

INDEPENDENT • NON-PROFIT • SCIENCE  
*protecting public health*



Toxicology Excellence for Risk Assessment (TERA)

ANNUAL REPORT  
2016

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# CONTENTS

**5** Board of Directors    **6** About us    **7** Mission

**8** Core Principles and Values    **10** Fellows and Visiting

Scientists    **11** Awards    **12** Highlights

**15** Publications    **16** The Numbers

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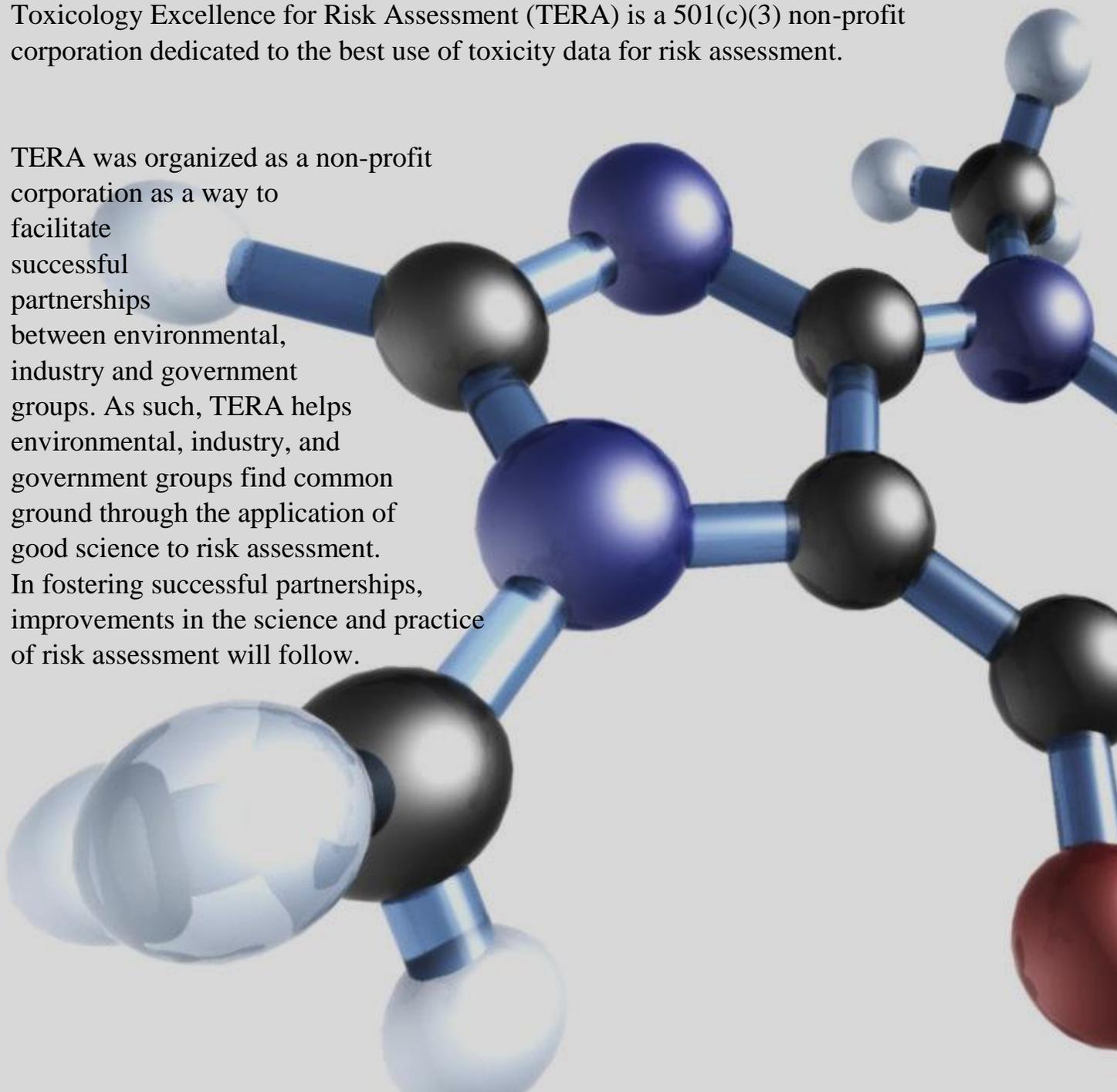
AUDIT COMMITTEE Chair



# ABOUT US

Toxicology Excellence for Risk Assessment (TERA) is a 501(c)(3) non-profit corporation dedicated to the best use of toxicity data for risk assessment.

