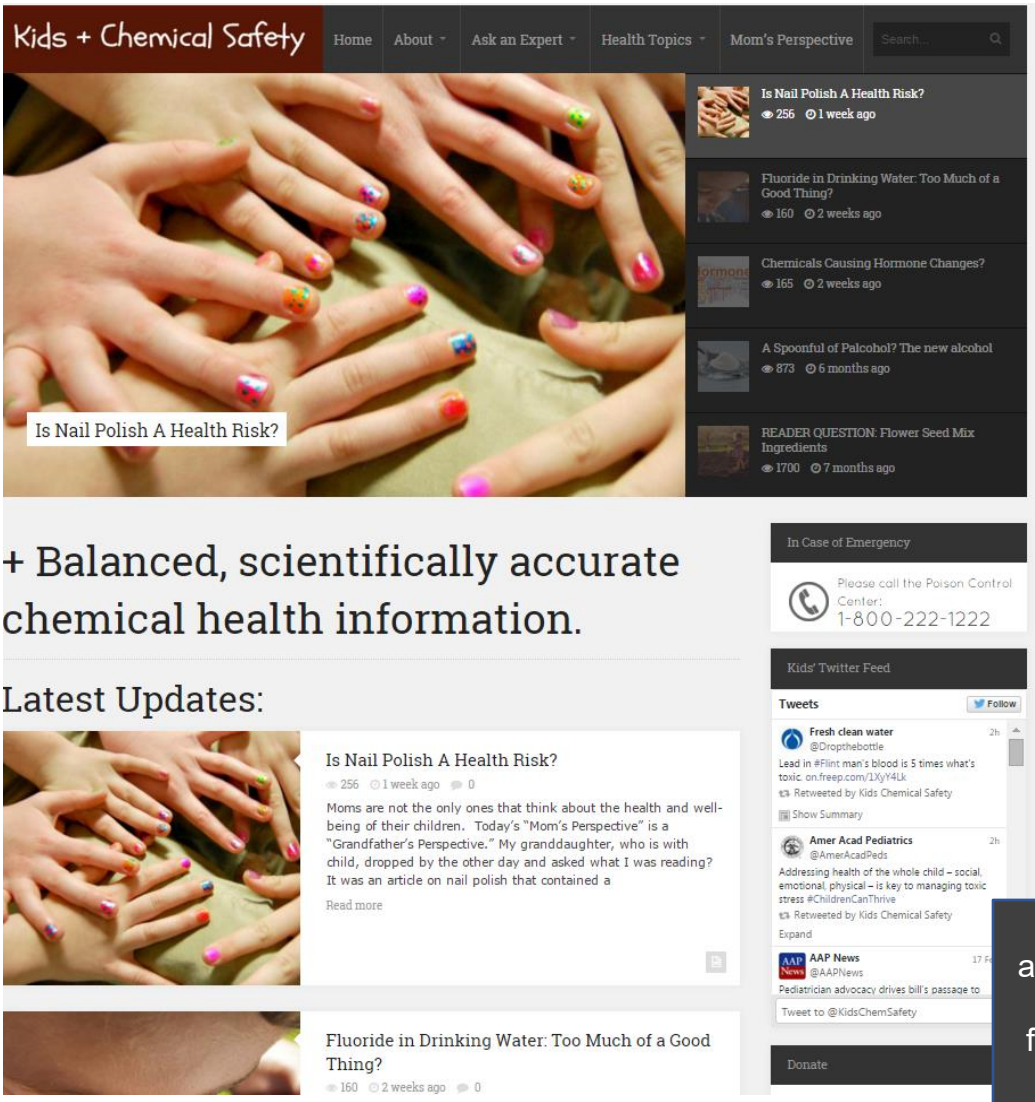
What is *ITER*ate?

