ORAL ARGUMENT HAS NOT YET BEEN SCHEDULED

No. 17-1201

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ENVIRONMENTAL DEFENSE FUND,
Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; AND SCOTT PRUITT, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Defendants-Appellees,

AMERICAN CHEMISTRY COUNCIL; et al.,
Intervenors for Respondents.

PETITION FOR REVIEW OF RULE OF U.S. ENVIRONMENTAL PROTECTION AGENCY, "TSCA INVENTORY NOTIFICATION (ACTIVE-INACTIVE) REQUIREMENTS," 82 FED. REG. 37,520 (AUG. 11, 2017)

PETITIONER ENVIRONMENTAL DEFENSE FUND'S STANDING ADDENDUM VOLUME II

Robert P. Stockman
Environmental Defense Fund
1875 Connecticut Ave. NW,
Suite 600
Washington, DC 20009
(202) 572-3398
rstockman@edf.org

TABLE OF CONTENTS

<u>Volume I</u>

<u>Volume II</u>

No. 17-1201

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ENVIRONMENTAL DEFENSE FUND,
Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; AND SCOTT PRUITT, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondents,

AMERICAN CHEMISTRY COUNCIL; et al.,
Intervenors for Respondents.

PETITION FOR REVIEW OF RULE OF U.S. ENVIRONMENTAL PROTECTION AGENCY, "TSCA INVENTORY NOTIFICATION (ACTIVE-INACTIVE) REQUIREMENTS," 82 FED. REG. 37,520 (AUG. 11, 2017)

DECLARATION OF LINDSAY MCCORMICK

I, Lindsay McCormick, declare as follows:

1. My name is Lindsay McCormick. I am over 18 years of age. The information in this declaration is based on my personal knowledge and experience.

2. I am a Project Manager within the Health Program at the Environmental Defense Fund (EDF). I have held this position for approximately 1.5

years, before which I was a Research Analyst at EDF for 2 years. My work at EDF is focused on protecting public health from hazardous chemical exposures, including those regulated under TSCA as well as lead in water. I earned an MPH in Environmental Health Science from Columbia University (2012) and a BS in Biology from Haverford College (2010). From 2012-2014, I served as an Associations of Schools and Programs of Public Health (ASPPH) Fellow placed in EPA's Office of Children's Health Protection (OCHP).

3. I have attached my *curriculum vitae* as Attachment A.
4. EDF relies on science, economics, and law to protect and restore the quality of our air, water, and other natural resources, and to support policies that mitigate the impacts of climate change.
5. One of the Health Program's goals is to significantly reduce exposure to high-risk chemicals in consumer products, water, and food. The Health Program works to transform data into meaningful, actionable information that will enable smarter policies and practices. One of the Health Program's goals is to keep both our members and the public informed about chemical risks and exposures.
6. It is my understanding that EDF has long studied the public's exposure to chemical substances and the public health and environmental effects of

chemical substances, and EDF goes to great lengths to inform the public about these issues.

7. I understand one of my major goals at EDF to be informing our members and the public generally about chemical substances.

8. In my experience, one significant barrier to protecting people from exposures to chemicals that may present serious health risks is that there is little information on what people are actually exposed to in their daily lives. As a result, I believe that most Americans are unaware of the problem and there is far too little information on how to best avoid or reduce harmful chemical exposures.

9. I have worked on two EDF-led projects using chemical-detecting silicone wristbands to better understand chemical exposure. These wristbands act as sponges to passively absorb organic chemicals present in the environment of the wearer – from sources including air, water, and consumer products. The summary report from the first wristband project is attached as Attachment B. I have also attached one of the participant reports (with the participant's personal identity redacted) as Attachment C. We reported the results from the second project on our website, and I have attached PDFs of that website as Attachment D.

10. Over the course of 2015-2017, I and my EDF colleagues engaged 43 people, including 13 EDF members, to wear the wristbands and to gain experience in communicating chemical exposure information to the public.

11. In the first project, 28 people, including EDF staff, board members, and leaders at partnering public health organizations, wore the wristbands for one week. The wristbands were then shipped to a lab at Oregon State University where they were qualitatively screened for the presence of more than 1,400 chemicals and quantitatively analyzed for relative levels of any of 40 flame retardants. The qualitative screen detected a total of 57 chemicals, including 12 polycyclic aromatic hydrocarbons (PAHs), 9 plasticizers, and 7 flame retardants. On average, each wristband detected 15 chemicals. All 28 wristbands detected at least one persistent, bioaccumulative and toxic (PBT) chemical, with a total of 16 different PBTs detected. Every wristband detected galaxolide, a fragrance chemical commonly used in household cleaning and beauty products. The quantitative flame retardant analysis identified 12 distinct chemicals across all the wristbands, including specific polybrominated diphenyl ethers (PBDEs) and other halogenated flame retardants. Flame retardant levels varied greatly;

among wristbands with detects, PBDE 49 had the narrowest range of detection (3x concentration difference) and PBDE 99 had the largest range (255x concentration difference). I created individualized reports that were electronically delivered and verbally reviewed during in-person or phone meetings with each of the participants.

12. For the second project, we recruited 11 individuals with diverse backgrounds from across the country to wear the wristbands. The intention of this project was to raise awareness about harmful chemical exposures by putting human faces on the problem. We published a webpage presenting short profiles of 10 of our participants, highlighting their backgrounds, their individual wristband results, and their personal reflections on the results and experience. In this project, we detected a total of 26 chemicals through the qualitative screen. Every participant's wristband detected at least five phthalate plasticizing chemicals. The participant with the highest number of chemicals detected was a firefighter from Nashville, Tennessee, whose wristband even detected a pesticide that was banned in the 1980s.

13. As of February 23, 2018, the EDF webpage housing the summary report from the first project had over 1,200 page views and the report

itself had been viewed over 350 times. The webpage for the second project had been viewed over 5,000 times.

14. Our wristband projects only screened for chemical substances with known specific chemical identities. The screen performed by the lab at Oregon State University is not designed to detect or identify chemicals whose identities are not already known.

15. More generally, EDF is interested in better understanding chemical exposure by catalyzing the market for lower-cost personal exposure monitoring devices. EDF has invested staff time as well as money to hire consultants to conduct research and facilitate an expert workshop on this issue. I took the lead in organizing an EDF workshop called "Understanding Chemical Exposure, Accelerating the Market for Wearable Monitors" held in October 2017, which brought together over 30 public health, technology, and innovation experts. I have attached the Workshop Agenda and a related report summarizing interviews we conducted with a range of experts, as Attachments E and F respectively. Moving forward, EDF will focus on defining and amplifying the demand for personal chemical exposure information, with the intent of catalyzing the development of new technologies and scaling existing technologies.

16. Based on my research and reading of the pertinent literature, it is my understanding that most existing technologies for monitoring can only target known chemicals – not those whose identities are kept confidential.

17. One major constraint in all of these projects and on EDF's and my ability to obtain and share information with the public, and to communicate accurately about this information, is that the specific identities of thousands of chemicals listed on the TSCA Inventory and available for use in the U.S. are not public because companies have claimed that information to be confidential business information (CBI), and EPA has failed to ensure that such claims are warranted.

18. Among other efforts, knowledge of the specific chemical identities of existing chemicals would assist EDF in our advocacy efforts regarding new chemicals generally and EPA's new chemical program under TSCA section 5 specifically. New chemicals are sometimes developed to replace existing ones where there is concern about the existing chemicals' risks. Often in such cases, structurally similar chemicals are used as the substitutes. This creates a reasonable concern that the substitutes could pose the same or similar risks. Recent examples include the introduction of bisphenol S and F to replace bisphenol A

(BPA) and substitute perfluorinated chemicals to replace perfluorooctanoic acid (PFOA). When EDF knows the specific chemical identities of existing chemicals, then EDF can use that information when analyzing EPA's decisions made on structurally similar new chemicals. EDF can use that information in its advocacy both before EPA and with the public generally.

19. In addition, EPA often does not link pieces of non-confidential information about a confidential chemical substance, so EDF cannot discern that various pieces of information all pertain to the same chemical substance. If EDF had access to the specific identities of chemicals now considered confidential, or – even if EPA decides to protect the specific identity of a chemical – if EPA provided a single unique identifier for each chemical and consistently applied it to all publicly available pieces of information about that chemical, EDF could take a number of steps both to better understand the chemicals' health risks and to advocate for greater public health protections. EDF could determine, for example:

- whether the chemical was reviewed for safety by EPA before it entered the market;

- if so, whether EPA imposed restrictions or testing or notification requirements on the chemical as a condition of going to market, through orders or rules;
- whether EPA has utilized its information authorities to require information submission (TSCA section 8) or information development (TSCA section 4) for the chemical;
- whether EPA has health and safety studies on the chemical; and
- whether EPA has received from companies any section 8(e) substantial risk notices.

If EPA provided specific chemical identities or unique identifiers, then EDF could locate and aggregate these pieces of information about each chemical.

20. The following case is an example of the limitations that our lack of access to specific chemical identities or other consistently applied unique identifiers place on EDF's efforts to provide feedback on EPA chemical reviews, as well as our ability to identify relevant hazard and exposure information on chemicals. In August 2015, EPA released a Problem Formulation and Data Needs Assessment on a cluster of brominated phthalate flame retardants, which, at the time, was the first step in EPA's process of developing a risk evaluation for these

chemicals. The assessment listed two of the seven members of the brominated phthalates cluster only as “Confidential A” and “Confidential B.” EPA provided no further identifying information, not even the chemicals’ generic names or tracking numbers (which by definition are not confidential), making it impossible for EDF or others in the public to find whether other information on them existed. EDF raised our strong concerns about this approach directly to EPA staff. We were told that EPA had unilaterally decided to withhold the generic names and tracking numbers for these two chemicals, based on an argument that associating even the generic names of these two chemicals with this cluster might somehow help someone to discern their confidential identities. In response to our complaints about this approach, EPA contacted the compan(ies) that made these chemicals and was told, we understand, that they did not object to the generic names and tracking numbers being made available. EPA then publicly disclosed this information for these two chemicals. Using this identifying information, EDF was then able to search the Federal Register to locate notices that identified when the chemicals were first proposed to be manufactured and when their actual manufacture commenced. We were able to identify that EPA issued a TSCA section

5(e) consent order on one of the chemicals, based on risk concerns EPA identified during its review of the chemical prior to its first manufacture. We then requested and received from EPA a copy of the consent order. The consent order (despite being heavily redacted) indicated EPA had identified serious health concerns, based on the chemical's close structural similarity to another chemical that exhibited liver and kidney toxicity; potential persistent, bioaccumulative and toxic (PBT) characteristics; and potential carcinogenicity due to formation of byproducts during combustion of consumer products containing the chemical in municipal incinerators. We were also able to discern that the other chemical appears to have had no conditions placed by EPA on its commercialization, because we were not able to identify any associated consent order or rule. With this information, EDF was able to more meaningfully comment on the Problem Formulation and Data Needs Assessment on this cluster of brominated phthalate flame retardants. I have attached our comments as Attachment G.

21. Were EDF to have knowledge of the specific identities of these or other confidential chemicals, or consistently applied unique identifiers where the specific identity is legitimately withheld as confidential information,

EDF could take a number of actions to gather additional information and advocate for greater health protections where appropriate. As explained above, we could aggregate various pieces of information to identify high-risk chemicals. EDF could then take action based on that aggregated information. For example, EDF could file a TSCA section 21 citizen petition to compel EPA to issue a TSCA section 8 information submission rule or a TSCA section 4 test order to fill critical data gaps for select chemicals. EDF, along with other organizations, has submitted a TSCA section 21 petition seeking such information in the past. I have attached that petition as Attachment H. We could also use the information to argue that EPA should designate chemicals presenting significant potential risks as high-priority substances, which would then subject them to risk evaluation under TSCA section 6.

22. No confidential chemicals are on the TSCA Work Plan, EPA's list of priority chemicals developed in 2014. If EDF knew the identity of confidential chemicals – allowing us to identify relevant risk information – we could potentially advocate for their inclusion in future prioritization processes, if warranted. We already submitted comments

on behalf of EDF recommending that EPA use an augmented Work Plan approach to select candidates for prioritization.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: 3/5/18

LINDSAY MCCORMICK

McCormick

Attachment A

Lindsay A. McCormick

Education

Columbia University, New York, NY. (MPH) *May 2012*

- Master of Public Health in Global Environmental Health Sciences, Mailman School of Public Health
- Thesis title: "Programming of Adult Disease: Does Early Life Chronic Malnutrition Increase the Risk of Developing Metabolic Syndrome?"
- Merit Scholar *(2010-2012)*

Haverford College, Haverford, PA. (BS) *May 2010*

- Bachelor of Science in Biology, Neural Behavioral Science Concentration
- Thesis title: "The Role of NF-Y in Regulating microRNAs Involved in Differentiation and Proliferation of Hematopoietic Stem Cells."
- Awards and honors: graduated magna cum laude, awarded membership to Phi Beta Kappa**, r**eceived High Honors in Biology, selected as Marian E. Koshland Integrated Natural Sciences Center (KINSC) Scholar

Professional Experience

Project Manager, Environmental Defense Fund, Health Program, Washington, DC *Oct 2016–Present*

- Advocate for the successful implementation of the updated Toxic Substances Control Act (TSCA) through research, policy analysis, and engagement in EPA stakeholder processes
- Provide general project management support for the Health Program's initiative to reduce lead exposure, including coordination of the Lead Service Line Replacement Collaborative and management of a pilot program testing and radiating lead in water in childcare centers
- Manage ongoing projects utilizing novel exposure monitoring tools
- Managing junior staff, interns, and consultants across multiple projects

Research Analyst, Environmental Defense Fund, Health Program, Washington, DC *Sept 2014–Oct 2016*

- Provide coordination and analysis support for environmental monitoring project, "A Week in Chemicals"
- Monitor and comment on regulatory and science activity at the U.S. Environmental Protection Agency (U.S. EPA)
- Provide research support on ongoing efforts to reform the current federal chemical safety legislation
- Research and write about emerging topics in environmental health

Environmental Health Fellow, U.S. Environmental Protection Agency, Washington, DC *Sept 2012–Aug 2014*

- Association of Schools and Programs of Public Health (ASPPH) Environmental Health Fellow placed at the U.S. Environmental Protection Agency (EPA)'s Office of Children's Health Protection (OCHP)
- Reviewed risk assessments and other technical science documents and supported staff on regulatory workgroups
- Researched pesticide regulation at EPA and strategies to improve consideration of children's health
- Managed compilation of OCHP FY13 strategic plan

Occupational Health Intern, UC Berkeley Labor and Occupational Health Program, Berkeley, CA *June–Aug 2012*

- Developed a bilingual survey tool on health and safety hazards in the recycling industry
- Interviewed 46 recycling workers with the International Longshore Warehouse Union (ILWU) in Spanish
- Translated findings and compiled a report "Sorting Through Occupational Hazards in the Recyling Industry in Alameda County, California" used by UC Berkeley and ILWU to develop worker trainings

Intern, Save the Bay, environmental nonprofit, Oakland, CA *June–Aug 2008*

- Researched objectives of grant-making foundations
- Created a comprehensive database of prospective donors

Lindsay A. McCormick

Research and Teaching Experience

Intern, Pontificia Universidad Católica de Chile, Santiago, Chile *July–Dec 2011*

- Collaborated to design and implement a retrospective cohort study on the association between early life malnourishment and metabolic syndrome in adulthood
- Led effort to compile and analyze exposure data from historical medical records
- Performed a literature review for future publications
- Assisted at centers for malnourished and abandoned children

Student Researcher, Stem Cell Laboratory, Haverford College, Haverford, PA *Sept 2009–May 2010*

- Developed and implemented independent thesis research project investigating dysregulation of stem cell differentiation
- Performed technical laboratory procedures including protein cloning, siRNA, and qPCR gene analysis
- Critically analyzed data, developed solutions to technical obstacles, and evaluated future implications of the research

Teaching Assistant, Biology 200, Haverford College, Haverford, PA *Sept 2009–May 2010*

Intern, Children's Hospital Oakland Research Institute, Oakland, CA *June–Aug 2009*

- Analyzed the role of estrogen in gastrointestinal health in the Nutrition and Metabolism Department
- Performed scientific database searches and experiment protocol development
- Conducted a variety of laboratory techniques, including adipose explant assays and ELISAs

Teaching Assistant, Organic Chemistry, Haverford College, Haverford, PA *Sept 2008–Dec 2008*

Tutor, General Chemistry, Haverford College, Haverford, PA *Sept 2007–May 2008*

Expert Workshops and Meetings

Expert workshop, "Eliminating Lead Risks in Schools and Child Care Facilities: A United and Urgent Call to Action for Children." Hosted by Children's Environmental Health Network, Healthy Schools Network, Learning Disabilities Association of America, December 2017. (Panelist, presenter, and participant)

Webinar, "Solutions: Find It and Fix It — Or Flush or Filter it." Hosted by National Drinking Water Association and Kaiser Permanente, November 2017. (Presenter)

Webinar, "Lead and Water." Hosted by Green and Healthy Homes Initiative, November 2017. (Presenter)

EDF Expert Workshop, "Understanding Chemical Exposure, Accelerating the Market for Wearable Monitors." October 2017. (Co-organizer and contributor)

EPA Stakeholder Meeting, "Public Workshop on Use of Methylene Chloride in Furniture Refinishing." September 2017. (Presenter)

EDF Expert Workshop, "EDF's Chemical Detection Initiative: Expert convening to evaluate research proposals." December 2015. (Co-organizer and contributor)

Conference Presentations

Oral Presentation, "Using Simple Wristband Samplers to Detect Chemical Exposures, Engage Citizen Scientists, and Inform Policy." International Society of Exposure Science's Annual Meeting, October 2016.

Poster Presentation, "Biomonitoring Trends in Women of Child-Bearing Age and Potential Prenatal Programming Effects, from EPA's America's Children and the Environment." Prenatal Programming and Toxicity (PPTOX) IV, October 2014. *(Presented by co-author.)*

Poster Presentation, "Children's Health Risk Assessment at EPA and its Implications for Policy Decisions and Identifying Data Gaps." Society of Teratology's Annual Meeting, June 2014.

Poster Presentation, "Children's Environmental Health Risk Assessment: U.S. Concepts, Methods, Tools and Examples." Eastern and Central European Conference on Health and the Environment in Cluj-Napoca, Romania, May 2014.

Oral Presentation, "Career Exploration Day: Environmental and Energy Affairs." Presented on experience working at U.S. EPA to college students, March 2014.

Poster Presentation, "Utilization of the Food Quality Protection Act's Infant and Children Safety Factor and Implications for Dietary Pesticide Exposure in Children." International Society of Environmental Epidemiology's and International Society for Exposure Science's joint meeting in Basel, Switzerland, August 2013.

Oral Presentation, "Identifying Hazards in Recycling Operations in Alameda County, CA." American Public Health Association's Annual Meeting, October 2012.

Oral Presentation, "Salud y Seguridad en la Industria de Reciclaje." ILWU Local 6 meeting, Aug 2012.

Poster Presentation, "Can Infant Malnutrition Lead to Chronic Disease in Adulthood? A Retrospective Cohort Study in Chilean Adults." Columbia University, April 2012.

Oral Presentation, "Estrogen Deficiency Leads to Weight Gain in Mice and is Associated with Impaired gut and Fat Energy Metabolism." Haverford College as a KINSC Scholar, September 2009.

Select Reports and Publications

McCormick, L., Lovell, S., and Neltner, R. (2017) "*Grading the Nation: State Disclosure Policies for Lead Pipes*," Environmental Defense Fund, Washington, DC.

EDF, (2015). "*Chemical Detection Project: New Technology Sheds Light on Chemicals in Our Environment*," Environmental Defense Fund, Washington, DC.

Regular contributions to EDF Health Blog: http://blogs.edf.org/health/?s=lindsay+mccormick&searchsubmit=Search.

Select Newspapers and Media

Provided background information, guidance for, and/or quoted in news reports on chemical policy.

USA Today
CBS Today Show
WebMD
Oregonian
Bloomberg BNA
Inside EPA
Chemical Watch
Chemical & Engineering News

Short Courses and Trainings

Writing in the Sciences, online course taught by Stanford professor	*Sept–Nov 2015*
Environmental Law and Policy, online course taught by UNC law professor	*Jan–Feb 2014*
Benchmark Dose Modeling, Society of Risk Analysis preconference workshop	*Dec 2013*
Climate Change and Health, International Society of Environmental Epidemiology preconference workshop	*Aug 2013*
Gonadal Development, Function and Toxicology, Society of Toxicology preconference workshop	*March 2013*
Toxic Effects of Metals, Society of Toxicology preconference workshop	*March 2013*
Action Development Process, EPA	*Jan 2013*
Food Toxicology, online course hosted by University of Idaho	*March–April 2013*

McCormick
Attachment B

Report

Chemical Detection Project: New Technology Sheds Light on Chemicals in Our Environment

Chemical Detecting Wristbands Show Americans Can't Avoid Toxic Chemicals

A simple looking wristband can shed new light on the previously invisible problem of toxic chemicals in our midst. Environmental Defense Fund (EDF) conducted a pilot project asking 28 individuals to wear the wristbands for one week. The project's findings make clear the power of this technology to detect the presence of chemicals in our everyday lives and to advance our understanding of the health effects of exposures.

Thousands of chemicals are used in the products that surround us every day—from our couches, to our carpets and even the clothes on our backs. Chemicals are used to make 96% of all products sold in America, and some 85,000 chemicals are available for use on the market.

Scientific research is increasingly linking chemicals in common use to some cancers, infertility, diabetes, Parkinson's and other illnesses. Pregnant woman, infants, and children are especially vulnerable. National CDC studies routinely detect hundreds of chemicals in the blood and urine of virtually all Americans tested, and many babies are born with hundreds of chemicals already in their bodies.

Key findings from 28 wristbands

- ***100%*** *detected PBTs.*
- ***86%*** *detected flame retardants chemicals.*
- ***93%*** *detected one or more pesticides.*
- ***100%*** *detected the fragrance* ***galaxolide****.*

Yet, we still have a very limited understanding of the chemicals in our own lives and little assurance of their safety.

Harnessing a new technology to overcome an environmental health challenge

A cutting edge monitor from MyExposome, Inc., developed by researchers at Oregon State University (OSU), promises to transform our understanding of environmental exposures to chemicals—to make the invisible, visible—and, in so doing, open up new opportunities for reducing exposures.

The monitors are surprisingly simple: Silicone wristbands, like the ones worn in support of various causes, are specially prepared to act as a sponge to absorb hundreds of different chemicals (current analytic methods detect over 1,400) in our environment—the air, water, and even personal care products. (Detailed background on the wristbands is at myexposome.com.)

The simplicity of this new technology opens a range of opportunities to empower individuals with information about what chemicals are present in the environment. They also offer the possibility to explore important questions about the efficacy of interventions to reduce exposures.

To better understand the potential and limitations of this technology, EDF conducted a small pilot project to engage individuals to become "environmental sensors" for a week. Detailed findings follow.

Key Findings

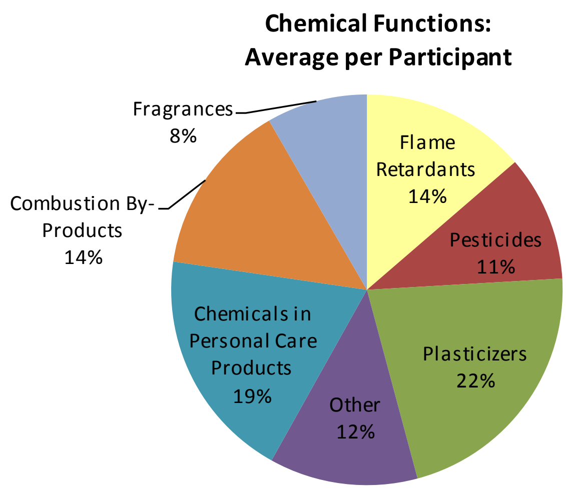
Summary Results

- **28** people participated in this project.
- The wristbands were analyzed for a total of **1,418** chemicals.
- A total of **57** chemicals were detected in all the wristbands.
- Each wristband detected an average of **15** chemicals (range: **10-27**).
- All of the wristbands detected persistent, bioaccumulative and toxic chemicals ("**PBTs**").
- **86%** of the wristbands (24 of 28) detected one or more flame retardants.
- **93%** of the wristbands (26 of 28) detected one or more pesticides.
- Every wristband detected **galaxolide**, a common fragrance used in cleaning and beauty products.

Where might these chemicals be found?

The wristbands detected chemicals used in a wide variety of consumer products – from plastics and personal care products to furniture. The primary functions of the chemicals detected in this project include:

- **13** combustion by-products
- **12** pesticides
- **9** plasticizers
- **7** flame retardants
- **4** chemicals in personal care products*
- **4** fragrances



Are any of these chemicals hazardous**?

- The most common hazards associated with the **57** chemicals detected in this project are **cancer** (35%), **developmental** and/or **reproductive effects** (28%), **endocrine disruption activity** (61%), **respiratory effects** (28%) and **skin sensitization** and/or **skin irritation** (42%).

- Of the **8** phthalates detected, **2** (**DEHP** and **BPP**) have been permanently banned by Congress for use in toys and certain children's products due to their adverse effects on the male reproductive system. Bans are pending for **3** additional phthalates detected: **DCHP**, **DIBP**, and **DHEXP**. These phthalates remain legal for many other uses.

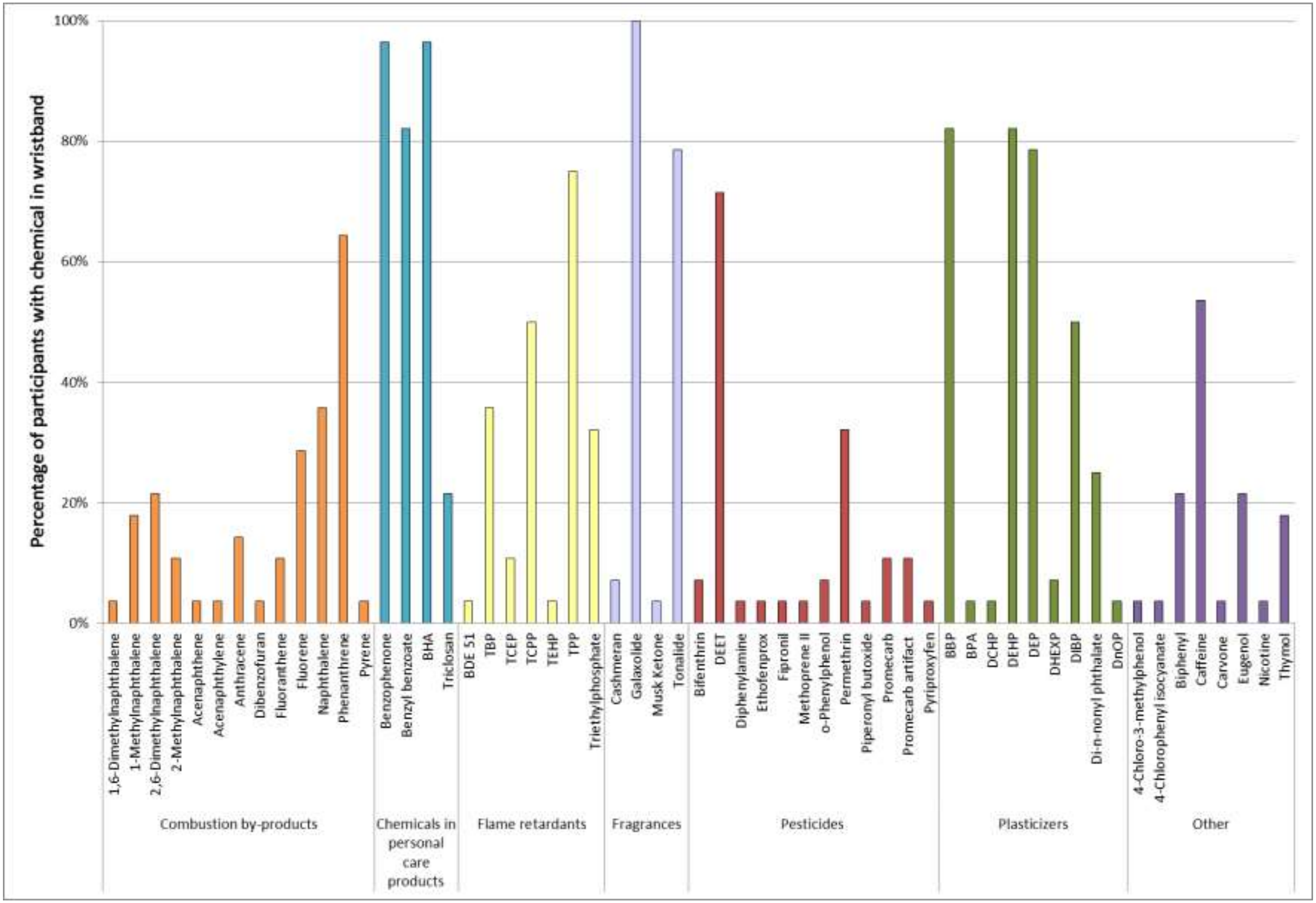
- Several hazardous flame retardant chemicals were detected, including **TCEP**, banned in the EU due to its toxicity to the reproductive system.

- A number of polycyclic aromatic hydrocarbons (PAHs) detected are persistent in the environment and associated with health effects such as cancer, including **naphthalene**, **phenanthrene**, and **anthracene**.

* The chemicals in personal care products category includes preservatives, antimicrobials, UV filters and fragrance enhancers. Plasticizers and fragrances may also be found in personal care products.

** The hazard of a chemical refers to its intrinsic ability to cause harm or induce a toxic effect. Risk is a function of both hazard and exposure, the amount of the chemical substance that enters a person's body.

Chemicals Detected



Appendix

I. Definitions

Hazard – The hazard of a chemical refers to its intrinsic ability to cause harm or induce a toxic effect, such as those listed below in "Chemical Hazard Types." Risk is a function of both *hazard* and *exposure*, the amount of the chemical substance that enters a person's body. Assuming a constant exposure, chemicals will differ in the type and magnitude of toxic effect(s) that they may induce.

Persistent bioaccumlative toxic chemicals ("PBTs") – Chemicals that do not break down readily from natural processes, accumulate in organisms – concentrating as they move up the food chain, and are harmful in small quantities.

Chemical Hazard Types[1]

Cancer (i.e., carcinogenicity) – Can cause or increase the risk of cancer.

Developmental effects – Can harm the developing child; effects may include birth defects, low birth weight, and biological or behavioral problems that appear as the child grows.

Reproductive effects – Can disrupt the male or female reproductive systems, changing sexual development, behavior or functions, decreasing fertility, or resulting in loss of the fetus during pregnancy.

Endocrine disruption activity – Can interfere with hormone communication and production, which controls metabolism, development, growth, reproduction, and behavior.

Respiratory effects – Can result in high sensitivity such that small quantities trigger asthma, rhinitis or other allergic reactions in the respiratory system.

Skin sensitization – Can trigger allergic reactions on the skin.

Skin irritation – Can irritate or seriously damage the skin.

Functions & Uses

Chemicals in personal care products – Chemicals added to personal care products (e.g., lotions, soaps, and cosmetics), such as preservatives and antimicrobials. Plasticizers and fragrances (see below) are excluded from this category.

Combustion by-products – Chemicals formed from the incomplete burning of coal, oil, gas, garbage, or other organic substances. Most chemicals included in this category are polycyclic aromatic hydrocarbons (PAHs).

Flame retardants – Chemicals added to a variety of materials, including textiles, electronics, plastics, and foam to reduce flammability.

[1] Chemical hazard type definitions are based on the Pharos Project, available here: https://www.pharosproject.net/

Fragrances – Chemicals with an inherent odor. These chemicals are often added to personal care products, cleaning products, food products, and more.

Pesticides – Chemicals designed to kill, repel, or mitigate any pest (insects, rodents, weeds, fungi, and microorganisms). This category excludes antimicrobials designed for use in personal care products.

Plasticizers – Chemicals used to provide plasticity and flexibility to plastics, such as polyvinylchloride (PVC). This category includes phthalate chemicals, which are added to a variety of items, including construction materials, personal care products, toys, food packaging, medical devices, and more.

Other – The "Other" category includes food additives, tobacco derivatives, chemical intermediates, and chemicals that cannot be classified due to many overlapping functions.

II. Full List of Chemicals Detected

1,6-DIMETHYLNAPHTHALENE *(CASRN: 575-43-9)*
Specific Hazards:[2] No data
Primary Function(s): Combustion by-product
Found in or Used in the Manufacture of:[3] Air
Government Resource: http://toxnet.nlm.nih.gov/ (search term: 1,6-dimethylnaphthalene)

1-METHYLNAPHTHALENE *(CASRN: 90-12-0)*
Specific Hazards: Little human data available; harmful if swallowed
Primary Function(s): Combustion by-product, chemical intermediate
Found in or Used in the Manufacture of: Air; pesticides (inert ingredient); food packaging and additives; ink, pigments, and dyes
Government Resource: http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=43

2,2',4,6'-TETRABROMODIPHENYL ETHER (BDE 51) *(CASRN: 189084-57-9)*
Specific Hazards: Medium hazard for endocrine disruption activity
Primary Function(s): Flame retardant
Found in or Used in the Manufacture of: Building materials; fabric, furniture, and upholstery; electronics
Government Resource: http://www.toxtown.nlm.nih.gov/text_version/chemicals.php?id=79

2,6-DIMETHYLNAPHTHALENE *(CASRN: 581-42-0)*
Specific Hazards: No data
Primary Function(s): Combustion by-product
Found in or Used in the Manufacture of: Air; food packaging and additives
Government Resource: Not available

2-METHYLNAPHTHALENE *(CASRN: 91-57-6)*
Specific Hazards: Little human data available; harmful if swallowed
Primary Function(s): Combustion by-product, chemical intermediate
Found in or Used in the Manufacture of: Air; pesticides (inert ingredient); building materials; ink, pigments, and dyes; petroleum products/fuels
Government Resource: http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=43

[2] Chemical hazards data is based on the Pharos Project database, available here: https://www.pharosproject.net/
[3] Chemical uses data is based primarily on EPA's CPCat database (http://actor.epa.gov/cpcat/faces/home.xhtml), ATSDR's Substance List (http://www.atsdr.cdc.gov/substances/indexAZ.asp), and EPA's InertFinder database (http://iaspub.epa.gov/apex/pesticides/f?p=101:1).