TERA was organized as a non-profit corporation as a way to facilitate successful partnerships between environmental, industry and government groups. As such, TERA helps environmental, industry, and government groups find common ground through the application of good science to risk assessment. In fostering successful partnerships, improvements in the science and practice of risk assessment will follow.



# 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.



Independence from all parties and groups is essential in order for our science and results to be seen as credible by all parties. TERA has instituted policies and procedures, and maintains a corporate environment that ensures that all of our work efforts are conducted in a manner that maintains our independence. We conduct all our work in a scientifically objective fashion with our results reflecting our best critical analysis and objective evaluation of the scientific information. We are continuously vigilant to make sure that we remain open to new ideas, but we are not swayed or influenced by our funding sponsors, or any other party, in reaching our conclusions or communicating our results.

# CORE PRINCIPLES AND VALUES



## **TERA Core Principles and Values**

### **Honesty and Integrity**

We operate at the highest level of ethical and scientific standards, fully communicating issues and uncertainties.

### **Independence**

We approach our work with an open mind and objectivity, without regard to sponsor or stakeholder interests.

### **Transparency**

We share our work broadly to maximize benefit to public health.

### **Collaboration**

We use collaboration as a fundamental and preferred approach to technical problem resolution.

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. A number of measures insure our work is based upon our principles.

TERA recognizes the importance of independence and scientific objectivity and continually monitors projects and personal work efforts to insure we maintain our high ethical and scientific standards.

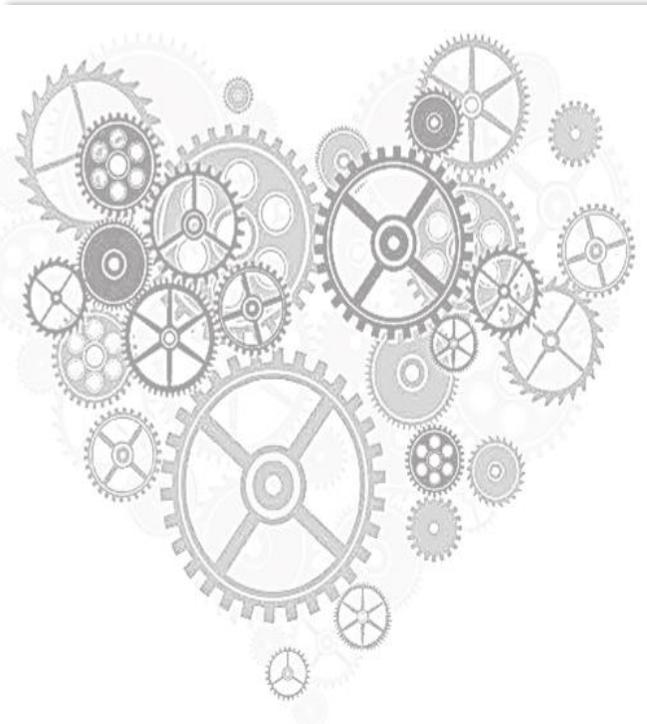
- We are transparent about how we do our work and the methods and approaches we use, so that others can evaluate and judge the strength and scientific validity of our conclusions.

- We strive to fully characterize and communicate scientific uncertainties and limitations in our work.
- We are transparent about who our funders are and what role they had, if any, in commenting on the TERA scientific opinions or results. We make it clear to all funders and sponsors of our work that TERA is an independent scientific organization and as such we will provide them our independent scientific evaluation and conclusions. We discuss (prior to starting work) the level and types of involvement of the sponsors and other outside parties.
- We offer our independent scientific services to a broad range of sponsors, including government agencies, industry, non-governmental organizations, and consultants. By collaborating with many types of organizations, TERA gains an appreciation and understanding of the scientific perspectives of these various parties. We utilize this understanding and the resulting relationships to identify and encourage collaboration among a range of parties to improve risk assessment and protection of public health.
- We seek to have a balance of work among public and private sector. In recent years about 2/3 of our work has been for government agencies and the other 1/3 for industry and others. See: <http://www.tera.org/about/FundingSources.html> for a breakdown by year.
- TERA evaluates each new project to ensure that it is mission related, will benefit public health, and that TERA's participation will make a quality contribution to the effort. We decline projects that do not meet these criteria.
- We strive to publish our work in the peer-reviewed literature or on our website to make the work available to a broad audience.