*ITER*ate is a new program from TERA to review chemical risk values from published peer-reviewed journals for loading onto the International Toxicity Estimates for Risk (*ITER*) (www.tera.org/iter; http://toxnet.nlm.nih.gov/) Through *ITER*ate, TERA convenes a small group of toxicology and risk assessment experts to evaluate the Enter *ITER*ate. This process will help fill data gaps for missing values or outdated assessments. TCDD example: This controversial chemical has no risk guidance from EPA. The *ITER* database contains data from ATSDR for noncancer endpoints only. The *ITER*ate process was utilized to upload an independently derived cancer value for TCDD. Now, states needing to act to protect human health regarding TCDD have access to this newly derived value.

How to Participate Experts in risk assessment are invited to volunteer for review panels. Authors of risk value papers are invited to submit to *ITERate*.



Kids + Chemical Safety



A new resource addressing the needs of parents and families by providing balanced and scientifically accurate health information on chemical hazards and safe use of chemicals around children.

Partnerships:

Superfund Research Program, Harvard University

Drug and Poison Information Center (DPIC)

Training

Workshops, Courses, and Webinars. Off-the-shelf or Customized

Dose-Response Assessment Boot Camp continues to be our most popular course. Our original 5-day course which is an intensive hands-on training in hazard characterization and dose-response assessment.

Boot Camp Basics begins with an introduction to toxicology for risk assessors. It addresses the fundamental approaches used in hazard characterization and dose-response assessment, as well as introducing complex concepts and modeling.

Boot Camp Advanced Framework and Modeling provides applications of advanced concepts and models, including mode of a provides applications of advanced concepts and models, including mode of action evaluation techniques, use of dosimetry and PBPK models, benchmark dose modeling, structure activity evaluation tools and methods, systems biology and other tools essential to the advanced risk assessment practice.

Practitioner's Guide to Development & Reproductive Toxicology (DART) A 4 hour webinar intended for health scientists and product stewardship professionals, addressing key issues for understanding and interpreting reproductive and developmental toxicity assays, as well as how such data are interpreted in a risk assessment context.

Non-Cancer and Cancer Risk Assessment A 6 hour course providing key concepts of non-cancer and cancer risk assessment followed by a detailed discussion of the methods for hazard characterization and dose-response.

Dosimetric Adjustments in Dose-Response Assessment A 4 hour course designed to provide basic training in dosimetric adjustments for oral and inhalation exposures in dose-response assessment.

Use of Chemical Specific Adjustment Factors A 6 hour course teaching participants methods for refining interspecies and intraspecies uncertainty factors based on toxicokinetic or toxicodynamic data, using chemical-specific adjustment factors (CSAFs)/ data-derived extrapolation factors (DDEFs).

Benchmark Dose Modeling An 8 hour course designed to give an overview of benchmark modeling software for cancer and non-cancer dose-response assessment. This course also provides hands-on experience in using the EPA BMDS software.

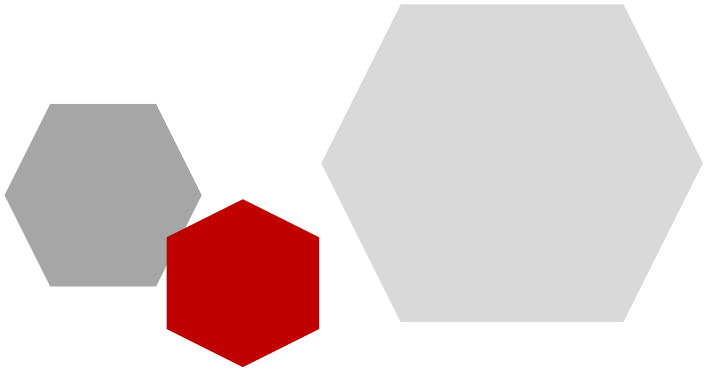
Children's Risk Issues A 1.5 day course discussing the major issues relating to risk assessment for children, such as toxicokinetic differences between adults and children, consideration of windows of susceptibility, and adequacy of the database uncertainty factor.