4-CHLORO-3-METHYLPHENOL *(CASRN: 59-50-7)*
Specific Hazards: High hazard for skin sensitization; medium hazard for endocrine disruption activity, skin irritation
Primary Function(s): Preservative in personal care products (antimicrobial), antiseptic, pesticide (industrial preservative) ("Other")
Found in or Used in the Manufacture of: Personal care products; pesticides; food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; ink, pigments, and dyes; pharmacological products
Government Resource: Not available

4-CHLOROPHENYL ISOCYANATE *(CASRN: 104-12-1)*
Specific Hazards: High hazard for skin irritation; medium hazard for cancer, respiratory effects, organ toxicity
Primary Function(s): Chemical intermediate in manufacture of pesticides and pharmaceuticals ("Other")
Found in or Used in the Manufacture of: Pesticides (inert ingredient); pharmacological products
Government Resource: http://toxnet.nlm.nih.gov/ (search term: 4-Chlorophenyl isocyanate)

ACENAPHTHENE *(CASRN: 83-32-9)*
Specific Hazards: PBT; high hazard for cancer
Primary Function(s): Combustion by-product
Found in or Used in the Manufacture of: Air; pesticides (manufacture); building materials; ink, pigments, and dyes; pharmacological products
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/pahs.pdf

ACENAPHTHYLENE *(CASRN: 208-96-8)*
Specific Hazards: PBT; high hazard for cancer
Primary Function(s): Combustion by-product
Found in or Used in the Manufacture of: Air
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/pahs.pdf

ANTHRACENE *(CASRN: 120-12-7)*
Specific Hazards: PBT; high hazard for cancer, skin sensitization; medium hazard for endocrine disruption activity, respiratory effects, skin irritation
Primary Function(s): Combustion by-product
Found in or Used in the Manufacture of: Air; pesticides (manufacture); building materials; manufacture/maintenance of vehicles; ink, pigments, and dyes; pharmacological products
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/anthrace.pdf

BENZOPHENONE *(CASRN: 119-61-9)*
Specific Hazards: High hazard for cancer; medium hazard for endocrine disruption activity
Primary Function(s): UV filter and fragrance enhancer in personal care products, food additive
Found in or Used in the Manufacture of: Personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; paper products; ink, pigments, and dyes; toys and children's products; electronics; cigarette chemicals; pharmacological products
Government Resource: http://hpd.nlm.nih.gov/cgi-bin/household/brands?tbl=chem&id=570&query=119-61-9&searchas=TblChemicals

BENZYL BENZOATE *(CASRN: 120-51-4)*
Specific Hazards: Little human data available; harmful if swallowed
Primary Function(s): Fragrance fixative and preservative in personal care products, food additive, antiparasitic (treats scabies), pesticide, solvent, plasticizer
Found in or Used in the Manufacture of: Personal care products; air fresheners; pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; manufacture/maintenance of vehicles; cigarette chemicals; pharmacological products
Government Resource: http://hpd.nlm.nih.gov/cgi-bin/household/brands?tbl=chem&id=2881&query=120-51-4&searchas=TblChemicals

BIFENTHRIN *(CASRN: 82657-04-3)*
Specific Hazards: PBT; high hazard for organ toxicity; medium hazard for cancer, endocrine disruption activity, respiratory effects, skin irritation
Primary Function(s): Pesticide
Found in or Used in the Manufacture of: Pesticides
Government-Academic Collaboration: http://npic.orst.edu/factsheets/biftech.pdf

BIPHENYL *(CASRN: 92-52-4)*
Specific Hazards: High hazard for skin irritation; medium hazard for cancer, endocrine disruption activity, respiratory effects, organ toxicity
Primary Function(s): Chemical intermediate ("Other")
Found in or Used in the Manufacture of: Air; personal care products; pesticides (inert ingredient); food packaging and additives; building materials; paper products
Government Resource: http://www.epa.gov/ttnatw01/hlthef/biphenyl.html

BIS(2-ETHYLHEXYL)PHTHALATE (DEHP) *(CASRN: 117-81-7)*
Specific Hazards: High hazard for cancer, developmental effects, reproductive effects; medium hazard for endocrine disruption activity, respiratory effects, organ toxicity, skin irritation; potential concern for neurotoxicity
Primary Function(s): Plasticizer
Found in or Used in the Manufacture of: Air; personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; ink, pigments, and dyes; arts, crafts, hobby materials; toys and children's products; electronics; pharmacological products
Government Resource: http://www.atsdr.cdc.gov/phs/phs.asp?id=376&tid=65

BISPHENOL A (BPA) *(CASRN: 80-05-7)*
Specific Hazards: High hazard for developmental effects, reproductive effects, skin sensitization; medium hazard for endocrine disruption activity, respiratory effects, organ toxicity, skin irritation
Primary Function(s): Plasticizer
Found in or Used in the Manufacture of: Food packaging and additives; building materials; manufacture/maintenance of vehicles; paper products; ink, pigments, and dyes; arts, crafts, hobby materials; toys and children's products; electronics; petroleum products/fuels
Government Resource: https://www.niehs.nih.gov/health/assets/docs_a_e/bisphenol_a_bpa_508.pdf

BUTYL BENZYL PHTHALATE (BBP) (CASRN: 85-68-7)
Specific Hazards: High hazard for developmental effects, reproductive effects; medium hazard for cancer, endocrine disruption activity, respiratory effects, skin irritation
Primary Function(s): Plasticizer
Found in or Used in the Manufacture of: Air; personal care products; pesticides (inert ingredient); food packaging and additives; building materials; manufacture/maintenance of vehicles; paper products; ink, pigments, and dyes; arts, crafts, hobby materials; toys and children's products
Government Resource: http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/phthalates.html

BUTYLATED HYDROXYANISOLE (BHA) *(CASRN: 25013-16-5)*
Specific Hazards: High hazard for cancer, skin sensitization; medium hazard for developmental effects, reproductive effects, endocrine disruption activity
Primary Function(s): Preservative (antioxidant) in personal care products and food
Found in or Used in the Manufacture of: Personal care products; pesticides (inert ingredient); food packaging and additives; building materials; toys and children's products; pharmacological products
Government Resource: https://ntp.niehs.nih.gov/ntp/roc/content/profiles/butylatedhydroxyanisole.pdf

CAFFEINE *(CASRN: 58-08-2)*
Specific Hazards: Medium hazard for endocrine disruption activity
Primary Function(s): Food additive ("Other")
Found in or Used in the Manufacture of: Personal care products; pesticides (inert ingredient); food packaging and additives; cigarette chemicals; pharmacological products
Government Resource: http://www.fda.gov/downloads/UCM200805.pdf

CARVONE *(CASRN: 99-49-0)*
Specific Hazards: Little human data available; harmful if swallowed
Primary Function(s): Preservative (antimicrobial) in personal care products, food additive, fragrance, pesticide (insect repellent) ("Other")
Found in or Used in the Manufacture of: Personal care products; pesticides; food packaging and additives; cleaning products; cigarette chemicals
Government Resource: http://toxnet.nlm.nih.gov/ (search term: carvone)

CASHMERAN *(CASRN: 33704-61-9)*
Specific Hazards: Medium hazard for endocrine disruption activity
Primary Function(s): Fragrance
Found in or Used in the Manufacture of: Personal care products; pesticides (inert ingredient); cleaning products
Government Resource: Not available

DIBENZOFURAN *(CASRN: 132-64-9)*
Specific Hazards: PBT
Primary Function(s): Combustion by-product
Found in or Used in the Manufacture of: Air
Government Resource: http://www.epa.gov/ttnatw01/hlthef/di-furan.html

DICYCLOHEXYL PHTHALATE (DCHP) *(CASRN: 84-61-7)*
Specific Hazards: High hazard for reproductive effects; medium hazard for endocrine disruption activity, respiratory effects
Primary Function(s): Plasticizer
Found in or Used in the Manufacture of: Food packaging and additives; building materials; ink, pigments, and dyes
Government Resource: http://www.cdc.gov/biomonitoring/DCHP_BiomonitoringSummary.html

DIETHYL PHTHALATE (DEP) *(CASRN: 84-66-2)*
Specific Hazards: High hazard for reproductive effects, skin sensitization; medium hazard for endocrine disruption activity, respiratory effects, skin irritation
Primary Function(s): Plasticizer
Found in or Used in the Manufacture of: Personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; manufacture/maintenance of vehicles; ink, pigments, and dyes; toys and children's products; pharmacological products
Government Resource: http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=112

DIISOBUTYL PHTHALATE (DIBP) *(CASRN: 84-69-5)*
Specific Hazards: High hazard for developmental effects, reproductive effects; medium hazard for endocrine disruption activity, respiratory effects
Primary Function(s): Plasticizer
Found in or Used in the Manufacture of: Food packaging and additives; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; paper products; ink, pigments, and dyes; toys and children's products
Government Resource: http://toxtown.nlm.nih.gov/text_version/chemicals.php?id=24

DI-N-HEXYL PHTHALATE (DHEXP) *(CASRN: 84-75-3)*
Specific Hazards: High hazard for reproductive effects; medium hazard for developmental effects, endocrine disruption activity, respiratory effects
Primary Function(s): Plasticizer
Found in or Used in the Manufacture of: Pesticides (inert ingredient); food packaging and additives; building materials; manufacture/maintenance of vehicles; toys and children's products
Government Resource: http://toxtown.nlm.nih.gov/text_version/chemicals.php?id=24

DI-N-NONYL PHTHALATE *(CASRN: 84-76-4)*
Specific Hazards: Little human data available; harmful if swallowed
Primary Function(s): Plasticizer
Found in or Used in the Manufacture of: Data unavailable
Government Resource: http://toxtown.nlm.nih.gov/text_version/chemicals.php?id=24

DI-N-OCTYL PHTHALATE (DnOP) *(CASRN: 117-84-0)*
Specific Hazards: High hazard for skin sensitization; medium hazard for developmental effects, endocrine disruption activity, respiratory effects; low hazard for reproductive effects
Primary Function(s): Plasticizer
Found in or Used in the Manufacture of: Personal care products; pesticides (inert ingredient); food packaging and additives; building materials; manufacture/maintenance of vehicles; arts, crafts, hobby materials; toys and children's products; electronics; pharmacological products
Government Resource: http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=204

DIPHENYLAMINE *(CASRN: 122-39-4)*
Specific Hazards: High hazard for skin sensitization; medium hazard for cancer, developmental effects, reproductive effects, organ toxicity
Primary Function(s): Pesticide (antioxidant)
Found in or Used in the Manufacture of: Pesticides; food packaging and additives; building materials; manufacture/maintenance of vehicles; ink, pigments, and dyes; petroleum products/fuels
Government Resource: http://www.epa.gov/opp00001/reregistration/REDs/factsheets/2210fact.pdf

ETHOFENPROX *(CASRN: 80844-07-1)*
Specific Hazards: High hazard for developmental effects; medium hazard for endocrine disruption activity
Primary Function(s): Pesticide (used to repel bed bugs)
Found in or Used in the Manufacture of: Pesticides
Government Resource: http://householdproducts.nlm.nih.gov/cgi-bin/household/brands?tbl=chem&id=2105&query=80844-07-1&searchas=TblChemicals

EUGENOL *(CASRN: 97-53-0)*
Specific Hazards: High hazard for respiratory effects, skin sensitization; medium hazard for skin irritation
Primary Function(s): Fragrance, food additive, antiseptic, analgesic ("Other")
Found in or Used in the Manufacture of: Personal care products; air fresheners; pesticides (active and inert ingredient); food packaging and additives; cleaning products; building materials; manufacture/maintenance of vehicles; pharmacological products; petroleum products/fuels
Government Resource: http://householdproducts.nlm.nih.gov/cgi-bin/household/brands?tbl=chem&id=1925&query=97-53-0&searchas=TblChemicals

FIPRONIL *(CASRN: 120068-37-3)*
Specific Hazards: PBT; high hazard for organ toxicity; medium hazard for reproductive effects, endocrine disruption activity; potential concern for neurotoxicity
Primary Function(s): Pesticide
Found in or Used in the Manufacture of: Pesticides
Government-Academic Collaboration: http://npic.orst.edu/factsheets/fipronil.html

FLUORANTHENE *(CASRN: 206-44-0)*
Specific Hazards: PBT; high hazard for cancer; medium hazard for endocrine disruption activity
Primary Function(s): Combustion by-product
Found in or Used in the Manufacture of: Air; building materials
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/pahs.pdf

FLUORENE *(CASRN: 86-73-7)*
Specific Hazards: PBT; high hazard for cancer; medium hazard for endocrine disruption activity
Primary Function(s): Combustion by-product
Found in or Used in the Manufacture of: Air; pesticides (manufacture); building materials; ink, pigments, and dyes
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/flourene.pdf

GALAXOLIDE *(CASRN: 1222-05-5)*
Specific Hazards: PBT; high hazard for developmental effects[4]; medium hazard for endocrine disruption activity
Primary Function(s): Fragrance
Found in or Used in the Manufacture of: Personal care products; air fresheners; pesticides (inert ingredient); cleaning products; building materials; manufacture/maintenance of vehicles
Government Resource: http://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=245534

[4] Evidence for reproductive/developments effects for galaxolide is based on preliminary studies. The majority of research demonstrates that galaxolide exerts its toxic effects on the environment; there is limited data to indicate that this chemical is toxic to humans.

METHOPRENE II *(CASRN: 999045-03-3)*
Specific Hazards: Medium hazard for endocrine disruption activity
Primary Function(s): Pesticide
Found in or Used in the Manufacture of: Pesticides
Government-Academic Collaboration: http://npic.orst.edu/factsheets/methogen.html#whatis

MUSK KETONE *(CASRN: 81-14-1)*
Specific Hazards: PBT; medium hazard for cancer, endocrine disruption activity
Primary Function(s): Fragrance
Found in or Used in the Manufacture of: Personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products
Government Resource: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7694

N,N-DIETHYL-M-TOLUAMIDE (DEET) *(CASRN: 134-62-3)*
Specific Hazards: High hazard for skin irritation
Primary Function(s): Pesticide (insect repellent)
Found in or Used in the Manufacture of: Personal care products; pesticides;
Government Resource: http://www2.epa.gov/insect-repellents/deet

NAPHTHALENE *(CASRN: 91-20-3)*
Specific Hazards: PBT; high hazard for cancer, organ toxicity, skin sensitization; medium hazard for endocrine disruption activity, skin irritation
Primary Function(s): Combustion by-product, chemical intermediate (manufacture of plastic and moth repellants)
Found in or Used in the Manufacture of: Air; pesticides (inert ingredient); cleaning products; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; ink, pigments, and dyes; petroleum products/fuels; pharmacological products
Government Resource: http://www.epa.gov/ttnatw01/hlthef/naphthal.html

NICOTINE *(CASRN: 54-11-5)*
Specific Hazards: High hazard for developmental effects; medium hazard for reproductive effects, endocrine disruption activity; potential concern for neurotoxicity
Primary Function(s): Tobacco derivative ("Other")
Found in or Used in the Manufacture of: Cigarette chemicals; pharmacological products
Government Resource:
http://www.fda.gov/TobaccoProducts/default.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=tobacco&utm_content=1

o-PHENYLPHENOL *(CASRN: 90-43-7)*
Specific Hazards: High hazard for cancer, skin irritation; medium hazard for endocrine disruption activity, respiratory effects, organ toxicity
Primary Function(s): Pesticide
Found in or Used in the Manufacture of: Personal care products; pesticides; food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; paper products
Government Resource: http://www.cdc.gov/biomonitoring/Orthophenylphenol_BiomonitoringSummary.html

PERMETHRIN *(CASRN: 52645-53-1)*
Specific Hazards: High hazard for respiratory effects; medium hazard for endocrine disruption activity, organ toxicity, skin sensitization, skin irritation
Primary Function(s): Pesticide
Found in or Used in the Manufacture of: Personal care products; pesticides; building materials; fabric, furniture, and upholstery; paper products; pharmacological products
Government Resource: http://www.epa.gov/oppsrrd1/reregistration/REDs/factsheets/permethrin_fs.htm

PHENANTHRENE *(CASRN: 85-01-8)*
Specific Hazards: PBT; high hazard for cancer, skin sensitization; medium hazard for endocrine disruption activity
Primary Function(s): Combustion by-product
Found in or Used in the Manufacture of: Air; pesticides (manufacture); building materials; ink, pigments, and dyes; pharmacological products; explosives
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/phenanth.pdf

PIPERONYL BUTOXIDE *(CASRN: 51-03-6)*
Specific Hazards: Medium hazard for endocrine disruption activity, skin irritation
Primary Function(s): Pesticide (synergist)
Found in or Used in the Manufacture of: Personal care products; pesticides (inert ingredient); pharmacological products
Government-Academic Collaboration: http://npic.orst.edu/factsheets/pbotech.pdf

PROMECARB *(CASRN: 2631-37-0)*
Specific Hazards: Little human data available; harmful if swallowed
Primary Function(s): Pesticide
Found in or Used in the Manufacture of: Pesticides
Government Resource: Not available

PROMECARB ARTIFACT [5-isopropyl-3-methylphenol] *(CASRN: 485106)*
Specific Hazards: Little human data available; harmful if swallowed
Primary Function(s): Pesticide
Found in or Used in the Manufacture of: Pesticides
Government Resource: Not available

PYRENE *(CASRN: 129-00-0)*
Specific Hazards: PBT; high hazard for cancer; medium hazard for endocrine disruption activity
Primary Function(s): Combustion by-product
Found in or Used in the Manufacture of: Air; pesticides (manufacture); personal care products; cleaning products; building materials; manufacture/maintenance of vehicles; ink, pigments, and dyes
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/pyrene.pdf

PYRIPROXYFEN (CASRN: 95737-68-1)
Specific Hazards: Medium hazard for endocrine disruption activity
Primary Function(s): Pesticide
Found in or Used in the Manufacture of: Pesticides
Government Resource: http://hpd.nlm.nih.gov/cgi-bin/household/search?queryx=95737-68-1&tbl=TblChemicals&prodcat=all

THYMOL *(CASRN: 89-83-8)*
Specific Hazards: Very high hazard for skin irritation; medium hazard for respiratory effects
Primary Function(s): Preservative (antimicrobial) in personal care products, food additive, fragrance, pesticide ("Other")
Found in or Used in the Manufacture of: Personal care products; pesticides; food packaging and additives; cleaning products; building materials; cigarette chemicals; pharmacological products
Government Resource: http://hpd.nlm.nih.gov/cgi-bin/household/brands?tbl=chem&id=437&query=thymol&searchas=TblChemicals

TONALIDE *(CASRN: 1506-02-1)*
Specific Hazards: Medium hazard for endocrine disruption activity
Primary Function(s): Fragrance
Found in or Used in the Manufacture of: Personal care products; pesticides (inert ingredient); cleaning products; building materials
Government Resource: http://toxnet.nlm.nih.gov/ (search term: tonalide)

TRIBUTYL PHOSPHATE (TBP) *(CASRN: 126-73-8)*
Specific Hazards: High hazard for skin irritation; medium hazard for cancer, developmental effects; potential concern for neurotoxicity
Primary Function(s): Flame retardant, plasticizer, solvent
Found in or Used in the Manufacture of: Pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; ink, pigments, and dyes; electronics; toys and children's products; petroleum products/fuels
Government Resource: http://www.atsdr.cdc.gov/phs/phs.asp?id=1118&tid=239

TRICLOSAN *(CASRN: 3380-34-5)*
Specific Hazards: PBT; high hazard for skin irritation; medium hazard for endocrine disruption activity
Primary Function(s): Preservative (antimicrobial) in personal care products and other consumer products, pesticide
Found in or Used in the Manufacture of: Personal care products; pesticides; cleaning products; building materials; fabric, furniture, and upholstery; pharmacological products
Government Resource: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm205999.htm

TRIETHYLPHOSPHATE *(CASRN: 78-40-0)*
Specific Hazards: Little human data available; harmful if swallowed
Primary Function(s): Flame retardant, plasticizer, chemical intermediate, solvent
Found in or Used in the Manufacture of: Pesticides (inert ingredient); food packaging and additives; building materials; electronics
Government Resource: http://toxnet.nlm.nih.gov/ (search term: triethylphosphate)

TRIPHENYL PHOSPHATE (TPP) *(CASRN: 115-86-6)*
Specific Hazards: Medium hazard for endocrine disruption activity; potential concern for neurotoxicity
Primary Function(s): Flame retardant
Found in or Used in the Manufacture of: Pesticides (inert ingredient); food packaging and additives; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; paper products; ink, pigments, and dyes; arts, crafts, hobby materials; toys and children's products; electronics
Government Resource: http://www.atsdr.cdc.gov/phs/phs.asp?id=1118&tid=239

TRIS(2-CHLOROETHYL) PHOSPHATE (TCEP) *(CASRN: 115-96-8)*
Specific Hazards: PBT; high hazard for cancer, reproductive effects; medium hazard for skin irritation
Primary Function(s): Flame retardant
Found in or Used in the Manufacture of: Personal care products; building materials; manufacture/maintenance of vehicles; toys and children's products
Government Resource: http://www.atsdr.cdc.gov/phs/phs.asp?id=1118&tid=239

TRIS(2-CHLORO-1-METHYLETHYL) PHOSPHATE (TCPP) *(CASRN: 13674-84-5)*
Specific Hazards: PBT
Primary Function(s): Flame retardant
Found in or Used in the Manufacture of: Pesticides (inert ingredient); building materials; fabric, furniture, and upholstery; electronics
Government Resource: http://www.atsdr.cdc.gov/phs/phs.asp?id=1118&tid=239

TRIS(2-ETHYLHEXYL) PHOSPHATE (TEHP) *(CASRN: 78-42-2)*
Specific Hazards: Medium hazard for skin irritation
Primary Function(s): Flame retardant, plasticizer, solvent
Found in or Used in the Manufacture of: Pesticides (inert ingredient); food packaging and additives; building materials; fabric, furniture, and upholstery
Government Resource:
http://oehha.ca.gov/prop65/public_meetings/CIC101211/101211Tris2ethylhexylphosphate.pdf

III. Additional Information on the Wristband Technology

EDF partnered with MyExposome, Inc. on this project using the wristband technology and analytic methods from MyExposome. You can find more information here: www.MyExposome.com.

The personal environmental monitors used in this project are designed to detect organic chemical compounds in the environment. The monitors cannot detect metals (e.g., lead and mercury) or inorganic air pollutants (e.g., ozone and sulfur dioxide).

See here for the full list of chemicals the wristbands are able to detect:
http://www.myexposome.com/testedchems

McCormick

Attachment C

Participant Code: 6996

Thank you for participating in *A Week in Chemicals*!

Synthetic chemicals surround us. They are used to make 96 percent of all products sold in America. Approximately 80,000 chemicals are available for use in the US market today. The Centers for Disease Control (CDC) routinely detects over three hundred chemicals in the blood or urine of virtually every American tested. And yet, we know very little about how and where we may come into contact with chemicals in our everyday lives. To better protect our health from hazardous chemicals we need to better understand our environment. EDF conducted this project to learn about the potential of MyExposome wristband monitors to illuminate the presence of chemicals in our everyday environment. To make the invisible, visible!

Summary Results

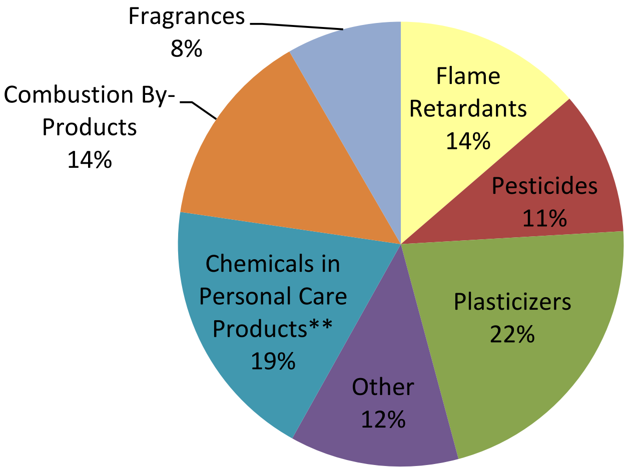
- You were one of **28** participants.
- The wristbands were analyzed for a total of **1,418** chemicals.
- A total of **57** chemicals were detected in all the wristbands.
- A range of **10-27** chemicals were detected per wristband.
- **19** chemicals were detected in your wristband.
- **86%** of the wristbands detected at least one flame retardant.
- **93%** of the wristbands detected at least one pesticide.
- **28%** of the chemicals detected are toxic to and persistent in the environment.
- Every wristband detected **galaxolide**, a common fragrance used in cleaning products and beauty products.

Chemicals Detected in Your Wristband

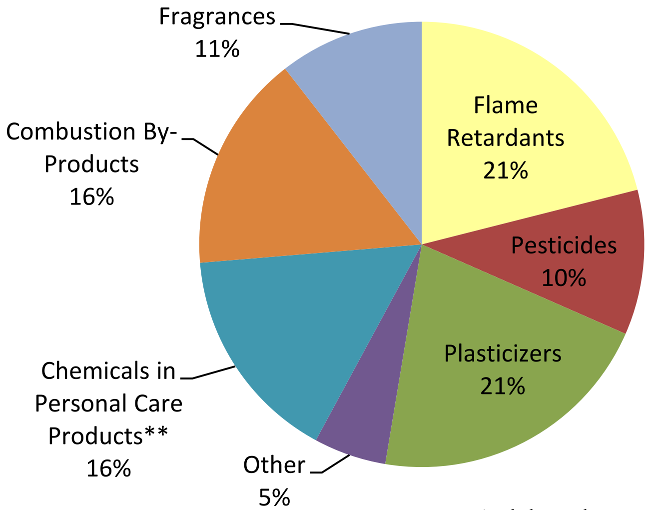
Benzophenone	Butyl benzyl phthalate	Diisobutyl phthalate	N,N-Diethyl-m-toluamide	TPP
Benzyl benzoate	Butylated hydroxyanisole	Fluoranthene	Phenanthrene	Tributyl phosphate
Bifenthrin	Caffeine	Fluorene	TCPP	Triethylphosphate
Bis(2-ethylhexyl)phthalate	Diethyl phthalate	Galaxolide	Tonalide	

Where might these chemicals be found in my environment?*

Group Average



Your Results



*Chemicals are categorized by their primary function or use.

** "Chemicals in Personal Care Products" includes preservatives, antimicrobials, UV filters and fragrance enhancers. Plasticizers and fragrances are represented in separate categories; however, they may also be found in personal care products.

Participant Code: 6996

Should I be concerned?

Below we've provided information on the types of hazards that are associated with the chemicals detected in this project. It is important to remember that the wristbands only detected whether or not the chemical was present in your environment. We do not know whether or not the chemical entered your body. Therefore, no conclusions can be made about the risks any of these chemicals may present to your health.

The most common hazards associated with the 57 chemicals detected in this project are **cancer** (35%), **developmental** and/or **reproductive effects** (28%), **endocrine disruption** (60%), **respiratory effects** (28%) and **skin sensitization** and/or **skin irritation** (42%).

Toxic chemicals, called "PBTs", present a concern because they persist for generations and bioaccumulate in the body and the food chain. A total of **16** PBT chemicals were detected in the project. **6** PBTs were detected in your environment.

The chart below shows the different hazards of all the chemicals detected in the project as well as those detected in your wristband. Please note that many of the chemicals have more than one hazardous characteristic. For additional information on all the chemicals, please see the appendix.

Hazards	Total in project	Your wristband	Chemicals in your wristband
Cancer	20	9	Benzophenone, Bifenthrin, Bis(2-ethylhexyl)phthalate, Butyl benzyl phthalate, Butylated hydroxyanisole, Fluoranthene, Fluorene, Phenanthrene, Tributyl phosphate
Developmental/ Reproductive effects	16	7	Bis(2-ethylhexyl)phthalate, Butyl benzyl phthalate Butylated hydroxyanisole, Diisobutyl phthalate Diethyl phthalate, Galaxolide, Tributyl phosphate
Endocrine disruption	34	13	Benzophenone, Bifenthrin, Bis(2-ethylhexyl)phthalate, Butyl benzyl phthalate, Butylated hydroxyanisole, Caffeine, Diethyl phthalate, Diisobutyl phthalate, Fluoranthene, Galaxolide, Phenanthrene, Tonalide, TPP
Respiratory effects	16	5	Bifenthrin, Bis(2-ethylhexyl)phthalate, Butyl benzyl phthalate, Diethyl phthalate, Diisobutyl phthalate
Skin sensitization/ skin irritation	24	8	Bifenthrin, Bis(2-ethylhexyl)phthalate, Butyl benzyl phthalate, Butylated hydroxyanisole, Diethyl phthalate, N,N-Diethyl-m-toluamide (DEET), Phenanthrene Tributyl phosphate
Persistent, bioaccumulative and toxic ("PBT")	16	6	Bifenthrin, Fluoranthene, Fluorene, Galaxolide, Phenanthrene, TCPP

The solution?

The results may raise questions for you about how you came in contact with these chemicals and how you can avoid them in the future. Unfortunately, even people who took steps to lower their exposures could not completely avoid contact with hazardous chemicals.

What then can we do? This project demonstrates that we as individuals cannot simply shop our way out of the problem — we need a more comprehensive, national solution. Reducing the presence of hazardous chemicals demands a three-pronged strategy:

1. Congress must reform our nation's outdated chemical safety law to better protect public health.
2. Our country should accelerate science on chemicals and health through investments in cutting-edge technologies and expanded research.
3. Companies need to take action to remove hazardous chemicals from products and the supply chain and innovate in safer chemicals.

To be successful, none of these actions can occur in a vacuum. We need influential voices weighing in and pushing for all of these changes. That means major media outlets covering the problem in an in-depth and sophisticated manner. It also means more people weighing in directly with members of Congress on the need for strong chemical laws—from every day citizens to thought leaders. And as we explore the major causes of disease, we need more researchers and resources to examine the impacts of chemical exposures on our health — and to deploy new technologies like the wristbands.

EDF is working across all three of these solutions for safer chemicals and healthier people. We plan to use the results of this pilot project to leverage action across these initiatives. Here are our next steps.

Communicating about the problem
We plan to use the results to raise broad public awareness about the presence of hazardous chemicals in our everyday lives through media outlets from blogs to local and national stories. We are also hoping participants might be interested in telling a story about their results. Some stories could highlight the need for legislative reforms while others could focus on the need for greater research and investigation into understanding our everyday chemical exposures.

We are currently conducting a quantitative analysis of the flame retardants present in the wristbands of the vast majority of participants. These results can provide more focused stories about these hazardous and problematic chemicals to illustrate the flaws in our regulatory system and gaps in our scientific knowledge. This next analytical step will also further illustrate potential uses and limitations of these wristbands for future research.

Informing research priorities
We plan to convene experts and interested participants to discuss how these wristbands can be integrated into existing and new research to significantly expand our understanding of chemical exposures and identify near-term research objectives.

We'd love to continue to work with you on these next steps and to hear your thoughts and feedback on the project, the technology and our effort.

Appendix

The Appendix provides more detailed information on the chemicals detected in this project, their uses and potential hazards, as well as additional information about the wristband technology.

I. Definitions

Hazard – The hazard of a chemical refers to its intrinsic ability to cause harm or induce a toxic effect, such as those listed below in "Chemical Hazard Types." Risk is a function of both *hazard* and *exposure*, the amount of the chemical substance that enters a person's body. Assuming a constant exposure, chemicals will differ in the type and magnitude of toxic effect(s) that they may induce.

Persistent bioaccumlative toxic chemicals ("PBTs") – Chemicals that do not break down readily from natural processes, accumulate in organisms concentrating as they move up the food chain, and are harmful in small quantities.

Chemical Hazard Types*

Cancer – Can cause or increase the risk of cancer.

Developmental – Can cause harm to the developing child including birth defects, low birth weight and biological or behavioral problems that appear as the child grows.

Reproductive – Can disrupt the male or female reproductive systems, changing sexual development, behavior or functions, decreasing fertility, or resulting in loss of the fetus during pregnancy.

Endocrine disruption – Can interfere with hormone communication and production, which controls metabolism, development, growth, reproduction and behavior.

Respiratory – Can result in high sensitivity such that small quantities trigger asthma, rhinitis or other allergic reactions in the respiratory system.

Skin Sensitization – Can trigger allergic reactions on the skin.

Functions & Uses

Combustion by-products – Chemicals formed from the incomplete burning of coal, oil, gas, garbage, or other organic substances. Most chemicals included in this category are polycyclic aromatic hydrocarbons (PAHs).

Chemicals in Personal Care Products – Chemicals added to personal care products (e.g., lotions, soaps, and cosmetics), such as preservatives and antimicrobials. Plasticizers and fragrances (see below) are excluded from this category.

Flame retardants – Chemicals added to a variety of materials, including textiles, electronics, plastics, and foam to reduce flammability.

Fragrances – Chemicals with an inherent odor. These chemicals are often added to personal care products, cleaning products, food products, and more.

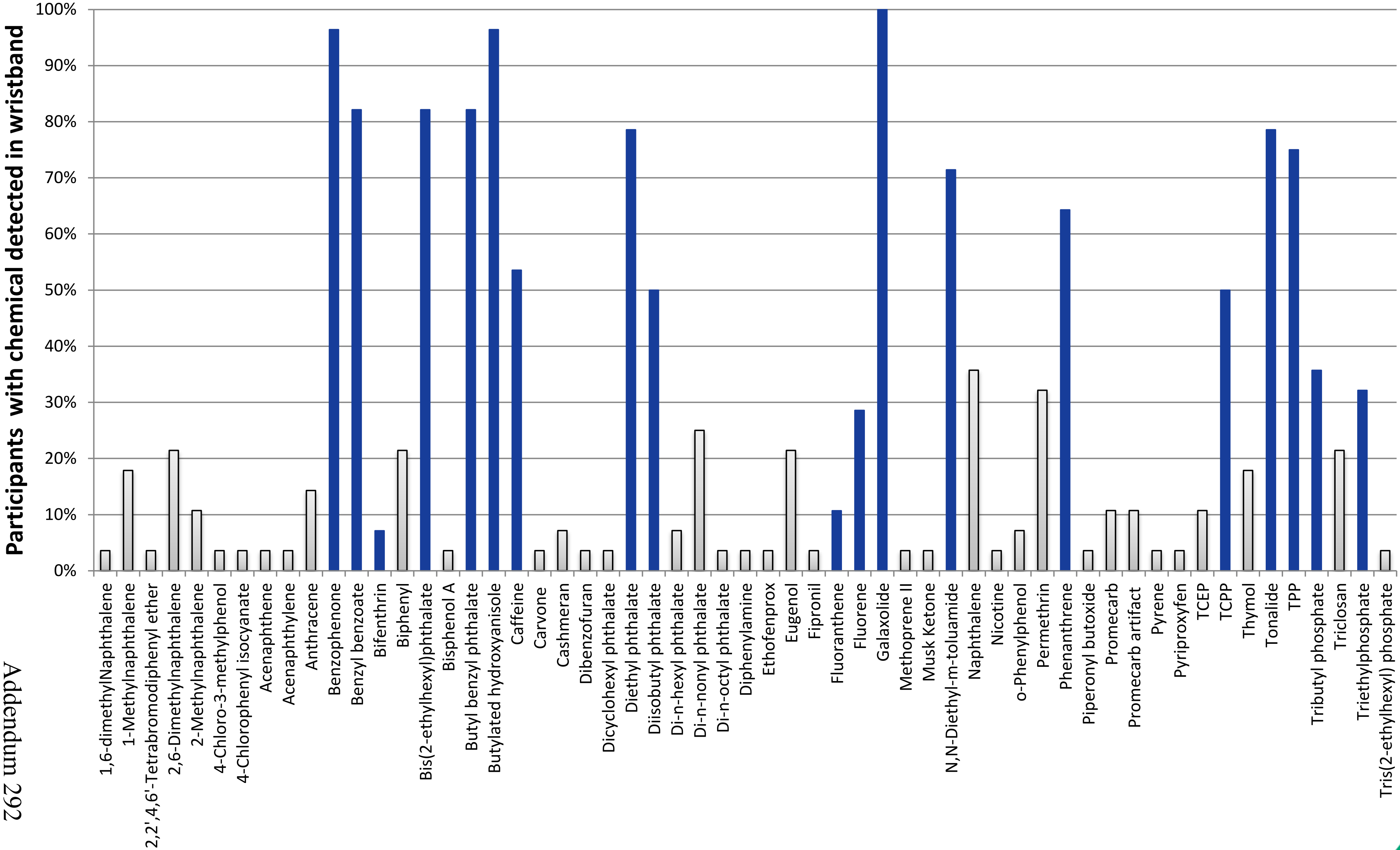
Pesticides – Chemicals designed to kill, repel, or mitigate any pest (insects, rodents, weeds, fungi, and microorganisms). This category includes pesticides registered with the U.S. EPA, but excludes antimicrobials designed for use in personal care products.

Plasticizers – Chemicals used to provide plasticity and flexibility to plastics, such as polyvinylchloride (PVC). This category includes phthalate chemicals, which are added a variety products including construction materials, personal care products, toys, food packaging, medical devices, and more.

Other – The "Other" category includes food additives, tobacco derivatives, chemical intermediates, and chemicals that cannot be classified due to many overlapping functions.

* Chemical hazard type definitions are based on the Pharos database, available here: https://www.pharosproject.net/

II. Chemicals Detected in the Project



Chemicals detected in your wristband are highlight in blue.

III. Full Chemical List

Below you'll find detailed information on hazard, function, and uses of the chemicals detected in your wristband and other chemicals detected in this project. The primary function used in the pie charts is the first listed under "Primary Function(s)" for each chemical. Chemicals classified in the other category in the pie chart are noted with ("Other").

Chemicals in your wristband

Benzophenone (CASRN: 119-61-9)
Overall Hazard*: High
Specific Hazards: high hazard for cancer; medium hazard for endocrine disruption
Primary Function(s): UV filter and fragrance enhancer in personal care products
Used or Found in**: personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; paper products; ink, pigments, and dyes; toys and children's products; electronics; cigarette chemicals; pharmacological products
Government Resource: http://toxnet.nlm.nih.gov/ (search term: benzophenone)

Benzyl benzoate (CASRN: 120-51-4)
Overall Hazard: Potential†
Specific Hazards: No known human hazards
Primary Function(s): Fragrance fixative and preservative in personal care products, food additive, antiparasitic (treats scabies), pesticide, solvent, plasticizer
Used or Found in: personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; manufacture/maintenance of vehicles; toys and children's products; cigarette chemicals; pharmacological products
Government Resource: http://toxnet.nlm.nih.gov/ (search term: benzyl benzoate)

Bifenthrin (CASRN: 82657-04-3)
Overall Hazard: High
Specific Hazards: PBT; medium hazard for cancer, endocrine disruption, respiratory effects, organ toxicity, skin irritation
Primary Function(s): Pesticide
Used or Found in: pesticides; building materials
Government Resource: http://npic.orst.edu/factsheets/biftech.pdf

Bis(2-ethylhexyl)phthalate (CASRN: 117-81-7)
Overall Hazard: High
Specific Hazards: high hazard for cancer, developmental effects, reproductive effects; medium hazard for endocrine disruption, respiratory effects, organ toxicity, skin irritation; potential hazard for neurotoxicity
Primary Function(s): Plasticizer
Used or Found in: air; personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; ink, pigments, and dyes; arts, crafts, hobby materials; toys and children's products; electronics; pharmacological products
Government Resource: http://www.atsdr.cdc.gov/phs/phs.asp?id=376&tid=65

Butyl benzyl phthalate (CASRN: 85-68-7)
Overall Hazard: High
Specific Hazards: high hazard for developmental effects, reproductive effects; medium hazard for cancer, endocrine disruption, respiratory effects, skin irritation
Primary Function(s): Plasticizer
Used or Found in: air; personal care products; pesticides (inert ingredient); food packaging and additives; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; paper products; ink, pigments, and dyes; arts, crafts, hobby materials; toys and children's products; electronics
Government Resource: http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/phthalates.html

Butylated hydroxyanisole (CASRN: 25013-16-5)
Overall Hazard: High
Specific Hazards: high hazard for cancer; medium hazard for developmental effects, reproductive effects, endocrine disruption, skin sensitization
Primary Function(s): Preservative in personal care products and food (antioxidant)
Used or Found in: water; personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; toys and children's products; pharmacological products
Government Resource: https://ntp.niehs.nih.gov/ntp/roc/content/profiles/butylatedhydroxyanisole.pdf

Caffeine (CASRN: 58-08-2)
Overall Hazard: Medium
Specific Hazards: medium hazard for endocrine disruption
Primary Function(s): Food additive ("Other")
Used or Found in: personal care products; pesticides (inert ingredient); food packaging and additives; cigarette chemicals; pharmacological products
Government Resource: http://www.fda.gov/downloads/UCM200805.pdf

Diethyl phthalate (CASRN: 84-66-2)
Overall Hazard: High
Specific Hazards: high hazard for reproductive effects; medium hazard for endocrine disruption, respiratory effects, skin sensitization, skin irritation
Primary Function(s): Plasticizer
Used or Found in: personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; manufacture/maintenance of vehicles; ink, pigments, and dyes; toys and children's products; pharmacological products
Government Resource: http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=112

Diisobutyl phthalate (CASRN: 84-69-5)
Overall Hazard: High
Specific Hazards: high hazard for developmental effects, reproductive effects; medium hazard for endocrine disruption, respiratory effects
Primary Function(s): Plasticizer
Used or Found in: personal care products; food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; paper products; arts, crafts, hobby materials; toys and children's products
Government Resource: http://toxtown.nlm.nih.gov/text_version/chemicals.php?id=24

Fluoranthene (CASRN: 206-44-0)
Overall Hazard: High
Specific Hazards: PBT; high hazard for cancer; medium hazard for endocrine disruption
Primary Function(s): Combustion by-product
Used or Found in: air; building materials; pharmacological products
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/pahs.pdf

Fluorene (CASRN: 86-73-7)
Overall Hazard: High
Specific Hazards: PBT; high hazard for cancer; potential hazard for endocrine disruption
Primary Function(s): Combustion by-product
Used or Found in: air; pesticides (inert ingredient)
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/flourene.pdf

Galaxolide (CASRN: 1222-05-5)
Overall Hazard: High
Specific Hazards: PBT; high hazard for developmental effects‡; medium hazard for endocrine disruption
Primary Function(s): Fragrance
Used or Found in: personal care products; pesticides (inert ingredient); cleaning products; building materials; manufacture/maintenance of vehicles
Government Resource: http://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=245534

N,N-Diethyl-m-toluamide (DEET) (CASRN: 134-62-3)
Overall Hazard: Potential
Specific Hazards: medium hazard for skin irritation
Primary Function(s): Pesticide (insect repellent)
Used or Found in: personal care products; pesticides; food packaging and additives; cleaning products
Government Resource: http://www2.epa.gov/insect-repellents/deet

Phenanthrene (CASRN: 85-01-8)
Overall Hazard: High
Specific Hazards: PBT; high hazard for cancer; medium hazard for endocrine disruption, skin sensitization
Primary Function(s): Combustion by-product
Used or Found in: air; pesticides (inert ingredient); ink, pigments, and dyes; pharmacological products; petroleum products/fuels
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/phenanth.pdf

TCPP (CASRN: 13674-84-5)
Overall Hazard: High
Specific Hazards: PBT
Primary Function(s): Flame retardant
Used or Found in: building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; electronics
Government Resource: http://www.atsdr.cdc.gov/phs/phs.asp?id=1118&tid=239

Tonalide (CASRN: 1506-02-1)
Overall Hazard: Medium
Specific Hazards: medium hazard for endocrine disruption
Primary Function(s): Fragrance
Used or Found in: personal care products; pesticides (inert ingredient); cleaning products; manufacture/maintenance of vehicles; petroleum products/fuels
Government Resource: http://toxnet.nlm.nih.gov/ (search term: tonalide)

TPP (CASRN: 115-86-6)
Overall Hazard: Medium
Specific Hazards: medium hazard for endocrine disruption; potential hazard for neurotoxicity
Primary Function(s): Flame retardant
Used or Found in: personal care products; pesticides (inert ingredient); food packaging and additives; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; paper products; arts, crafts, hobby materials; toys and children's products; electronics
Government Resource: http://www.atsdr.cdc.gov/phs/phs.asp?id=1118&tid=239