In addition to our paid work, TERA provides significant *pro bono* support to local and state governments, NGOs and others to help them address important human health and risk issues.



# VISITING SCIENTISTS AND FELLOWS PROGRAMS



TERA has developed both the Visiting Scientist and Fellow Programs to encourage collaboration with others and to improve risk assessment practices.

**Visiting Scientists** are those engaged with TERA for a fixed period of time or on a defined project. Project work may or may not be onsite at TERA's Cincinnati office. While visiting scientists are often senior, positions can also be considered for scientists who are beyond internship level, but for whom a period at TERA would be of mutual benefit.

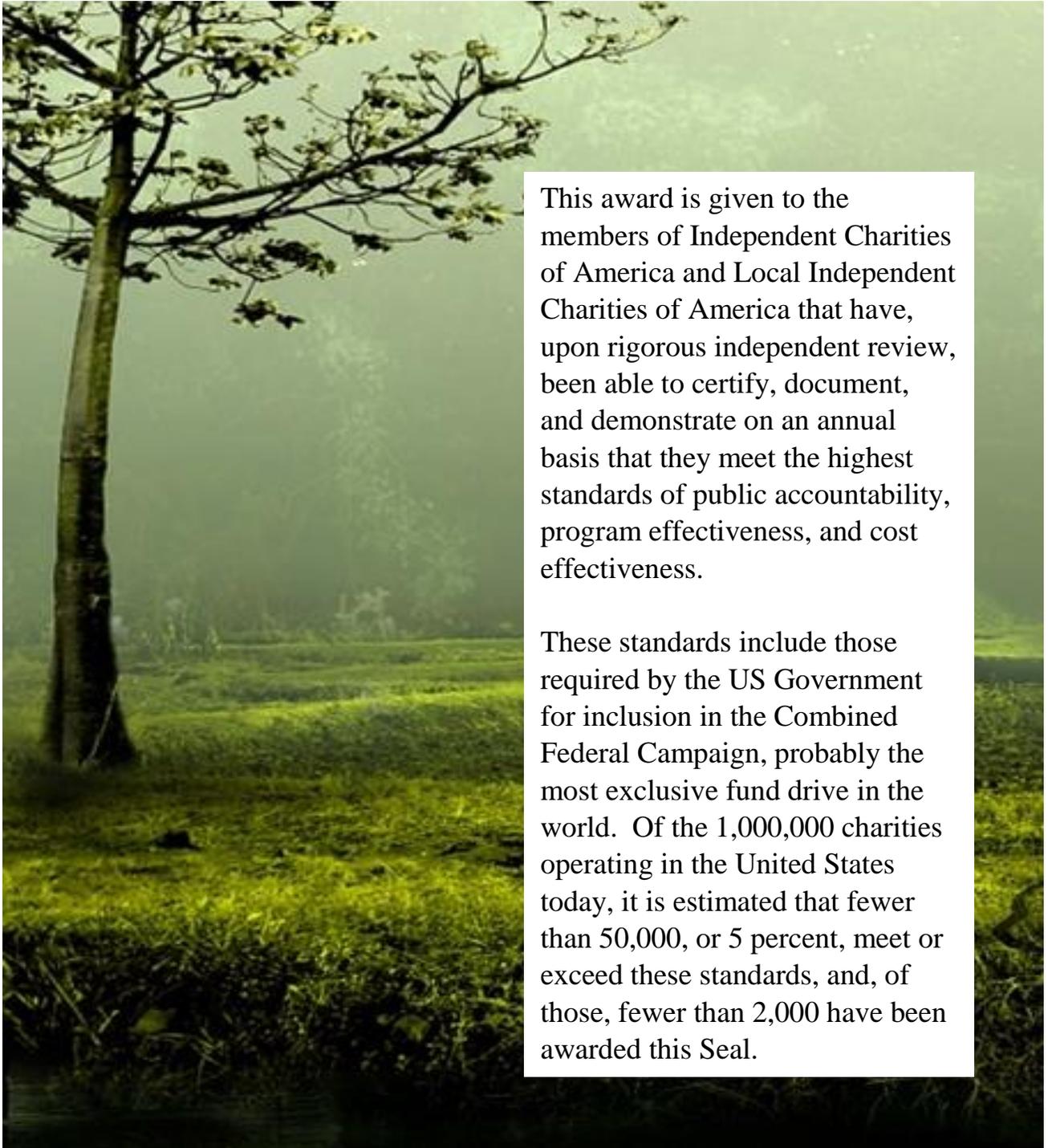
**TERA Fellows** are senior scientists associated with TERA on a longer-term basis with ongoing scientific interactions.