Mixtures A 2 day course helping scientists to understand and apply methods for risk assessment for multiple exposures or multiple routes ("mixtures risk assessment" or "combined exposures" or "cumulative and aggregate exposure"). Topics include additivity approaches, consideration of interactions, and strategies for addressing complex exposures scenarios.

Occupational Exposures Limit (OEL) Course A 4 day course similar to the Dose-Response Assessment Boot Camp, but focuses on the development of occupational exposure limits (OELs). The training covers the development of OELs, appropriate safety factors, exposure assessment, and hands-on activities to engage all participants.

Globally Harmonized System (GHS) Training A training tailored to corporate needs and circumstances. TERA provides firms with written certification as proof of meeting OSHA requirements. We are familiar with GHS as it relates to the Environmental, Health and Safety (EHS) needs and interests of private corporations and public agencies alike.

Emergency Management and Response Training A 3 day course touching on key toxicology and risk assessment concepts, with an in-depth focus on tools for preventing and responding to chemical emergencies including CAMEO, ALOHA, and MARPLOT. This course is offered onsite to members of your ERM team. CEU credits are available from the University of Cincinnati.



Risk Assessment Lecture Series

TERA is sponsoring a new monthly Risk Assessment Lecture Series within the Department of Environmental Health, University of Cincinnati. The lecture series will be on a range of "risk assessment" topics from a variety of risk assessment experts from various organizations and fields of study.

Dr. Charles Menzie, Global Executive Director for the Society of Environmental Toxicology and Chemistry (SETAC) and a principal with Exponent Inc., a science and engineering consulting company, was the inaugural speaker Friday, November 20th. He presented on "*Using Causal Analysis for Evaluating Environmental and Health Issues.*" Since then, topics covered have ranged from issues on hazard & dose response assessment, TOXCAST/TOX21, epidemiology-based risk assessment, and asthma. Speakers have volunteered from various organizations and agencies, such as National Institute of Occupational Safety and Health (NIOSH), U.S. Environmental Protection Agency (EPA), University of Cincinnati, and many others.

The Seminar series is held every third Friday of the month. Anyone outside of the Cincinnati area can participate via webinar. Details on the seminars and how to register can be found on the website at http://eh.uc.edu/tera/seminars/