Tributyl phosphate (CASRN: 126-73-8)
Overall Hazard: Medium
Specific Hazards: medium hazard for cancer, developmental effects, skin irritation ; potential hazard for neurotoxicity
Primary Function(s): Flame retardant, solvent
Used or Found in: personal care products; food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; ink, pigments, and dyes; electronics
Government Resource: http://www.atsdr.cdc.gov/phs/phs.asp?id=1118&tid=239

Triethylphosphate (CASRN: 78-40-0)
Overall Hazard: Potential†
Specific Hazards: No known human hazards
Primary Function(s): Flame retardant, plasticizer, chemical intermediate, solvent
Used or Found in: pesticides (inert ingredient); food packaging and additives; building materials; fabric, furniture, and upholstery; electronics
Government Resource: http://toxnet.nlm.nih.gov/ (search term: triethylphosphate)

Other chemicals detected in the dry run

1,6-dimethylnaphthalene (CASRN: 575-43-9)
Overall Hazard: Unknown
Specific Hazards: No known human hazards
Primary Function(s): Combustion by-product
Used or Found in: air
Government Resource: http://toxnet.nlm.nih.gov/ (search term: 1,6-dimethylnaphthalene)

1-Methylnaphthalene (CASRN: 90-12-0)
Overall Hazard: Medium †
Specific Hazards: No known human hazards
Primary Function(s): Combustion by-product, chemical intermediate
Used or Found in: air; incense; pesticides (inert ingredient); food packaging and additives; ink, pigments, and dyes; petroleum products/fuels
Government Resource: http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=43

2,2',4,6'-Tetrabromodiphenyl ether (CASRN: 189084-57-9)
Overall Hazard: Medium
Specific Hazards: medium hazard for endocrine disruption
Primary Function(s): Flame retardant
Used or Found in: building materials; fabric, furniture, and upholstery
Government Resource: http://www.toxtown.nlm.nih.gov/text_version/chemicals.php?id=79

2,6-Dimethylnaphthalene (CASRN: 581-42-0)
Overall Hazard: Unknown
Specific Hazards: No known human hazards
Primary Function(s): Combustion by-product
Used or Found in: air; incense; food packaging and additives
Government Resource: Not available

2-Methylnaphthalene (CASRN: 91-57-6)
Overall Hazard: Medium†
Specific Hazards: No known human hazards
Primary Function(s): Combustion by-product, chemical intermediate
Used or Found in: air; incense; pesticides (inert ingredient); food packaging and additives; ink, pigments, and dyes; petroleum products/fuels
Government Resource: http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=43

4-Chloro-3-methylphenol (CASRN: 59-50-7)
Overall Hazard: Medium
Specific Hazards: medium hazard for endocrine disruption, skin sensitization
Primary Function(s): Preservative in personal care products (antimicrobial), antiseptic, pesticide (industrial preservative) ("Other")
Used or Found in: personal care products; pesticides; food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; paper products; ink, pigments, and dyes; pharmacological products
Government Resource: Not available

4-Chlorophenyl isocyanate (CASRN: 104-12-1)
Overall Hazard: Medium
Specific Hazards: medium hazard for cancer, respiratory effects, organ toxicity, skin irritation
Primary Function(s): Chemical intermediate in manufacture of pesticides and pharmaceuticals ("Other")
Used or Found in: pesticides (inert ingredient); toys and children's products; pharmacological products
Government Resource: http://toxnet.nlm.nih.gov/ (search term: 4-Chlorophenyl isocyanate)

Acenaphthene (CASRN: 83-32-9)
Overall Hazard: High
Specific Hazards: PBT; high hazard for cancer
Primary Function(s): Combustion by-product
Used or Found in: air; pesticides (inert ingredient)
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/pahs.pdf

Acenaphthylene (CASRN: 208-96-8)
Overall Hazard: High
Specific Hazards: PBT; high hazard for cancer
Primary Function(s): Combustion by-product
Used or Found in: air; incense
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/pahs.pdf

Anthracene (CASRN: 120-12-7)
Overall Hazard: High
Specific Hazards: PBT; high hazard for cancer; medium hazard for endocrine disruption, respiratory effects, skin sensitization, skin irritation
Primary Function(s): Combustion by-product
Used or Found in: air; personal care products; building materials; manufacture/maintenance of vehicles
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/anthrace.pdf

Biphenyl (CASRN: 92-52-4)
Overall Hazard: Medium
Specific Hazards: medium hazard for cancer, endocrine disruption, respiratory effects, organ toxicity, skin irritation
Primary Function(s): Chemical intermediate ("Other")
Used or Found in: air; personal care products; pesticides (inert ingredient); food packaging and additives; building materials; paper products; petroleum products/fuels
Government Resource: http://www.epa.gov/ttnatw01/hlthef/biphenyl.html

Bisphenol A (CASRN: 80-05-7)
Overall Hazard: High
Specific Hazards: high hazard for developmental effects, reproductive effects; medium hazard for endocrine disruption, respiratory effects, organ toxicity, skin sensitization, skin irritation
Primary Function(s): Plasticizer
Used or Found in: food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; paper products; ink, pigments, and dyes; arts, crafts, hobby materials; toys and children's products; electronics; petroleum products/fuels
Government Resource: https://www.niehs.nih.gov/health/assets/docs_a_e/bisphenol_a_bpa_508.pdf

Carvone (CASRN: 99-49-0)
Overall Hazard: Potential †
Specific Hazards: No known human hazards
Primary Function(s): Preservative (antimicrobial) in personal care products, food additive, fragrance, pesticide (insect repellent) ("Other")
Used or Found in: personal care products; pesticides; food packaging and additives; cleaning products; cigarette chemicals
Government Resource: http://toxnet.nlm.nih.gov/ (search term: carvone)

Cashmeran (CASRN: 33704-61-9)
Overall Hazard: Medium
Specific Hazards: medium hazard for endocrine disruption
Primary Function(s): Fragrance
Used or Found in: personal care products; cleaning products
Government Resource: Not available

Dibenzofuran (CASRN: 132-64-9)
Overall Hazard: High
Specific Hazards: PBT
Primary Function(s): Combustion by-product
Used or Found in: air; incense
Government Resource: http://www.epa.gov/ttnatw01/hlthef/di-furan.html

Dicyclohexyl phthalate (CASRN: 84-61-7)
Overall Hazard: High
Specific Hazards: high hazard for reproductive effects; medium hazard for endocrine disruption, respiratory effects
Primary Function(s): Plasticizer
Used or Found in: food packaging and additives; building materials; paper products; ink, pigments, and dyes
Government Resource: http://www.cdc.gov/biomonitoring/DCHP_BiomonitoringSummary.html

Di-n-hexyl phthalate (CASRN: 84-75-3)
Overall Hazard: High
Specific Hazards: high hazard for reproductive effects; medium hazard for developmental effects, endocrine disruption, respiratory effects
Primary Function(s): Plasticizer
Used or Found in: pesticides (inert ingredient); food packaging and additives; building materials; toys and children's products
Government Resource: http://toxtown.nlm.nih.gov/text_version/chemicals.php?id=24

Diphenylamine (CASRN: 122-39-4)
Overall Hazard: Medium
Specific Hazards: medium hazard for cancer, developmental effects, reproductive effects, organ toxicity, skin sensitization
Primary Function(s): Pesticide (antioxidant)
Used or Found in: personal care products; pesticides; food packaging and additives; building materials; manufacture/maintenance of vehicles; ink, pigments, and dyes; electronics; petroleum products/fuels
Government Resource: http://www.epa.gov/opp00001/reregistration/REDs/factsheets/2210fact.pdf

Ethofenprox (CASRN: 80844-07-1)
Overall Hazard: High
Specific Hazards: high hazard for developmental effects; medium hazard for endocrine disruption
Primary Function(s): Pesticide (used to repell bed bugs)
Used or Found in: pesticides
Government Resource: Not available

Eugenol (CASRN: 97-53-0)
Overall Hazard: Medium
Specific Hazards: medium hazard for respiratory effects, skin sensitization, skin irritation
Primary Function(s): Fragrance, food additive, antiseptic, analgesic (“Other”)
Used or Found in: personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; toys and children's products; pharmacological products; petroleum products/fuels
Government Resource: Not available

Fipronil (CASRN: 120068-37-3)
Overall Hazard: High
Specific Hazards: PBT; medium hazard for reproductive effects, endocrine disruption, neurotoxicity, organ toxicity
Primary Function(s): Pesticide
Used or Found in: pesticides; food packaging and additives
Government Resource: http://npic.orst.edu/factsheets/fipronil.html

Methoprene II (CASRN: 999045-03-3)
Overall Hazard: Medium
Specific Hazards: medium hazard for endocrine disruption
Primary Function(s): Pesticide
Used or Found in: pesticides
Government Resource: http://npic.orst.edu/factsheets/methogen.html#whatis

Musk Ketone (CASRN: 81-14-1)
Overall Hazard: High
Specific Hazards: PBT; medium hazard for cancer, endocrine disruption
Primary Function(s): Fragrance
Used or Found in: personal care products; food packaging and additives; cleaning products; pharmacological products
Government Resource: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7694

Nicotine (CASRN: 54-11-5)
Overall Hazard: High
Specific Hazards: high hazard for developmental effects; medium hazard for reproductive effects, endocrine disruption; potential hazard for neurotoxicity
Primary Function(s): Tobacco derivative “Other”
Used or Found in: cigarette chemicals; pharmacological products; personal care products
Government Resource: http://www.fda.gov/TobaccoProducts/default.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=tobacco&utm_content=1

o-Phenylphenol (CASRN: 90-43-7)
Overall Hazard: High
Specific Hazards: high hazard for cancer; medium hazard for endocrine disruption, respiratory effects, organ toxicity, skin irritation
Primary Function(s): Pesticide
Used or Found in: personal care products; pesticides; food packaging and additives; cleaning products; building materials; paper products; toys and children’s products
Government Resource: http://www.cdc.gov/biomonitoring/Orthophenylphenol_BiomonitoringSummary.html

Permethrin (CASRN: 52645-53-1)
Overall Hazard: High†
Specific Hazards: medium hazard for endocrine disruption, respiratory effects, organ toxicity, skin sensitization, skin irritation
Primary Function(s): Pesticide
Used or Found in: personal care products; pesticides; food packaging and additives; building materials; paper products; ink, pigments, and dyes; pharmacological products
Government Resource: http://www.epa.gov/oppsrrd1/reregistration/REDs/factsheets/permethrin_fs.htm

Piperonyl butoxide (CASRN: 51-03-6)
Overall Hazard: Medium
Specific Hazards: medium hazard for endocrine disruption, skin irritation
Primary Function(s): Pesticide (synergist)
Used or Found in: personal care products; pesticides (inert ingredient); food packaging and additives; cleaning products; pharmacological products
Government Resource: http://npic.orst.edu/factsheets/pbotech.pdf

Promecarb (CASRN: 2631-37-0)
Overall Hazard: Medium†
Specific Hazards: No known human hazards
Primary Function(s): Pesticide
Used or Found in: pesticides
Government Resource: Not available

Promecarb artifact [5-isopropyl-3-methylphenol] (CASRN: 485106)
Overall Hazard: Medium†
Specific Hazards: No known human hazards
Primary Function(s): Pesticide
Used or Found in: pesticides
Government Resource: Not available

Pyrene (CASRN: 129-00-0)
Overall Hazard: High
Specific Hazards: PBT; high hazard for cancer; medium hazard for endocrine disruption
Primary Function(s): Combustion by-product
Used or Found in: air; personal care products; cleaning products; building materials; manufacture/maintenance of vehicles; ink, pigments, and dyes
Government Resource: http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/pyrene.pdf

Pyriproxyfen (CASRN: 95737-68-1)
Overall Hazard: Medium
Specific Hazards: medium hazard for endocrine disruption
Primary Function(s): Pesticide
Used or Found in: personal care products; pesticides
Government Resource: http://www.cdpr.ca.gov/docs/emon/pubs/fatememo/pyrprxfn.pdf

TCEP (CASRN: 115-96-8)
Overall Hazard: High
Specific Hazards: PBT; high hazard for cancer, reproductive effects; medium hazard for skin irritation
Primary Function(s): Flame retardant
Used or Found in: personal care products; food packaging and additives; building materials; fabric, furniture, and upholstery; manufacture/maintenance of vehicles; toys and children's products
Government Resource: http://www.atsdr.cdc.gov/phs/phs.asp?id=1118&tid=239

Thymol (CASRN: 89-83-8)
Overall Hazard: Medium
Specific Hazards: medium hazard for respiratory effects, skin irritation
Primary Function(s): Preservative (antimicrobial) in personal care products, food additive, fragrance, pesticide ("Other")
Used or Found in: personal care products; pesticides; food packaging and additives; cleaning products; building materials; cigarette chemicals; pharmacological products
Government Resource: http://toxnet.nlm.nih.gov/ (search term: thymol)

Triclosan (CASRN: 3380-34-5)
Overall Hazard: High
Specific Hazards: PBT; medium hazard for endocrine disruption, skin irritation
Primary Function(s): Preservative (antimicrobial) in personal care products and other consumer products, pesticide
Used or Found in: personal care products; cleaning products; building materials; fabric, furniture, and upholstery; pharmacological products
Government Resource: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm205999.htm

Tris(2-ethylhexyl) phosphate (CASRN: 78-42-2)
Overall Hazard: Potential
Specific Hazards: medium hazard for skin irritation
Primary Function(s): Flame retardant, plasticizer, solvent
Used or Found in: pesticides (inert ingredient); food packaging and additives; cleaning products; building materials
Government Resource:
http://oehha.ca.gov/prop65/public_meetings/CIC101211/101211Tris2ethylhexylphosphate.pdf

*Chemical hazards based on the Pharos database, available here: https://www.pharosproject.net/

**Chemical uses data is based primarily on EPA's CPCat database, available here: http://actor.epa.gov/cpcat/faces/home.xhtml

† Overall hazard for these chemicals is based on either aquatic toxicity or fatality from ingestion of large quantities.

‡ Evidence for reproductive/developments effects for Galaxolide are based on preliminary studies. The majority of research demonstrates that Galaxolide exerts its toxic effects on the environment; there is limited data to indicate that this chemical is toxic to humans.

IV. Additional Information on the Technology

The personal environmental monitors used in this project are designed to detect organic chemical compounds in the environment. The monitors cannot detect metals (e.g., lead and mercury) or inorganic air pollutants (e.g., ozone and sulfur dioxide).

See here for the full list of chemicals the wristband were able to detect in your environment: http://www.myexposome.com/testedchems

Thank you for participating in *A Week in Chemicals*!

Wristband Results: Quantitative Flame Retardant Levels

Participant Code: 6996

During the first phase of the pilot project, we screened the wristbands for the presence of over 1,400 chemicals. To further explore the potential uses of the wristbands, we conducted a quantitative analysis on one particular class of chemicals – flame retardants. These chemicals are an advocacy priority for EDF because of their known hazardous effects and ubiquitous use.

This analysis shows how *much* of a flame retardant chemical was present in the wristband. Because the quantitative analysis uses a more sensitive analytic technique, more flame retardants were detected in this analysis (12 unique flame retardants) than in the original qualitative analysis (7 unique flame retardants).

Summary of results

- You were one of **28** participants.
- The wristbands were analyzed for quantitative levels of **40*** different flame retardants.
- A total of **12** different flame retardants were detected across all of the participants' wristbands. Each wristband detected between **4** and **9** flame retardants.
- See page 3 for ways to help reduce your exposure.

- **7** flame retardants were detected in your wristband:
  - Polybrominated diphenyl ether 47 (PBDE 47)
  - Polybrominated diphenyl ether 99 (PBDE 99)
  - Triphenyl phosphate (TPP)
  - Tributyl phosphate (TBP)
  - Tris(2-chloroethyl) phosphate (TCEP)
  - Tris(1,3-dichloroisopropyl)phosphate (TDCPP)
  - Triethyl phosphate

* Note that two of the flame retardants detected in the initial qualitative screen were not included in this quantitative analysis (TCPP and TEHP) .

How was I exposed and how can I reduce my exposure?

As a result of a 1975 California flammability standard, flame retardant chemicals have been added to hundreds of millions of everyday foam products in the U.S., such as couches and foam baby products. Despite health concerns and evidence that these chemicals do little to prevent fire, widespread use continues.

Polybrominated diphenyl ether (PBDE) flame retardants came into common use in the 1970s and were phased out of production in the mid-2000s due to evidence of health impacts, such as adverse neurological development, and persistence in the environment. Since this phase out, a new suite of flame retardants has emerged and replaced PBDEs in foam products, electronics, and other products (read more on pages 5-6).

Everyday Sources of Flame Retardants
Polyurethane foam consumer products: Furniture, automobile seating, carpet padding, mattress pads, foam baby products like nursing pillows, car seats, and changing table pads
Electronics: Coatings for electrical equipment like televisions, computers, and cable wires; circuit boards
Building and construction materials: Paints and coatings, insulation, pipes, laminates, ducts
Other: Textiles, apparel, military applications

As furniture and other products get old and breakdown, flame retardants are released into surrounding air and settle in the dust in our homes. While there is limited research on effective exposure reduction methods for flame retardants, the following actions may reduce your exposure:

- Purchase furniture with the new flame retardant-free label
- Repair or replace torn furniture to cover exposed foam
- Vacuum with a *HEPA filter* or clean with a damp cloth to remove household dust
- Wash your hands frequently to reduce the amount of flame retardants that enter your body

The fight to remove flame retardants

In recent years, there has been a large advocacy push to remove harmful flame retardants from the market.

➢ **California's new law**

Due to health concerns and advocacy efforts, California recently updated its laws to 1) allow furniture manufacturers to meet the flammability standard without use of flame retardants and 2) require certain polyurethane-based products to display a label (see above). These changes are expected to have a ripple effect throughout the U.S. market.

➢ **"Retail regulation"**

Increased pressure and public awareness has pushed retailers and large-scale purchasers to make their own commitments to phase out flame retardants – known as "retail regulation."

- Furniture retailers: Ashley Furniture, IKEA, Walmart, West Elm, Crate and Barrel, and several other retailers are taking steps to eliminate flame retardants from their supply chain.
- Large purchasers: In 2014, Kaiser Permanente announced it would stop buying furniture treated with flame retardants. Several companies, like Facebook and Staples, have made similar public commitments.

What's next?

EDF is launching a Chemical Detection Initiative – expanding this pilot through a number of potential second phase projects to learn more about everyday chemical exposures.

This fall, we held a social media campaign around our pilot project that asked if others were interested in participating in similar projects. We garnered more than 4,500 volunteers, mostly women, from all 50 states and D.C.

We're in the early stages of developing projects to engage these individuals in collecting exposure information by wearing the wristband. Through this process participants will have the opportunity to learn about environmental exposures as well as current chemicals policy and actions to reduce chemical exposures. Simultaneously, through this initiative we will work with academic researchers and partnering organizations to incorporate the wristbands into existing research studies.

EDF's objectives for the Chemical Detection Initiative are to:

- better understand real-world chemical exposures;
- raise awareness about this issue across a geographically diverse population;
- build a network of informed citizens to cultivate opportunities for shared learning, further research and advocacy engagement;
- support efforts to prioritize chemicals and mixtures of chemicals for evaluation, monitoring, and action by government and companies; and
- contribute to on-going efforts to better characterize the wristband technology.

Quantitative data (like the flame retardant data presented here) can be used to investigate and identify sources of exposure. This kind of information can provide better insight into how to effectively reduce exposures. For example, in future projects, the wristbands could help to identify if there is a relationship between the frequency of vacuuming and relative level of exposure to flame retardants – allowing us to identify evidence-based practices that can reduce exposures.

The true power of this technology will be realized when hundreds – or even thousands – of people wear these wristbands; then we can begin to understand what chemicals appear widely across the population, what typical exposures look like, and how outliers might be linked to specific products or lifestyle factors.

Thank you for your help!

The pilot project that you participated in helped us to set the stage for the next set of projects in the Chemical Detection Initiative. Your feedback and input on the pilot is invaluable as we built out the next set of projects. Please let us know if you are interested in learning more about upcoming projects.

Appendix

I. Detailed quantitative results

Flame retardant chemical	Number of people with detections	Limit of detection (LOD)*	Range	Your wristband
PBDE 47	28	0.56**	22.1 – 3,050**	204**
PBDE 49	3	0.51	18.4 – 46.4	<LOD
PBDE 66	3	0.68	58.4	<LOD
PBDE 99	23	0.62	14.1 – 3,590	150
PBDE 100	10	0.64	25.1 - 310	<LOD
PBDE 154	5	0.43	16.4 – 63.2	<LOD
TPP	27	0.31	253– 5,660	1210
TBP	12	0.85	209 – 20,800	281
TCEP	8	4.21	24 – 3,420	92.6
TDCPP	27	6.41	57.3 – 8,180	758
Triethyl phosphate	15	1.42	43.3 -- 684	288
TBB	2	0.74	407 – 769	<LOD

* Limit of detection = the lowest chemical concentration that the wristband technology can reliably detect
** Units = nanogram of chemical per gram of wristband (ng/g)

The table above provides more detail on the exposure levels (i.e., nanograms of chemical per gram wristband) detected across the 28 wristbands for each flame retardant. The rightmost column provides the level of each flame retardant detected in your wristband. Because of differences in chemicals properties, the data can only be used to compare differences in exposure levels of a specific chemical across the participant group (e.g., compared to the range of exposure levels). It is *not* meaningful to compare the levels of different chemicals in your own wristband (vertically).

II. Learn more about these flame retardants

Polybrominated diphenyl ether ("PBDE") flame retardants can be found in upholstered furniture, electronic devices such as televisions, and other consumer products. These flame retardants first came onto the U.S. market in the 1970s and were phased out in the mid-2000s due to concerns about their health effects and their persistence in the environment. Because PBDEs break down very slowly, it is expected that these chemicals will persistent in our environment for generations.

Exposure to PBDEs is widespread. National biomonitoring by the Centers of Disease Control (CDC) demonstrates that most people have PBDEs in their blood and body fat. People are most likely exposed to PBDEs from using or handling consumer products containing PBDEs, breathing contaminated air or household dust, eating contaminated foods (such as fish with high fat content), and drinking contaminated water.

There is strong evidence that PBDEs are linked with a number of health effects, including disruption of thyroid function and adverse neurological development.

As a result, there are mounting concerns about the impacts of these flame retardants on learning and behavior in children.

Since PBDEs were phased out in the mid-2000s, a new suite of flame retardants has emerged. Among these are certain phosphate ester flame retardants (including TCEP, TDCPP and TCPP) as well as other brominated flame retardants (including TBB) detected by the wristbands. Most troubling is that these flame retardants are in widespread use with little or no prior review of their safety.

There is much less research on these replacement flame retardants. In recent years, however, studies have detected increases in these chemicals found in the environment, including indoor house dust, wastewater, and wildlife. This pilot project contributes to this emerging body of exposure research.

Potential health hazards of these replacements are also not as well-characterizes as for the PBDEs. Limited research, however, links some of these replacement flame retardants to similar health effects, such as endocrine disruption and neurological impacts.

There has been enough research, however, to sound the alarm. The European Union recently banned TCEP due to reproductive toxicity concerns. Maryland, New York, and Vermont also banned TCEP as well as TDCPP from use in furniture and/or certain children's products. Furthermore, the U.S. EPA is in the early stages of assessing the risk of TCEP, TDCPP, and TBB (along with several other flame retardants) to determine if risk management steps, such as regulation, need to be taken on a national level.

III. Additional government resources

- National Institute of Health (NIH)
  - "Tox Town" on PBDEs: http://toxtown.nlm.nih.gov/text_version/chemicals.php?id=79

- Agency for Toxic Substances & Disease Registry (ATSDR)
  - ATSDR Toxic Substances Portal – PBDEs: http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=900&tid=183
  - ATSDR Toxic Substances Portal – Phosphate Ester Flame Retardants: http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=239

- Environmental Protection Agency (EPA)
  - Factsheet on PBDEs: http://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_perchlorate_january2014_final_0.pdf
  - EPA Action on PBDEs: http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/polybrominated-diphenyl-ethers-pbdes

McCormick

Attachment D

EDF ENVIRONMENTAL DEFENSE FUND
Finding the ways that work

10 people and chemicals in their midst

New wristband technology detects chemical exposures in everyday life

This woman is wearing a chemical-detecting wristband, technology we asked 10 people to wear for a week.

We're exposed to potentially hazardous chemicals daily – in everything from clothes to lotions to couches – putting our health at risk. Yet, scientists know surprisingly little about these exposures.

EDF engaged 10 people across the country to wear a novel wristband technology designed to detect chemicals in their environment for one week.

We detected **26 potentially harmful chemicals** – including a highly toxic pesticide banned in the 1980s.

Every participant came into contact with at least five phthalates – chemicals commonly added to plastics and used in cosmetics, personal care products, adhesives and household cleaners.

Our 10 participants and what we found

Name:
Gordon

Profession:
Firefighter

Generation:
Baby boomer

Location:
Memphis, Tennessee

Background: Gordon is a lieutenant for the Memphis Fire Department. His wristband detected a banned pesticide.

While there were no fires to fight the week he wore the wristband, he still came into contact with a number of hazardous chemicals – through his home environment and routine work maintaining fire station equipment, responding to medical calls, and visiting commercial and industrial sites. Among those chemicals found include gamma-chlordane, a pesticide that has been banned in the U.S. since the 1980s, and 3,4-dichlorophenyl isocyanate, a "chemical intermediate," which is reportedly used exclusively for chemical manufacturing processes. Gordon wondered if he came into contact with these chemicals from a site visit to a location that formerly housed chemical stockpiles, his local auto repair shop, the nearby highway – or even his fire suit.

Read less ▲

Gordon's chemical profile

- **Plasticizers:** 6
- **Fragrances:** 2
- **Flame retardants:** 1
- **Pesticides:** 3
- **Preservatives:** 1
- **Combustion by-products:** 0
- **Other:** 3

Hover over a chemical group name for more information

Name:
Arsany

Profession:
Pharmacy student

Generation:
Generation Z

Location:
New Brunswick, New Jersey

Background: Arsany is a graduate pharmacy student at the Ernest Mario School of Pharmacy (Rutgers University). Among other chemicals, his wristband detected the flame retardants TPP and TCPP.

Flame retardants have been added to hundreds of millions of everyday foam products like furniture, as well as electronics casings, insulation and textiles. After participating in the project, Arsany reflected: "I didn't realize that if I was sitting on a couch or sofa, or in a chair in class, I could be exposed to all that. I've never had the opportunity to quantify it until this project. I thought that was really cool."

Read less ▲

Arsany's chemical profile

- **Plasticizers:** 6
- **Fragrances:** 3
- **Flame retardants:** 2
- **Pesticides:** 1
- **Preservatives:** 2
- **Combustion by-products:** 0
- **Other:** 0

Hover over a chemical group name for more information

Name:
Star

Profession:
Green Labs Program coordinator

Generation:
Generation X

Location:
Athens, Georgia

Background: Star is a former chemical safety specialist who spearheaded the University of Georgia's Green Labs Program.

Star has committed her career to reducing toxic chemical exposure, yet her wristband detected several pesticides and an alphabet soup of phthalate plasticizers: DEHP, BBP, DEP, DIBP, DBP, DHEXP and di-n-nonyl phthalate. After wearing the wristband, she reflected, "I was shocked by the plasticizers. In terms of behavioral modifications and awareness, I'm generally well-informed – what does the average person have?"

Read less ▲

Star's chemical profile

- **Plasticizers:** 7
- **Fragrances:** 2
- **Flame retardants:** 1
- **Pesticides:** 2
- **Preservatives:** 1
- **Combustion by-products:** 0
- **Other:** 0

Hover over a chemical group name for more information

Name:
Christina

Profession:
Zookeeper

Generation:
Millennial

Location:
El Paso, Texas

Background: Christina is a zookeeper who spends her days in the Africa exhibit of the El Paso Zoo.

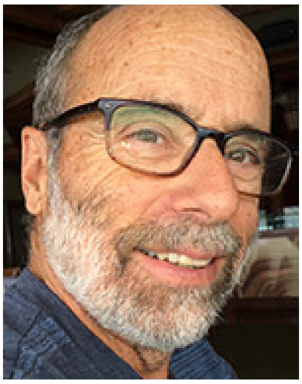
Among the chemicals detected by Christina's wristband were three pesticides, including the bug repellent DEET and piperonyl butoxide – found in household pesticides, agricultural pesticides and veterinary products. Christina expressed concern about chemicals' effects on the environment and our health, noting "the more information we have, the more we can do about this problem."

Read less ▲

Christina's chemical profile

- **Plasticizers:** 6
- **Fragrances:** 1
- **Flame retardants:** 0
- **Pesticides:** 3
- **Preservatives:** 1
- **Combustion by-products:** 0
- **Other:** 0

Hover over a chemical group name for more information



Name:
Misha

Profession:
Retired physician

Generation:
Baby boomer

Location:
Los Angeles, California

Background: Misha is a retired family medical doctor, who now spends much of his time outdoors hiking.

Addendum 315

Among the chemicals detected by Misha's wristband were benzophenone – a sunscreen chemical that is highly toxic to coral – and the common insect repellent pesticide DEET. His wristband also detected six phthalate plasticizers. "I use Nalgene water containers for hiking... they took all the BPA out. So they are BPA-free, but they don't mention all these other things," Misha reflected, noting how difficult it is to know what chemicals are in the products we buy.

Read less ▲

Misha's chemical profile

- **Plasticizers:** 6
- **Fragrances:** 2
- **Flame retardants:** 0
- **Pesticides:** 1
- **Preservatives:** 1
- **Combustion by-products:** 0
- **Other:** 2

Hover over a chemical group name for more information

Name:
Karen

Profession:

Middle school science teacher

Generation:

Generation X

Location:

Boulder, Colorado

Background: Karen is an 8th grade science teacher who engages her students in citizen science projects like measuring air pollutants using portable air monitors.

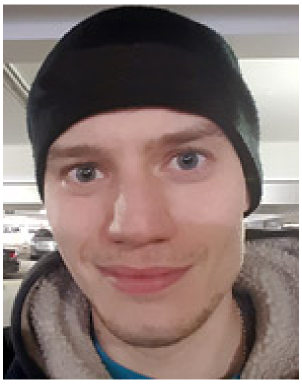
Most recently Karen wore the chemical-detecting wristband as a teaching tool for her students. Karen's wristband detected the flame retardant BDE 47, which was phased out of U.S. production in the mid-2000s due to health impacts and persistence in the environment. Her wristband was also the only one in the project to detect combustion byproducts called polycyclic aromatic hydrocarbons (PAHS). Karen hopes that personal exposure monitors like the wristband will become more available to the general public in the future, noting that her students would love to wear the wristbands themselves: "The students are very curious. They love this project."

Read less ▲

Karen's chemical profile

- **Plasticizers:** 6
- **Fragrances:** 1
- **Flame retardants:** 2
- **Pesticides:** 0
- **Preservatives:** 0
- **Combustion by-products:** 2
- **Other:** 0

Hover over a chemical group name for more information



Name:
Josh

Profession:
Airport valet

Generation:
Millennial

Location:
Indianapolis, Indiana

Background: Josh works in an airport parking garage in Indianapolis and works on his truck during his free time.

Josh's wristband detected two flame retardant chemicals, triphenyl phosphate and tris(1-chloro-2-propyl) phosphate, commonly added to foam-based products. His wristband also detected six phthalate chemicals, three pesticides and the synthetic fragrance galaxolide. Josh speculated on the sources of these chemicals, considering air fresheners in his home and that "new car" smell.

Read less ▲

Josh's chemical profile

- **Plasticizers:** 6
- **Fragrances:** 1
- **Flame retardants:** 2
- **Pesticides:** 3
- **Preservatives:** 1
- **Combustion by-products:** 0
- **Other:** 0

Hover over a chemical group name for more information

Name:
Averi

Profession:
College student

Generation:
Generation Z

Location:
Wooster, Ohio

Background: Averi is a student at The College of Wooster, currently doing her senior research project on sustainable interior design.

Averi's wristband detected several chemicals that can be found in personal care products – such as lotions, shampoos and conditioners – including the fragrance enhancer diethyl phthalate, the preservative benzyl benzoate and the synthetic fragrance galaxolide. "It struck me that I may be interacting with the most toxic chemicals when I am showering… in the place where I am trying to get clean."

Read less ▲

Averi's chemical profile

- **Plasticizers:** 5
- **Fragrances:** 1
- **Flame retardants:** 1
- **Pesticides:** 1
- **Preservatives:** 1
- **Combustion by-products:** 0
- **Other:** 0

Hover over a chemical group name for more information

Name:
Kim

Profession:
Law enforcement dispatcher

Generation:
Millennial

Location:
Helena, Montana

Background: Kim is a dispatcher living in a small town in Montana. She was eight months pregnant while wearing the chemical-detecting wristband.

Her wristband picked up several phthalates including DEHP and DBP, which have been banned in the U.S. for use in children's products like toys and pacifiers. Kim was surprised to see the synthetic fragrance ingredient galaxolide among her results, in particular: "With the baby, everything we use is fragrance-free. I've done what I can to avoid them, but just walking around in an enclosed space, I'm exposed to it. And there's nothing I can do."

Read less ▲

Kim's chemical profile

- **Plasticizers:** 5
- **Fragrances:** 1
- **Flame retardants:** 0
- **Pesticides:** 0
- **Preservatives:** 1
- **Combustion by-products:** 0
- **Other:** 2

Hover over a chemical group name for more information

Name:
Sheena

Profession:
Artist

Generation:
Baby boomer

Location:
Taos, New Mexico

Background: Sheena lives in the high desert of New Mexico, where she creates ceramic works of art, drawing on her Celtic heritage.

She takes great care to avoid chemicals in her job and everyday life, because she suffers from a condition called multiple chemicals sensitivity (MSC). Even so, some chemicals like phthalates are ubiquitous in the environment and virtually impossible to avoid. "People that are chemically sensitive try everything – drugs and all sorts of things – but some of the best ways that help people get better are avoidance and simplicity."

Read less ▲

Sheena's chemical profile

- **Plasticizers:** 5
- **Fragrances:** 0
- **Flame retardants:** 0
- **Pesticides:** 0
- **Preservatives:** 0
- **Combustion by-products:** 0
- **Other:** 0

Hover over a chemical group name for more information

What can you do?

The Environmental Protection Agency (EPA) plays a critical role in understanding the impacts of chemical exposure and protecting public health. Unfortunately, President Trump wants to cut EPA's by 31% and dismantle critical health protections.

Media contact

Keith Gaby
(202) 572-3336 (office)
Email | Follow

Our topic expert

Sarah Vogel
Vice President, Health
Email

See all health experts »

Toxic chemicals at home

Where might you encounter toxic chemicals in your home?

EDF ENVIRONMENTAL DEFENSE FUND
Finding the ways that work

257 Park Avenue South, New York, NY 10010

McCormick

Attachment E

EDF ENVIRONMENTAL DEFENSE FUND
Finding the ways that work

WORKSHOP

Understanding Chemical Exposure, Accelerating the Market for Wearable Monitors

26th- 27th October 2017

Environmental Defense Fund

1875 Connecticut Ave NW, Washington DC

Background

Chemicals are used to make 96% of products in the United States, from couches and carpets to the clothes we wear. While chemicals are a critical part of our economy, they are also released into our environment—and end up in our food, water and air—which can result in harmful exposures. Although some promising tools exist to measure individuals' chemical exposures, technological limitations and cost barriers have limited widespread adoption. EDF is convening a workshop to explore opportunities to enable the development and use of lower-cost, portable or wearable technologies to accurately assess a variety of chemicals in an individual's environment. Because there is significant momentum behind volatile organic compound (VOC) exposure monitoring and an array of technologies at various stages of commercialization, certain sessions in the workshop will focus on VOC monitors.

Meeting Objectives

1. Identify key challenges and opportunities in developing and scaling personal chemical exposure monitors (PCEMs);
2. Identify lessons that can be applied from VOC monitors to the broader PCEM market;
3. Develop a shared understanding of strategies to drive development and adoption of PCEM technologies; and
4. Activate a diverse network of players to jointly identify priority areas for action.

DAY 1: October 26th

8:00 **Breakfast and coffee**

8:30 – 9:15 **Workshop Opening: Welcome, mission, and vision**
Speakers: Sarah Vogel (EDF) and Aileen Nowlan (EDF)

9:15 – 10:00 **Highlights and discussion from the analysis brief**
This session will review findings from a report, "EDF Year of Innovation: Analysis brief," on the landscape of innovation in personal chemical exposure monitors (PCEMs) compiled by Research into Action (RIA).
Speaker: Erik Funkhouser (RIA)

10:00 – 11:00 **What do users want from new technologies?**
Different users may require different functionality from personal chemical exposure monitors. This session will address two questions: What key functions do users need? Where is there broad overlap between functions needed by various users?
Facilitator: Roel Vermeulen (Utrecht University)

11:00 – 11:15 **Break**

11:15 – 12:30 **Exploring the horizon: Current and upcoming technologies**
Promising devices may include new arrivals on the scene, or devices that are becoming established and accepted. Technologies may differ in their barriers to adoption, opportunities, and cost drivers. In this session, participants will define the space for new technologies through a pitch competition.
Facilitator: David Rejeski (Environmental Law Institute)

12:30 – 1:00 **Introduction to EDF's work on VOCs**
Speakers: Beth Trask (EDF) and David Lyon (EDF)

1:00 – 2:30 **Lunch and panel discussion on market demand**
This session will bring together panelists with experience in either developing or utilizing emerging technologies in personal chemical exposure monitoring and the broader monitored-self space in a discussion about catalyzing a new market.
Facilitator: Roger McFadden (McFadden and Associates, LLC)
Panelists: Benjamin Bunes (Vaporsens); Davida Herzl (Aclima); Priya Premchandran (Google); Janie Shelton (23andMe)

2:30 – 2:45 **Break**

2:45 – 4:15 **Concurrent sessions**

VOC monitors: Recent developments and opportunities for improvements
There are several categories of VOC monitors, including samplers and sensors. Across emerging and available devices, user applications and technologies vary significantly. This diversity provides a wide swath of opportunities to influence technology development and deployment at different R&D, supply chain, and use case junctures. Participants will address the following questions: What specific aspects of the value chain present the lowest hanging opportunities for VOC monitors? Are there key "value-chain" lessons learned that could be applied to advance other personal chemical exposure monitors?
Facilitator: Romain Lacombe (Plume Labs)

PCEMs: Lessons from different fields
Expertise and resources for developing personal chemical exposure monitors (PCEMs) exist across various disciplines. This session will explore ways in which technological and

process innovation focused on environmental monitoring and the monitored-self can support PCEM development for public health applications. Participants will address the following questions: What were the successes and challenges from the advent of other environmental monitoring and monitored-self technologies? What key lessons learn can be applied to the PCEM space?