Fellows and Visiting Scientists are not employees of TERA, but rather scientists who share TERA's mission and values and seek to improve the practice of risk assessment. TERA collaborates with Visiting Scientists and/or TERA Fellows on projects of mutual interest.

In the past, scientists have worked with TERA and coauthored manuscripts or reports on a variety of topics, including methods for evaluating persistent and bioaccumulative chemicals, exposure assessment methods, dose-response modeling, mixtures assessment, and investigating the magnitude of adult-to-child toxicokinetic differences in inhalation dosimetry of gases.

# AWARDS

Toxicology Excellence For Risk Assessment (TERA) earned and maintains the Independent Charities Seal of Excellence.



This award is given to the members of Independent Charities of America and Local Independent Charities of America that have, upon rigorous independent review, been able to certify, document, and demonstrate on an annual basis that they meet the highest standards of public accountability, program effectiveness, and cost effectiveness.

These standards include those required by the US Government for inclusion in the Combined Federal Campaign, probably the most exclusive fund drive in the world. Of the 1,000,000 charities operating in the United States today, it is estimated that fewer than 50,000, or 5 percent, meet or exceed these standards, and, of those, fewer than 2,000 have been awarded this Seal.

# 2016 HIGHLIGHTS

## SUMMARY

In 2015, TERA initiated transition of the independent nonprofit organization to an academic institution (for further background, see TERA's 2015 Annual Report) with the intent to fully transition all activities to the university by 2017. During 2016, projects were conducted interactively and collaboratively by both current and former TERA staff at both organizations. Some projects remained at TERA and were conducted under TERA's leadership, whereas other projects transitioned to the university and were conducted under the leadership of the university counterpart.

The projects described below were led by the nonprofit corporation TERA.

## PROJECTS



### **Composition, Production and Use of Phthalates**

Sponsor: Consumer Product Safety Commission, Bethesda, MD.

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The Consumer Product Safety Act (CPSA) requires testing of children's products for compliance with applicable children's product safety rules. The 2008 Consumer Product Safety Improvement Act (CPSIA) restricts the presence of 6 phthalates in children's toys and child care articles above 0.1%; several other phthalates are permanently banned based on toxicity and exposure data or are under an interim ban pending sufficient toxicity and exposure data to determine potential health risks. As part of CPSC's efforts to reduce the burden for third party testing of products by manufacturers, we conducted a literature search and review of the raw materials, manufacturing processes, physical/chemical properties, application in consumer and nonconsumer products, and potential routes of introduction of 11 phthalates into phthalate-free materials. The tiered research approach applied to identify relevant data sources was efficient and effective: authoritative secondary sources, web sites, primary literature searches and targeted gap searching provided confidence that data gaps were identified and available relevant information was obtained. The largest gap was for information regarding migration of the phthalates between materials (e.g., from packaging to a product). Generalizations about the phthalates, including their lipophilicity, hydrophobic nature, synthesis, and movement, may assist in CPSC decision-making regarding testing requirements. Eight of the 11 phthalates were found to be widely present in consumer products, including children's products. Evidence of concentrations above the 0.1% limit was found for some of the phthalates.

## Potential for Presence of Phthalates in Selected Plastics

Sponsor: Consumer Product Safety Commission, Bethesda, MD.