Posters & Presentations

Presented at the 2015 SOT Annual Meeting

Sunday, 12:00 PM - 1:00 PM, Marriott Marquis Miramar Room: Alliance for Risk Assessment - "Beyond Science and Decisions"	
"Beyond Science and Decisions": Update and new developments	**L. Haber and M. Dourson**, Toxicology Excellence for Risk Assessment, Cincinnati, OH
Monday, 9:30 AM to 12:30 PM, CC Exhibit Hall: Poster Session: Risk Assessment I (J. Patterson, Chair)	
MCHM Spill in the Elk River—Toxicology and Risk Assessment. (#219)	**J. Patterson[1], M. L. Dourson[1]**, J. Rosen[2], and A. Whelton[3]. [1]Toxicology Excellence for Risk Assessment, Cincinnati, OH; [2]Corona Environmental Consulting, Boston, MA and [3]Purdue University, West Lafayette, IN.
Mode of Action and Meta-Regression Analysis of the Effect of Trans Fatty Acids (TFAs) on LDL-Cholesterol (#224)	**L. T. Haber[1], J. F. Reichard[1], M. J. Vincent[1]**, B. C. Allen[2], Liska, D.J.[3] and **M. L. Dourson[1]**. [1]Toxicology Excellence for Risk Assessment, Cincinnati, OH; and [2]BCA Associates, Chapel Hill, NC., [3]Biofortis
Monday, 12:15 PM -1:30 PM, Marriott Marquis, Del Mar Room: Turning Big Data to Knowledge (BD2K) Session	
Data Science and 21st Century Toxicology (12:15 PM)	**J. Reichard**, Toxicology Excellence for Risk Assessment, Cincinnati, OH
Monday, 1:00 PM to 4:30 PM, CC Exhibit Hall: Poster Session: Genetic Toxicology I	
Evaluation of cII Mutations in Lungs of Male Big Blue Mice Exposed to Vanadium Pentoxide by Inhalation for Up to 8 Weeks (#521)	M. G. Manjanatha[1], S. D. Shelton[1], **L. T. Haber[2]**, B. Gollapudi[3], and M. M. Moore[1,4]. [1]Genetic and Molecular Toxicology, FDA/NCTR, Jefferson, AR; [2]Toxicology Excellence for Risk Assessment, Cincinnati, OH; [3]Center for Toxicology and Mechanistic Biology, Exponent Inc., Midland, MI; and [4]ENVIRON International Corporation, Little Rock, AR.
Quantification of Kras Codon 12 Mutations in Lung DNA of B6C3F1 Mice following Inhalation of Aerosolized Particulate Vanadium Pentoxide (#522)	M. Banda[1], K. L. McKim[1], **L. T. Haber[2]**, J. A. MacGregor[3], B. Gollapudi[4], and B. L. Parsons[1]. [1]Division of Genetic and Molecular Toxicology, National Center for Toxicological Research, US FDA, Jefferson, AR; [2]Toxicology Excellence for Risk Assessment, Cincinnati, OH; [3]Toxicology Consulting Services, Arnold, MD; and [4]Exponent, Chicago, IL.
Monday, 3:15-4:15, Room 24A: Chemical Risk Assessment Best Practices Session	
Risk assessment databases: dissemination & communication of findings & risk values	**M. Dourson, P. Nance, O. Kroner**, Toxicology Excellence for Risk Assessment, Cincinnati, OH
Tuesday, 9:00 AM to 11:45 AM, CC Ballroom 6E: Workshop Session: Understanding and Communicating Uncertainty in Hazard Assessment and Dose Response	
Unpacking Toxicity Assessments to Understand and Improve Confidence (#873; 9:34AM)	R. L. Grant[2], S. L. Santos[3], **M. L. Dourson[4]**, S. Shirley[2], N. K. Erraguntla[2], R. J. Lewis[5], and N. B. Beck[1]. [1]Regulatory and Technical Affairs, American Chemistry Council, Washington, DC; [2]Texas Commission on Environmental Quality, Austin, TX; [3]FOCUS GROUP Risk Communication and Environmental Management Consultants, Medford, MA; [4]Toxicology Excellence for Risk Assessment (TERA), Cincinnati, OH; and [5]ExxonMobil Biomedical Sciences, Inc, Annandale, NJ.
Presenting Uncertainty in the Context of Biological Monitoring and Exposure Information (#874; 10:03AM)	W. H. Farland[1], N. B. Beck[2], J. S. LaKind[3], **P. Nance[4]**, and T. Simon[5]. [1]Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, CO; [2]Regulatory and Technical Affairs, American Chemistry Council, Washington, DC; [3]LaKind Associates, Catonsville, MD; [4]Toxicology Excellence for Risk Assessment, Cincinnati, OH; and [5]Ted Simon, LLC, Winston, GA.
Tuesday, 4:30 PM – 6:30 PM, Hard Rock Hotel, Satisfaction Room, OTR Planning Meeting	
Occupational Toxicology Roundtable (OTR) Planning Meeting	**R. Sandhu[1], P. Nance[1]**, A. Adler[2], R. Sussman[2]. [1]Toxicology Excellence for Risk Assessment, Cincinnati, OH; [2]Safebridge Consultants, Inc., New York/California
Wednesday, 1:00 PM to 4:30 PM, CC Exhibit Hall: Poster Session: Bioinformatics	
Big Data to Knowledge (BD2K)—A Graphical Approach for Data Coordination and Integration (#2199)	**J. F. Reichard[1]**, M. Medvedovic[2], and S. Sivagas[2].[1]Toxicology Excellence for Risk Assessment (TERA), Cincinnati, OH; and [2]Department of Environmental Health, University of Cincinnati, Cincinnati, OH.
Thursday 8:30 AM –12:00 PM, Sails Pavilion: Late-Breaking Poster Session 4: Developmental Basis of Adult Disease and Developmental Toxicology	
Developmental Toxicity of Ethanol as a Topical Antiseptic in an Occupational Setting: A Review (#2675)	R. York[1], **B. Gadagbui[2]**, A. Maier[3], A. Quiñones-Rivera[4]. [1]RG York and Associates, Manlius, NY, [2]Toxicology Excellence For Risk Assessment, Cincinnati, OH, University Cincinnati College of Medicine, Cincinnati, OH, [3]GOJO Industries, Inc., Akron, OH.