Facilitator: Kristin DeWitt (Intelligence Advanced Research Projects Activity)

4:15 – 4:30 **Break**

4:30 – 5:30 **Keynote and Networking Happy Hour**
MyExposome: A story of entrepreneurship and a case study from Hurricane Harvey
Speaker: Marc Epstein (MyExposome)

6:30 **Dinner at Mission**
Join us for dinner at Mission, a six minute walk from the office just north of Dupont Circle (1606 20th Street NW)

DAY 2: October 27th

8:00 **Breakfast and coffee**

8:30 – 9:00 **Welcome and recap of day 1**
Speaker: Sarah Vogel (EDF)

9:00 – 10:15 **Concurrent sessions**

Funding: Thinking creatively about funding strategies
Funding resources for health studies often do not specifically support the development of necessary analytical or exposure tools. Due to inadequate funding for development, testing, and validation of such tools, researchers often use or leverage funds allocated for specific research projects. This session will address two questions: Which aspects of the PCEM critical technology path are most likely to need funding support outside the current system? What opportunities exist to make underfunded development activities more appealing to the PCEM funders?

Facilitator: R. Darryl Banks (RIA)

Validation: Ensuring quality in the promise of new technologies
Advancement and deployment of promising new PCEM technologies is hindered by the slow pace of relevant studies to validate integrity, processes, and data quality. Participants will explore the following questions: What approaches to validation are most convincing? What opportunities exist to systematically call for and fund validation studies in coordination with researchers and key organizations in the PCEM ecosystem? What is the role of standards?

Facilitator: Erik Funkhouser (RIA)

10:15 – 10:30 **Break**

10:30 – 12:00 **Short, medium and long term strategies and programmatic ideas: Overview, discussion, and prioritization**
Facilitator: Chris Portier (EDF)

12:00 – 1:30 **Workshop closing and lunch**
Facilitator: Sarah Vogel (EDF)

McCormick

Attachment F

EDF Year of Innovation

Analysis Brief

September 27, 2017

Prepared by

research into action inc

3934 NE Martin Luther King Jr. Blvd., Suite 300 | Portland, Oregon 97212
www.researchintoaction.com

Draft Analysis Brief

Year of Innovation

September 27, 2017

Funded By:

Environmental Defense Fund

Prepared By:

Research Into Action, Inc.

www.researchintoaction.com

PO Box 12312
Portland, OR 97212

3934 NE Martin Luther King Jr. Blvd., Suite 300
Portland, OR 97212

Phone: 503.287.9136
Fax: 503.281.7375

Contact:
Jane S. Peters, President
Jane.Peters@researchintoaction.com

Table of Contents

1. Introduction

In early 2017, Environmental Defense Fund (EDF) set out to design a process to catalyze the innovation of, investments in, and, ultimately, the use and adoption of personal chemical exposure monitors (PCEMs) that measure an individual's chemical exposure. This Year of Innovation project ("Project") seeks to: (1) identify key resources, network actors, and network strategies for a successful PCEM market acceleration program, and (2) activate network strategies and engage key actors and resources in accelerating the PCEM market.

For the initial stage of the Project, EDF and Research Into Action collaborated to design an expert elicitation study to understand the state of the art in PCEMs. Because definitions vary, we began by defining PCEMs to include chemical sensors and chemical samplers. Chemical sensors include technologies or tools that identify analytes at the point of detection by transforming chemical information into a signal; chemical samplers include technologies that collect compounds in a physical matrix over a certain time period.

We collaborated with EDF staff for several weeks to operationalize the study and identify the researchable issues that stem from three high-level research questions:

- What is known about resolving deployment bottlenecks for similar technologies?
- What are the technology capabilities and use needs of public health researchers?
- What is the technical and market potential for PCEMs to meet the needs of chemical exposure research?

This brief provides a summary of findings from expert elicitation interviews Research Into Action conducted with 20 subject matter experts (SMEs) with unique experience in cutting-edge applied public health research and PCEM technology development.[1] We supplemented these findings with insights from a systematic scan of relevant business case literature.

Section 1.1 introduces the pipeline model of innovation and discusses specific lessons learned from case studies and the experience of SMEs. Section 1.2 provides an overview of the study methodology and SME profiles. Section 2 provides in-depth discussion of the interview findings. Finally, Section 3 presents conclusions, potential implications of the findings, and areas for further exploration.

1.1. Innovation Pipeline Model

Technology innovation is a dynamic process, and PCEMs are no exception. Research Into Action's assessment of the state of the art in PCEMs examines how numerous components fall along a known spectrum of development toward commercial readiness. Before assessing the state of the art and user needs, we first introduce the generalized innovation pipeline model popularized by Branscomb and

[1] See Section 1.2 for more detail on subject composition.

Auerswald.[2] Additionally, we draw specific insights from similar technology case studies and from the professional experience of our interview subjects to better understand the current locations of PCEMs in the innovation-commercialization pipeline.

The innovation pipeline model is a simple framework that describes a generalized path to commercialization for technologies like PCEMs. The model consists of four innovation process stages that link basic research to technology development; product development and commercialization:

- **Stage 1:** The process of basic research, proof of concept, and invention leading to functional inventions and patents.
- **Stage 2:** Early-stage technology development leading to business validation.
- **Stage 3:** Product development leading to the creation of new firms or programs.
- **Stage 4:** Product manufacturing, commercialization, and marketing that leads to continued growth of new firms and programs, and, ultimately, to viable businesses.

Each stage is linked by learning and feedback processes that represent both “downstream” and “upstream” flows across the continuum from research to development to commercialization. The “overlap and redundancy” that results from the feedback flows provides peer review, verification and validation all of which increase the ability for innovations to attract funds and funders. Across the four stages, funding sources can vary, with foundational funding coming from government agencies, corporate research, and angel investors. As innovation progresses, project funding sources diversify into venture capital, equity, corporate venture funds, and commercial debt. Each stage of the innovation pipeline has a set of unique challenges that must be overcome to continue to the subsequent stages of innovation.

Early-stage innovation challenges include problems associated with knowledge creation, information sharing, lab testing, resource acquisition, team creation, and business analysis. Later stage innovation challenges include the potential continuation of early-stage challenges, in addition to obstacles related to product assemblage, as well as issues with forming a business management team, defining and maintaining the firm’s values and logic, and expanding into the broader market.

The range of technologies and processes that compose PCEMs currently falls primarily along stages 1 and 2 of the innovation pipeline model. The following discussion reviews the progression of relevant technologies at each of these two stages, as published in case studies or reported by SMEs.

1.1.1. First-hand early stage experience with PCEMs from SMEs and case studies

Most PCEM research and information available in public forums describes the early stages of the innovation process. We searched several relevant journals and case study repositories for published case studies with insights related to the fundamental components of the Branscomb and Auerswald model, as well as issues related to the following:

- The impact that firm size has on the commercialization outcomes for PCEM

[2] Branscomb, L.M. and P.E. Auerswald. Between Invention and Innovation: An Analysis of Funding for Early-Stage Technology Development, 2002.

- The outcome of more disruptive technologies, especially those that feature multidisciplinary technology components
- The inclusion of firms that have experience improving their processes as the underlying science evolves
- Variation across firms that develop technologies with varying means of analysis

As we anticipated, the search returned few results that met a minimum threshold of relevance, likely due to the emerging state of PCEMs. To supplement case study insights, we reviewed the relevant experience of SMEs, which yielded additional insights to help develop an initial understanding of development pathway experienced by some PCEM developers to date. The following discussion summarizes key takeaways from the review.

Stage 1

We identified two case studies that highlighted technologies that were in the process of basic research and proof of concept. One study described a PCEM that detects toxic hydrocarbons and acids in the environment.[3] The developers followed two proof of concept validation processes to contextualize their findings on device efficacy. First, the team used an inter-lab validation approach to test device sensitivity compared against the standard bearer methodology from the National Institute for Occupational Safety and Health (NIOSH). Using this approach, they confirmed device sensitivity was on par with the NIOSH standard. Second, the team conducted field testing that demonstrated the spectrum of accurate detection as well as real-time detection. Benchmarking against the NIOSH standard was key to the teams' relatively swift proof of concept.

Another study on ambient measurements of air pollution[4] illustrated persistent challenges to chemical monitoring technology innovation. One issue identified is a lack of accessible data for calibration, validation, and testing, due to the expense and feasibility issues associated with generating personal exposure monitoring.[5] Separately, the authors found a high prevalence of measurement error, disproportionately high for some compounds, while identifying that spatial and environmental considerations appear to be the main source of device measurement error. Ultimately, the authors determine that new methods are needed to validate the outputs from the current generation of detection devices.

SMEs provided details regarding their own experience relevant to stage 1:

- **Laboratory technology development involves user experience feedback** – While developing a chemical sampler for research practitioners, a team encountered a litany of technical challenges related to user experience. With user feedback, it became necessary to address a number of issues related to environmental factors such as exposure to sunlight that become salient due to

3 Negi, Indira, et.el., *Novel monitor paradigm for real-time exposure assessment*, 2011.

4 Study used daily measurement collected by the EPA of total mass of chemical constituents, including ion chromatography for nitrate (NO3-), sulfate (SO2−4), ammonium (NH+4), and sodium ion (Na+); thermal optical analysis for elemental carbon (EC) and organic carbon; and X-ray fluorescence for silicon (Si).

5 Bell, Michelle, Ebisu, Keita, and Peng, Roger, *Community-level spatial heterogeneity of chemical constituent levels of fine particulates and implications for epidemiological research*, 2011.

mail delivery of the devices and return of samples. In another example, a development team found that fine tuning a sensor was expensive but manageable. The more complicated challenges for the developer surfaced when trying to develop data protocols that would work well for users and lead to quality data for analysis. Lack of interoperability between analysis and data management software impeded the team's progression to viable prototypes.

- **Manufacturing practices need to be defined and product-focused during the prototype phase.** According to one SME, to ensure that a PCEM has the potential to scale, it is necessary to create a criteria checklist to help ensure that the considerations involved in developing manufacturing specification improve and don't hinder the usability of the device. The criteria may include reasonable storage and transportation requirements for end-users.

Stage 2

We identified two case studies that highlighted some challenges of moving an innovative technology into product development. In one case study, a private firm that attempted to gain regulatory approval in the U.S. for a device that treats emphysema had to abandon the project and sell its assets after the U.S. Food and Drug Administration (FDA) did not approve the device.[6] This case highlighted the challenges associated with moving an innovative medical technology from Stage 2 into Stage 3 of the innovation pipeline model.

The FDA pushed back on another firm with a warning letter, which developed an innovative technology related to personal genetic testing, due to uncertainty on how to regulate the new industry.[7] These regulatory issues eventually made it difficult for the firm to attract and maintain investors.

SMEs provided details regarding their own experience relevant to stage 2:

- **Public funding may shift focus** – Currently, a great deal of funding that supports development of PCEMs flows from federal research and development funds. A limitation for technology developers has been a lack of alignment between the requirements of funding sources, usually tailored toward specific outcomes such as treating asthma or cancer, and technology gaps the developers want to close. Usually, some sort of workaround is needed. Once new technologies are validated, private funding is more likely to flow the technologies. Private funding sources typically expect the technology to be mature and relatively close to being market-ready.
- **Product validation is a simultaneous up- and downstream challenge** – Organizing structures specific to PCEMs that could support market development, like standards and testing organizations, are lacking. This makes it difficult to convince funders that a product will align with user expectations. Looking downstream, this also poses a problem when conveying to potential users that results will be valid and accepted.

6 Denend, Lyn, et. al., *Emphasys Medical: Navigating Complex Clinical and Regulatory Challenges on the Path to Market*, 2010.

7 Siegal, Robert and Rosenthal, Sara, *23andMe*, 2017

1.2. Methodology

In-depth interviews with SMEs were the main source of data for this study. They provided valuable insights surrounding issues that address the central questions of the study. We interviewed 20 SMEs between May and July 2017 (Table 1-1). These respondents represented a variety of organizations involved in the PCEM market chain, from academia, government, and non-profit and private sectors.

To ensure that the interviews captured the full range of perspectives and adequately addressed all research objectives, we determined that the sampling frame should include input from public health practitioners with experience deploying PCEMs in an applied setting, as well as SMEs with broad experience in public health and occupational health administration. We also included SMEs with direct experience developing PCEM technologies and processes for using and validating device outputs. Table 1-1 provides a breakdown of the subject composition within each group of SMEs.

Table 1-1: Respondents by SME Group

Public Health		Technical Developers		Total Respondents
Public Health Users	Public Health or Occupational Health Experts	Developers	Process Experts	
4	5	6	5	20

Study SMEs were invited by email for 30-60 minute phone interviews. The interviews followed a semi-structured format, tailored to the SMEs' background and expertise.[8] This interview approach was appropriate as a means to address a wide range of research questions for which expertise across several distinct disciplines was necessary.

8 Additional information about the research questions can be found in the next section, and study questionnaires can be found in Appendix A.

2. Findings

The discussion in this section highlights the main findings that address the study's three high-level research questions. Table 2-1 provides a summary of sub-questions the team developed to explore the central research questions.

Table 2-1: Research Questions and Sub Questions

Research Questions	Sub Question
What is known about resolving deployment bottlenecks for similar technologies?	What has been the role of network mobilization/engagement?
	What strategies have been used?
	Which have been most successful?
	What cost factors – such as manufacturing, data processing, and analysis – were meaningful?
What are the technology functionalities and use needs of public health researchers?	What are public health researchers' priorities for front-end* functionality?
	What are public health researchers' priorities for back-end functionality?
	How do the use needs of researchers vary?
	What is the relationship between different use needs and technical requirements of a specific technology?
	Do use needs correlate with other fields that, if addressed, would solve a need in the research field?
What is the technical and market potential for PCEMs to meet the needs of chemical exposure research?	What underlying technical components correspond with the spectrum of user needs?
	Where do potential features lie on a spectrum from most to least market ready?
	Among the user needs for which there are no market ready solutions, what type of R&D or innovation is needed?
	How have investors responded to wearable "monitored self" business concepts?

* Front-end functionality refers to what PCEMs can do, or what data they can collect. Back-end functionality refers to how the PCEMs facilitate data management

As context for the sections below, our SMEs informed us of the following ways a PCEM might be used.

- Public health researchers can use PCEMs as part of their research to assess risk factors associated with asthma, cancer, and other ailments.
- Occupational health specialists and industrial hygienists could use these devices to protect workers in hazardous environments.
- The military could use them to alert soldiers when they may be exposed to a hazardous environment

- Police and security professionals could use them to help detect explosives or narcotics at airports, train stations, and other public places.
- Space research programs and organizations such as NASA could use PCEMs as part of assessing risk for astronauts.
- Coaches and trainers could use PCEMs to improve athletic performance by minimizing exposure to chemicals that may inhibit performance.
- Like the activity trackers put on the market over the last several years, the public could use them to inform themselves about their exposure to potentially harmful chemicals, particulates, or metals.

The remaining sections go into detail about the issues around PCEMs and their use for these different groups.

2.1. What barriers exist to bringing a technology like wearables to the market and what can be done to address those barriers?

Many factors shape the arc of technology development. For technologies like PCEMs, which are largely underwritten by public research and public-private efforts, the interplay between key network actors (e.g., researchers, practitioners, public and occupational health administrators, and agencies that fund research, development and demonstration (RD&D) is as essential to success or failure as any other factor. Inadequate network composition can stymie production of social, technological, and economic value, while well-cultivated networks can play an outsized role in accelerating development and improving outcomes.

Network Signals and Structure

The experts in our study devoted a significant amount of time to the topic of network signals and structure, pointing to deficiencies and opportunities. Shared efforts, especially across disciplines, benefit immensely from clear, shared understanding of the strengths and limitations of the current generation of a technology. This shared understanding has been lacking for PCEMs.

In some cases, it has been effective to involve a heavyweight issue "champion" – one SME mentioned organizations like the Kaiser Family Foundation – to help mitigate the natural silos across the research and technology communities. Along the same lines, many SMEs across our study populations noted that lack of coordination among federal public agencies, as well as between federal and state agencies, impedes the development of effective networks. Experts cited several barriers that may result from this lack of coordination, including:

- Needlessly redundant efforts
- Competing agency goals
- Inconsistent priorities
- Higher burden around long-term funding and development strategies

Mobilization Techniques and Elimination of Bottlenecks

The mobilization technique most cited by the study experts was narrow, focused meetings or workshops with professionals with similar interests or potential use needs. These are generally led by early technology adopters or methodology pioneers, and tend to be small and loosely structured, or even ad hoc. Over time, consortia-level interaction can emerge. Currently in the PCEM space, the organizations and customs that facilitate these interactions largely have not formed.

One expert described a further possible step, which has not yet occurred in the PCEM area. Public health agencies in Europe have organized groups to routinely connect interested parties to emerging technologies to communicate their potential benefits and facilitate network coordination.

SMEs discussed several key opportunities to resolve development bottlenecks, including:

- Improving coordination across disciplines to develop a PCEM
- Improving access to funding for research and development of PCEMs
- Tolerating the long timeline needed to produce PCEMs relative to other recent technologies
- Considering all the potential pitfalls a wearable could run into by validating the technology extensively
- Overcoming skepticism toward new instruments and methods
- Accessing personnel who can develop wearables

Each of these topics is described in further detail below.

2.1.1. Collaboration and coordination across disciplines interested in the development and use of wearables is limited.

Existing PCEM research appears largely to be happening in academic settings, and the development of these devices will require academic disciplines to collaborate with groups outside of academia to develop devices. Users of data that could come from a PCEM, such as public health researchers and those responsible for occupational health in commercial and industrial settings, need to work with materials scientists and engineers to develop practical and useful devices.

SMEs provided vivid examples of the efforts they make to cultivate multidisciplinary relationships, from attending material science conferences as the only participant from the public health field, to direct outreach to instrumentation experts in other departments. When asked how they kept abreast of developments in wearable technologies, most SMEs noted they monitored public health journals and the popular press, but overall had little interaction with other disciplines, such as materials science or engineering, that may be developing useful wearable technologies.

Key take-away: Researchers and developers working with PCEMs make ad-hoc efforts to forge necessary relationships, but outcomes would improve if more formal multidisciplinary collaborations were facilitated.

2.1.2. Funding for research and development is limited.

Acquiring funds to support research related to developing a device that does not connect to a specific health problem such as cancer or asthma can be challenging. According to one respondent, “No one wants to pay for development costs of a device that does not address a specific concern.” A PCEM might potentially inform what is associated with cancer, for example, but groups like the National Institutes of Health (NIH) want a device they are confident will provide this information. Funders resist investing in unproven methods, making it difficult to secure funding for PCEM development. Two respondents actively trying to validate PCEMs noted they use their own money or resources to validate so they can eventually convince funders that their wearable can be valuable to cancer, asthma, or other public health research.

Key take-away: Fostering support for PCEM research and development among health-related funding agencies, independent of outcome-oriented funding, may help developers on a number of fronts, including financing to develop practical PCEMs.

2.1.3. The timeline needed to create a practical PCEM device will take longer than the development of other recent advancements in wearables.

Funding for research and development of a novel, untested product can be difficult. Developing an entirely new product takes far longer than modifying an existing product into a wearable. For example, activity monitors such as the FitBit used existing technologies like accelerometers and GPS to create a product. There is nothing comparable to an accelerometer or GPS in the PCEM space, and developing corollaries for chemical detection will take large sums of money, resources, and time.

Key take-away: PCEMs have a longer development path because they are largely creating entirely new devices and methods, as opposed to devices like activity monitors, which were built largely on existing technologies.

2.1.4. Validating data outputs to ensure confidence among users will take time, resources, and coordination.

Validating PCEMs to ensure they work in a variety of settings, can be transported without eroding data, and compare favorably to proven methodologies will be costly and time consuming. Furthermore, it may require time to overcome the skepticism among a research community accustomed to traditional analysis methods and inspire confidence that a PCEM is “fit-for-purpose.”[9]

Respondents mentioned the following study types that are being done or will need to be done to adequately validate PCEMs:

- Transportation of devices: Can a sampler be transported via mail for analysis without compromising data?

[9] “Fit for purpose” describes a product developed to satisfy specific uses for its intended user audience.

- Exposure of devices to different environments: Can a sensor or sampler be left in direct sunlight? Can a sensor or sampler be reliable when exposed to large temperature fluctuations? How does humidity affect a sensor or sampler?
- Replicability of sampler analysis: What is the protocol for analysis to ensure that different labs arrive at the same results when analyzing samplers?
- Comparison of data from a sensor or sampler to known analytical techniques: For example, how PCEMs compare to stationary air pollution monitors?

Key take-away: Supporting research aimed at validating wearable technology is key to the adoption of wearables by public health researchers.

2.1.5. Skepticism about generating reliable data from devices inhibits development of PCEMs and can limit their uptake.

According to many of our study experts, consistent data quality and demonstration of accepted results across the multiple disciplines likely to use device data is an observed or anticipated challenge. Even without observed data quality issues, the risk of inadequate quality data alone is a barrier to development, according to SMEs who observed blowback after new devices delivered data of low or inconsistent quality.

In addition to data quality, important cost drivers included end-user acceptance and access to in-demand labor. Educating potential adopters about the technology potential of an emerging PCEM is a non-obvious and acute challenge. On the one hand, the device capabilities, uses, and value-add of a device can be difficult to communicate, or differentiate. Presumably, this challenge makes adopter "acquisition" more expensive. Some middle market challenges crop up as well. For instance, device users or data users may not understand these new data sources or formats can limit opportunities for demonstration and diffusion.

Key take-away: Work to overcome skepticism of new instruments by continuing to support efforts to validate instruments, widely promote how wearables are being validated in scientific literature and conferences, and promote the best applications (e.g. occupational health, public health) for specific PCEMs.

2.1.6. The pool of staff or researchers qualified to develop PCEMs is very small.

The skillset required to develop user friendly PCEMs is unique and in demand. To illustrate how in demand the talent pool tends to be, one subject described the ideal job candidate as a software engineer with expertise in either electro chemistry or molecular biology. In the RD&D space where many of the device development teams are working, it can be challenging to secure quality staff.

Key take-away: The availability of essential personnel may impact the growth of PCEM developers.

2.2. What do public health researchers want from a wearable device?

For PCEMs to be useful to public health researchers, they should meet some of the following criteria:

- Can accurately detect multiple chemicals, be relatively inexpensive to analyze, and be deployable to large populations.
- If the device is electronic, it must have a long battery life.
- The device should have the ability to provide data in a format that can be easily compared to existing, vetted data.
- Have multiple applications, including informing public health research, occupational safety, law enforcement, and public safety.

The following discusses each of these needs in further detail.

2.2.1. Sensitivity to multiple chemicals must become reliable, inexpensive, and deployable to large populations.

We asked the SMEs to identify technical shortcomings of the current generation of PCEMs that need to be addressed for the technology to improve. The technical gaps they pointed to were largely a consequence of developing devices as part of cause-specific funding, wherein researchers develop technology with funding around the edges of purpose-specific research. As a result, technologies tend to be tailored for specific purposes and somewhat path dependent.

Respondents provided some insights into the characteristics of a PCEM they would like to see.

- **Accurate multiple chemical detection** – Scalable portable chemical detection devices that effectively distinguish between priority compounds have not emerged. Stationary devices that accurately analyze samples exist, but they are too expensive for widespread deployment, while devices at accessible price points lack accuracy, validation, and broad-spectrum capacity.
- **Cost of analysis** – Accurate and scalable tend to be competing technical gaps. Less accurate devices can produce data that is less expensive to access, while more accurate devices, especially samplers, have additional steps in the analysis process that add expense. Post-collection analysis processes, such as analytical chemistry, are difficult to effectively address, because, unlike digital-only platforms, the cost can only be reduced but not eliminated. And, according to several SMEs, the cost of post-collection analysis has not been falling.
- **Population scale PCEMs** – Deployment of population-scale data collection has lagged due to lack of certainty in data quality and in the reliability of devices. Multiple SMEs conveyed their perception that PCEMs, rightly or wrongly, are viewed not to produce sufficiently reliable data to justify long-term investment in population scale research.

Key Take-away: Because PCEM funding flows largely from purpose-specific programs, technology gaps that impact widespread usability are persistent.

2.2.2. Developing comparable data formats to existing vetted data are necessary.

We asked SMEs about the critical device components for PCEMs to meet essential user needs. They identified reference materials that allow users to compare results to data previously collected by a validated data source, as a priority component of PCEMs.

Key take-away: To build trust in the community of potential PCEM users, demonstrating how results from wearable devices compare to existing trusted sources will be necessary.

2.2.3. For electronic PCEMs, the device must have specific characteristics.

The other components that our experts tied to improved usability applied to digital platforms. A high-quality dissemitor, paired with processes to produce quantitative data, not limited to threshold levels, was a priority component of digital technology platforms. To be used in the public health space, device batteries need to be rechargeable, small, light-weight, and have a long lifespan. Battery life should aim for five to seven days per charge.

Key take-away: Electronic PCEMs must have specific characteristics, including long lasting battery life and ability to produce quantitative data easily.

2.2.4. Different users have different threshold needs related to the accuracy of wearable devices.

In general, many public health researchers were willing to sacrifice some accuracy of a wearable device for lower cost and the ability to disseminate devices widely. This differs from users interested in commercial deployment and occupational health applications, which require higher levels of accuracy. Twelve subjects discussed the need to provide different user audiences accuracy levels commensurate to their needs. For example, a less accurate, inexpensive, and easily deployable device was preferable to a highly accurate yet expensive and cumbersome device. One respondent from an academic organization provided a succinct explanation about the accuracy needs of different groups this way:

> *"In the public health arena…we want to collect data on large populations. Of course, that has particular requirements, so we need to have something that is scalable, and we may not be concerned about being accurate to a certain decimal... we are more interested in getting samplers out and averaging the error across the population… we are interested in the average to get it right, not one sampler to get it right."*

Conversely, respondents interested in occupational health and commercial applications aimed at specific audiences, such as soldiers or athletes, reported a greater interest in the accuracy of a single device. These populations require a high level of accuracy from the wearable device because the device needs to alert an individual to a risk or hazard in real time. Additionally, high accuracy devices are required for anyone using PCEMs where data may be reported to a regulatory body such as the Occupational Health and Safety Administration (OSHA).

Key take-away: Do not let imperfect device accuracy hinder development and fielding of devices. Populations such as academic health researchers that need devices to be inexpensive and distributable can tolerate slightly less accuracy than those that need devices that can alert workers or

others about a risk. Opportunities exist to develop technology variants that accomplish both on parallel paths.

2.3. What is the market potential for wearables, and what technical and cost barriers need to be addressed before being market ready?

Experts identified many potential uses for PCEMs from the very specific, occupational health and safety applications, to general consumer use similar to activity trackers. Regardless of the application, there are considerable technical barriers to overcome, including developing low-cost analytical techniques and putting detected data in context with other data, such as location and time exposure to turn the data into useful information. Furthermore, regardless of the market application, PCEMs and the information they provide must be in the low hundreds of dollars range per unit to be useful for public health researchers. Each of these topics is further described below.

2.3.1. There are several technical issues with a wearable that need resolution before they can be market ready.

There are several technical barriers that must be overcome before a market for PCEMs is realistic. We heard from experts about the following technical issues.

- **Developing a low-cost process using existing analytical methods to lower the analysis costs.** The analysis necessary to detect a broad array of chemicals cannot likely be done with one process, machine or device. For example, analyzing sampler data requires an expensive and time-consuming laboratory environment for analysis. To overcome this problem, one respondent noted that developing a "crowdsourced" and open source approach to analysis, where multiple labs analyze results from a single device and look for specific compounds, may offer a way to lower the analytical costs. Another respondent suggested a more traditional approach to lowering analytical costs: Negotiating bulk discounts with labs by guaranteeing the labs a certain number of items to analyze.
- **Overcoming the size of instrumentation to make PCEMs useful.** Equipment size is often associated with the accuracy and precision of equipment. The larger the equipment, the more precise and accurate; the smaller it is, the less precise and accurate. Current PCEMs often have limited applications because they identify a limited set of chemicals, and they only provide users an indication they may be exposed to something. These PCEMs can alert users that additional, more expensive analysis, using larger instruments and specifically trained staff to interpret, may be warranted. However, these PCEMs are not useful beyond this rudimentary level and it will be a large technical hurdle to develop a small, yet useful instrument.
- **Linking ancillary data such as exposure time and location to detected chemical data is crucial for PCEMs to be useful in public health.** Analysis of data from a PCEM includes detection of chemicals and the length of time exposed and location of exposure. Understanding what detection of a chemical means as it relates to location and duration of exposure is critical.

- **Devices must be rugged.** To be useful, PCEMs must work in a variety of environments, and survive activities like being dropped to a hard surface and exposure to direct sunlight for prolonged periods of time. While this is a technical hurdle, there is precedent to making rugged devices.

Key take-away: The number and complexity of technical challenges to developing PCEMs is extensive. Supporting research aimed at overcoming these barriers, especially development of open-source and crowd-sourced approaches to analysis, could accelerate development of PCEMs.

2.3.2. To be widely employed, PCEMs must cost in the low hundreds of dollars, particularly if they are to be used in public health research.

Before devices can be widely employed in public health research, the per-unit cost of PCEMs and analysis must be in the low hundreds of dollars. Public health researchers need a device they can provide to large populations and easily replace if lost, damaged, or stolen, without dramatically affecting project budgets. As alluded to above (section 2.2.4), one way to reduce costs for public health researchers is by sacrificing some device accuracy for a less expensive readily deployable device.

Those designing devices for specific populations, such as employees of a specific kind of manufacturing facility or soldiers potentially exposed to hazardous materials, however, might be able to spend more per unit than public health researchers because they don't need to deploy the devices to large populations. However, SMEs still noted that there is a preference for devices to cost hundreds of dollars per unit – not thousands.

Key take-away: The cost per unit of a wearable can differ based on the application but the cost has to be in the low hundreds of dollars range (or less) to be used by public health researchers.

3. Conclusions and Takeaways

Our interviews with SMEs operating at the cutting edge of WMCD research and development makes clear a few overall takeaways:

- To date, little experience exists commercializing PCEMs.
- Most development funding flow from public agencies, and includes purpose-oriented restrictions.
- The connective fibers that produce enabling environments for innovation and diffusion of emerging technologies, such as consortia, trade associations, and standards and testing organization, have yet to form and take root for PCEMs.
- Validation of the veracity of data outputs, and perceptions of data quality overall, are significant barriers to broader uptake of PCEMs, and therefore the current market potential.

Across the three central research questions that this study posed, a cross-cutting finding is that greater clarity is needed around how PCEMs will be used by practitioners across various and unrelated disciplines. To clearly align the priorities of technology development and demonstration, the diverse spectrum of use needs must be categorized, prioritized, and RD&D focus harmonized accordingly. A second cross-cutting finding, which was echoed across all four SME groups, was the extent to which purpose-specific funding negatively impacts the development of broadly applicable PCEMs.

These takeaways and findings are consistent with systemic barriers that are common for emerging technology systems. There are, however, favorable conditions that set the stage for addressing these barriers. The community of PCEM users and developers have established informal networks of working relationships and collaborations. Additionally, SMEs expressed awareness of ancillary applications for PCEMs for in fields such as defense, personal health, and sports that could help to broaden the sources of funding for technology development.

Appendix A. Interview Guides

A.1. Health Expert Interview Guide

We are conducting research on behalf of the Environmental Defense Fund, exploring the state of the art in wearable chemical monitors able to detect diverse array organic compounds, as well as strategies that have been used to help reduce cost and improve accessibility for other technologies used for public health research.

Because of your unique experience, we would like to get your perspective on a number of topics under consideration for further research.

We use the term chemical monitors to mean chemical sensors and chemical samplers. Chemical sensors are technologies (or tools) that identify analytes at the point of detection by transforming chemical information into a signal. Chemical samplers are technologies that collect compounds in a matrix over a certain period of time. Subsequent laboratory analysis is then used to identify the collected compounds.

I would like to record this interview for my note-taking purposes, the recordings will not be released outside of our study team and are for reference only. Do I have your permission? Do you have any questions before we start?

A.1.1. Subject Background

The first portion of the interview will be about your experience with the application of uptake of emerging technologies broadly.

Based on your experience, I’d like to hear how public health or research communities have mobilized to bring promising new technologies or methodologies into use. To get started, I have a few questions about your professional experience

Q1. Please provide a brief overview of your role at your current organization, and any relevant details from previous posts.

[*PROBE ABOUT*] Have you also worked in the private / public sector?

Q2. In your current or prior roles, what experience have you had validating or otherwise demonstrating emerging technologies or methodologies?

A.1.2. Identifying and Resolving Use Barriers

Sometimes new technologies or methodologies are market ready before professionals are aware of them or able to use them. I have a few questions about how you and your colleagues come to be aware of new technologies or methodologies.

Q3. How do you normally become aware of promising new technologies or methodologies?

Q4. At which point do you or your colleagues begin to make an effort to make a new technology or methodology available or accessible to other professionals?

[*PROBE ABOUT*] If not you, do other professionals play this role? If so, who?

Sometimes there are reasons that make it difficult to begin to demonstrate or use new technologies and methodologies. These we call use barriers and they can be technological, economic, professional, or regulatory, such as need for formal approval. I have a couple questions about your experience with use barriers.

Q5. Whether or not you were involved, can you recall any times that experts in your field needed to actively address barriers to using a new technology or methodology? Yes/No - Please explain.

- If yes, what factors made up the barrier(s) – financial, technological, regulatory?

Q6. How have you seen different groups of public health professionals brought together to accelerate the usability of new technologies or methodologies?

[*PROBE IF NOT ADDRESSED*] Which professionals are often early movers in taking action to resolve use barriers?

Do you recall any individuals or organizations who were especially effective at capturing the attention of colleagues?

Q7. How were other professionals identified that could improve the effectiveness of these acceleration efforts?

- How were they engaged?
- Were any consortia or outside organizations involved?

[*If YES, PROBE*]

- At what stage did they become involved?
- What was their role? Were they effective?

Q8. Apart from what you've already told me, what strategies can be effective for reducing use barriers?

Q9. Some strategies are probably more effective for some barriers than others. What strategies are most effective for addressing use barriers stemming from professional or regulatory standards?

- • What are most effective for addressing economic use barriers?
- • What are most effective for addressing technologies use barriers?

A.1.3. Wearable Chemical Monitoring Devices

I'd now like to discuss wearable chemical samplers and sensors. The Environmental Defense Fund's Year of Innovation Program is exploring opportunities to make wearable chemical monitoring devices cheaper and increase their functionality. We would like your input on a few related topics.

Q10. Sampling is important to the study of human exposure to a range of chemicals, and wearable samplers and sensors increasingly play a role in environmental health research. In your experience, what sampling capabilities are most important?

Q11. What are the common ways that wearable chemical monitors are used for assessing human chemical exposure?

[*PROBE IF NOT ADDRESSED*] How do researchers in different research areas differ in how they use wearable chemical monitors?

Q12. In your area of research, how would you use or how else might you use a wearable chemical monitor?

[*PROBE IF NOT ADDRESSED*] What capabilities would it have to have for you to begin using?

What price point or range would a device need to meet before you could begin integrating it into your work?

What type of study design would make use of a wearable chemical monitor most valuable, in a best-case scenario?

[Potential follow up: What is the minimum subject cohort size that would be necessary to make use of a wearable chemical monitor?]

Wearable samplers and sensors have been used for many years across the public health field. I'd like to hear your thoughts about the technological potential they hold.

Q13. For any wearable chemical monitor capabilities that lack broad uptake, to what extent is this a consequence of lacking technological capacity?

[*PROBE IF NOT ADDRESSED*]

- To what extent is it due to lack of demonstration or validation?
- To what extent is it due to lack of professional or regulatory approval?
- To what extent is it due to the cost of integrating a wearable chemical monitor into the study design?
- To what extent is it due to data quality issues?

Q14. I'm going to read a list of a few aspects of wearable monitors. For each aspect, please tell me if you have observed challenges to successfully using a wearable monitor: [If NEEDED: In your research, or a colleague's research.]

- Collecting samples
- Developing data from samples
- In the context of sensors, transferring data from the wearable device to a data storage host

Q15. Once samples are collected by wearable monitors, the data must be transformed into a meaningful, usable dataset. For simplicity, we term all the related capabilities as “back-end” functionality. In your experience, what back end functionalities are most important?

[*PROBE IF NOT ADDRESSED*]

- In what ways could back-end functionality be improved?
- Would tracking of time-activity-exposure improve?

Q16. I’m going to read a list of data processing aspects of back end functionality. For each aspect, please tell me if you have observed challenges to successfully using wearable monitors: [If NEEDED: In your research, or a colleague’s research.]

- The mechanism for exporting data from the device into a computational format
- The quality of initial data
- The format of initial data
- The ease of identifying the data of interest
- The ease of identifying the completeness of data

Q17. Wearable chemical monitors have been used in fields other than public health. Are you aware of any non-public heath fields using wearable chemical monitors in a manner that could be repurposed for public health research? If yes, what are those fields and how are they using the monitors?

Q18. Do you know of any monitor capabilities in development for other fields that, if made operable, could also be used in the study of chemical exposure?

Q19. Do you know of anyone else we should speak with on this topic? Would you be willing to make an introduction?

EDF will be hosting a workshop in late summer or early fall to delve into these issues further. The team at EDF may reach out to you in the coming weeks with an invitation to participate.

A.2. Technology Producer Interview Guide

We are conducting research on behalf of the Environmental Defense Fund, exploring the state of the art in wearable chemical monitors able to detect diverse array organic compounds, as well as strategies that have been used to help reduce cost and improve accessibility for other technologies used for public health research.

Because of your unique experience, we would like to get your perspective on a number of topics under consideration for further research.

We use the term chemical monitors to mean chemical sensors and chemical samplers. Chemical sensors are technologies (or tools) that identify analytes at the point of detection by transforming chemical information into a signal. Chemical samplers are technologies that collect compounds in a matrix over a certain period of time. Subsequent laboratory analysis is then used to identify the collected compounds.

I would like to record this interview for my note-taking purposes, the recordings will not be released outside of our study team and are for reference only. Do I have your permission? Do you have any questions before we start?

A.2.1. Subject Background

The first portion of the interview will be about your experience with the application of uptake of emerging technologies broadly.

I'd like to hear about your experience with innovative technologies. To get started, I have a few questions about your professional experience.

Q1. Please provide a brief overview of your role at your current organization, and any relevant details from previous posts.

[*PROBE ABOUT*] Have you also worked in the private / public sector?

Q2. In your current or prior roles, what experience have you had introducing or demonstrating emerging technologies?

A.2.2. Technology Bottlenecks

Sometimes new technologies are market ready before professionals are aware of them or able to use them. I have a few questions about your experience taking to market wearable devices and other innovative technology.

Q3. Have you been involved in, or privy to, a go-to-market strategy for technologies to be used, at least in part, for public health research?

Q4. Have you been involved in, or privy to, a go-to-market strategy for wearable devices?

Q5. Please describe any barriers to customer uptake that you encountered?

Q6. Which barriers to customer uptake were most challenging to resolve? [If NEEDED: Were any challenges unresolvable?]

In the public health setting, numerous factors can affect costs and play a role in helping or hindering acceptance and use of promising new technologies. These cost factors may include regulatory hurdles, demonstration of bankability, manufacturing and tooling, cleaning data or performing analysis, or handling samples. I now have a few questions about factors that might have hindered your progress when developing a technology or getting it to market.

Q7. Considering all the barriers to customer uptake that you've encountered, what cost factors helped or hindered the go-to-market strategy?

[*PROBE ABOUT*] Was manufacturing or tooling an issue?