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The Consumer Product Safety Act (CPSA) requires testing of children's products for compliance with applicable children's product safety rules. The 2008 Consumer Product Safety Improvement Act (CPSIA) restricts the presence of certain phthalates in children's toys and child care articles above 0.1%; several other phthalates are permanently banned based on toxicity and exposure data or are under an interim ban pending sufficient toxicity and exposure data to determine potential health risks. As part of CPSC's efforts to reduce the burden for third party testing of products by manufacturers, we were tasked to research the raw materials, manufacturing processes, and typical applications in consumer products (especially children's toys and child care articles), for 4 specific plastics: polypropylene (PP), polyethylene (PE), high impact polystyrene (HIPS), and acrylonitrile butadiene styrene (ABS). The objective was to determine whether the plastics could potentially contain certain phthalates at concentrations greater than 0.1%. We also considered use of recycled materials and potential migration of phthalates from other materials due to packaging, storage, or use. Our research resulted in identification of 3 phthalates (specifically DEHP, DBP, and DIBP) in 3 of the specified plastics (PP, PE, ABS) with concentrations generally < 200 ppm (or 0.02%), < the 0.1% limit. Specifically, we identified a manufacturing process that utilizes a Ziegler-Natta catalyst, which may include the DEHP, DBP, or DIBP at very low concentrations; however, use of this catalyst is unlikely to result in a concentration of the phthalate greater than 0.1% in the plastic. Phthalates were identified in recycled high density PE regranelles from household waste (up to 200 ppm or 0.02% HDPE) that could potentially be used to make new PP. Phthalates were also detected in a baby bottle made of PP and coffee capsules made of PS, PE, PP. Studies on product concentration or migration of phthalates reported either no phthalates or very low levels in the ppb or ppt range. While phthalates have been reported in children's toys and child care products, the specific types of materials the toys and products are made from were not typically identified.

## Potential for the Presence of Phthalates in Materials at Concentrations Above 0.1 Percent

Sponsor: Consumer Product Safety Commission, Bethesda, MD.

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The Consumer Product Safety Act (CPSA) requires testing of children's products for compliance with applicable children's product safety rules. The 2008 Consumer Product Safety Improvement Act (CPSIA) restricts the presence of 6 phthalates in children's toys and child care articles above 0.1%; several other phthalates are permanently banned based on toxicity and exposure data or are under an interim ban pending sufficient toxicity and exposure data to determine potential health risks. As part of CPSC's efforts to reduce the burden for third party testing of products by manufacturers, we developed an efficient and effective tiered literature review strategy to identify relevant data sources and information to determine the potential for the presence of 10

specified phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP, DIBP, DPENP, DHEXP, DCHP) at concentrations above 0.1% in 11 plastic materials. We evaluated the raw materials and manufacturing processes used to produce the plastics; typical applications for the specified plastics in consumer products; the potential use of recycled materials containing the phthalates in the production of the plastics; and the potential for phthalate migration between materials. These plastics are used widely in consumer products, some for toys and child care articles. Out of the 10 specified phthalates, we found no evidence that 6 specified phthalates would be found in the plastics. We often found no direct measurements of the phthalates in the plastic materials themselves; however, we found some indirect evidence that one or more of the phthalates (DEHP, DBP, DnOP, DIBP) might be found in certain plastics (PMMA/PAN, EBR, EBC, EVA/EVOH, EPM/EPDM, polycarbonate, GPS/MIPS/SHIPS, and silicone rubber). Some of the phthalates exceed the threshold of the 0.1% limit specified in section 108 of the CPSIA.