Presented at the 2015 SRA Annual Meeting

Session	Day	Paper#	Room	Author(s)	Title
WK4S/11S	Sunday 8:30-5:30PM	Workshop		Haber; Musso	Fundamentals of the Risk Assessment Paradigm, From Hazard Characterization to Risk Communication, with an Emphasis on Contaminated Sites
M3-A	Monday	M3-A	A	Haber, Chair	D3: Doing Dose- Response Differently
	Monday	M3-A.1	A	Haber; Reichard; Vincent; Allen; Liska; Dourson	Mode of action and meta-regression analysis of the effect of trans fatty acids (TFAs) on LDL-cholesterol
P	Monday	P.27		Lange; Tao; Rhomberg; Goodman; Dourson; Honeycutt	Dose response curves derived from clinical ozone exposures can inform public policy
P	Monday	P.118		Willis; Ovesen; Reichard; Sandhu; Maier	Using pharmacokinetic data to replace default adjustment factors in assessing risk from non-clinical exposures to pharmaceuticals
P	Monday	P.189		Kroner; Haber; Dourson	The Dose-Response Framework: An online compendium of risk methods organized by problem formulation
P	Monday	P. 207		Nance, Dourson	Alliance for Risk Assessment Project: 1,4-Dioxane Reanalysis in Support of a Regenerative Hyperplasia Mode of Action (MOA)
T3-A	Tuesday	T3-A.3	A	Willis; Ovesen; Reichard; Sandhu; Maier	How does setting an Acceptable Daily Exposure (ADE) for pharmaceutical risk assessment differ from the U.S. EPA Reference Dose (RfD) approach?
W1-A	Wednesday	W1-A.2	A	Deveau; Maier; Meek; Krewski	Incorporation of chemical-specific data in dose–response assessments for occupational and environmental exposure limits
W4-D	Wednesday	W4-D.3	DE	Patterson; Kroner; Lee; Willis	A Tiered Approach to Investigate Metal Contamination in Unfinished Natural Materials Used in Children's Products
WK15T	Thursday 8:30AM-12:00PM	Workshop		Haber	Developments in Risk Assessment: State of the Science for Evaluating Toxicity Data for Human Health Risk Assessment

Special Issue Articles

- State-of-the-Science: The Evolution of Occupational Exposure Limit Derivation and Application
- Historical Context and Recent Advances in Exposure-Response Estimation for Deriving Occupational Exposure Limits
- Advances in Inhalation Dosimetry Models and Methods for Occupational Risk Assessment and Exposure Limit Derivation
- Systems Biology and Biomarkers of Early Effects for Occupational Exposure Limit Setting
- The Scientific Basis of Uncertainty Factors Used in Setting Occupational Exposure Limits
- Considerations for using Genetic and Epigenetic Information in Occupational Health Risk Assessment and Standard Setting
- Setting Occupational Exposure Limits for Chemical Allergens—Understanding the Challenges
- Exposure Estimation and Interpretation of Occupational Risk: Enhanced Information for the Occupational Risk Manager
- Aggregate Exposure and Cumulative Risk Assessment—Integrating Occupational and Non-occupational Risk Factors
- The Global Landscape of Occupational Exposure Limits—Implementation of Harmonization Principles to Guide Limit Selection