Q8. Did uncertainty about how accepting or trusting users would be of the product's data play a role?

Q9. Did any factors that slowed down the go-to-market strategy reduce or slow the amount of internal development capital invested in the product?

[If subject is from Tech Developer cohort, proceed to Q10; from Process Expert cohort, skip to Q23]

A.2.3. Wearable Chemical Monitoring Device User Needs

We are investigating the opportunities and barriers to advancing wearable chemical monitors for the study of human exposure to chemicals. The remainder of our conversation will focus on wearable chemical monitors, include sensing and sampling devices.

Q10. Wearable chemical monitors have been used in fields other than public health. Are you aware of any non-public heath fields using wearable chemical monitors in a manner that could be repurposed for public health research? [If YES, what are those fields and how are they using the monitors?

Q11. Do you know of any monitor capabilities in development for other fields that, if made operable, could also be used in the study of chemical exposure?

A.2.4. Wearable Chemical Monitoring Device Market and Technology Potential

Our current understanding is that wearable chemical monitoring devices are usually made up of various component technologies from separate original equipment manufacturers (OEMs), combined to provide monitoring, and in some cases data analysis and management functions. I now have a few questions about the current and potential product features of wearable chemical monitors.

Q12. What are the key components of chemical monitoring devices that monitor individual chemical exposure?

Q13. What device functions correspond to each technical component?

Q14. Based on your understanding of wearable chemical monitors, what current applied research uses are you aware of?

Q15. Based on your understanding of wearable chemical monitors, what potential applied research uses do you think are promising?

[*PROBE ABOUT*] Are the limitations for introducing potential research uses technical in nature? [IF NO] Are they professional? Regulatory? Cost? Access? Awareness of capabilities?

Q16. What technology improvements are needed to expand the available research applications of wearable chemical monitors?

[*PROBE ABOUT*] What type of development activities are needed to carry out the improvements?

Q17. Are there opportunities to broaden geospatial tracking capabilities?

Q18. Are there opportunities to broaden the ability of chemical monitors to detect multiple classes of chemicals, in a non-targeted fashion?

Q19. Where do potential features lie on a spectrum from most to least market ready?

Q20. Whether for public health research or other uses, to the best of your knowledge how have investors responded to wearable “monitored self” business concepts?

[*PROBE ABOUT*] What end users do you feel are of greatest interest to investors?

Q21. What wearable device applications have received the most investment?

Q22. Do you know of anyone else we should speak with on this topic? Would you be willing to make an introduction?

We are investigating the opportunities and barriers to advancing wearable chemical monitors for the study of human exposure to chemicals. The remainder of our conversation will focus on the cost and quality factors that affect sensing and sampling technologies, that could also apply to wearable chemical monitors.

Q23. What approaches do you use to process and analyze samples in your work?

Q24. What aspects of processing and analysis drive costs?

Q25. In your experience, what has helped you to minimize the cost of this analysis?

Q26. What do see as the tradeoffs between cost and quality of post-collection analysis?

Q27. What do you see as the barriers to further reductions in cost?

Q28. What do you see as the barriers to further improvements in quality of analysis?

Q29. Do you know of anyone else we should speak with on this topic? Would you be willing to make an introduction?

EDF will be hosting a workshop in late summer or early fall to delve into these issues further. The team at EDF may reach out to you in the coming weeks with an invitation to participate.

McCormick
Attachment G

Comments on

TSCA Work Plan Chemical Problem Formulation and Data Needs Assessment:

Brominated Phthalates Cluster Flame Retardants

EPA Document # 740-Q1-4004, August 2015

EPA–HQ–OPPT–OPPT-2014-0491; FRL–9929–31

80 Federal Register 49997-49999 (Tuesday, August 18, 2015)

Submitted January 20, 2015

Summary

Environmental Defense Fund (EDF) strongly supports EPA's efforts to assess chemicals through the TSCA Work Plan Chemical Program, including several clusters of flame retardant chemicals. We appreciate the opportunity to comment on the Problem Formulation and Data Needs Assessment and related documents for the Brominated Phthalates Cluster (BPC). Our comments address the following EPA documents:

- **TSCA Work Plan Chemical Problem Formulation and Data Needs Assessment: Brominated Phthalates Cluster Flame Retardants** (EPA document# 740-Q1-4004, referred to as the "Problem Formulation and Data Needs Assessment" in our comments)
- **TSCA Work Plan Chemical Technical Supplement – Hazard Assessment of the Brominated Phthalates Cluster (BPC) Chemicals** (EPA document# 740-Q1-4003, referred to as the "Technical Supplement on Hazard" in our comments)
- **TSCA Work Plan Chemical Technical Supplement - Use and Exposure of the Brominated Phthalates Cluster (BPC) Chemicals** (EPA document #740-Q1-5001, referred to as the "Technical Supplement on Use and Exposure" in our comments)
- **TSCA Work Plan Chemical Technical Supplement – Physicochemical Properties and Environmental Fate of the Brominated Phthalates Cluster (BPC) Chemicals** (EPA document #740-Q1-4001)

Our comments raise the following points and recommendations:

- EPA's highest priority should be conducting, as soon as possible, risk assessments of the Firemaster products containing cluster chemicals that are currently in use.
- EPA should acknowledge and rectify serious problems with transparency, data availability, and confidentiality claims in its documents and take steps to avoid such problems in the future.
- EPA should clearly summarize data needs and set forth a plan to promptly obtain needed data.
- EPA has inadequately described its approach to searching the broader literature and has excluded relevant published literature.
- EPA's historically passive approach to obtaining and reviewing data on the risks of the BPC chemicals and their use in Firemaster products is in significant part responsible for its current inability to conduct risk assessment on these chemicals.
- EPA should better articulate its overall strategy and timeline for the TSCA Work Plan Chemical Program.

Table of Contents

Introduction

Environmental Defense Fund (EDF) strongly supports EPA's current efforts to assess the risks of priority chemicals through the TSCA Work Plan Chemical Program. We appreciate the opportunity to comment on the Problem Formulation and Data Needs Assessment for the Brominated Phthalates Cluster (BPC) of flame retardants. As discussed in detail below, however, EDF believes these documents raise serious concerns regarding transparency, data availability, and confidentiality claims.

When polybrominated (PBDE) flame retardants were phased out of the market in the mid-2000s due to health and environmental concerns, the use of Chemtura's replacement Firemaster products skyrocketed. Unfortunately, these replacement flame retardant formulations, which contain the BPC flame retardants 2-Ethylhexyl 2,3,4,5- tetrabromobenzoate (TBB) and bis(2-Ethylhexyl) -3,4,5,6-tetrabromophthalate (TBPH), flooded the market without sufficient data and review to determine if their use was safe.

Today, use of Firemaster products is widespread, and its components are showing up around the world – in everything from indoor house dust and wastewater to animals like polar bears and dolphins.[1] Both TBB and TBPH are high production volume (HPV) chemicals.[2] According to EPA's Chemical Data Reporting (CDR) database,[3] the annual production of TBPH is 1-10 million pounds;[4] however, the manufacturer of TBB has claimed its production volume, as well as its own identity and virtually everything else about this chemical, to be confidential business information (CBI).[5] As recognized by EPA in the current documents, these chemicals have persistent, bioaccumulative, and

[1] See Technical Supplement on Use and Exposure, pp. 23-25.

[2] See Problem Formulation and Data Needs Assessment, p. 11.

[3] See CDR data in EPA's Chemical Data Access Tool (CDAT): http://java.epa.gov/oppt_chemical_search/

[4] Problem Formulation and Data Needs Assessment, p. 18. Also search for the CDR data in EPA's CDAT (http://java.epa.gov/oppt_chemical_search/) using TBPH's CAS number (26040-51-7).

[5] Searching EPA's CDR data in EPA's CDAT (http://java.epa.gov/oppt_chemical_search/) using TBB's CAS number (183658-27-7) yields a single record where most fields, including Company Name, are marked "CBI." Given that Chemtura is widely publicly known to be TBB's manufacturer, it is puzzling and disturbing that this CBI claim for company name has not be challenged and denied by EPA, as information that is publicly known cannot be claimed to be CBI.

toxic (PBT) characteristics; in 2011, both TBPH and TBB were identified as Persistent Organic Pollutants ("POP") candidates under the Stockholm Convention.[6]

Since their expansion in the market, concern has only increased about exposure to and potential health effects of Firemaster flame retardant products. Although not mentioned in EPA's documents, due to these concerns, the National Toxicology Program (NTP) selected Firemaster 550 and its four components for further testing in 2013.[7] (Some of this testing has actually been completed, yet none of the results have been integrated into EPA's documents.) Furthermore, a 2008 California Office of Environmental Health Hazard Assessment (OEHHA) document describes that while data are lacking on TBPH and TBB, both are structurally similar to di(ethylhexyl)phthalate (DEHP) – which is identified by the State of California as known to cause cancer and reproductive/developmental toxicity under Proposition 65.[8] In 2013, both TBPH and TBB were added to California's priority list for biomonitoring.[9]

In carrying out the TSCA Work Plan Chemical Program, we encourage the Agency to thoughtfully balance the dual importance of using robust science and comprehensive assessment methodologies on the one hand, and providing for timely decision-making on the other. As stated in the National Academy of Sciences' (NAS) 2009 report *Science and Decisions*:[10] "The design of a risk-assessment process should balance the pursuit of individual attributes of technical quality in the assessment and the competing attribute of timeliness of input into decision-making" (p. 72). While it is critical that, over time, the Agency addresses major data gaps to fully understand the risks associated with all TSCA uses of a chemical, or group of chemicals, this process should in no way hinder the forward movement of risk

---

[6] Lambert, N., Rostock, C., Bergfald, B., Bjorvik, L.M., "Identifying POP Candidates for the Stockholm Convention, TA-2871/2011." November 2011. Available at: http://www.miljodirektoratet.no/old/klif/publikasjoner/2871/ta2871.pdf

[7] Toxicology Program (NTP), "Nomination Summary for Firemaster 550 (N21305)." Last Updated 23 December 2015. Available at: http://ntp.niehs.nih.gov/testing/noms/search/summary/nm-n21305.html

[8] California Office of Environmental Health Hazard Assessment (OEHHA), "Brominated and Chlorinated Organic Chemical Compounds Used as Flame Retardants." 2008.Available at: http://oehha.ca.gov/multimedia/biomon/pdf/120408flamedoc.pdf

[9] OEHHA, "Biomonitoring California Priority Chemicals." May 2013. Available at: http://oehha.ca.gov/multimedia/biomon/pdf/PriorityChemsCurrent.pdf

[10] NRC (National Research Council), 2009. "Science and Decisions: Advancing Risk Assessment (NAS Final Report)." Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=202175.

assessments for those uses and exposures for which adequate information exists or can be quickly developed, and prompt management and reduction of identified risks.

We fully recognize the data constraints under which the Agency is operating. In light of these, we encourage EPA to generally take a two-fold approach in carrying out risk assessments under the Work Plan Chemical Program:

1) Move forward swiftly with completing risk assessments in relatively data-rich areas and with taking regulatory actions to address identified risks.

2) Fully acknowledge the limited scope of and exclusions from these assessments; actively take steps to fill data gaps in data-poor areas; and revisit and expand the scopes of the assessments as new data become available.

We encourage EPA to apply this paradigm to the assessment of the BPC chemicals through the Work Plan Chemical Program. In the current Problem Formulation and Data Needs Assessment, EPA has concluded that there are insufficient data to move forward with a quantitative risk assessment of any of the cluster members at this time. However, through a relatively limited review of the published literature, we have identified considerable additional data EPA appears not to have identified and considered. In light of all of these data, EPA should reconsider whether data are in fact sufficient to initiate a risk assessment of Firemaster BZ-54 for at least some major use/exposure scenarios and health effects, and should either: 1) initiate such a risk assessment or 2) provide a robust rationale as to why the data are currently inadequate to do so, clearly identify the critical gaps, and take active steps to promptly obtain the needed data. We also recommend that EPA simultaneously take aggressive steps to gather additional data through every available means, including prompt regulatory action, to enable EPA to assess the risks of the Firemaster 550 mixture, as well as individual mixture components where needed and relevant. As such data are obtained, EPA should revisit already initiated assessments, and initiate any additional appropriate assessments of mixtures or component chemicals using the more complete data.

It is essential that EPA prioritize the assessment of <u>commercial mixtures</u> containing BPC chemicals, given that humans and the environment are being widely exposed to these chemicals primarily (or in some cases even exclusively) through ongoing use of the mixtures.

Response to Request for Public Comment

I. EPA's highest priority should be conducting, as soon as possible, risk assessments of Firemaster products containing cluster chemicals that are currently in use.

EPA should promptly initiate assessments as soon as possible of products containing cluster chemicals that are on the market and being widely used and released to the environment. In our comments below, we draw EPA's attention to additional data on the mixtures or the components that EPA appears not to have considered. In light of these additional data, EPA should consider whether data are sufficient to initiate a risk assessment of any of the Firemaster products containing BPC chemicals. If not, it should identify which specific data would be needed to do so and act immediately to obtain the needed data.

While we agree there are data gaps on individual components and some mixtures of BPC chemicals (e.g., Firemaster 550) that need to be filled, actions to fill those gaps need to be coupled with actions to address the known or suspected risks from widespread ongoing exposures to these chemicals.

This is an urgent matter. Human exposure to TBB and TBPH is well documented and is likely primarily a result of the widespread use of Firemaster products. According to EPA, Firemaster products are the *only* identified use of TBB[11] and one of the major uses of TBPH.[12] Firemaster BZ-54 is composed of a mixture of TBB and TBPH (4:1), while Firemaster 550 contains the same TBB/TBPH mixture supplemented with two aryl phosphate components: triphenyl phosphate (TPP) and isopropylated triphenyl phosphate (ITPP).[13]

Because TBB and TBPH are present as additives in Firemaster products (i.e., not chemically bound), they are readily released into the environment. EPA notes in the Technical Supplement on Use and Exposure that monitoring studies demonstrating co-occurrence of TBB and TBPH in a variety of media suggest that the observed environmental releases are occurring from a common source:

> Levels of **TBPH** and **TBB** in the environment and biota are comparable to each other. Occurrence of both chemicals follow a similar pattern with higher levels found in sludge, sediment, and indoor dust and a similar amount and distribution of non-detects (ND)… There is likely a correlation between reported dust concentrations and the total amount of **TBPH** and **TBB** contained within source products. (pp. 23-24)

The prevalence of Firemaster flame retardant products as well as co-occurrence of TBB and TBPH in environmental media and indoor environments (e.g., household dust) strongly suggest that significant exposures to these BPC chemicals are occurring via the use of Firemaster products, although

[11] See Technical Supplement on Use and Exposure, p. 5.

[12] See Technical Supplement on Use and Exposure, p. 10. Evidence suggests that TBPH's use in Firemaster products may be its primary route of release into the environment.

[13] See Technical Supplement on Use and Exposure, p. 10.

other uses and sources of TBPH may be important as well. (For example, TBPH is used in electronics and PVC;[14] to the extent that TBPH is used in other formulations, especially as an additive plasticizer in electronics or PVC, EPA should consider these potential routes of exposure as well.)

While there may be reason also to conduct risk assessments on TBB and TBPH individually (the approach EPA seems to be taking in the Problem Formulation and Data Needs Assessment), we encourage EPA to prioritize getting data it needs to conduct risk assessments on Firemaster products. To the extent that additional data on the individual components are necessary to conduct a fuller assessment of the Firemaster products, we urge UPA to take aggressive steps to actively obtain these data (see section IV below). However, pursuing data on the individual components solely for the purpose of attributing specific health effects to specific chemical components in the mixture should not preclude assessing the mixtures now, but rather should be viewed as a sequential need.

A. EPA should immediately identify and act to obtain data needed to conduct an assessment of Firemaster BZ-54.

We recommend that EPA assemble and clearly present all available data on the Firemaster BZ-54 mixture and the individual components, including available studies in the published literature (see below), which appear to be relatively extensive but have not been considered by EPA. In light of all of these data, EPA should consider whether data are now sufficient to initiate a risk assessment of Firemaster BZ-54 for at least some major use/exposure scenarios and health effects. Based on a review of all of these data, EPA should either: 1) initiate such a risk assessment or 2) provide a robust rationale as to why the data are currently inadequate to do so, identify the critical gaps, and take active steps to promptly obtain the needed data.

In the Problem Formulation and Data Needs Assessment, EPA has not provided a clear explanation as to why it concluded that the data on Firemaster BZ-54 are inadequate. Throughout the documents, EPA minimizes the extensive hazard data on Firemaster BZ-54, citing its concern that any risk conclusions could not be attributed to individual chemical components. For example, the Human Health Data Assessment states: "The nature and extent of reproductive and developmental effects observed as a result of exposure to commercial products that may be attributable to TBB or TBPH (or another component of the mixture) is confounded due to the lack of data with individual components" (p. 30, Figure 2-5 description).

Yet, EPA concludes in the Executive Summary that "the data for Firemaster® BZ-54 are sufficient to support a determination that TBB may present an unreasonable risk in certain scenarios." (p. 7).

We disagree that the Firemaster BZ-54 hazard data cannot be utilized for a risk assessment of the mixture without a complete understanding of the toxicity of the individual components (i.e., TBB and TBPH) for a number of reasons:

---

[14] See Technical Supplement on Use and Exposure, p. 9 and p. 12.

1. Given that available data strongly indicate that exposure to TBB and TBPH occurs in large part through use of mixtures containing them, it is not only warranted, but beneficial, to use hazard data from Firemaster BZ-54. Respected scientific entities, such as the National Academy of Sciences (NAS), [15,16] as well as EPA scientists[17] recognize the importance of evaluating the risks of exposures to mixtures of chemicals.

2. As risk arises primarily from exposure to the mixtures and risk management would likely focus on the mixtures as well, delaying initiation of any assessment of risk until EPA can fully determine how much of the risk is coming from which component seems, to us, to be a recipe for unnecessary delay and continued risk to exposed populations. While aspects of risk management decisions may require knowledge of individual chemical effects, that is no reason to delay initiating a risk assessment of the Firemaster BZ-54 mixture.

3. According to comments submitted by Chemtura,[18] TBB is *only* produced as a mixture of TBB and TBPH. Given this, studying the toxicity of pure TBB – which apparently does not exist in commerce and to which people are unlikely to be exposed except in the form of the mixture – should not be elevated in priority over determining the extent of risk posed by the mixture in which it is apparently exclusively used.

4. TBB was reviewed twice through the New Chemicals Program (see section VIII.A.), and as a result of each review, the Agency required Chemtura to conduct a number of studies on the PMN substance. EPA allowed for testing of TBB in the Firemaster BZ-54 mixture; hence, it is unclear why now EPA is suggesting that data developed on the mixture are inappropriate.

We recognize that there may be some variability in the composition of the Firemaster BZ-54 mixture over time or between batches. But that variability will be a complication under any assessment scenario, and would need to be grappled with even when combining risk estimates for individual components. In addition, any resulting uncertainty needs to be balanced against the urgency of assessing and addressing to the maximum extent and as soon as possible risks of exposure to the mixture currently in use.

---

[15] The National Academies, "Phthalates and Cumulative Risk Assessment: The Task Ahead." 2008. Available at: http://www.nap.edu/catalog/12528/phthalates-and-cumulative-risk-assessment-the-task-ahead.

[16] The National Academies, "Cumulative Risk Assessment for Environmental Mixtures: New Approaches Based on Pathways." September 2012. Newsletter. Available at: http://nas-sites.org/emergingscience/files/2011/05/mixtures-newsletter-9.17-posting.pdf.

[17] See, for example, Rider, C. V., et al. "Cumulative effects of in utero administration of mixtures of reproductive toxicants that disrupt common target tissues via diverse mechanisms of toxicity." 2010. *Int J Androl.* Available at: http://www.ncbi.nlm.nih.gov/pubmed/20487044.

[18] See Chemtura's comments here: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2014-0491-0014.

i. Hazard data

While hazard data on TBB alone are limited, as noted above, there are significant data on the Firemaster BZ-54 mixture. Considerable data were produced by Chemtura pursuant to EPA's review of TBB in the New Chemicals Program. For example, as required by the two consent orders, EPA received a 28-day repeated-dose study, a Prenatal Developmental Toxicity study, and a 2-Generation Reproductive Toxicity study from Chemtura. The Problem Formulation and Data Needs Assessment indicates that these studies all demonstrate potential health impacts to the developing fetus (p. 38); however, later in the document, the Agency identifies as a data gap "reliable information to characterize the hazard for reproductive/developmental toxicity" for both TBPH and TBB, implying that it does not intend to utilize, or does not consider adequate, these data on the Firemaster BZ-54 mixture (Table 3.1 Problem Formulation and Data Needs Assessment, pp. 42-43).

In addition to the Chemtura data on the Firemaster BZ-54 mixture, considerable data in the published literature on both the mixture as well individual components, much of which is not identified by EPA, are available.

We encourage EPA to utilize or better explain why it cannot utilize existing data; for example, the above-referenced Chemtura data demonstrate effects such as lower body weights and altered fetal bone development – which could be used to assess certain risks of Firemaster BZ-54 exposure for women of childbearing age and the developing fetus. In addition to these studies, Saunders et al. (2015) recently published a study demonstrating a link between the TBB/TBPH mixture and reproductive health impacts.[19]

To illustrate the extent of available data, Table 1 below lists available hazard data that we (as well as EPA in some cases) have identified on both the TBB/TBPH chemical mixture and the individual TBB and TBPH components (this is not an exhaustive list).

[19] Saunders, D. M. V., et al. "A mixture of the novel brominated flame retardants TBPH and TBB affects fecundity and transcript profiles of the HPGL-axis in Japanese medaka." 2015. Aqua*tic Toxicology*. Available at: http://www.ncbi.nlm.nih.gov/pubmed/25461741.

Table 1. Aquatic and Human Health Hazard Data on Firemaster BZ-54 mixture and its individual components

Endpoint	Relevant Test Substance(s)	Reference	Cited by EPA?*
Aquatic Toxicity – BZ-54 Mixture			
Algal Growth Inhibition	FM BZ-54	Chemtura, 1998	YES
Acute Toxicity (Daphnia magna)	FM BZ-54	Chemtura, 1998	YES
Acute Fish Toxicity (Trout)	FM BZ-54	Chemtura, 1998	YES
15 Day Chronic Tox/Reprotox (Daphnia carinata)	FM BZ-54	Chemtura, 2003	YES
Accumulation & DNA Damage (Fathead minnow)	FM BZ-54 (& FM 550)	Bearr et al., 2010	†
Fecundity & Endocrine Disruption (Japanese medaka)	TBB/TBPH mixture	Saunder et al., 2015	NO
Gene Expression (Daphnia)	FM BZ-54 (&FM 550)	Scanlan et al., 2015	NO
Human Health – BZ-54 Mixture			
Acute Oral Toxicity (Rat)	FM BZ-54	Chemtura, 1996	YES
Acute Oral Toxicity (Rat)	FM BZ-54	Chemtura, 1997	YES
Acute Dermal Toxicity (Rat)	FM BZ-54	Chemtura, 1997	YES
Acute Skin Irritation (Rabbit)	FM BZ-54	Chemtura, 1997	NO
Acute Eye Irritation (Rabbit)	FM BZ-54	Chemtura, 1997	NO
Skin Sensitization (Guinea Pig)	FM BZ-54	Chemtura, 1997	NO
Skin Sensitization (Guinea Pig)	FM BZ-54	Chemtura, 1999	NO
28 Day Repeat Oral Gavage (Rat)	FM BZ-54	Chemtura, 1997	YES
Reverse Mutation Assay (in vitro)	FM BZ-54	Chemtura, 1997	NO
Chromosome Aberration Test (*in vitro*)	FM BZ-54	Chemtura, 1997	NO
Prenatal Developmental (Rat)	FM BZ-54	Chemtura, 2008	YES‡
2 Generation Reproduction (Rat)	FM BZ-54	Chemtura, 2008	YES‡

*Based on references section of all Problem Formulation and Data Needs Assessment documents as well as Table 1-3 "Human Health Data for Brominated Phthalates Cluster" in the Technical Supplement on Hazard.
† While this study is referenced in the Technical Supplement on Use Exposure, the hazard findings are not acknowledged in the documents.
‡No robust summaries are available for these studies.

Endpoint	Relevant Test Substance(s)	Reference	Cited by EPA?*
Aquatic Toxicity – Individual Components			
Acute Toxicity (Daphnia magna)	TBPH	HPV Challenge, 1989	YES
Acute Fish Toxicity (Trout)	TBPH	HPV Challenge, 1989	NO
Acute Fish Toxicity	TBPH	ECHA	YES
Acute Toxicity (Green Algae)	TBPH	ECHA	YES
Acute Toxicity (Daphnia magna)	TBPH	ECHA	YES
Physiological Effects (Fathead minnows)	TBPH	de Jourdan et al., 2012	YES
Cardiac abnormalities (Zebra fish)	TBB, TBPH, TPP, ITPP	McGee et al., 2013	NO
Human Health – Individual Components			
Acute Oral Toxicity (Rat)	TBPH	HPV Challenge, 1987	YES
Acute Dermal Toxicity (Rabbit)	TBPH	HPV Challenge, 1987	YES
28 Day Repeat Oral Gavage (Rat)	TBPH	HPV Challenge, 1987	YES
Chromosome Aberration Test (*in vivo*)	TBPH	HPV Challenge, 1987	YES
Chromosome Aberration Test (*in vitro*)	TBPH	HPV Challenge, 1987	YES
Gene Mutation (in vitro)	TBPH	HPV Challenge, 1987	YES
Acute Skin Irritation (Rabbit)	TBPH	HPV Challenge, 1987	YES
Acute Eye Irritation (Rabbit)	TBPH	HPV Challenge, 1987	YES
Skin Sensitization (Guinea Pig)	TBPH	HPV Challenge, 1987	YES
Thyroid, Liver, and Fetal Testis Toxicity (Rat, *in vitro*)	TBPH	Springer et al., 2012	YES
Endocrine Disruption (*in vitro*)	TBB, TBPH	Saunders et al., 2013	NO
Metabolism (Human and rat tissues)	TBB, TBPH	Roberts et al., 2012	NO
Hormone levels (Epidemiological)	TBPH	Johnson et al., 2013	NO
PPARγ Activity (*in vitro*)	TBB, TBPH, TPP, ITPP	Fang et al., 2015	NO
PPARγ Activity (*in vitro*)	FM 550 + all individual components	Belcher et al., 2014	NO
Accumulation and Endocrine Disruption (Rat)	FM 550 + all individual components	Patisaul et al., 2013	NO
Adipogenesis and Osteogenesis (*in vitro*)	FM 550 + all individual components	Pallai et al., 2014	NO

*Based on references section to all Problem Formulation and Data Needs Assessment documents as well as Table 1-3 "Human Health Data for Brominated Phthalates Cluster" in the Technical Supplement on Hazard.

Furthermore, while not sufficient to complete a full separate assessment of TBPH, there are considerable data on that chemical from EPA's High Production Volume (HPV) Challenge. These data include a number of acute toxicity and genetic toxicity studies as well as a 28-day repeated dose toxicity study. EPA may be able to use these data to gain insight into individual risks presented by TBB and TBPH from exposure to the Firemaster BZ-54 mixture.

ii. Exposure data

EPA also points to a number of gaps in the exposure data. While we acknowledge that additional exposure data would be beneficial, we believe there are already relatively extensive data available that may be sufficient to conduct an exposure assessment on the TBB/TBPH mixture at least in certain scenarios, especially exposures via house dust. According to the Technical Supplement on Use and Exposure, there are 11 data sources reporting TBB and 13 data sources reporting TBPH in indoor dust – and the amount of data is continuing to grow.[20] While the data needs described in Table 3-1 (e.g., percent weight of chemical in PUF and PUF product, migration of chemical out of PUF product) would enable EPA to better characterize the specific source of a particular exposure, lack of this detailed knowledge should not preclude EPA from utilizing the data it has now in a broader assessment. Identifying the major source(s) of dust contamination is more of a risk management question that does not need to be fully resolved before initiating a risk assessment.

Instead, we encourage EPA to consider commencing an assessment of exposure to the Firemaster BZ-54 mixture via indoor dust with the data currently available, in order to broadly characterize and determine the extent of risk from such exposures. If EPA identifies significant risk associated with the levels of TBB/TBPH in dust, it may then need to further investigate the specific contamination sources in order to refine its assessment and identify appropriate restrictions.

B. EPA should act promptly to obtain the data needed to conduct a risk assessment on Firemaster 550.

Firemaster 550 likely presents a greater public health concern than Firemaster BZ-54. Firemaster 550 is the most ubiquitous Firemaster product, as it was the primary replacement for PBDEs in polyurethane foam (PUF).[21] Recent estimates indicate that Firemaster 550 is the second most common

[20] See, for example: Peng, H., et al., "Detection, identification, and quantification of hydroxylated bis(2-ethylhexyl)-tetrabromophthalate isomers in house dust." 2015. *Environmental Science and Technology*. Available at: http://www.ncbi.nlm.nih.gov/pubmed/25621784; LaGuardia M.L., and Hale, R. C., "Halogenated flame-retardant concentrations in settled dust, respirable and inhalable particulates and polyurethane foam at gymnastic training facilities and residences." 2015. *Environment International*. Available at: http://www.ncbi.nlm.nih.gov/pubmed/25812808.

[21] California Office of Environmental Health Hazard Assessment (OEHHA), "Brominated and Chlorinated Organic Chemical Compounds Used as Flame Retardants." 2008. Available at: http://oehha.ca.gov/multimedia/biomon/pdf/120408flamedoc.pdf.

flame retardant added to PUF products[22] and is the most common flame retardant used in products sold in California.[23]

In addition to its widespread use, Firemaster 550 may present toxicity concerns in addition to those posed by Firemaster BZ-54. While TBB is the primary component of the Firemaster 550 formulation,[24] new research – not considered by EPA – suggests that the mixture's toxicity may be driven in significant part by the aryl phosphate components. For example, Pillai et al. 2014 hypothesize that Firemaster 550's obesogenic effect is driven by TPP, as they found that TPP bound to and activated PPARγ – a nuclear receptor that regulates adipocyte cell differentiation and lipid storage.[25,26] Other research, also not considered by EPA, indicates that the aryl phosphate components of Firemaster 550 induce cardiac abnormalities during embryogenesis in zebrafish, while similar effects were not observed from the brominated phthalate components.[27, 28] Notably, TPP and ITPP are both listed under EPA's Work Plan Chemical Program, and both received a hazard score of three (based on acute and chronic aquatic toxicity for TPP and neurotoxicity and aquatic toxicity for ITPP) in the Work Plan prioritization process, compared to hazard scores of two for both TBB and TBPH.[29]

EPA acknowledges the hazard potential of the phosphate components in the Technical Supplement on Hazard: "Available screening-level data on these phosphates [TPP and ITP] (ECHA, 2013; EPA, 2010b; OECD, 2002) suggest that these constituents pose a hazard to human health and the environment. Firemaster® BZ-54 does not have phosphates in its formulation (Chemtura, 2010, 2013a)"

---

[22] Bailey, J.M. and Levin, E.D. "Neurotoxicity of FireMaster 550® in zebrafish (Danio rerio): Chronic developmental and acute adolescent exposures." 2015. *Neurotoxicology and Teratology.* Available at: http://www.ncbi.nlm.nih.gov/pubmed/26239867; Stapleton, H.N., et al., "Identification of Flame Retardants in Polyurethane Foam Collected from Baby Products." 2011. *Environmental Science and Technology*. Available at: http://pubs.acs.org/doi/abs/10.1021/es2007462.

[23] Elizabeth Grossman. *Chasing Molecules: Poisonous Products, Human Health, and the Promise of Green Chemistry*. 2009. Island Press. P. 116.

[24]See Chemtura's website: http://chemturaflameretardants.com/scientificStudies.html.

[25] Pillai, H.K., et al., "Ligand Binding and Activation of PPARγ by Firemaster® 550: Effects on Adipogenesis and Osteogenesis in Vitro." 2014. *Environmental Health Perspectives*. Available at: http://ehp.niehs.nih.gov/1408111/.

[26] Boston University, "The Flame Retardant Firemaster 550, Fat Cells, and Bone Health." 28 August 2014. Available at: http://www.bu.edu/sph/research/research-landing-page/superfund-research-program-at-boston-university/news/the-flame-retardant-firemaster-550-fat-cells-and-bone-health/.

[27] McGee, S.P.,et al., "Aryl phosphate esters within a major PentaBDE replacement product induce cardiotoxicity in developing zebrafish embryos: potential role of the aryl hydrocarbon receptor." 2013. *Toxicological Sciences*. Available at: http://www.ncbi.nlm.nih.gov/pubmed/23377616.

[28] Gerlach, C.V., et al., "Mono-substituted isopropylated triaryl phosphate, a major component of Firemaster 550, is an AHR agonist that exhibits AHR-independent cardiotoxicity in zebrafish." 2014. *Aquatic Toxicology*. Available at: http://www.ncbi.nlm.nih.gov/pubmed/24865613.

[29] EPA, "TSCA Work Plan for Chemical Assessments: 2014 Update." 2014. Available at: http://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

(p. 15). But EPA appears to dismiss these findings as not relevant to its predetermined set of brominated phthalate cluster flame retardants.

Indeed, EPA's discussion of Firemaster 550 in the current Problem Formulation and Data Needs Assessment seems to be limited only to the extent to which it helps to inform risk assessment of the individual brominated phthalate flame retardants;[30] EPA explicitly states that "[r]isk determination of aryl phosphates is outside the scope of the brominated phthalates Problem Formulation and Data Needs Assessment" (Technical Supplement on Hazard, p. 18). While there is a limited discussion of the toxicity data on phosphate components in the Technical Supplement on Hazard (with sources linking to data developed for TPP and ITPP under the OECD SIDS program and U.S. HPV Challenge, respectively, pp. 15-16), the actual data are not included in the data availability tables or considered in EPA's identification of data gaps/needs.

We argue that EPA should not base its risk assessment scoping decisions on artificial clustering of chemicals, but rather on potential risk and real-world exposures to chemicals and chemical mixtures and their public health impact. EPA should be prioritizing efforts to obtain data sufficient to assess risks of exposure to the Firemaster 550 mixture. We recognize, however, that currently available data are likely inadequate to conduct such a risk assessment. While there is some published literature on the mixture (see Part VI, which includes academic studies identified through our own limited search of the peer-reviewed literature), there are no toxicity studies publically available from the chemical manufacturer on this commercial mixture resulting from a review through the New Chemicals Program or the HPV challenge, or otherwise. CPSC's 2006 *Preliminary Assessment of Flame Retardant (FR) Chemicals in Upholstered Furniture Foam*,[31] which assessed Firemaster 550, indicated that there were no toxicological or bioavailability data on the Firemaster 550 mixture. (Bizarrely, CPSC concluded that there is no appreciable risk from use of Firemaster 550[32] despite the extremely limited data on the mixture, instead relying on toxicity data on compounds structurally related to TPP and ITPP. Since 2006, more literature has been published, but, to the best of our knowledge, EPA still has not required testing nor does it have access to any industry-developed data on the Firemaster 550 mixture.

[30] See, for example: "These latter aryl phosphates are considered to have a mode of action unlike the brominated phthalates cluster and may exert toxic effects on exposed organisms different than those noted for the brominated phthalates. However, insufficient experimental data are available to characterize ecotoxicity of the Firemaster® 550 formulation and, thus, a comparison of the more homogenous brominated phthalate formulations to the more heterogeneous aryl phosphate and brominated phthalate formulations cannot be made. Risk determination of aryl phosphates is outside the scope of the brominated phthalates Problem Formulation and Data Needs Assessment" (Technical Supplement on Hazard, p. 18).

[31] Babich, M.A., et al., "CPSC Staff Preliminary Risk Assessment of Flame Retardant (FR) Chemicals in Upholstered Furniture Foam." 30 January 2006. Available at: https://www.cpsc.gov/PageFiles/88163/uhff1.pdf.

[32] Note that CPSC more specifically concluded that the phosphate components do not pose an appreciable risk, while they could not come to a conclusion for the brominated components.

EPA's inaction on Firemaster 550 has earned warranted media attention. In September 2015, a Chicago Tribune article[33] lamented that "The EPA vowed in 2012 to take a closer look at Firemaster 550. But in a statement this week, the agency said it still doesn't know enough about the flame retardant to take action." [34]

Given the public health urgency of understanding the risks posed by the widespread use of Firemaster 550, we strongly recommend that EPA prioritize identifying the specific data needed to assess the mixture and promptly act to obtain these data. To the extent data on both the mixture and the individual components are necessary to conduct such an assessment, EPA should simultaneously act to obtain both types of data. (We note that both TPP and ITPP are slated for Work Plan Chemical review; it would make sense at this time to include these chemicals in a risk assessment focused on Firemaster 550, although doing so should not constitute the full extent of EPA's assessment of these chemicals, given that they have other uses.)

II. EPA's documents raise serious concerns regarding transparency, data availability, and confidentiality claims.

EDF is very concerned about a serious lack of transparency in the present documents, including:

1) EPA's failure to make available or provide a means for the public to access information in EPA's possession or that EPA cites relating to cluster members;

2) its failure to clearly indicate the extent to which information on which it is relying is available even to the agency or to which summarizes of information EPA does provide were developed by EPA or, if not, have been reviewed for accuracy and completeness by the Agency;

3) its initial withholding of generic , non-confidential identifiers for two cluster members (identified by EPA only as "Confidential A" and "Confidential B"), which only after considerable public pressure were released, eventually leading commenters' to seek and gain access to a heavily redacted consent order EPA had negotiated with the manufacturer of one of the two chemicals that indicates EPA

[33] Hawthorne, M., "CPSC considers ban on toxic flame retardants in household products." 2015. *Chicago Tribune*. Available at: http://www.chicagotribune.com/news/watchdog/ct-flame-retardants-toxic-chemicals-met-20150925-story.html.

[34] A July 2012 *Chicago Tribune* article further explains that: "Jones said the EPA will use its limited authority under the existing law to target several flame retardants, including one chemical mixture that the agency promoted as safe nearly a decade ago and is now widely sold under the brand name Firemaster 550." Article available at: http://articles.chicagotribune.com/2012-07-18/news/ct-met-flame-retardants-hearing-20120718_1_tobacco-and-chemical-industries-flame-retardants-firemaster.

However, the Senate Hearing referenced by the *Chicago Tribune* discusses specifically EPA's addition of TBB and TBPH to the Work Plan Chemical process. It does not indicate that EPA will assess the Firemaster 550 mixture. Senate Hearing available at: https://www.gpo.gov/fdsys/pkg/CHRG-112shrg75478/html/CHRG-112shrg75478.htm.

had raised significant concerns about the potential health and environment impacts of the chemical and had imposed testing requirements – neither of which are described in the present documents; and

4) most concerning of all, the Agency's apparent longstanding unquestioning acceptance – in direct conflict with the requirements of TSCA – of claims asserted by submitters of health and safety studies upon which EPA is relying that such information is confidential and cannot be shared with the public.