## **Potential for Phthalates or Elements in Undyed Fibers and their Dyes**

Sponsor: Consumer Product Safety Commission, Bethesda, MD

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The Consumer Product Safety Improvement Act (CPSIA) restricts the presence of certain phthalates in children's toys/childcare articles and restricts certain heavy metals in toys for children. We investigated the potential for the restricted elements/phthalates to be present in undyed textile fibers and their dyes that may be used to make toys and childcare articles. This poster focuses on the challenges that arose due to the large number and diversity of dyes, proprietary manufacturing processes and data, use of pre- and post-dyeing treatments, and use of dye auxiliaries. Confusing dye classifications ( $\geq 25$  chemical classes and  $\geq 9$  fiber application methods) made it difficult to assess in a systematic way. However, we were able to overcome these challenges utilizing a systematic research approach and synthesizing multiple lines of evidence from alternative sources of data. The research strategy investigated raw materials and manufacturing processes, utilized a comprehensive literature search, and developed an approach and rationale for addressing the most commonly used dyes. The research found that the restricted elements/phthalates could be present either as impurities in certain fibers/dyes themselves or introduced through manufacturing. Specifically, antimony, arsenic, barium, cadmium, chromium, mercury, butyl benzyl phthalate, dibutyl phthalate, di-2-ethylhexyl phthalate, diisodecyl phthalate, and dioctylphthalate have the potential to be present, and although little information on their concentrations was identified, most were well below the limits. The concentrations of phthalates were all less than the 0.1% limit (1000 ppm) specified by CPSIA. In only two instances were elements found to exceed their limits: antimony and chromium. However, both data points were from textiles of undetermined finishing and it was not known if the source in the samples was the fiber, the dye, or other finishing chemicals.

# PUBLICATIONS AND REPORTS

In 2015, TERA initiated transition of the independent nonprofit organization to an academic institution (for further background, see TERA's 2015 Annual Report) with the intent to fully transition all activities to the university by 2017. During 2016, projects were conducted interactively and collaboratively with both current and former TERA staff at both organizations. Some projects remained at TERA and were conducted under TERA's leadership, whereas other projects transitioned to the university and were conducted under the leadership of the university counterpart.

The presentations and reports described below were led by TERA.

**McGinnis, P.**, J. Patterson, B. Gadagbui, J. Martinez, C. Onyema, A. Pecquet, M. Vincent. (2016). Exposure Assessment: Potential for the Presence of Phthalates and Other Specified Elements in Undyed Manufactured Fibers and their Colorants. Task Order 17 Final Report. Consumer Product Safety Commission. Bethesda, MD.

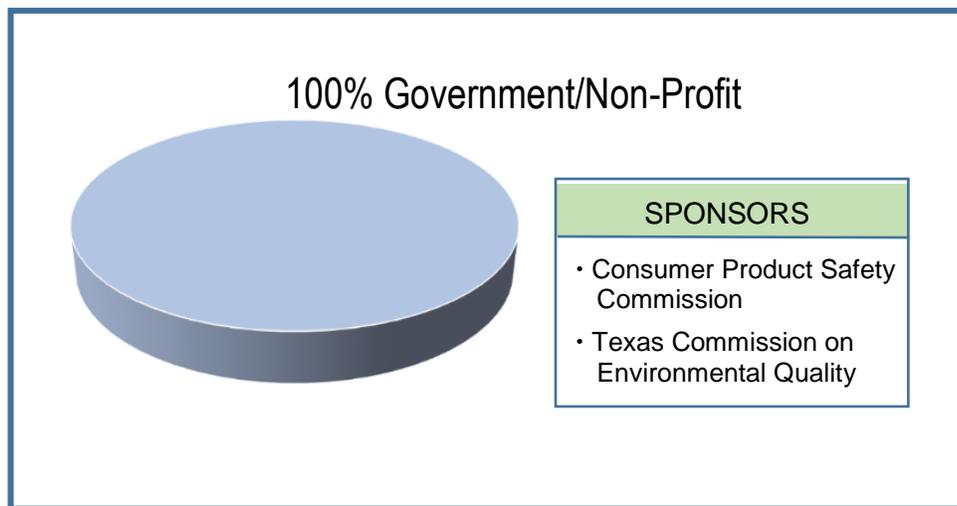
**McGinnis, P.**, B. Gadagbui, J. Martinez, J. Patterson, A. Parker, C. Onyema, S. Thiel (2016). Exposure Assessment: Potential for the Presence of Phthalates in Materials at Concentrations Above 0.1 Percent. Task Order 16 Final Report. Consumer Product Safety Commission. Bethesda, MD.

Pecquet, AM; Gadagbui, B; Martinez, J; Onyema, C; Parker, A; Patterson, J; **McGinnis, PM**; Vincent, M. (2016) Finding Data in Alternative Places: Approaches to Data Mining for Phthalates/Elements in Materials used to make Toys/Childcare Articles. Presented at SETAC North America 37th Annual Meeting in Orlando, Florida. November 2016.



# THE NUMBERS

## 2016 Project Time by Sponsor



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Please note: in 2016, TERA was transitioning contracts to an academic institution.