Publications

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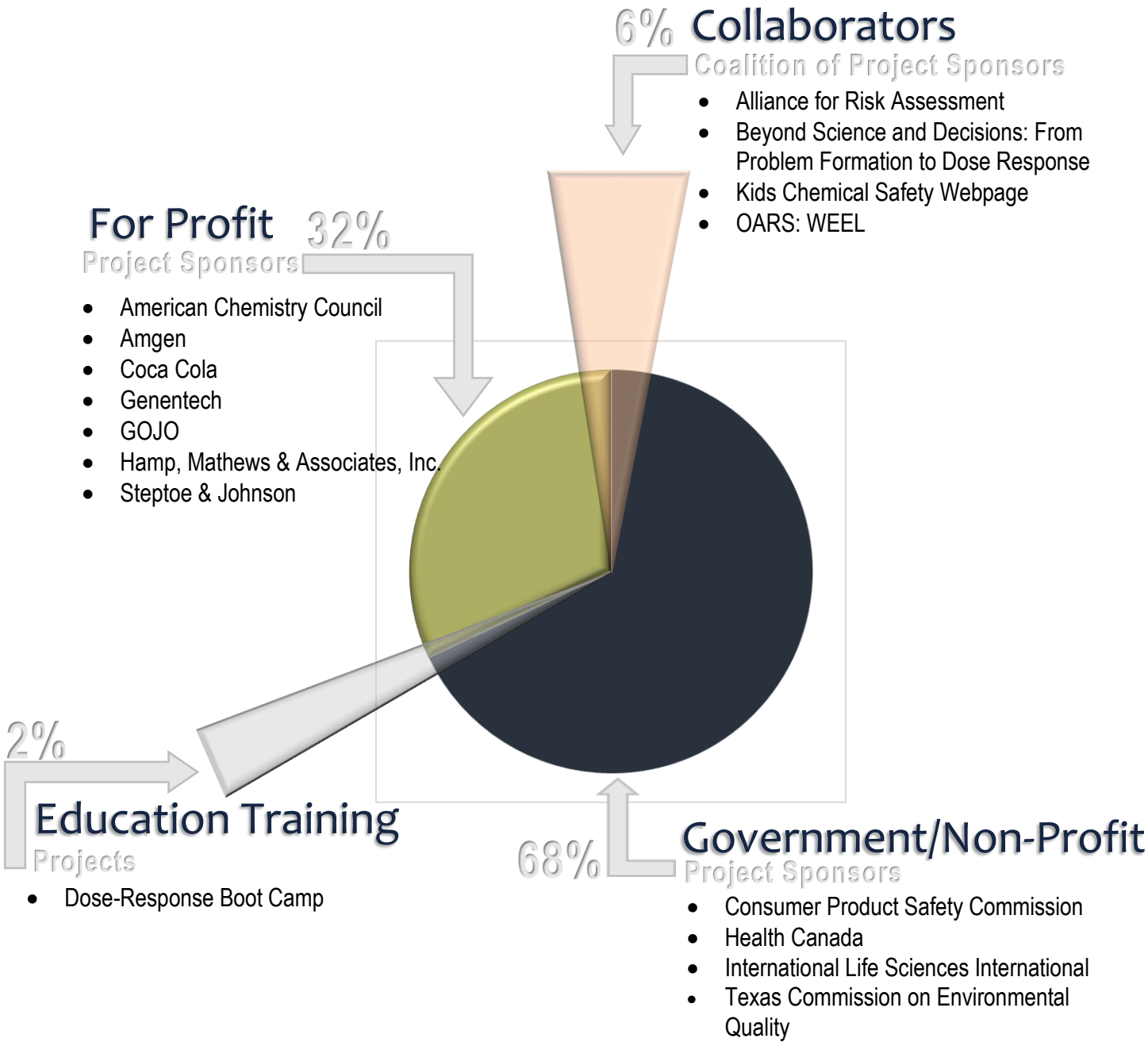

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