A. Unchallenged unlawful confidentiality claims

EPA repeatedly cites, as a basis for statements in its documents, a source referenced as "Chemtura, 2012a." That reference leads to an August 27, 2012 letter from Chemtura Corporation to EPA – described by the company as providing "[t]he non-CBI portions of Chemtura's August 27, 2012 submission of information for 3 workplan chemicals." An attachment to the letter lists health and safety studies the company was transmitting to EPA on a member of the current cluster, TBB (CAS# 183658-27-7). The letter notes that it enclosed a "CD containing CONFIDENTIAL studies" on TBB (emphasis in original).

EPA's documents include other references to "confidential" health and safety studies or data. For example, the Technical Supplement on Hazard states (p. 17):

> The environmental hazard of brominated phthalates reviewed and summarized in this section is based on studies located and reviewed from EPA's TSCATS databases (public), public literature searches, and **other confidential sources; information from confidential sources not already public were excluded from this assessment**. (p. 17, emphasis added)

Section 14(b) of TSCA precludes health and safety studies and their underlying data from being protected from disclosure as confidential business information (CBI), with two narrow exceptions for information that would reveal process or mixture portionality. Yet EPA appears never to have even challenged the company's blanket confidentiality claim covering these studies and as a result has not made the studies available or provided any means of accessing them in the present documents.

B. Reliance on "robust summaries"

When we made inquiries about these studies, EPA indicated that "robust summaries" of each of them are provided in a 2004 risk assessment conducted by the Australian government on a mixture, Firemaster BZ-54, containing TBB. While summaries of many of the referenced studies are indeed in an attachment to the Australian assessment,[35] there are not summaries for four.[36] After considerable

[35] National Industrial Chemicals Notification and Assessment Scheme (NICNAS, Australia), "Full Public Report: BZ-54." ("NICNAS report".) Available at: http://www.nicnas.gov.au/__data/assets/pdf_file/0004/9418/NA649FR.pdf.

further investigation, we were able to discern that these four studies were mandated by consent order EPA negotiated with Chemtura, three of them several years after publication of the Australian report. No summaries appear to be publicly available anywhere for these studies.

Even for those studies for which summaries are available through the Australian report, it is entirely unclear whether those summaries were prepared by Chemtura or the Australian government agency, or whether their quality and completeness was assessed and affirmed by the Australian government agency or by EPA. It appears most likely that the summaries were prepared by TBB's manufacturer and simply passed along by the Australian government agency via their attachment to its assessment, and now by EPA via its reference to the Australian report.

This is an unacceptable situation: It violates the clear language of TSCA; it obscures the extent to which EPA is relying on the manufacturer's conclusions as to the findings of the studies; and it denies the public any ability to independently assess the conclusions EPA draws as to the adequacy of available data on TBB or the data needs EPA has identified.

<u>EPA needs to act promptly to rectify this situation:</u>

- It should promptly reject the confidentiality claims asserted by Chemtura, and provide public access to these health and safety studies.
- If EPA intends to utilize robust summaries as a primary means of providing public access to health and safety studies, it must, at a minimum:
    - itself prepare the summaries, or carefully review summaries prepared by another entity (whether Chemtura or the Australian agency) against the full studies and vouch for their accuracy and completeness;
    - make clear that such studies are not eligible for CBI protection and make the full studies publicly available upon request; and
    - if EPA does not have access to a full study it cites, EPA must:
        - make that abundantly clear;
        - promptly seek access to the full study, using all available authorities; and
        - clearly identify the preparer of any summary of the study to which EPA refers, and in the case of summaries prepared by companies making or using the chemical, take into account the potential for bias in any decision EPA makes that relies to any extent on such a summary.
- It must put in place procedures and enforce practices internally to ensure this situation does not arise in future work plan chemical reviews.

---

[36] Robust summaries cannot be found for the 2-Generation Reproductive Study, the Prenatal Developmental Toxicity Study, the Migration Protocol, and the Porous Pot test. While we recognize that EPA includes a brief description of the two reproductive/developmental studies in the documents (see p. 14 of the Technical Supplement on Hazard), the only references provided (Chemtura 2012 letter, an MSDS, and the NICNAS report) do not provide robust summaries. Therefore, it is impossible to discern if the conclusions and NOAELs presented in the current document for these critical studies have been vetted by EPA or are those of Chemtura. Note also that the reference for these two studies in Table 1-3 of the Hazard supplement is footnote "14," which does not have a corresponding description/citation.

C. Inappropriate withholding of *non-confidential* identifying information for cluster members identified as "Confidential A" and "Confidential B"

When EPA released this Problem Formulation and Data Needs Assessment, it listed two members of the cluster only as "Confidential A" and "Confidential B." No further identifying information was provided in the cluster documents. This was wholly unacceptable.

TSCA and its implementing regulations[37] require that, where the specific identity of a chemical is deemed confidential business information (CBI), the CBI claimant is to provide a *structurally descriptive* generic name and EPA is to use that name to publicly identify the chemical. EPA has provided extensive instructions[38] to claimants on how to develop such generic names, which precludes using names that do not provide structural class information. Once manufacture of such a chemical commences, the generic name and an accession number are to be placed on the non-confidential portion of the TSCA Inventory.

Yet EPA did not even provide the generic names and accession numbers – which by definition are NOT confidential – for these two cluster members. Importantly, those generic identifiers are already public on the TSCA Inventory and in various Federal Register notices (see below), but in the context of the Problem Formulation and Data Needs Assessment are impossible for the public to find because EPA has replaced them with "Confidential A" and "Confidential B."

EDF raised our strong concerns about this approach directly to EPA staff. We were told that EPA had unilaterally decided to withhold the generic names and accession numbers for these two chemicals, based on an argument that associating even the generic names of these two chemicals with this cluster might somehow reveal their confidential identities. That argument appears far-fetched – how would generic identifiers allow someone to glean the specific identities? – and it flies in the face of the very purpose of a generic name – which is to be used publicly to refer to a chemical the identity of which is confidential and cannot be disclosed.

In response to our pressing on this, EPA contacted the company(ies) and was told they did not object to the generic names being made available. After several additional inquiries from us, EPA disclosed the generic names and Premanufacture Notice (PMN) case numbers for these two chemicals through a memo released on December 7th, 2015.[39] EDF used these identifiers to locate the Federal Register notices announcing receipt of their respective PMNs and of their subsequent notices of commencement (NOCs). The limited information we were able to find is below.

---

[37] TSCA Section 5(d)(2); 40 C.F.R. §§ 720.85(b)(5), 720.90(c), (d).

[38] EPA, "Instructions for Developing Generic Names for Premanufacture Notices (PMNs) in the TSCA Inventory." Last Updated 10 September 2015. Available at: http://www.epa.gov/tsca-inventory/instructions-developing-generic-names-premanufacture-notices-pmns-tsca-inventory.

[39] Szilagyi, M., EPA, "PMN number associated with two substances identified as Confidential A and Confidential B in the Brominated Phthalates Cluster Flame Retardants Data Needs Assessment: Docket EPA-HQ-OPPT-2014-0491." Available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2014-0491-0009.

While inconspicuous in the documents,[40] EPA issued a Section 5(e) consent order in 2009[41] on Confidential A as a result of its review through the New Chemicals Program. Once EPA made public the PMN case number for Confidential A, as described above, we were able to obtain a heavily redacted version of this consent order. Based on data from chemicals structurally similar to Confidential A, the consent order indicates serious concerns regarding liver and kidney toxicity; potential PBT characteristics; and potential carcinogenicity due to formation of byproducts during combustion of consumer products in municipal incinerators. In the consent order, the Agency concluded that "the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance," and imposed testing requirements triggered at a specified (redacted) production volume, which has not been triggered according to the current Problem Formulation and Data Needs Assessment.[42] Because Confidential A is not in the CDR,[43] we expect that the production of this chemical substance is less than 25,000 lb/year/site of production, the threshold for CDR reporting.

This contrasts with the New Chemicals Program review for Confidential B, which we were able to determine – once EPA released its generic name and PMN case study – was submitted to the program 8 years earlier.[44] Despite apparently strong structural similarity to Confidential A and other cluster members, Confidential B seems to have sailed through the New Chemicals program: there is no evidence we could find that EPA issued a Section 5(e) consent order to restrict its use or require any testing, and today Confidential B is produced in very large quantities (more than 1 million lb/year).[45] It is troubling that Confidential B went through the New Chemicals Program without any imposed testing requirement or other restrictions, given that EPA has now included it in a cluster of chemicals with known toxicity and PBT characteristics.

Furthermore, given that Confidential A and Confidential B are structurally similar, it is puzzling why the same structural analogue data used in the New Chemicals review process for Confidential A (as described in the consent order) would not have been applied similarly to Confidential B. While we recognize the possibility that new information on Confidential A or the analogue chemicals were

---

[40] There are two brief mentions of the consent order, one on p. 19 of the Problem Formulation and Data Needs Assessment and another on p. 4 of the Technical Supplement on Use and Exposure supplement. There are no citations or indications as to how to obtain the referenced consent order.

[41] Consent Order for P-04-0404, 2009. Available at: http://blogs.edf.org/health/files/2016/01/P04-404-Consent-Order_Confidential-A.pdf

[42] See Problem Formulation and Data Needs Assessment, p. 19.

[43] It can be inferred that Confidential A is not on the CDR, as p. 11 of the Problem Formulation and Data Needs Assessment indicates that "Only one of the two confidential cluster member was reported in CDR" and p. 19 indicates that Confidential B 2012 CDR data is available but withheld.

[44] This can be determined by comparing the first set of numbers from the PMN of Confidential A ('04) and Confidential B ('96).

[45] See p. 11 of the Problem Formulation and Data Needs Assessment: "All chemicals, except for Bromo Alkyl Ester (CASRN 7415-86-3) and Confidential A, are all found in commerce at volumes greater than one million pounds."

developed during the eight years after EPA's review of Confidential B, it is not clear why EPA did not raise any concerns about Confidential B even as its production volume soared.

Given that Confidential B, a chemical that passed through the New Chemicals Program despite the absence of toxicity data,[46] is currently being produced at volumes greater than 1 million lb/year, we strongly urge EPA to prioritize obtaining the data needed to conduct an assessment of this chemical. The data needs for Confidential B (as well as Confidential A) are completely obscured in these documents. For example, both of these chemicals are excluded from the two Data Needs Conclusions Tables (3.1 and 3.2) in the Problem Formulation and Data Needs Assessment, an omission we can only presume is related to EPA's inappropriate withholding of even generic identifying information on these chemicals.[47]

We fail to understand how identifying data needs for these chemicals would constitute disclosure of legitimate CBI. These omissions raise a host of issues: Have the manufacturers of these chemicals actually asserted CBI claims for these data needs, or has EPA withheld them on its own initiative? If the former, has EPA reviewed such claims to determine whether they actually constitute trade secrets? If the latter, on what basis has EPA determined that their disclosure would breach legitimate CBI?

Had we not pressed EPA to release generic identifying information on these chemicals, the public would not be able to discern that they:

- were new chemicals that went through the PMN process;
- are now listed on the TSCA Inventory and are in commerce;
- for one of the chemicals (Confidential A), would not have been able to locate the consent order EPA negotiated based on significant toxicity concerns, which included testing requirements (although EPA indicates those were tied to its production reaching a certain volume (considered CBI and hence not disclosed) which has not (yet) been reached);
- for the other of the two (Confidential B), apparently had no conditions placed by EPA on its commercialization arising from EPA's review of its PMN, because no associated consent order or significant new use rule was found (however, because EPA does not routinely make consent orders public available, we cannot be certain about this); and
- were first made by Great Lakes Chemicals Corporation and a company that claimed its own identity confidential, respectively.

In sum, we are very concerned that EPA unilaterally withheld *non-confidential* information about these two chemicals from the public, based on an argument that is wholly inconsistent with TSCA and its

[46] No data are available for Confidential B, according to Table 1-2: Availability of human health data for the Brominated Phthalates Cluster of the Technical Supplement on Hazard (pp. 8-10).

[47] Footnotes to these tables indicate: "The nature of Confidential A and Confidential B cannot be disclosed. Data Gaps and Data Needs should be considered for both reactive and additive uses."

implementing regulations, which expressly provides for the public disclosure of generic identifiers where specific chemical identity is claimed to be CBI.

In the future, EPA should take and publicly describe steps to ensure such withholding of information from the public does not occur again, absent a sufficient legal rationale for any withholding.

Information EDF found on Confidential A and Confidential B:

	Case No.	Received Date	Projected Notice End Date	Manufacturer	Use	Generic name
Confidential A	P–04–0404	03/03/04	05/31/04	CBI	(G) Open, non-dispersive use	(G) Tetrabromophthalate diol diester
Confidential B	P–96–0965	04/17/96	07/16/96	Great Lakes Chemical Corporation	(G) Flame retardant for polymers	(G) Brominated phthalate diol

Links to the respective PMNs,NOCs, and Consent Order are as follows:

Confidential A/P-04-0404: PMN Receipt, Notice of Commencement, Consent Order

Confidential B/P-96-0965: PMN Receipt, Notice of Commencement

D. Missing studies

The extent of industry-conducted studies on the BPC cluster chemicals and mixtures is not fully or appropriately reflected in the current documents, and many are difficult or impossible to track down from the information provided. For example, Table 3-1 in the Hazard Supplement, excludes a number of studies on the Firemaster BZ-54 mixture that were noted in the Australian assessment (the "NICNAS" report) as well as on Chemtura's website (see also the rightmost column in Table 1 in Section I above). Specially, EPA does not include two studies on genotoxicity, two sensitization studies, as well as skin and eye irritation studies.

Due to the concerns outlined above, we (along with other NGOs) requested a formal extension of the comment deadline until the Agency made public: 1) the consent order for Confidential A and any resulting health and safety studies, and 2) the health and safety studies and any underlying data on Firemaster BZ-54 that had been claimed confidential by Chemtura (as described earlier in this Section).[48] While we have been informally assured that our comments will be considered and included in the

[48] See EDF's request for an extension here: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2014-0491-0013.

official docket on Regulations.gov, EPA's denial[49] of our requested extension is unfortunate, as it ensured that those who provided comments within the official comment period were unable to evaluate and discuss these documents. In addition, access to the "confidential" studies has yet to be provided.

We understand that the Work Plan Chemical Program is relatively new and that the current Problem Formulation and Data Needs Assessment is the first to be published through this program. However, we are concerned that the early products of this program will be precedent-setting to some extent. We urge EPA to strive to improve transparency, clarity, and data availability regarding the BPC chemicals as they move through review under the program, and also to recognize the need for improvement in developing Problem Formulation and Data Needs Assessments in the future.

III. EPA needs to clearly summarize the data needs upfront.

Data needs are scattered throughout the Problem Formulation and Data Needs Assessment and the associated Technical Supplements. The background provided on the data needs throughout this document as well as the Data Needs Conclusions Tables (3-1 and 3-2) are useful; however, the main document would benefit from a clear summary of the priority data needs upfront.

We recommend that EPA create and make available such a summary, in which EPA succinctly (1-2 pages) encapsulates and prioritizes minimum data needs it believes are required to conduct a risk assessment for each relevant mixture or individual chemical component. How the hierarchy of data needs is being applied should be reflected in these summaries. The Data Needs sections in the Technical Supplement on Use and Exposure (pp. 25 and 34) may serve as a starting point, but are not currently comprehensive.

IV. EPA needs to set forth a plan and specific steps to obtain needed data.

EPA has taken a passive approach with regard to obtaining needed data identified in the Problem Formulation and Data Needs Assessment. EPA has not only failed to clearly state the priority data needs, but does not identify any steps it intends to take to obtain the needed data, e.g.: 1) explicitly request these data from the parties that would be able to provide it, and 2) put forth a regulatory plan to fill the data gaps.

In order to promptly move forward with a risk assessment, EPA must without delay act to obtain any data on hazard and exposure it deems necessary to conduct an assessment. We propose the following process and timeline:

---

[49] See EPA's denial of our requested extension here: http://blogs.edf.org/health/files/2016/01/2015_Dr.-Denison_Ms.-McCormick-BPC_denying_Ltr.pdf

1. Clearly lay out the minimum data needs to conduct a risk assessment (as described in Section III) (within ***30 days of receipt of these comments***).

2. Request submission of available data from industry (***60 days after minimum data needs document is published***).

3. Provide a deadline for the submission of those data (***90 days after information request published***).

4. Simultaneously with steps 2 and 3, begin developing TSCA Section 8 data call-ins as a supplement to data requests to industry and TSCA Section 4 test rules. If EPA does not receive the necessary data from the information request, it should promptly propose the Section 8 and/or Section 4 rules to obtain the data through regulatory action (***within 60 days of the information request deadline***).

In the case of TBB, we urge EPA to immediately begin promulgating a Section 4 test rule to fill any data gaps that the Agency believes are necessary to conduct a risk assessment. EPA has already met its "may present an unreasonable risk" statutory requirement for a Section 4 test rule as the basis for its issuance of the Section 5(e) consent orders on TBB.[50] The 2006 modified consent order[51] concludes that "pursuant to § 5(e) (1) (A) (ii) (I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment" (p. 12). Given that EPA has already fulfilled this critical statutory requirement, EPA should not delay in advancing Section 4 test rule(s) for TBB.

V. EPA has provided unclear or inadequate rationales for certain data needs decisions.

EPA rationales for prioritizing or omitting certain data needs are unclear or inadequate. We provide select examples below.

A. Decisions on hazard data needs for BPC chemicals

EPA does not provide a robust rationale for its decision to focus solely on reproductive/developmental toxicity and endocrine effects (thyroid and testes) as data needs for TBB and TBPH, and not other hazard endpoints. No hazard data needs are identified for the reactive BPC chemicals, TBPA-Diol and TBPA-Diol (mixed esters) (see below for further discussion). The basis for

[50] As described in the SNUR for TBB. Significant New Use of Certain Chemicals; 63 Federal Register, 3394. (January 22, 1998). Available here: https://www.gpo.gov/fdsys/pkg/FR-1998-01-22/pdf/98-1074.pdf.

[51] Modified Consent Order for P-95-1128, 2005. Available at: http://blogs.edf.org/health/files/2016/01/P-95-1128-Modified-Consent-Order.pdf.

EPA's decision to exclude carcinogenicity as a data need for the BPC chemicals is particularly vague and problematic.

The Problem Formulation and Data Needs Assessment states that "Screening level data do not suggest a concern for carcinogenicity with TBPH and the potential for a mode of action not relevant to humans (PPARα) further lowers the potential concern and the need for data for this chronic toxicity endpoint" (p. 38). It seems that EPA is using this statement as its sole rationale for excluding carcinogenicity as a data need for *any* of the BPC chemicals, as no other discussion of carcinogenicity is provided. EPA provides no citations to support its claim.

It appears that EPA's conclusion may be based partially on the available genotoxicity data, which mainly demonstrate negative findings. According to Table 1-3 of the Technical Supplement on Hazard, three genetic toxicity studies have been conducted on TBPH: Gene Mutation, *in vitro* (negative); Chromosomal Aberrations, *in vitro* (positive); and Chromosomal Aberrations, *in vivo* (negative). Although excluded from this table and not mentioned elsewhere in the documents,[52] it is our understanding that two other genetic toxicity tests have also been conducted on Firemaster BZ-54: Bacterial Reverse Mutation, *in vitro* (negative) and Chromosomal Aberrations, *in vitro* (negative).[53]

These data are not sufficient, however, to conclude that further investigation of the carcinogenic potential of the cluster chemicals is unwarranted. First, they reflect a limited data set (a handful of mostly *in vitro* studies) that interrogate only one potential mode of action for carcinogenicity (genotoxicity). Furthermore, we identified an additional study (cited by EPA but not in the context of the BPC chemicals' carcinogenicity potential) that found DNA damage in liver tissue of fathead minnows exposed to Firemaster BZ-54 and Firemaster 550, indicating genotoxic potential.[54] As a general matter, no comprehensive studies of carcinogenicity are presented.

EPA needs to consider the possibility that the cluster chemicals may be carcinogenic through a non-mutagenic mode of action, which would not be flagged through these genotoxicity assays. DEHP – a BPC chemical analogue, as described in EPA's current documents[55] – may be carcinogenic through a non-mutagenic mode of action. In 2000, IARC concluded that there is "sufficient evidence in experimental animals for the carcinogenicity of di(2-ethylhexyl) phthalate" and that DEHP is "possibly carcinogenic to humans (Group 2B)."[56] EPA also determined that DEHP is a probable human carcinogen

---

[52] See Section II for further discussion on issues with data availability throughout the documents.

[53] See NICNAS report, pp. 17-20.

[54] Bearr, J.S., Stapleton, H.M., Mitchelmore, C.L., "Accumulation and DNA damage in fathead minnows (Pimephales promelas) exposed to 2 brominated flame-retardant mixtures, Firemaster 550 and Firemaster BZ-54." 2010. *Environmental Toxicology and Chemistry*. Available here: http://www.ncbi.nlm.nih.gov/pubmed/20821500.

[55] See Problem Formulation Data Needs Assessment, p. 22.

[56] IARC Monograph, "Di(2-ethylhexyl) Phthalate." Volume 101. (Update to 2000 IARC monograph). Available at: http://monographs.iarc.fr/ENG/Monographs/vol101/mono101-006.pdf.

in its 1988 Integrated Risk Information System (IRIS) review,[57] and California listed it as "known to cause cancer" on its Proposition 65 list.[58] According to the 2000 IARC monograph, "DEHP produces liver tumors in rats and mice by a non-DNA-reactive mechanism involving peroxisome proliferation."[59] Furthermore, EPA's own 2015 Design for the Environment (DfE) Flame Retardant Alternatives Assessment, *Flame Retardants Used in Flexible Polyurethane Foam*, concludes that TBB has "Moderate hazard" for Carcinogenicity and "Low hazard" for Genotoxicity,[60] supporting again that it may be carcinogenic through a non-mutagenic mode of action.

EPA has also not substantiated its claim that carcinogenicity data are unnecessary because the potential mode of action (PPARα) is not relevant to humans. EPA's Problem Formulation and Data Needs Assessment documents provide no citations or even discussion to support this assertion. Furthermore, EPA has not adhered to its own 2003 policy, *Proposed OPPTS Science Policy: PPARα Mediated Hepatocarcinogenesis in Rodents and Relevance to Human Health Risk Assessments*.[61] The policy states (p. 16):

> Chemicals can produce tumors at a given site by more than one mode of action. Thus, before a PPARα agonist MOA can be defined as a cause of the liver tumors, it is also critical to ensure that other MOAs do not contribute significantly to the development of the tumors. For instance, it is important to ensure that direct DNA reactivity is not the source of the carcinogenic findings.

EPA has provided no evidence that PPARα is the only plausible mode of action through which the cluster chemicals might be carcinogenic.

Moreover, the updated IARC monograph on DEHP specifically calls into serious question the notion that a PPARα mode of action identified in a rodent study is not relevant to humans:

> [I]t should be noted that although important species differences in the activation of PPARα or its signalling network by peroxisome proliferators exist, human cells express PPARα and are not devoid of transactivation responses to many peroxisome proliferators, including MEHP. Important interindividual differences in PPARα expression have been reported, suggesting that the differences in expression between species may need to be verified using larger samples of both humans and animal strains. Thus,

---

[57] EPA, "Bis(2-ethylhexyl) phthalate (DHEP)." 2000. Last Updated 10 September 2015. Available at: http://www3.epa.gov/airtoxics/hlthef/eth-phth.html; EPA, Integrated Risk Information System (IRIS), "Di (2-ethylhexyl)phthalate (DEHP) Quickview (CASRN 117-81-7)." Last Updated 19 January 2016.

Available at: http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showQuickView&substance_nmbr=0014.

[58] OEHHA, "Chemicals Known to the State to Cause Cancer or Reproductive Toxicity." 4 December 2015. Available at: http://oehha.ca.gov/prop65/prop65_list/files/P65single120415.pdf.

[59] IARC Monographs Vol 77, 2000. Di(2-ethylhexyl) phthalate (DEHP). Available at: http://monographs.iarc.fr/ENG/Publications/techrep42/TR42-18.pdf (emphasis added, p. 188).

[60] EPA, "Flame Retardants Used in Flexible Polyurethane Foam: An Alternatives Assessment Update." August 2015. http://www.epa.gov/sites/production/files/2015-08/documents/ffr_final.pdf.

[61] EPA, Office of Prevention, Pesticides & Toxic Substances. "Proposed OPPTS Science Policy: PPARα-Mediated Hepatocarcinogenesis in Rodents and Relevance to Human Health Risk Assessments." 2003. Policy available at: http://archive.epa.gov/scipoly/sap/meetings/web/pdf/peroxisomeproliferatorsciencepolicypaper.pdf.

> although quantitative differences between species may well exist, qualitative similarities cannot be ignored, especially because DEHP and other PPARα activators are known to induce molecular responses independent of PPARα activation. It remains a possibility that these pathways contribute to human risk in ways that differ somewhat from those postulated for liver cancer in rats and mice. (pp. 254-255)[62]

Finally, it is also noteworthy that the DfE Alternatives Assessment also concludes that TBB has "Moderate hazard" for neurological effects, which are not addressed at all in the Problem Formulation and Data Needs Assessment.

B. Occupational Exposure

EPA provides the following description of the availability of occupational exposure data in the Problem Formulation and Data Needs Assessment:

> Limited data are available for occupational exposure to the cluster members leading to uncertainties in the exposure assessment. To reduce these uncertainties, workplace monitoring information (personal and/or area sampling for workers handling the chemical) would aid the risk assessment. Alternatively, in the absence of the monitoring data, information on manufacturing process, information on worker activities (activities performed during work shift, number of work hours/day, days/year of operation, concentration of the chemical and identification of worker activities which may result in inhalation exposure), and information on workplace industrial hygiene practices and control technologies would assist in the occupational exposure assessment. (p. 35)

The same information needs are listed in a footnote to the two Data Needs Conclusions tables (3-1 and 3-1) under the "data gaps" for worker exposure.

However, these data needs are not included in the "data needs" columns in those tables. Similarly, they are not included in the Human Exposure Data Needs presented in the Technical Supplement on Use and Exposure (Section 3.6, p. 34).[63] It is unclear if this is simply an inconsistency in summarizing data needs (as described in section III), or if EPA is intentionally not raising these gaps to the level of data needs, which would be more troubling. If the latter is the case, EPA has not adequately justified its decision not to address these gaps in occupational exposure data.

C. Prioritizing exposure data at the expense of hazard data

We caution EPA to carefully consider the implications of deprioritizating data needs based on limited exposure information. EPA appears to be employing a strategy in which exposure data are

[62] IARC Monograph, "Di(2-ethylhexyl) Phthalate." Volume 101. (Update to 2000 IARC monograph). Available at: http://monographs.iarc.fr/ENG/Monographs/vol101/mono101-006.pdf.

[63] It is possible that there is an error in Section 3.6 Data Needs (p. 34) under Human Exposure, as it is identical to Section 2.2 Data Needs (p. 25) under Environmental Exposure.

systematically to be prioritized over hazard data: "When exposure isn't expected, the characterization of hazard is not considered a priority, and while there may be hazard data gaps there is no need to generate these data to determine the risk for this exposure scenario" (Problem Formulation and Data Needs Assessment, p. 27). While we fully appreciate the need to prioritize data needs to move forward in a timely manner, we caution EPA against using weak, uncertain or incomplete data on exposure to justify not collecting either more exposure data or hazard data.

For example, it is inappropriate that EPA has chosen to ignore hazard data for the reactive chemicals, TBPA-Diol and TBPA-Diol (mixed esters), until potential worker and consumer exposure are determined.[64] This decision is presumably based on the assumption that there is little exposure to the reactive chemicals. However, it is unclear whether investigators have actually rigorously looked for the release of such chemicals; if so, EPA does not discuss or reference any such investigations. Further, EPA repeatedly claims that the reactive chemicals are not expected to migrate from PUF products without providing any confirming evidence or citations (see for example p. 17 of the Problem Formulation and Data Needs Assessment: "[b]ased on available data [nature of chemical reactivity and no detection in the environment], it is not anticipated that these chemicals are released from the PUF or PUF product.")

Yet EPA itself notes that rigid foam patents "suggest that additive BFR, like TBPH/TBB, *or excess unreacted reactive BFR*, are needed to make certain rigid foam applications meet certain safety requirements" (Problem Formulation and Data Needs Assessment, p. 15, emphasis added). In the absence of evidence, the potential for unreacted reactive flame retardants to migrate from the PUF products has to be considered a potential significant source of release.

We recommend a balanced approach of simultaneously acting to obtain both more hazard and exposure data on these chemicals. Waiting to obtain hazard data until after there is evidence of exposure will not only further delay assessment of these chemicals but also allow potentially dangerous exposures of humans and the environment to continue. Given the structural similarity of TBPA-Diol and TBPA-Diol (mixed esters) to the other cluster members, it seems that, at a minimum, testing data are needed on reproductive and developmental toxicity as well as endocrine disruption.

VI. Literature review of published data

The Problem Formulation and Data Needs Assessment and associated Technical Support documents do not provide an adequate description of the approach EPA used to search the broader literature, or the approach it intends to use in identifying, collecting, evaluating, and selecting studies for inclusion moving forward. The *only* insight into this process is the following: "EPA/OPPT reviewed the public literature (nominally to August 2013) and its own files (public and confidential) in the preparation of this assessment. Data adequacy was determined following published EPA/OPPT criteria" (Problem Formulation and Data Needs Assessment, p. 13).

[64] See Table 3-2 in the Problem Formulation and Data Needs Assessment, p. 45-46.

The lack of clarity on the literature review process it used is particularly troubling, given that EPA appears to have already decided that there are insufficient data to move forward with a risk assessment at this time. Future Problem Formulation and Data Needs Assessments should more fully describe the process for identifying and evaluating scientific research studies, government documents, and grey literature (e.g., REACH dossiers; unpublished industry regulatory studies).

We are also concerned that the Agency is ignoring relevant published literature. While some references to published literature are made in various places throughout the documents, it is unclear whether the Agency is considering these data for use in quantitative risk assessment or when concluding insufficient data exist. In the Technical Supplement on Hazard, EPA presents the data availability and hazard data for the cluster chemicals in Tables 1-2 and 1-3 (pp. 8-12), which includes Chemtura data received pursuant to the TBB modified consent order, High Production Volume (HPV) program, ECHA[65] and NICNAS. Notably missing from these tables, however, are published, peer-reviewed studies in the scientific literature.

Similarly, EPA claims that there are only two available chronic aquatic toxicity studies on TBPH and the TBPH/TBB mixture.[66] However, a 2010 Bearre et al.[67] study (listed below) – the toxicity data from which are not referenced anywhere in EPA's documents – provides data on fathead minnows exposed to Firemaster 550 and Firemaster BZ-54 for 56 days. The results demonstrated that exposure to Firemaster BZ-54 led to reversible DNA damage in the liver.

It also appears that EPA is overemphasizing Good Laboratory Practice (GLP) and guideline studies conducted by the regulated industry at the expense of the published, peer-reviewed studies in the literature. Where published research studies are referenced in these documents, they are labeled as "non-guideline studies."[68] Yet GLP/guideline studies are not inherently of higher quality than published, peer-reviewed studies; indeed, GLP and related processes were made necessary due to misconduct and fraud in laboratory practices by chemical, pesticide, and drug companies.[69] Not only are published studies typically subject to a rigorous peer review process, unlike industry studies, but they are less likely to suffer from "funder bias" than industry studies.[70,71]

---

[65] Note that EPA does not have access to the full studies. See footnote 4 on p. 8 of the Technical Supplement on Hazard.

[66] See Problem Formulation and Data Needs Assessment, p. 39.

[67] Bearr, J.S., Stapleton, H.M., Mitchelmore, C.L., "Accumulation and DNA damage in fathead minnows (Pimephales promelas) exposed to 2 brominated flame-retardant mixtures, Firemaster 550 and Firemaster BZ-54." 2010. *Environmental Toxicology and Chemistry*. Available here: http://www.ncbi.nlm.nih.gov/pubmed/20821500.

[68] For example, see p. 13 of the Problem Formulation and Data Needs Assessment.

[69] See EDF's 2013 blog, "EDF comments at National Academy of Sciences workshop on "weight of evidence" in chemical assessments": http://blogs.edf.org/health/2013/03/29/edf-comments-at-national-academy-of-sciences-workshop-on-weight-of-evidence-in-chemical-assessments-2/.

[70] Bero, L. Powerpoint: Name that bias: lessons learned from empirical studies of bias in clinical research. https://ntp.niehs.nih.gov/ntp/ohat/evaluationprocess/presentations/march2013/bero20130320_508.pdf and

Based on our own relatively cursory review of the literature, we identified 20 relevant published, peer-reviewed studies, listed below, that were not addressed or even cited in the present EPA documents. Many of these studies directly evaluate the toxicity of Firemaster products, and some include data on the individual components. Furthermore, the August 2013 date EPA cites as its cut-off for published literature excludes a considerable amount of data published between August 2013 and August 2015, including most of those studies we identify below (12 of the studies were published between August 2013 and August 2015).

(Note: In the list below, if the test substance is not clear from the citation we have added the relevant chemical or Firemaster products evaluated in brackets at the end of the citation. Studies published after August 2015 are marked with an asterisk.)

Metabolism & Hazard

- Bailey, J. M. and Levin, E. D. (2015). "Neurotoxicity of FireMaster 550® in zebrafish (*Danio rerio*): Chronic developmental and acute adolescent exposures." *Neurotoxicology and Teratology*, 52(Part B): 210-219.*

- Bearr, S. J., Stapleton, H. M., and Mitchelmore, C. L. (2010). "Accumulation and DNA Damage in Fathead Minnows (*Pimephales Promelas*) Exposure to 2 Brominated Flame-Retardant Mixtures, Firemaster 550 and Firemaster BZ-54." *Environmental Toxicology and Chemistry*, 29(3): 722-729.[72]

- Belcher, S. M., Cookman, C. J., Patisaul, H. B., et al. (2014). "In vitro assessment of human nuclear hormone receptor activity and cytotoxicity of the flame retardant mixture FM 550 and its triarylphosphate and brominated components." *Toxicology Letters*, 288(2): 93-102.

- Dishaw, L. V., Macaulay, L. J., Roberts, C. S., et al. (2014). "Exposures, mechanisms, and impacts of endocrine-active flame retardants." *Current Opinion in Pharmacology*, 19: 125-133. [Review article including Firemaster 550]

- Fang, M., Webster, T. F., Ferguson, P. L, et al. (2015). "Characterizing the Peroxisome Proliferator-Activated Receptor (PPARγ) Ligand Binding Potential of Several Major Flame Retardants, Their Metabolites, and Chemical Mixtures in House Dust." Environmental Health Perspectives, 123(2): 166-172. [TBB, TBPH, TPP, ITPP]

Bero, L. "Reducing Bias in Research": https://ntp.niehs.nih.gov/ntp/ohat/evaluationprocess/presentations/march2013/bero20130320_508.pdf.

[71] Comments from Earthjustice, NRDC, and Washington Toxics Coalition on Problem Formulation and Initial Assessment Documents for Three Flame Retardant Clusters, p. 8: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2014-0730-0020.

[72] Note that while this study was cited in the Supplement on Exposure and Use, its findings regarding toxicity are not mentioned in any of the documents.

- Johnson, P. I., Stapleton, M. H., Mukherjee, B., et al. (2013) "Associations between brominated flame retardants in house dust and hormone levels in men." *Science of the Total Environment*, 445-445: 177-184. [TBPH]

- McGee, S. P., Konstantinov, A., Stapleton, H. M., et al. (2013). "Aryl Phosphate Esters Within a Major PentaBDE Replacement Product Induce Cardiotoxicity in Developing Zebrafish Embryos: Potential Role of the Aryl Hydrocarbon Receptor." *Toxicological Sciences*, 133(1): 144-156. [TBB, TBPH, TPP, ITPP isomers]

- Pallai, H. K., Fang, M., Beglov, D. et al. (2014). "Ligand Binding and Activation of PPARγ by Firemaster® 550: Effects on Adipogenesis and Osteogenesis in Vitro." *Environmental Health Perspectives*, 122(11): 1225-1232.

- Patisaul, H. B., Roberts, S., Mabrey, N., et al. (2013). "Accumulation and Endocrine Disrupting Effects of the Flame Retardant Mixture Firemaster® 550 in Rats: An Exploratory Assessment." *J Biochem Mol Toxicol.*, 27(2): 124-136.

- Roberts, S. C., Macaulay, L., J., and Stapleton, H. M. (2012). "In Vitro Metabolism of the Brominated Flame Retardants 2-Ethylhexyl-2,3,4,5-Tetrabromobenzoate (TBB) and Bis(2-ethylhexyl) 2,3,4,5-Tetrabromophthalate (TBPH) in Human and Rat Tissues." *Chem. Res. Toxicol., 25* (7): 1435–1441.

- Saunders, D. M. V., Higley, E. B., Hecker, M. et al. (2013). "In vitro endocrine disruption and TCDD-like effects of three novel brominated flame retardants: TBPH, TBB, & TBCO." *Toxicology Letters*, 223: 252-259.

- Saunders, D. M. V., Podaima, M., Codling, G., et al. (2015) "A mixture of the novel brominated flame retardants TBPH and TBB affects fecundity and transcript profiles of the HPGL-axis in Japanese medaka." *Aquatic Toxicology*, 158: 14-21.

- Scanlan, L, D., Loguinov, ZA. V., Teng, Q., et al. (2015). "Gene Transcription, Metabolite and Lipid Profiling in Eco-Indicator Daphnia magna Indicate Diverse Mechanisms of Toxicity by Legacy and Emerging Flame-Retardants." *Environmental Science & Technology*, 49(12): 74000-7410. [Firemaster 550 and Firemaster BZ-54]

<u>Exposure</u>

- Abbasi, G., Saini, A., Goosey, E., et al. (2016). Product screening for sources of halogenated flame retardants in Canadian house and office dust. Science of the Total Environment, 545-546: 299-307.* [TBB and TBPH]

- Bradman, A., Castorina, R., Gaspar, F., et al. (2014). "Flame retardant exposures in California early childhood education environments." *Chemosphere,* 116: 61-66.[73] [TBB and TBPH]

- Butt, C. M, Congleton, J., Hoffman, K., et al. (2012). "Metabolites of Organophosphate Flame Retardants and 2-Ethylhexyl Tetrabromobenzoate in Urine from Paired Mothers and Toddlers." E*nviron. Sci., Technol.*, 48: 10432-10438. [TBBA, metabolite of TBB]

- Hoffman, K., Fang, M., Horman, B., et al. (2014). "Urinary Tetrabromobenzoic Acid (TBBA) as a Biomarker of Exposure to the Flame Retardant Mixture Firemaster® 550." *Environmental Health Perspectives*, 122(9): 963-969.

- La Guardia, M L., and Hale, R. C. (2015). "Halogenated flame-retardant concentrations in settled dust, respirable and inhalable particulates and polyurethane foam at gymnastic training facilities and residences." *Environment International*, 79: 106-114. [TBB, TBPH]

- Peng, H., Saunders, D. M., Sun, J., et al. (2015). "Detection, identification, and quantification of hydroxylated bis(2-ethylhexyl)-tetrabromophthalate isomers in house dust." *Environmental Science & Technology*, 49(5): 2999-3006.

- Stapleton, H. M., Misenheimer, J., Hoffman, K., et al. (2014). "Flame retardant associations between children's handwipes and house dust." *Chemosphere,* 116 (2014): 54–60. [TBB, TBPH]

VIII. Longstanding data gaps: Consequences and shortcomings of EPA's historically passive approach to obtaining and reviewing data on the risks of the BPC chemicals and their use in Firemaster products.

A. Continued data gaps on TBB twenty years after initial EPA review exemplifies shortcomings of the New Chemicals Program.

Chemtura submitted a premanufacture notice (PMN)[74] for TBB to EPA in 1995 for its use in Firemaster flame retardant products. Five studies on a chemical analogue (identity redacted) were submitted with the PMN. Based on the initial review by the New Chemicals Program, EPA concluded that there may be toxicity concerns for the PMN substance and entered into a Section 5(e) consent order with the company in 1996. The consent order required the company to submit a number of

[73] Note that EPA did include a related report, *Environmental Exposures in Early Childhood Education Environments.* Available at: http://www.arb.ca.gov/research/apr/past/08-305.pdf.

[74] See p-95-1128 in Certain Chemicals; Premanufacture Notices; 60 Federal Register, 41298 (August 11, 1995). Available at: https://www.gpo.gov/fdsys/pkg/FR-1995-08-11/pdf/95-19903.pdf.

studies on the PMN substance[75] prior to the manufacturing or importing a specified volume of TBB (volume redacted).

In 2004, EPA initiated a second review, based on concerning new data on and structural similarities to the flame retardant chemicals that TBB was meant to replace (PBDEs). A modified consent order[76] issued in 2005 required the company to submit additional data (again, at a specified but redacted production volume trigger) and imposed some limited restrictions (e.g., label containers of the substance and provide worker trainings).

In 2012, EPA Assistant Administrator Jim Jones testified[77] before a Senate committee that the Agency's review of TBB missed key concerns because it failed to identify the chemical's persistence, bioaccumulative and toxic potential:

> EPA first reviewed a new flame-retardant component of several products in 1995 for use in polyurethane foam and was unable to identify that a component of flame retardants [TBB] was persistent, bioaccumulative and toxic. Later, after the chemicals were in commerce, information became available that showed the chemicals were being found in humans and the environment.

It is deeply troubling that TBB has been reviewed through the New Chemicals Program twice, yet two decades after initial market entry and a decade after its second review, not only is there concern and uncertainty regarding the risk posed by this chemical, but EPA maintains that there continue to be insufficient data to conduct a risk assessment. The Problem Formulation and Data Needs Assessment concludes:

> EPA/OPPT found that while the data for FiremasterBZ-54 are sufficient to support a determination that TBB may present an unreasonable risk in certain scenarios, this review identified critical data gaps and uncertainties related to exposure and hazard which preclude EPA/OPPT from moving forward with an assessment for any of the chemicals in the Brominated Phthalates Cluster. (p. 7)

EPA notes the inadequacy of the available data throughout the document. For example, it notes that "no hazard data are available for TBB"[78] (Problem Formulation and Data Needs Assessment, p. 22), and that "[a]vailable chronic toxicity data (Firemaster BZ-54) are inconclusive" (Table 3-1 in Problem Formulation and Data Needs Assessment, p. 42). Similarly, EPA's prior review of TBB (i.e., as presented in the modified consent order) concluded that "EPA is unable to determine the potential for human health effects, including developmental and reproductive effects, from consumer exposure to the PMN

[75] Note that the submitted studies were on the Firemaster BZ-54 mixture.

[76] Modified Consent Order for P-95-1128, 2005. Available at: http://blogs.edf.org/health/files/2016/01/P-95-1128-Modified-Consent-Order.pdf.

[77] Statement of James J. Jones, Senate Hearing. "Are consumers adequately protected from flammability of upholstered furniture? Hearing on the effectiveness of furniture flammability standards and flame-retardant chemicals." Hearing 112-705. 18 July 2012. https://www.gpo.gov/fdsys/pkg/CHRG-112shrg75478/html/CHRG-112shrg75478.htm.

[78] We note that EPA is referring to data specific to TBB, not in the TBB/TBPH mixture found in Firemaster BZ-54.

substance" due to insufficient information available to the Agency to "permit a reasoned evaluation."[79] In the absence of what EPA deemed would be sufficient data, the Agency ultimately concluded that:

> In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e) (1) (A) (ii) (I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment. (p. 12)

EPA's current and earlier conclusions regarding the potential risks and data availability on TBB are in stark contrast to the following bold statement on Chemtura's website:[80]

> EPA required a rigorous review of the brominated component, TBB. In total, 15 studies were submitted to the EPA during the agency's decade-long assessment of TBB. Another 17 studies were conducted for regulatory authorities in other countries. These included studies specifically designed to assess the potential exposure of consumers to the substance, as well as the persistence and potential for bioaccumulation…Based on these studies our scientists concluded – and the EPA agreed – TBB is less persistent and less likely to bioaccumulate than the product it replaced. It was found to be suitable for use as a flame retardant in highly flammable foam.

This quote from Chemtura's website makes a number of misleading claims. First, Chemtura implies that the persistence and bioaccumulation of TBB is low (note that it makes a similar claim[81] in its recently submitted comments on the Problem Formulation and Data Needs Assessment) – and implicates EPA as supporting this conclusion. This assertion may have been based on a press release that EPA issued in 2003 stating: "EPA has recently completed a preliminary assessment of a Penta substitute, Firemaster® 550, and concluded that this alternative chemical is not persistent, bioaccumulative or toxic to aquatic organisms."[82]

However, EPA's 2003 statement *precedes* its initiation of a second review of TBB in 2004, which was based on new evidence of significant persistence and bioaccumulation of the structurally related chemicals (PBDEs) that TBB was intended to replace. It also significantly predates Assistant Administrator Jim Jones' testimony in 2012, cited above, noting that EPA had missed the persistence and bioaccumulation potential of TBB. Indeed, EPA has stated multiple times that TBB has significant

---

[79] See. P. 12 of Modified Consent Order for P-95-1128, 2005. Available at: http://blogs.edf.org/health/files/2016/01/P-95-1128-Modified-Consent-Order.pdf

[80] See Chemtura's website: http://chemturaflameretardants.com/index.html.

[81] Chemtura claims, without providing any citation: "Based on these studies, EPA determined that TBB has low potential for persistence and bioaccumulation." See Chemtura's December 2015 comments in the docket associated with these comments: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2014-0491-0014.

[82] See 2003 EPA Press Release: http://yosemite.epa.gov/opa/admpress.nsf/0/26f9f23c42cd007d85256dd4005525d2?OpenDocument.

potential for persistence and bioaccumulation, including in the current Problem Formulation and Data Needs Assessment[83] as well as in the Flame Retardant Alternatives Assessment, *Flame Retardants Used in Flexible Polyurethane Foam.*[84]

Second, Chemtura's language conflates and obscures the test substance evaluated in the Chemtura studies. Not only are the 32 studies referenced not actually on TBB (from our understanding, these data are on the Firemaster BZ-54 mixture, which also contains TBPH), but including these data under the website title "About Firemaster® 550 Flame Retardant" implies that conclusions as to the toxicity of Firemaster BZ-54 can be extended to Firemaster 550. As described above, the toxicity of Firemaster 550 may be different – and greater – than Firemaster BZ-54, given that it also contains two aryl phosphate flame retardant components. While Firemaster BZ-54 has undergone some review through the New Chemicals Program, there is no evidence to suggest that TBB as used in Firemaster 550 has undergone even this limited extent of review.

At the very least, this example highlights the major limitations of both the New Chemicals Program and the Existing Chemicals Program under TSCA. Over two decades, EPA has been unsuccessful in acquiring the data it believes are necessary to conduct a robust risk assessment of TBB and/or the Firemaster products and other component chemicals. Further, the limited screening assessment that was done is being used by the chemical's manufacturer to claim that a "robust review" has occurred – and that the product has EPA's stamp of approval.

To EPA's credit, it did initiate a second review due to new concerns about and structural similarities to the chemicals that TBB was to replace (PBDEs); following the modified consent order, Chemtura provided the Agency with a Prenatal Developmental Toxicity study and a Two Generation Reproduction study in 2008. However, seven years after obtaining these studies, EPA maintains that it does not have "[r]eliable information to characterize the hazard for reproductive/developmental toxicity" for either TBB or TBPH (Table 3-1 in Problem Formulation and Data Needs Assessment, p. 42-43). We must question why EPA has not required additional developmental and/or reproductive toxicity tests before now, if the ones it received a number of years ago were insufficient for risk assessment.

Until EPA receives the data it deems necessary and reaches risk conclusions regarding TBB and/or Firemaster products through comprehensive assessment, EPA should request that Chemtura remove the misleading language from its website.

---

[83] For example, see p. 9: "The cluster members are expected to be persistent, bioaccumulative and potentially hazardous to human health (developmental toxicity) and the environment (acute and chronic toxicity)."

[84] EPA, "Flame Retardants Used in Flexible Polyurethane Foam: An Alternatives Assessment Update." August 2015. http://www.epa.gov/sites/production/files/2015-08/documents/ffr_final.pdf.

B. EPA identified data gaps for BPC chemicals through HPV Challenge Program a decade ago that remain unfilled today.

As EPA notes, TBPH was sponsored under the HPV Challenge Program, and the sponsor's data and test plan were submitted to EPA in 2004.[85] That test plan argued that testing for reproductive/developmental toxicity was not necessary. In 2006, EPA provided the company comments on the test plan,[86] rejecting that argument and calling on the company to "provide data from a combined reproductive/ developmental toxicity screening test (OECD TG 421) using the sponsored substance." (EDF provided very similar comments on the test plan[87] calling for the same testing.) EPA's request appears to have gone unheeded. Yet EPA never included TBPH in any subsequent test rules for HPV chemicals for which the HPV Challenge program's requirements were not met. Now, a decade later, it is still in the position of identifying the same data gap as it did back then and holding up doing an assessment for that reason.

A very similar situation applies to cluster member TBPA Diol (mixed esters). It, too, was sponsored under the HPV Challenge Program, and the sponsor's data and test plan were submitted to EPA in 2004. That test plan argued that separate testing for reproductive/developmental toxicity was not necessary. In 2005, EPA provided the company comments on the test plan, rejecting that argument and called on the company to provide data "for the repeated-dose/reproductive/developmental toxicity endpoints, using the commercial product, according to OECD TG 422."[88] Again, EPA's request appears to have gone unheeded. Yet EPA never included this chemical in any subsequent test rules for HPV chemicals for which the HPV Challenge program's requirements were not met. Here again, a decade later, it is still in the position of identifying the same data gaps as it did back then and holding up doing an assessment for that reason.

C. EPA was directed by the TSCA Interagency Testing Committee (ITC) in 2011 to issue test and reporting rules for both TBB and TBPH, but has failed to do so.

In the Interagency Testing Committee's 69th report (November 2011), as reported by EPA in its Federal Register notice announcing receipt of the report,[89] the ITC recommended that TBB and TBPH be

[85] TBPH test plan: http://iaspub.epa.gov/oppthpv/document_api.download?FILE=c15484tp.pdf.

[86] EPA comments on TBPH test plan: http://iaspub.epa.gov/oppthpv/document_api.download?FILE=SN%20357%20EPA%20Comments.pdf.

[87] EDF's 2006 comments on TBPH test plan: http://iaspub.epa.gov/oppthpv/document_api.download?FILE=SN%20357%20ED%20Comments.pdf.

[88] The documents cited in these sentences are not currently accessible on EPA's website, so no links are able to be provided.

[89] Sixty-Ninth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments, 77 Fed. Reg. 30856 (May 23, 2012).

added to the TSCA Priority Testing List, and called on EPA to issue test rules for the two chemicals. According to TSCA Section 4(e), EPA was to have, within 12 months of the listing, either initiated test rules or published an explanation as to why it was not doing so. Implementing regulations at 40 CFR 712.30, 716.105 and 790.20, indicate these chemicals were also to have been added to the TSCA section 8(a) Preliminary Assessment Information Reporting (PAIR) rule (40 CFR part 712) and/or the TSCA section 8(d) Health and Safety Data Reporting (HaSDR) rule (40 CFR part 716).

We have been able to find no evidence that any test rule has been advanced or any explanation published as to why EPA chose not to do so. Nor does it appear that either of the section 8 rules was amended to add either of these chemicals. The failure of EPA either to initiate a test rule proceeding within 12 months of the ITC recommendation or to publish an explanation for why it was not doing so appears to be a failure to undertake a mandatory duty under TSCA section 4(e). More to the immediate point, this inaction represents yet another missed opportunity to have required the development or submission of information EPA is now saying is unavailable and necessary for it to be able to conduct a risk assessment for these chemicals.

VIII. EPA needs to better articulate its overall strategy and timeline for the TSCA Work Plan Chemical Program.

A. Risk assessments under the TSCA Work Plan Program should be viewed as ongoing.

The risk assessments completed and initiated thus far through the Work Plan Chemical program have been limited in scope,[90] typically due in large part to data gaps and limited resources. As new data are sought and become available, however, EPA should commit to update its risk assessments. It is critical that the Agency neither consider nor imply that its evaluations of these chemicals are in any way completed upon finalization of risk assessments of limited scope. We recommend that the Agency have a clear process to revisit work plan chemical assessments:

1) Based on new data obtained through section 4 test rules, section 8(a) and 8(d) rules, voluntary programs, other mechanisms used to close data gaps, or that otherwise become available.

2) Based on evidence of a change in the use patterns of a chemical. To the extent modeling informs a risk assessment, it may also be pertinent to rerun exposure models periodically (e.g., the pesticide program reruns its exposure models every time a new tolerance is considered).

[90] See, for example, EDF's comments on the TSCA Work Plan Chemical Problem Formulation Assessment for Chlorinated Phosphate Esters (CPEs): http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2015-0068-0015 and EDF and NRDC's joint comments on the Draft Chemical Risk Assessments from the EPA TSCA Work Plan: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2012-0723-0017.

B. EPA should establish and make publicly available a risk assessment development and completion schedule.

EPA should make public a target schedule for the draft and final assessments of TSCA Work Plan chemicals. Using this schedule, the status of individual assessments should be tracked and reported. Further, if EPA diverges from the schedule, a public explanation should be provided.

The schedules included in EPA's Integrated Review Plans (IRPs) – which serve a similar function as the current documents for the Agency's National Ambient Air Quality Standards (NAAQS) – serve as a good model. For example, the 2014 IRP for the Nitrogen Dioxide NAAQS[91] outlines an "Anticipated schedule," including major milestones and target dates from the initial stages of review through risk management steps (p. 2-3).

EDF appreciates the opportunity to provide these comments to the Agency on this important Problem Formulation and Data Needs Assessment.

Sincerely,

Richard A. Denison, PhD
Lead Senior Scientist

Lindsay A. McCormick, MPH
Research Analyst

Jon Choi
High Meadows Fellow

Jennifer McPartland, PhD
Senior Scientist

[91] US EPA, 2014. "Integrated Review Plan for the Primary National Ambient Air Quality Standards for Nitrogen Dioxide." Available at: http://www3.epa.gov/ttn/naaqs/standards/nox/data/201406finalirpprimaryno2.pdf.

McCormick

Attachment H

EARTHJUSTICE
Because the earth needs a good lawyer

ALASKA CALIFORNIA FLORIDA MID-PACIFIC NORTHEAST NORTHERN ROCKIES NORTHWEST ROCKY MOUNTAIN WASHINGTON, DC INTERNATIONAL

August 4, 2011

BY HAND DELIVERY

RECEIVED 8-4-2011 12:15pm

Lisa P. Jackson, Administrator
Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: Citizen Petition under Toxic Substances Control Act Regarding the Chemical Substances and Mixtures Used in Oil and Gas Exploration or Production

Dear Administrator Jackson:

The undersigned organizations ("Petitioners") hereby petition the U.S. Environmental Protection Agency ("EPA") pursuant to section 21 of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2620, to promulgate rules protecting public health and the environment from the serious risks posed by chemical substances and mixtures used in oil and gas exploration or production ("E&P Chemicals"). Specifically, Petitioners request that EPA adopt a rule under TSCA section 4, requiring that manufacturers and processors of E&P Chemicals conduct toxicity testing of all E&P Chemicals and identify all chemical substances and mixtures tested. *See id.* § 2603. Petitioners also seek promulgation of a rule under TSCA section 8, requiring maintenance and submission of various records related to E&P Chemicals, calling in records of allegations of significant adverse reactions to E&P Chemicals, and requiring submission of all existing health and safety studies related to E&P Chemicals. *See id.* § 2607(a), (c), (d). Rulemaking under TSCA sections 4 and 8 is necessary to ensure that the health and environmental risks posed by E&P Chemicals are fully understood.

EPA and the public lack adequate information about the health and environmental effects of E&P Chemicals, which are used in increasing amounts to facilitate the rapid expansion of oil and gas development throughout the United States. Within the next 20 years, the U.S. Department of Energy expects gas production to increase by more than four trillion cubic feet,[1] which could translate into the drilling of more than 60,000 wells in the Marcellus Shale in Pennsylvania alone.[2] Oil production, too, is on the rise for the first time in over 20 years, as a

---

* All documents cited in the following footnotes are reproduced on the enclosed CD-Rom.

[1] U.S. Dep't of Energy, U.S. Energy Info. Admin., Annual Energy Outlook 2009, 77 (Mar. 2009), *available at* http://www.eia.doe.gove/oiaf/aeo/pdf/trend_4.pdf.

[2] *See* Nels Johnson, *Pennsylvania Energy Impacts Assessment, Report 1: Marcellus Shale Natural Gas and Wind*, NATURE CONSERVANCY, 12 (Nov. 15, 2010), http://www.nature.org/media/pa/ tnc_energy_analysis.pdf.

result of the recent exploitation of unconventional plays such as the Bakken and Niobrara Shales.

The growth of the oil and gas industry is attributable to the widespread use of hydraulic fracturing, a technology that involves high-pressure injection of a mix of fluids, sand, and chemicals to stimulate the release of oil and gas from unconventional formations. Oil and gas development requires the use of both drilling muds, which are used to shorten drilling time and lubricate the drill bit, and fracturing fluids, which are used to create fractures in the formation and to hold the fractures open to release the oil and gas. Drilling muds and fracturing fluids require similar classes of chemical additives, including proppants, acids, breakers, bactericides, biocides, clay stabilizers, corrosion inhibitors, crosslinkers, friction reducers, gelling agents, iron controls, scale inhibitors, and surfactants.[3] Well operators vary the chemical additives that they use, based upon the characteristics of the well and production objectives.[4] More than ten thousand gallons of E&P Chemicals may be used to fracture a single well.[5]

Under the current regulatory scheme, manufacturers, processors, and distributors place substantial quantities of E&P Chemicals into commerce without first disclosing the chemicals' identity, toxicity, or health and environmental impacts. Chemical manufacturers and processors are, moreover, under no obligation to conduct toxicity testing or to develop or provide health and safety data for E&P Chemicals. As a result, the public lacks adequate information to evaluate the risks of harm to health and the environment posed by exposure to E&P Chemicals. Mounting reports of harm caused by E&P Chemicals, including injury to people, animals, and aquatic life, and degradation of air, water, and soil quality, demonstrate that unregulated E&P Chemicals may present an unreasonable risk of harm to health and the environment.

Congress enacted TSCA to ensure the availability of "adequate data" on the health and environmental effects of chemicals and "to assure that . . . chemical substances and mixtures do

---

[3] *See* N.Y. Dep't of Envtl. Conservation, Div. of Mineral Res., Draft Supplemental Generic Environmental Impact Statement on the Oil, Gas, and Solution Mining Regulatory Program, 5-45 to 5-51 (2009), *available at* ftp://ftp.dec.state.ny.us/dmn/download/OGdSGEISFull.pdf (hereinafter "DSGEIS"); Ronald E. Bishop, Ph.D., *Chemical and Biological Risk Assessment for Natural Gas Extraction in New York*, 11 (Mar. 28, 2011), http://www.ge.tt/#2VfEsZw (stating that "most hydraulic fracturing additives are also used in drilling fluids (or 'muds')").

[4] DSGEIS, *supra* note 3, at 5-33 to 5-34, 5-99.

[5] *See id.* at 5-34 (explaining that fracturing fluids typically are composed of 98 percent fresh water and sand and two percent chemicals), 5-92 to 5-93 (stating that the entire multi-stage fracturing operation for a single well requires between 2.4 and 7.8 million gallons of water); *cf.* Travis Madsen, Jordan Schneider & Erika Staaf, *In the Shadow of the Marcellus Boom*, PENNENVIRONMENT RESEARCH & POLICY CTR., 16 (May 2011), http://www.pennenvironment.org/uploads/49/f3/49f38a45f956d58a210d7e24a17ec26a/ In-the-Shadow-of-the-Marcellus-Boom.pdf (estimating that one gas well that requires three million gallons of fluid would require approximately 250,000 pounds of chemicals).

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

not present an unreasonable risk of injury to health or the environment."[6] At present, EPA and the public lack adequate data about the identity of E&P Chemicals, the number of E&P Chemicals in commerce, significant adverse reactions posed by E&P Chemicals, and health and environmental hazards, exposures, and risks posed by E&P Chemicals. Petitioners request that EPA ensure that E&P Chemicals do not present an unreasonable risk of harm to health and the environment by promulgating rules under TSCA sections 4 and 8.

I. Neither EPA's Study of the Potential Drinking Water Impacts of Hydraulic Fracturing nor a Voluntary Online Chemical Registry Is a Substitute for Rulemakings Under TSCA Sections 4 and 8.

EPA and other organizations recently have made attempts to address increased public concern about the potential risks to health and the environment posed by E&P Chemicals. EPA currently is conducting a study of the potential impacts of hydraulic fracturing on drinking water sources.[7] In addition, the Groundwater Protection Council ("GWPC") and the Interstate Oil and Gas Compact Commission ("IOGCC") recently created an online registry whereby well operators may voluntarily disclose the chemicals they use in their fracturing operations.[8] Neither EPA's study nor the voluntary registry imposes enforceable requirements upon manufacturers, processors, or distributors of E&P Chemicals, and rulemakings pursuant to TSCA sections 4 and 8 are necessary to fill this gap.

A. EPA's Study

EPA's study of the possible relationships between hydraulic fracturing and drinking water will not replace rulemakings under TSCA sections 4 and 8. Although E&P Chemicals do threaten drinking water supplies, their potential to cause harm to health and the environment does not stop there.[9] E&P Chemicals also threaten human health when they become airborne, and they pose significant risks of harm to soil quality, habitat for both terrestrial and aquatic wildlife, and the healthy functioning of complex ecosystems.

---

[6] 15 U.S.C. §§ 2601(b)(1), (3) (2006).

[7] *See* EPA, Office of Research and Dev., Draft Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources, at vii (Feb. 2011), *available at* http://water.epa.gov/type/groundwater/uic/class2/hydraulicfracturing/upload/HFStudyPlanDraft_SAB_020711.pdf (hereinafter "EPA Study") ("The overall purpose of this study is to understand the relationship between hydraulic fracturing and drinking water resources.").

[8] *See* GWPC & IOGCC, FracFocus Chemical Disclosure Registry, http://fracfocus.org/ (last visited Aug. 2, 2011).

[9] *See* EPA Study, *supra* note 7, at viii ("EPA recognizes that there are important potential research areas related to hydraulic fracturing other than those involving drinking water resources, including effects on air quality, aquatic and terrestrial ecosystem impacts, seismic risks, public safety concerns, occupational risks, and economic impacts. These topics are outside the scope of the current study, but should be examined in the future.").

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

To facilitate its study, EPA directed informational requests to nine hydraulic fracturing service providers, yet only five of those service providers also manufacture or process E&P Chemicals.[10] By relying largely on service providers to relay second-hand information from manufacturers, EPA's requests fail to reach many of those responsible for introducing E&P Chemicals into commerce in the first place.[11] Because manufacturers of E&P Chemicals often disclose minimal information about product compositions to their customers, any responses submitted by the service providers are likely to be incomplete.[12] Service providers, moreover, frequently resist disclosure. In fact, none of service providers responded to EPA's request within the 30-day deadline established in the letters, and one of them – Halliburton – promised compliance only after EPA subpoenaed the information.

EPA's study falls short of TSCA rulemakings because it will not require manufacturers and processors of E&P Chemicals to take proactive efforts to conduct testing or to develop health and safety data needed to evaluate the health and environmental risks of their substances and mixtures. Instead, EPA's study simply requires service providers to gather information available to them – much of which is obtained from the manufacturers – and submit it to EPA. EPA then will undertake its own efforts to evaluate the information submitted to determine the effects of hydraulic fracturing on drinking water supplies. Rulemakings under TSCA sections 4 and 8, on the other hand, would hold manufacturers and processors of E&P Chemicals responsible for gathering information, testing their products, and developing and submitting health and safety reports.[13]

B. The Voluntary Registry

The GWPC and the IOGCC recently created an online registry through which well operators may voluntarily disclose the chemicals that they use in hydraulic fracturing of oil and

---

[10] EPA issued voluntary information requests to the following nine natural gas service companies: BJ Services, Complete Production Services, Halliburton, Key Energy Services, Patterson-UTI, PRC, Inc., Schlumberger, Superior Well Services, and Weatherford. *See* Press Release, EPA, EPA Formally Requests Information from Companies About Chemicals Used in Natural Gas Extraction (Sept. 9, 2010), http://yosemite.epa.gov/opa/admpress.nsf/e77fdd4f5afd88a3852576b3005a604f/ec57125b66353b7e85257799005c1d64!OpenDocument. Only five of the companies – BJ Services, Inc., Halliburton, Schlumberger, Superior Well Services, and Weatherford – also function as manufacturers or processors of E&P Chemicals. EPA did not serve information requests on other manufacturers and processors of E&P Chemicals, such as Cudd Energy Services, Nalco Energy Services, Sanjel USA, and Aquaness Chemical.

[11] *See* TEDX, Health Effects Summary Statement, 5 (Jan. 27, 2011), http://www.endocrinedisruption.com/chemicals.multistate.php (follow link to "summary statement") (explaining that drilling and fracturing contractors companies largely rely on information from chemical manufacturers when responding to requests about the identity of the chemicals they use at well sites).

[12] *Id.*

[13] *See* 15 U.S.C. § 2601(b)(1).

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

gas wells.[14] Well operators that choose to use the registry have the opportunity to upload a variety of information about the chemicals they use at each well, including their functional purposes, ingredients, concentrations, and CAS numbers.[15] This voluntary registry is designed to allow the public to identify the chemicals being used at specific wells – at least those chemicals that are voluntarily disclosed.

Like EPA's study, the voluntary registry is not aimed at the manufacturers, processors, and distributors of E&P Chemicals who are answerable under TSCA. Moreover, the registry does not impose any enforceable requirements upon the well owners and operators that make – or choose not to make – voluntary disclosures. Because the registry is based upon voluntary disclosures, operators may choose to disclose only those chemicals posing the least risk to health and the environment, and the public could receive misleading or selective information.

II. Rulemakings Under TSCA Sections 4 and 8 Are Necessary to Fill Significant Gaps in Federal Regulation of E&P Chemicals.

Federal agencies have extremely limited authority to regulate E&P Chemicals.[16] Hydraulic fracturing is exempt from regulation under the Underground Injection Control program of the Safe Drinking Water Act, except when injected fluids contain diesel fuel.[17] Were hydraulic fracturing not specifically excluded from the definition of "underground injection," the oil and gas industry would be required to disclose in mandatory permit applications the "source and analysis of the physical and chemical characteristics" of all of the chemicals injected below ground to stimulate oil and gas production.[18] This exemption, commonly known as the "Halliburton Loophole," allows the oil and gas industry to conceal chemical formulas and to inject toxic fluids near drinking water supplies without EPA oversight.[19]

---

[14] *See* Frac Focus Chemical Disclosure Registry, *supra* note 8.

[15] The Chemical Abstracts Service is a division of the American Chemical Society and the "worlds [sic] authority for chemical information." CAS, FAQ List and Information for New Visitors, http://www.cas.org/aboutcas/faq.html (last visited Aug. 2, 2010). A CAS Number "provides an unambiguous way to identify a chemical substance or molecular structure when there are many possible systematic, generic, proprietary, or trivial names." *Id.*

[16] *See* Memorandum from Henry A. Waxman & Edward J. Markey to Members of the Subcommittee on Energy and Environment, Examining the Potential Impact of Hydraulic Fracturing, 2 (Feb. 18, 2010), *available at* http://democrats.energycommerce.house.gov/Press_111/20100218/hydraulic_fracturing_memo.pdf.

[17] 42 U.S.C. § 300h(d)(1)(B)(ii).

[18] EPA Form 7520-6: Underground Injection Control Permit Application, 5 (rev. Dec. 2008), *available at* http://www.epa.gov/safewater/uic/pdfs/reportingforms/7520-6.pdf.

[19] *See* Tracy Carluccio, *Will We Sacrifice Our Water for Gas?*, OUTDOOR AMERICA, Spring 2010, at 27-28, *available at* http://www.iwla.org/index.php?ht=a/GetDocumentAction/i/4272.

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

The oil and gas industry also avoids regulation under the Resource Conservation and Recovery Act ("RCRA"), which sets the standards for handling and disposal of hazardous wastes.[20] Wastes created by oil and gas exploration and production, including E&P Chemicals present in drilling fluids and produced waters, are not subject to regulation under RCRA.[21] Were oil and gas wastes subject to RCRA, those charged with handling the wastes would be required to demonstrate that the wastes were, for example, stored, transported, and disposed of in a way not harmful to the environment.[22]

In addition, the oil and gas industry is exempt from the provision of the Emergency Planning and Community Right to Know Act ("EPCRA"), under which EPA requires industrial and federal facilities with more than ten employees to report the toxic chemicals they release, store, and transfer.[23] Specifically, any facility that manufactures or processes a chemical in amounts over statutory thresholds must submit forms detailing the chemical identities, uses, and volumes; as well as onsite waste treatment and recycling methods and offsite transfer locations.[24] The chemical information contained in these reports, where otherwise mandated by EPCRA, is made publicly available in the Toxic Release Inventory, which is updated annually and serves to inform communities and citizens of chemical hazards to which they may be exposed.[25]

Although a few federal regulations require storage facilities and manufacturers to disclose certain information about the chemicals they store and manufacture, the information gathered pursuant to these regulations is extremely limited and not readily available to EPA or the public. First, under EPCRA, owners and operators of storage facilities holding in excess of 10,000 pounds of any hazardous chemical must submit chemical inventory information ("Tier II reports") to the state emergency response commission ("SERC"), local emergency planning committee ("LEPC"), and the local fire department in the area where the facilities are located.[26] Every state implementing the federal program has different Tier II reporting requirements, and the forms required to be completed by the storage facilities may differ by county and by

[20] *See* 42 U.S.C. § 6921(b)(2)(A).

[21] *See id.* ("[D]rilling fluids, produced waters, and other wastes associated with the exploration, development, or production of crude oil or natural gas or geothermal energy shall be subject only to existing State or Federal regulatory programs in lieu of this subchapter . . . .").

[22] *See* 42 U.S.C. § 6922.

[23] 40 C.F.R. §§ 372.22., 372.23 (2011).

[24] *Id.* §§ 372.25, 375.28; EPA, Form R: Approved OMB No. 2025-0009 (2010), http://www.epa.gov/tri/report/formR/RY2010_FormR_010511.pdf.

[25] *See id.*

[26] 42 U.S.C. § 11022(a)(1); 40 C.F.R. § 317.10 (setting the threshold for Tier II reports at 10,000 pounds for hazardous substances and 500 pounds for extremely hazardous substances).

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

company.[27] To obtain Tier II reports, moreover, the public must request them in writing from an SERC or LEPC.[28]

Second, under EPCRA and the Occupational Safety and Health Act, manufacturers and importers of E&P Chemicals are required to disclose certain chemicals on material safety data sheets ("MSDSs"), which are designed to protect employees working with hazardous chemicals by informing them about the risks associated with those chemicals.[29] MSDSs are governed by regulations promulgated by the Occupational Safety and Health Administration ("OSHA").[30] With or before the initial shipment, manufacturers and importers must provide MSDSs to any distributor or employer receiving their products, and employers must keep the MSDSs in the workplace and make them readily accessible to employees.[31] Employers required to maintain MSDSs at their facilities must file them with the SERC, LEPC, and fire department with jurisdiction over the facility.[32] The public may obtain MSDSs only upon written request to state and local agencies.[33]

MSDSs are the primary means by which the public has been able to obtain information about E&P Chemicals, yet the information they provide is inadequate to identify the full spectrum of E&P Chemicals or to evaluate the chemicals' health and environmental effects. This inadequacy results from OSHA's regulations governing MSDSs, which limit the information required to be disclosed in several ways. First, only "hazardous chemicals" need to be disclosed on MSDSs, and a chemical must have been subject to significant testing before it will be considered "hazardous" under the regulations.[34] There is, however, no requirement that E&P Chemicals ever be tested. Second, even where a chemical that has been sufficiently tested qualifies as "hazardous," the manufacturer may opt not to disclose it if it constitutes less than one percent of the volume of the product (or 0.1 percent of the volume of the product if the

---

[27] *See, e.g.*, EPA, Tier II Chemical Inventory Reports/Tier II Submit, http://www.epa.gov/oem/content/epcra/tier2.htm (last visited Aug. 2, 2011) (providing links to the different reporting requirements of each of the 50 states).

[28] 40 C.F.R. § 370.61.

[29] 42 U.S.C. § 11021(a)(1); 29 U.S.C. § 655; 29 C.F.R. § 1910.1200(g)(1) (requiring chemical manufacturers and importers to "obtain or develop" an MSDS for "each hazardous chemical they produce or import").

[30] 29 C.F.R. § 1910.1200.

[31] *Id.* § 1910.1200(g)(6)(i), (8).

[32] 42 U.S.C. § 11021(a)(1).

[33] *See* 40 C.F.R. § 370.60.

[34] *See* 29 C.F.R. § 1910.1200(c). A "[h]azardous chemical means any chemical which is a physical hazard or a health hazard." *Id.* A "physical hazard" is a "chemical for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive." *Id.* A "health hazard" is a "chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees." *Id.*

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

chemical is a carcinogen).[35] Third, a "hazardous chemical" need not be disclosed if the manufacturer claims that its identity is a trade secret.[36] The manufacturer unilaterally may withhold specific chemical information as proprietary if it determines that the trade secret classification can be "supported."[37]

Above all, MSDSs are an inadequate source of information because the chemical manufacturers have wide discretion in preparing the sheets.[38] OSHA publishes little guidance as to whether a chemical is hazardous and instead directs the manufacturers to "conduct a thorough evaluation" as to whether a chemical must be disclosed.[39] OSHA recognizes four separate lists identifying chemicals that are automatically "hazardous" as defined by the regulations,[40] but these lists are incomplete, contain only chemicals that already have been tested extensively, and are neither user-friendly nor readily understood by the ordinary citizen. Moreover, federal regulators provide little oversight in the manufacturers' decision-making process.[41] Given the broad exceptions carved out in OSHA's regulations, the manufacturers' ample discretion, and OSHA's lack of oversight, the regulations do not provide much incentive for disclosure on MSDSs.

In practice, when preparing MSDSs, manufacturers of E&P Chemicals take advantage of the ample discretion provided by OSHA's regulations and omit vital information about the chemical composition of their products.[42] For example, although manufacturers have

---

[35] *See id.* § 1910.1200(d)(5)(ii).

[36] *See id.* § 1910.1200(g)(2)(i).

[37] *Id.* § 1910.1200(i)(1)(i).

[38] *See, e.g.*, 29 C.F.R. § 1910.1200, App. B ("Hazard evaluation is a process which relies heavily on the professional judgment of the evaluator"); *see also* TEDX, Health Effects Summary Statement, *supra* note 11, at 1 ("The accuracy and completeness [of MSDSs] are entirely up to the company that produces the MSDS").

[39] 29 C.F.R. § 1910.1200, App. B.

[40] Chemical manufacturers must treat a chemical as hazardous and list it on an MSDS if it is listed (1) in 29 C.F.R. part 1910, subpart Z, (2) on the Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment, American Conference of Governmental Industrial Hygienists (latest edition), (3) as a carcinogen by the National Toxicology Program, or (4) as a carcinogen by the Annual Report on Carcinogens, International Agency for Research on Cancer Monographs. *See id.* §§ 1910.1200(d)(3)-(4).

[41] *See* 29 C.F.R. § 1910.1200, App. B. OSHA does not intervene in the decision-making process of the manufacturers when preparing MSDSs; however, upon OSHA's request, manufacturers must be able to "demonstrate that they have adequately ascertained the hazards of the chemicals produced or imported." *Id.*

[42] Theo Colborn, Carol Kwiatkowski, Kim Schultz, & Mary Bachran, *Natural Gas Operations from a Public Health Perspective*, INT'L J. HUMAN & ECOLOGICAL RISK ASSESSMENT (forthcoming 2011) (manuscript at 7), http://www.endocrinedisruption.com/files/Oct2011HERA10-48forweb3-3-11.pdf. TEDX studied what it refers to as chemical "products," which contain a variety of chemical substances. Although TEDX does not use the term "mixture" as it is defined under TSCA, the fracturing products evaluated in TEDX's

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

distributed hundreds of MSDSs for products used in gas development, a study performed by The Endocrine Disruption Exchange ("TEDX"), a non-profit organization that provides scientific information about endocrine disruptors, demonstrates that these MSDSs are "fraught with gaps."[43] Of the 980 MSDSs gathered by TDEX, 421 of them – representing 43 percent of the chemical products – disclosed less than one percent of the products' chemical composition.[44] Of the remaining MSDSs, only 133 of them – representing only 14 percent of the chemical products – disclosed more than 95 percent of the products' chemical composition.[45] In addition, many of these MSDSs either provided functional descriptions in place of chemical ingredients or omitted CAS numbers.[46] As TEDX explained, its review demonstrates that MSDSs can "easily be inaccurate and incomplete."[47]

III. Rulemakings Under TSCA Sections 4 and 8 Are Necessary to Fill Gaps in State Regulation of E&P Chemicals.

Most states do not routinely disclose to the public information they receive about E&P Chemicals, even when the information is not claimed to be proprietary, and no state is requiring toxicity testing or development of health and safety data. Wyoming has implemented the most far-reaching regulations governing disclosure of E&P Chemicals, yet even these regulations fall short of what a rulemaking under TSCA sections 4 and 8 would provide. Wyoming's rules require that well owners and operators disclose to the state's Oil and Gas Conservation Commission ("WYOGCC") the identities and concentrations of all chemicals that will be used at each well site.[48] Wyoming's rules, however, do not require toxicity testing or disclosure of health and environmental impacts of the chemicals. Moreover, like EPA's current study, Wyoming's rules do not reach manufacturers, processors, or distributors of E&P Chemicals, unless the well owner or operator is a company such as Halliburton or Schlumberger that also manufactures, processes, or distributes E&P Chemicals.

Wyoming's newly-enacted regulations and the oil and gas industry's response to them demonstrate that the oil and gas industry is resistant to disclosure of E&P Chemicals. In fact, since Wyoming's regulations were enacted in August 2010, the WYOGCC has received more

---

study meet TSCA's definition of mixture. *See* 15 U.S.C. § 2602(8) ("The term 'mixture' means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could a have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the mixture were combined.").

[43] Colborn, *supra* note 42, manuscript at 7.

[44] TEDX, Health Effects Summary Statement, *supra* note 11, at 2.

[45] *Id.*

[46] *Id.* at 1.

[47] Colborn, *supra* note 42, manuscript at 7.

[48] *See* Wy. Code R. Oil Gen. Ch. 3 § 45(d).

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

than 90 trade secret claims for E&P Chemicals.[49] Although some of those submitting trade secret claims disclosed all ingredients except for those chemical substances claimed to be proprietary, others submitted blanket confidentiality claims and refused to disclose any of the chemical substances used at the well sites on the grounds that some of them were proprietary.[50] Although TSCA also provides an opportunity for manufacturers, processors, and distributors to present trade secret claims, EPA currently is undertaking efforts to ensure that TSCA's limited trade secret provisions are not abused and that health and safety information submitted under TSCA is made publicly available.[51]

IV. There Is Insufficient Information Available to Permit a Reasoned Evaluation of the Health and Environmental Effects of E&P Chemicals.

In the absence of a federal rulemaking requiring disclosure of the identities of E&P Chemicals and information about the chemicals' health and environmental impacts, scientific organizations and state agencies, including TEDX and the New York State Department of Environmental Conservation ("NYSDEC"), have undertaken efforts to evaluate the health risks posed by E&P Chemicals. Two reports published by TEDX and NYSDEC, respectively, analyze the health effects of all chemical substances for which TEDX and NYSDEC could locate a CAS number.[52] These reports do not analyze any health effects related to chemical mixtures, in large part because manufacturers and processors rarely disclose the complete chemical composition of their products.[53] Read together, these reports demonstrate that the information currently

---

[49] *See* Telephone Conversation between Megan Klein, Associate Attorney, Earthjustice, and Gary Strong, Project Geologist, Wyoming Oil and Gas Conservation Commission (Mar. 21. 2011). Mr. Strong stated that, to his knowledge, 91 trade secret claims had been made since the regulations became effective on August 17, 2010, but he noted that this number could include duplicate claims or claims made for chemicals never actually used at the well sites. *Id.* Wyoming's regulations provide that "confidentiality protection shall be provided" for trade secrets, and privileged and confidential information when the party seeking to withhold disclosure provides written documentation of the "nature and extent of the proprietary information." Wy. Code R. Oil Gen. Ch. 3 § 45(f).

[50] *See* Telephone Conversation between Klein and Strong, *supra* note 49.

[51] *See* 15 U.S.C. § 2613(a) (providing statutory authority under which the chemical industry, or EPA after obtaining the information from the chemical industry, may withhold certain information as confidential business information ("CBI")), *id.* § 2613(b) (indicating that, outside of limited circumstances, information disclosed as part of health and safety data may not be withheld as CBI); 75 Fed. Reg. 29,754, 29,754 (May 27, 2010) (announcing that EPA will begin reviewing CBI claims for health and safety data to ensure all CBI claims for chemical identities are supportable under TSCA); *see also id.* at 29,755 (indicating that its review of CBI claims "will make more health and safety information available to the public and support an important mission of the Agency to promote public understanding of the potential risks posed by chemical substances in commerce").

[52] *See* DSGEIS, *supra* note 3, at 5-25 (identifying 260 chemical substances); *cf.* TEDX, Health Effects Summary Statement, *supra* note 11, at 3 (identifying 649 chemical substances).

[53] *See* TEDX, Health Effects Summary Statement, *supra* note 11, at 1.

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

available is insufficient to identify the full spectrum of E&P Chemicals or to permit a reasoned evaluation of their health and environmental effects.

A. TEDX Report

In an attempt to determine the identity of E&P Chemicals and to evaluate the health effects associated with them, TEDX gathered information from multiple sources, including MSDSs, state Tier II reports, Environmental Impact Statement and Environmental Assessment disclosures, rule-making documents, and accident and spill reports.[54] TEDX's review spanned several years and required TEDX to match the chemical substances that could be identified by CAS number with available health data. After performing this extensive and labor-intensive review, TEDX concluded that health data was available for "only a small percentage of the chemicals in use" in the gas industry.[55]

Using the available information, TEDX was able to form a list of 980 products containing 649 chemical substances.[56] It was not possible reliably to determine the health effects of almost half of the substances identified because TEDX could not locate CAS numbers for them.[57] The remaining substances that could be identified by CAS number were associated with multiple health effects, including effects on human sensory, respiratory, gastrointestinal, nervous, immune, cardiovascular, and endocrine systems. Specifically, over 78 percent of the substances that could be identified by CAS number were associated with serious short-term health effects such as burning eyes, rashes, coughs, sore throats, asthma-like effects, nausea, vomiting, headaches, dizziness, tremors, and convulsions.[58] Between 22 and 47 percent of the identifiable substances also were associated with longer-term health effects, including cancer, organ damage, and harm to the endocrine system.[59] In addition, 48 percent of the identifiable substances had "other" health effects not specifically classified as short- or long-term, such as changes in weight, effects on teeth and bones, and death.[60] Because the full chemical composition of the vast majority of the products was not available, TDEX was not able comprehensively to evaluate the health effects of the mixtures used in gas development.

---

[54] TEDX, Health Effects Summary Statement, *supra* note 11, at 1.
[55] Colborn, *supra* note 42, manuscript at 12.
[56] *See* TEDX, Health Effects Spreadsheet (2010), http://www.endocrinedisruption.com/files/MultistateSpreadsheet3-22-11States.xls.
[57] *See* TEDX, Health Effects Summary Statement, *supra* note 11, at 3 (indicating the TEDX could not locate CAS numbers for 44 percent of the chemicals identified).
[58] *Id.*
[59] *Id.*
[60] *Id.*

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

B. NYSDEC Analysis

In an attempt to analyze the health effects of fracturing chemicals likely to be used at well sites in New York State, NYSDEC collected MSDSs and sought additional information from well service providers and chemical manufacturers.[61] From the information it obtained, NYSDEC compiled a list of 260 chemical substances used within 197 fracturing products, although full chemical composition information was available for only 152 products.[62] NYSDEC's review of the identifiable chemical substances and mixtures demonstrated that "[c]ompound-specific toxicity data are very limited for many chemical additives to fracturing fluids."[63] Lacking compound-specific toxicity data, NYSDEC grouped the substances by their chemical structures and then matched each group of substances with health risks identified by the New York State Department of Health.[64] Listed below are some of the groups of chemical substances identified in the DSGEIS and the adverse health effects associated with those groups:

- BTEX compounds (benzene, toluene, ethylbenzene, and xylene): damage to the nervous system, liver, kidneys and blood cell-forming tissues;
- Petroleum distillate products: adverse effects on the gastrointestinal system and central nervous system, skin irritation, blistering, and peeling;
- Quarternary ammonium compounds, which can react with disinfectants used in drinking water systems to form nitrosamines: genetic damage and cancer;
- Microbicides: respiratory and gastrointestinal damage as well as damage to the kidneys, liver, and nervous system;
- Formaldehyde: irritation of the skin, eyes, nose, and throat, along with increased tearing; nasopharyngeal and lymphohematopoietic cancer;[65]
- Glycol ethers: damage to male reproductive systems and red blood cell formation; and
- 1,4-dioxane: eye and nose irritation, liver and kidney damage, and liver cancer.

Although NYSDEC was able to identify a range of adverse health impacts associated with groups of fracturing chemicals, NYSDEC acknowledged that its analysis of the health effects of fracturing chemicals was incomplete, because it was not able to identify health data for every chemical in each group.[66]

---

[61] DSGEIS, *supra* note 3, at 5-52 to 5-62. In addition to the 260 chemicals, the products identified also contained "40 compounds which require further disclosure since many are mixtures." *Id.* at 5-35.
[62] *Id.* at 5-35.
[63] *Id.* at 5-53.
[64] *Id.* at 5-52, 5-63 to 5-66.
[65] EPA recently released a draft formaldehyde-inhalation assessment that identifies formaldehyde as a widely-recognized carcinogen. EPA, IRIS Toxicological Review of Formaldehyde-Inhalation Assessment (External Review Draft), EPA/635/R-10/002A, at § 4.1.2 (2010).
[66] *See* DSGEIS, *supra* note 3, at 5-61.

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

V. E&P Chemicals May Present an Unreasonable Risk of Harm to Human Health, Terrestrial and Aquatic Life, and the Environment.

Numerous incidents of exposure to E&P Chemicals demonstrate that E&P Chemicals may present an unreasonable risk of harm to health and the environment at every stage of oil and gas development, including storage, transportation, treatment, and disposal. Leaks and spills of E&P Chemicals have been reported from Wyoming to Pennsylvania.[67] In 2010 alone, at least 34 million gallons of crude oil and E&P Chemicals were spilled nationwide.[68] The New Mexico Oil and Gas Conservation Division has identified close to 400 cases of groundwater contamination from oil and gas pits statewide.[69] Data gathered by the Colorado Oil and Gas Conservation Commission indicated that in the state of Colorado there were 134 spills of oil and gas products, including drilling muds and fracturing fluids, between 2003 and 2008.[70] The Pennsylvania Land Trust reviewed records of violations by service companies operating in the Marcellus Shale between January 2008 and August 2010, and found that there were 1,056 violations likely to have caused environmental harm.[71]

E&P Chemicals frequently are found in drinking water supplies near oil and gas development sites. Testing of drinking water wells in Dimock, Pennsylvania – a small town with more than 60 gas wells in a nine-square-mile area[72] – revealed high levels of toluene and ethylbenzene, which are carcinogenic chemicals believed to aid the fracturing process.[73] Residents of Sublette County, Wyoming tested their drinking water wells and found "fluoride – which is listed in Halliburton's hydraulic fracturing patent applications and can cause bone damage at high levels – at almost three times EPA's maximum limit."[74] A poorly lined pit near

---

[67] Jad Mouawad & Clifford Krauss, *Dark Side of a Natural Gas Boom*, N.Y. TIMES, Dec. 7, 2009, at B1, *available at* http://www.nytimes.com/2009/12/08/business/energy-environment/08fracking.html.

[68] Armen Keteyian, *Oil and Gas Industry Spills Happen "All the Time,"* CBS NEWS, Apr. 12, 2011, http://www.cbsnews.com/8301-31727_162-20054042-10391695.html.

[69] New Mexico Energy, Minerals, and Natural Resources Department, Groundwater Impact Update spreadsheet (2010), http://www.emnrd.state.nm.us/ocd/documents/GW_Impact_updTbl_000.xls.

[70] Exhibit 1 to Consolidated Final Prehearing Statement of the Oil and Gas Accountability Project et al., *In re Changes to R. & Regs. of Oil & Gas Conservation Comm'n of Colo.*, No. 0803-RM-02 (2008), *available at* http://cogcc.state.co.us/RuleMaking/PartyStatus/FinalPrehearingStmts/OGAPExh1.pdf (indicating that there were 134 spills of "other" products, which "included diesel fuel, glycol, amine, lubricating oil, hydraulic fracturing fluids, drilling muds, other chemicals, and natural gas leaks").

[71] Pennsylvania Land Trust Association, Marcellus Drillers in Pennsylvania Amass 1,614 Violations Since 2008 – 1,056 Identified as Most Likely to Harm the Environment (Oct. 2010), http://conserveland.org/violationsrpt (follow link to "Download Report").

[72] *See, e.g.*, Christopher Bateman, *A Colossal Fracking Mess*, VANITY FAIR, June 21, 2010, *available at* http://www.vanityfair.com/business/features/2010/06/fracking-in-pennsylvania-201006.

[73] Michael Rubinkam, *Report: Fracking Chemicals in NE Pa. Water Wells*, ABC NEWS, Sept. 16, 2010, http://abcnews.go.com/Business/wireStory?id=11653140&page=1.

[74] Abrahm Lustgarten & ProPublica, *Drill for Natural Gas, Pollute Water*, SCIENTIFIC AMERICAN, Nov. 17, 2008, *available at* http://www.scientificamerican.com/article.cfm?id=drill-for-natural-gas-pollute-water.

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

Parachute, Colorado, leaked 2,500 barrels of drilling muds into a tributary of Garden Gulch, and samples performed on the receiving waters demonstrated high levels of benzene and acetone.[75] In 2009 and again in 2010, EPA informed residents of Pavillion, Wyoming, that a number of drinking water wells in their area were contaminated with 2-butoxyethanol ("2-BE"), a chemical used as a general solvent that is associated with health effects such as narcosis, pulmonary edema, and severe liver and kidney damage.[76] More recently, samples of oil and gas wastewater discharged into public drinking water supplies in Indiana County, Pennsylvania, revealed concentrations of 2-BE at levels at more than 55 times the minimum risk level for intermediate exposure by children.[77] In response to complaints of cloudy and foul-smelling water by residents living near gas wells in Hickory, Pennsylvania, EPA performed testing of drinking water wells and found acrylonitrile, a chemical that Halliburton has listed on two U.S. patents for E&P Chemicals.[78] Water samples also have shown dramatic increases in levels of acrylonitrile, as well as benzene and styrene, in water wells located near gas development in Wetzel County, West Virginia.[79] Just recently, a breach of a containment area at a gas well in Canton, Pennsylvania, caused thousands of gallons of drilling fluids to spill, cross over farm fields, and reach a nearby stream.[80]

In addition to threatening human health via drinking water contamination, E&P Chemicals have proven fatal to animals and aquatic life. Again in Dimock, Pennsylvania, Cabot Oil and Gas reported spilling 8,500 gallons of fracturing fluid, much of which made its way into

---

[75] Colorado Oil and Gas Conservation Commission, March 31, 2008 Update on Garden Gulch Releases, at slides 13-14 (2008), http://oil-gas.state.co.us/Library/PiceanceBasin/Garden_Gulch_Releases_03-31-08_Update.pdf.

[76] See Fritz Mayer, *EPA Investigates 11 Polluted Wells*, THE RIVER REPORTER, Aug. 20, 2009, http://www.riverreporter.com/issues/09-08-20/news-wells.html (indicating EPA's investigation of the contamination); EPA, Glycol Ethers Hazard Summary (rev. 2000), http://www.epa.gov/ttnatw01/hlthef/glycolet.html#ref4 (indicating the uses and associated health hazards of 2-BE); Abrahm Lustgarten, *Feds Warn Residents Near Wyoming Gas Drilling Sites Not to Drink Their Water* (Sept. 1, 2010), http://www.propublica.org/article/feds-warn-residents-near-wyoming-gas-drilling-sites-not-to-drink-their-wate (noting that EPA warned Pavillion residents not to drink their water and to use ventilation while bathing).

[77] *See* Conrad D. Volz et al., *Contaminant Characterization of Effluent from Pennsylvania Brine Treatment Inc., Josephine Facility Being Released into Blacklick Creek, Indiana County, Pennsylvania*, Mar. 25, 2011, at 10-11, http://ia600608.us.archive.org/6/items/ContaminantCharacterizationOfEffluentFromPennsylvaniaBrineTreatment/Josephine_V2_CHEC_2011.pdf.

[78] Christie Campbell, *Water Problem Gets Closer Look from DEP, EPA*, OBSERVER-REPORTER (Washington, PA), Mar. 26, 2010, at B1.

[79] Isaac Wolf, *Rural Residents Say Natural Gas Drilling Has Tainted Their Drinking Water*, METROWEST DAILY NEWS, Nov. 23, 2010, http://www.metrowestdailynews.com/lifestyle/health/x1485353677/Rural-residents-say-natural-gas-drilling-has-tainted-their-drinking-water.

[80] Associated Press, *Driller Temporarily Stops Operations at Pa. Wells*, SAN DIEGO UNION-TRIBUNE, Apr. 21, 2011, http://www.signonsandiego.com/news/2011/apr/21/driller-temporarily-stops-operations-at-pa-wells.

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

Stevens Creek and killed fish and other aquatic life.[81] In May 2010, the Pennsylvania Department of Environmental Protection ("DEP") fined a drilling company $141,175 for leaking 250 barrels of diluted wastewater into a stream in Washington County, Pennsylvania, and thereby killing small fish, salamanders, and frogs.[82] A farmer living within 200 yards of gas wells in Grandview, Texas, witnessed six of his animals die after his water well became contaminated with at least one of the BTEX compounds.[83] The drilling company denied that its drilling operations had any relation to the water contamination, even though several other families living within 200 feet of the wells reported identical instances of water contamination.[84] In Spring Ridge, Louisiana, seventeen cows died after ingesting fracturing fluid that spilled into their pasture from a nearby gas well operated by Chesapeake Energy.[85]

Leaks and spills of E&P Chemicals endanger air quality as well as water supplies, sometimes even before the chemicals have a chance to reach the well sites. In June 2006, a chemical plant in Farmington, New Mexico operated by Halliburton Energy Services spilled approximately 30-60 gallons of a hydraulic fracturing product called Acidizing Composition.[86] The spill created a large cloud of acid vapors, which caused vomiting and nausea in the people living near the plant and prompted the evacuation of more than 220 people from their homes.[87] Despite the immediate health effects resulting from acute exposure to Acidizing Composition, its MSDS indicates "not determined" for all toxicity tests, including those for carcinogenicity and reproductive/developmental toxicity.[88] In addition to adverse health impacts caused by acute exposures, people also have reported injuries from prolonged exposure to E&P Chemicals. For example, a resident of Arlington, Texas, reported poor air quality and an increase in health problems immediately following the commencement of drilling operations by

---

[81] Steve McConnell, *Fracturing Fluids Spill into Susquehanna County Stream*, WAYNE INDEPENDENT, Sept. 17, 2009, http://www.wayneindependent.com/archive/x576510049/Fracturing-fluids-spill-into-Susquehanna-County-stream; Abrahm Lustgarten, *Frack Fluid Spill in Dimock Contaminates Stream, Killing Fish*, ProPublica, Sept. 21, 2009, http://www.propublica.org/article/frack-fluid-spill-in-dimock-contaminates-stream-killing-fish-921.

[82] Press Release, Pennsylvania Department of Environmental Protection, DEP Penalizes Range Resources $141,175 for Spill in High Quality Waterway (May 14, 2010), http://www.portal.state.pa.us/portal/server.pt/community/newsroom/14287?id=11412&typeid=1.

[83] Peter Gorman, *Water Foul*, FORTH WORTH WEEKLY, Apr. 30, 2008, http://archive.fwweekly.com/content.asp?article=6885.

[84] *See id*.

[85] Vickie Wellborn, *Chesapeake, Schlumberger Fined $22,000 Each in Cows' Deaths*, SHREVEPORT TIMES, Mar. 25, 2010, http://www.shreveporttimes.com/article/20100325/NEWS01/100325018/Chesapeake-Schlumberger-fined-22-000-each-in-cows-deaths.

[86] *Halliburton Spill Results in Acid Cloud, More Than 220 People Evacuated to Mall*, THE DAILY TIMES, FARMINGTON, NEW MEXICO, June 7, 2006, *available at* http://www.yourlawyer.com/articles/read/11832.

[87] *See id*.

[88] Halliburton, Material Safety Data Sheet, Product Trade Name: FE-1A Acidizing Composition, 1, 4 (Dec. 2006), *available at* http://newyork.sierraclub.org/fingerlakes/gasinfo.html (follow link to product name under heading "MSDS Data Sheets").

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

Carrizo Oil and Gas near her home.[89] Although Carrizo denied any responsibility, the resident received test results confirming the presence of ethylbenzene, xylene, hexane, and methylpentanes in her bloodstream, and her doctor issued an opinion that her inability to recover from her ongoing health problems was related to her continual exposure to diesel fumes and E&P Chemicals used at the Carrizo wells.[90]

E&P Chemicals can degrade soil and air quality in ways that may not be readily ascertainable to the public. In August 2006, a breach in surface casing at a gas well in Crosby, Wyoming, caused several releases of drilling muds, contaminating soil over an area of approximately 25,000 square feet.[91] Although no immediate impacts were reported, an analysis of the leaked chemicals indicated that 50 percent of them may cause ecological effects (harm to aquatic species, birds, amphibians, or invertebrates), and 32 percent of them were volatile, potentially causing injury to human respiratory systems, skin, sensory organs, and gastrointestinal systems.[92] In addition, while analysis of E&P Chemicals' effects on air quality are limited, researchers predict that emissions from Marcellus Shale gas wastewater stored in centralized impoundments have the potential to cause exceedances of the annual guidelines for acrylamide, glutaraldehyde, formaldehyde, and heavy naphtha.[93] When exposed to the air, BTEX compounds incorporated into E&P Chemicals have the potential to mix with nitrogen oxides from the exhaust of diesel-fueled equipment at the well sites and produce ground-level ozone.[94] Chemical exposures at and around well sites are exacerbated by certain common

---

[89] Jason Joyce, *Pyrrhic Pollution Finding*, FORT WORTH WEEKLY, Oct. 13, 2010, http://www.fwweekly.com/index.php?option=com_content&view=article&id=4265:pyrrhic-pollution-finding&catid=76:metropolis&Itemid=377.

[90] *Id.* (including a statement by Dr. Alfred Johnson that "it is my medical opinion that [Sandra DenBraber's] current illness and inability to recover is related to her constant and continual exposure to diesel exhaust fumes and other chemicals associated with the oil and gas drilling/fractionating and compressor station").

[91] TEDX, Analysis of Products Used for Drilling Crosby 25-3 Well – Windsor Energy, Park County, Wyoming, 1 (2009), http://www.endocrinedisruption.com/files/Crosby25-3wellsummary4-20-09Final.pdf.

[92] *See id.* at 3-4.

[93] *See* Susan Harvey, Review of DSGEIS and Identification of Best Technology and Best Practice Recommendations 31-33 (Dec. 29, 2009), submitted as Attachment C to Memorandum by Philip Sears, ARKF, to Kate Sinding et al., regarding comments on the Draft Supplemental Generic Environmental Impact Statement on the Oil, Gas, and Solution Mining Regulatory Program (Dec. 30, 2009) (on file with author).

[94] Colborn, *supra* note 42, manuscript at 5 (stating that ozone has a range of serious health and environmental effects, including various lung diseases as well as damage to conifers, aspen, forage, alfalfa, and other crops); *see also* Mead Gruver, *Gas Drilling Blamed for Soaring Ozone in Wyoming*, THE TIMES TRIBUNE, Mar. 9, 2011, http://thetimes-tribune.com/news/health-science/gas-drilling-blamed-for-soaring-ozone-in-wyoming-1.1116178 (reporting that ozone levels detected near gas drilling in western Wyoming were two-thirds higher than EPA's maximum healthy limit).

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

practices, such as air- and foam-lubricated drilling and the use of impoundments for flowback fluids.[95]

The health risks posed by E&P Chemicals have been most severe in cases involving direct human contact. In April 2008, an emergency room nurse in Durango, Colorado, was admitted to the intensive care unit after treating a gas industry employee who was caught in a fracturing fluid spill and tracked the chemical ZetaFlow into the hospital on his boots.[96] The nurse presented symptoms of yellow skin, vomiting, a swollen liver, erratic blood counts, and lungs filled with fluid and was diagnosed with chemical poisoning. To determine the exact nature of her chemical poisoning, the doctors looked at the MSDS for ZetaFlow, which indicated that ZetaFlow contained methanol and two undisclosed "proprietary" compounds. When the hospital requested the identity of the proprietary compounds to aid treatment of the nurse, Weatherford, ZetaFlow's manufacturer, refused to disclose the information. Weatherford continues to deny responsibility for the nurse's illness, yet it suspended its use of ZetaFlow following the incident.[97]

Finally, a recent report evaluating gas development in the Marcellus Shale demonstrates that E&P Chemicals threaten the people most vulnerable to injury from exposure to hazardous chemicals, such as children in day care facilities and schools and people hospitalized due to severe illness.[98] Children in particular face increased risk of harm due to exposure to toxic pollutants as a result of their vulnerable immune systems and their limited ability to detoxify.[99] Hundreds of well sites in Pennsylvania are situated within one or two miles of places designed to care for children and sick people, including 320 day care facilities, 67 schools, and nine hospitals.[100] In addition, at those same well sites, the Pennsylvania DEP reported almost 300 violations of regulations intended to protect water quality and the environment.[101]

The instances of harm and reports of potential harm cited above demonstrate that E&P Chemicals may present an unreasonable risk of harm to children and adults, terrestrial and aquatic life, water and air quality, and soil composition. With oil and gas exploration and production poised to grow exponentially, incidents of harm linked to it also are likely to

---

[95] *See* Bishop, *supra* note 3, at 2.

[96] Jim Moscou, *A Toxic Spew? Officials Worry About Impact of "Fracking" of Oil and Gas*, Newsweek, Aug. 20, 2008, http://www.newsweek.com/id/154394.

[97] *Id.*

[98] *See* Madsen, *supra* note 5, at 30-35; *see also* EPA, Environmental Assessment, Children's Health, http://cfpub.epa.gov/ncea/CFM/nceaQFind.cfm?keyword=Children's%20Health (last visited Aug. 2, 2011) (recognizing that children and the elderly are more susceptible than healthy adults to health risks posed by pollutants in the environment).

[99] Madsen, *supra* note 5, at 30-31.

[100] *Id.* at 30.

[101] *Id.* at 34.

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

increase, especially if EPA fails to promulgate regulations requiring disclosure and testing of E&P Chemicals and reporting of related health and environmental effects.

VI. Request for Relief

Petitioners hereby request that EPA take the following actions pursuant to TSCA section 21, 15 U.S.C. section 2620:

1. Adopt a rule pursuant to TSCA section 4 to require manufacturers and processors of E&P Chemicals to develop test data sufficient to evaluate the toxicity and potential for health and environmental impacts of all substances and mixtures that they manufacture and process. This rule must include a requirement for the manufacturer or processor to identify any substance or mixture for which testing is required.
2. Adopt a rule pursuant to TSCA section 8(a) requiring manufacturers and processors of E&P Chemicals to maintain records and submit reports to EPA disclosing the identities, categories, and quantities of E&P Chemicals, descriptions of byproducts of E&P Chemicals, all existing data on potential or demonstrated environmental and health effects of E&P Chemicals, and the number of individuals potentially exposed to E&P Chemicals.
3. Call in all records of allegations of significant adverse reactions received and maintained by manufacturers, processors, and distributors of E&P Chemicals pursuant to TSCA section 8(c) and 40 C.F.R. section 717.
4. Adopt a rule pursuant to TSCA section 8(d) to require submittal of all existing, not previously reported health and safety studies related to the health and/or environmental effects of E&P Chemicals.

A. Section 4 Testing

EPA and the public lack adequate data and experience upon which the health and environmental risks posed by E&P Chemicals can reasonably be determined or predicted. Petitioners request that EPA adopt a rule pursuant to TSCA section 4, requiring that manufacturers and processors of E&P Chemicals conduct acute and chronic toxicity studies sufficient to characterize and evaluate the hazards and potential health and environmental effects associated with the substances and mixtures they manufacture and process for use in oil and gas exploration and production. A TSCA section 4 rule may require testing of (1) effects on human respiratory, neurological, cardiovascular, reproductive, gastrointestinal, endocrine, sensory, and immune systems, including cancerous and developmental effects; and (2) effects on terrestrial and aquatic life and water, soil, and air quality.[102] A rule adopted under this section must function to ensure that EPA and the public can fully evaluate the hazards of all

[102] *See* 15 U.S.C. § 2603(b)(2)(A)

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

substances and mixtures used in oil and gas exploration and production and thereby determine whether those substances and mixtures may pose an unreasonable risk of harm to health and the environment. In addition, this rule must require the identification of each chemical substance or mixture for which testing is performed.[103]

EPA has ample and sufficient basis to issue a TSCA section 4 test rule. First, as illustrated in detail in section V above, E&P Chemicals meet the requirements in section 4(a) that "the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment."[104] Second, the significant volume of E&P Chemicals necessary to fracture a single well, combined with the number of wells anticipated throughout the United States, demonstrate that E&P Chemicals also meet the requirements of section 4(b) for an "exposure" finding, under which EPA shall by rule require that testing be conducted on a chemical substance or mixture that "is or will be produced in substantial quantities."[105]

B. Section 8(a) Reporting

Petitioners request that EPA adopt a rule pursuant to TSCA section 8(a) to require manufacturers and processors of E&P Chemicals to maintain certain records and submit to EPA reports on those records. Specifically, insofar as known to the person making the reports or insofar as reasonably ascertainable to that person, a rule issued pursuant to TSCA section 8(a) concerning the chemical substances and mixtures used in oil and gas exploration or production should require maintenance of records and reporting with respect to the following information:

1. The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required;
2. The categories or proposed categories of use of each substance or mixture;
3. The total amount of each substance or mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use;
4. A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture;
5. All existing data concerning the environmental and health effects of such substance or mixture;

---

[103] *See id.* § 2603(b)(1)(A).
[104] *Id.* § 2603(a)(1)(A)(i).
[105] *Id.* § 2603(a)(1)(B)(i).

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

6. The number of individuals exposed, and reasonable estimates of the number who will be exposed to such substance or mixture in their places of employment, including the duration of such exposures; and
7. The manner or method of disposal of any such substance or mixture.

Submission of this information is necessary for the effective enforcement of TSCA. In issuing a rule under TSCA section 8(a), EPA should consider the need to require periodic reporting as needed to account for all new substances and mixtures as well as for significant new information obtained by manufacturers and processors with respect to existing substances and mixtures.

C. Section 8(c) Call-In

Under TSCA section 8(c) and 40 C.F.R. section 717.12, chemical manufacturers, processors, and distributors must record and maintain all significant adverse reactions to human health or to the environment that are reported to or known by them and that are alleged to have been caused by chemical substances or mixtures that they manufacture, process, or distribute. A significant adverse reaction is one "that may indicate a substantial impairment of normal activities or long-lasting or irreversible damage to health or the environment."[106] Petitioners request that EPA exercise its authority under 40 C.F.R. section 717.17 and request submission of copies of any information related to significant adverse reactions to human health or the environment alleged to have been caused by E&P Chemicals manufactured, processed, or distributed by the following companies:

1. Baker Hughes d/b/a AquaNess Chemical and BJ Services Company[107]
2. Halliburton Energy Services, Inc.[108]
3. Schlumberger Technology Corporation[109]
4. RPC, Inc. d/b/a Cudd Energy Services
5. Superior Well Services, Inc.[110]

---

[106] 40 C.F.R. § 717.3(i).

[107] Petitioners are aware that Baker Hughes has acquired BJ Services Company. This request encompasses all records maintained by BJ Services Company prior to the acquisition as well as all records maintained by Baker Hughes following the acquisition.

[108] EPA's request should make it clear that the reports from Halliburton Energy Services must include all allegations that it has received related to its chemical substances and mixtures as manufactured by Halliburton Energy Services (in the United States and the United Kingdom) and Halliburton Australia Pty. Ltd.

[109] EPA's request should make it clear that the reports from Schlumberger Technology Corporation must include all allegations it has received related to its chemical substances and mixtures as manufactured by Schlumberger Technology Corporation in the United States, Schlumberger Canada, Ltd., and Schlumberger Ltd.

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

6. Sanjel USA
7. Weatherford International Ltd.[111]
8. Calfrac Well Services
9. Frac Tech Services

Petitioners believe these companies are the primary manufacturers, processors, and distributors of E&P Chemicals in the United States. Because a request involving nine entities would not be subject to the Paperwork Reduction Act notice requirements, EPA could act quickly.[112]

D. Section 8(d) Submission Request

Petitioners request that EPA adopt a rule pursuant to TSCA section 8(d) to require manufacturers, processors, and distributors of E&P Chemicals to submit to EPA lists and copies of all existing health and safety studies conducted or initiated by or for them, known to them, or reasonably ascertainable by them. Health and safety studies are defined broadly under EPA's regulations as "any study of any effect of a chemical substance or mixture on health or the environment or both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological or other studies of a chemical substance or mixture, and any test performed under TSCA."[113] Petitioners request that this rulemaking encompass all health and safety studies related to any substance or mixture used in oil and gas exploration or production, including, as called for under 40 C.F.R. section 716.3, the identity of the chemical substances and mixtures.[114] Submission of health and safety studies related to all E&P Chemicals is necessary to ensure that substances and mixtures do not present an unreasonable risk of injury to health or the environment.

---

[110]Petitioners are aware that Nabors Industries Ltd. recently acquired Superior Well Services, Inc. This request encompasses all records maintained by Superior Well Services, Inc. prior to the acquisition as well as all records maintained by Superior Well Services, Inc. and Nabors Industries Ltd. following the acquisition.

[111] EPA's request should make it clear that the reports from Weatherford International Ltd. must include all allegations that it has received related chemical substances and mixtures manufactured by its subsidiary, Clearwater International, LLC.

[112] *See* 44 U.S.C. § 3502(3)(A)(i) (defining a "collection of information" subject to regulation under the Paperwork Reduction Act as a request imposed on ten or more persons).

[113] 40 C.F.R. § 716.3

[114] *See id.* ("It is intended that the term health and safety study be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. Any data that bear on the effects of a chemical substance on health or the environment would be included. Chemical identity is part of, or underlying data to, a health and safety study.")

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

VII. Conclusion

In the absence of rulemakings pursuant to TSCA sections 4 and 8, EPA and the public lack the information necessary to assess the potential health and environmental effects of E&P Chemicals. To hold manufacturers, processors, and distributors of E&P Chemicals accountable for the consequences of placing their products into commerce, Petitioners respectfully request that EPA initiate rulemakings under TSCA sections 4 and 8.

Respectfully submitted,

Deborah Goldberg

Deborah Goldberg
Megan Klein
Earthjustice
156 William Street, Suite 800
New York, NY 10038
Phone: (212) 791-1881 x8227
Fax: (212) 918-1556
dgoldberg@earthjustice.org

On behalf of signatory organizations listed on the following pages

Enclosure

cc: Wendy Cleland-Hamnett
Office Director, EPA Office of Pollution Prevention and Toxics

Maureen Dill
Facilitator
Advocates for Morris
Morris, New York

Harry Levine
President
Advocates for Springfield
Springfield, New York

Matthew S. Tejada, PhD
Executive Director
Air Alliance Houston
Houston, Texas

David Moryc
Senior Director of River Protection
American Rivers
Washington, DC

Monona Rossol
Industrial Hygienist
Arts, Crafts & Theater Safety, Inc.
New York, New York

Philip S. Wallis
Executive Director
Audubon Pennsylvania
Harrisburg, Pennsylvania

Jeanette Vosburg
President
Ballona Network
Los Angeles, California

Jeanne Rizzo
President and CEO
Breast Cancer Fund
San Francisco, California

Cheryl Johncox
Executive Director
Buckeye Forest Council
Columbus, Ohio

Thomas B. Wilinsky
Catskill Citizens for Safe Energy
Fremont Center, New York

Wes Gillingham
Program Director
Catskill Mountainkeeper
Youngsville, New York

Rebecca Noblin
Alaska Director
Center for Biological Diversity
Anchorage, Alaska

Rachel Meeropol
Staff Attorney
Center for Constitutional Rights
New York, New York

Caroline Cox
Research Director
Center for Environmental Health
Oakland, California

Lois Marie Gibbs, PhD
Executive Director
Center for Health, Environment & Justice
Falls Church, Virginia

Gary Simpson
President
Chatham Citizens for Effective Communities, Inc. (CCEC)
Pittsboro, North Carolina

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

Ellen Rendulich
Director
Citizens Against Ruining the Environment
Lockport, Illinois

Sarah Eckel
Legislative & Policy Director
Citizens Campaign for the Environment
Syracuse, New York

Barbara J. Warren
Executive Director
Citizens' Environmental Coalition
Albany, New York

Vera Scroggins
Citizens for Clean Water
Brackney, Pennsylvania

Deb Thomas
Organizer
Clark Resource Council
Clark, Wyoming

Joseph O. Minott, Esq.
Executive Director
Clean Air Council
Philadelphia, Pennsylvania

Ann Brewster Weeks
Legal Director
Clean Air Task Force
Boston, Massachusetts

Lynn Thorp
National Campaigns Coordinator
Clean Water Action
Washington, DC

Hope Taylor, MSPH
Executive Director
Clean Water For North Carolina
Durham, North Carolina

Elizabeth Wheeler
Staff Attorney
Clean Wisconsin
Madison, Wisconsin

Elyse Kunz
Co-Founder
Community Advocates for Safe Emissions, Inc.
Ravena, New York

Michael Ashkin
Associate Professor of Economics and Public Policy
Corporate Toxics Information Project,
University of Massachusetts Amherst
Amherst, Massachusetts

Bernard Handler
Spokesperson
Damascus Watch
Damascus, Pennsylvania

Tracy Carluccio
Deputy Director
Delaware Riverkeeper Network
Bristol, Pennsylvania

Stephen M. Brittle
President
Don't Waste Arizona
Phoenix, Arizona

Jim Schermbeck
Director
Downwinders at Risk
Dallas-Ft. Worth, Texas

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

Margaret McCasland
Convenor
Earthcare Committee, Ithaca Monthly Meeting, Religious Society of Friends (Quakers)
Ithaca, New York

Jennifer Krill
Executive Director
Earthworks
Washington, DC

Judy Braiman
President
Empire State Consumer Project
Rochester, New York

Brian Segee
Staff Attorney
Environmental Defense Center
Santa Barbara, California

Richard A. Denison
Senior Scientist
Environmental Defense Fund
Washington, DC

Elsie Rhodes
Pastor
First Presbyterian Church
Cooperstown, New York

Ellen Z. Harrison
Director
Fleased
Ithaca, New York

Joyce Tarnow
President
Floridians for a Sustainable Population, Inc.
Cross City, Florida

Julie Huntsman
Spokesperson
Fly Creek/Otsego Neighbors
Fly Creek, New York

Barbara Jarmoska
President
Freshlife, Inc.
Williamsport, Pennsylvania

Kathleen G. Hundley, M.Ed.
President
Friends of the Rocky River (FORR)
Chatham County, North Carolina

Sheila Cohen
Outreach Chair
Gas Drilling Awareness for Cortland County (GDACC)
Cortland County, New York

Roberta Frampton Benefiel
Vice President
Grand Riverkeeper Labrador, Inc.
Happy Valley-Goose Bay, Canada

Stephen Ashkin
Executive Director
Green Cleaning Network
Bloomington, Indiana

156 WILLIAM STREET, SUITE 800 NEW YORK, NY 10038-5326
T: 212.791.1881 F: 212.918.1556 E: neoffice@earthjustice.org W: www.earthjustice.org

No. 17-1201

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ENVIRONMENTAL DEFENSE FUND,
Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; AND SCOTT PRUITT, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondents,

AMERICAN CHEMISTRY COUNCIL; et al.,
Intervenors for Respondents.

PETITION FOR REVIEW OF RULE OF U.S. ENVIRONMENTAL PROTECTION AGENCY, "TSCA INVENTORY NOTIFICATION (ACTIVE-INACTIVE) REQUIREMENTS," 82 FED. REG. 37,520 (AUG. 11, 2017)

DECLARATION OF JOHN STITH

I, John Stith, declare as follows:

1. I am Director of Database Marketing and Analytics at Environmental Defense Fund ("EDF"). I have had this position for more than twelve years. I am over 18 years of age. I have personal knowledge of the matters set forth herein.

2. My duties include maintaining an accurate list of members. My colleagues and I provide information to members, acknowledge gifts and volunteer actions, and manage the organization's member databases. My work requires me to be familiar with EDF's purposes, staffing, activities, and membership.

3. EDF is a membership organization incorporated under the laws of the State of New York. It is recognized as a not-for-profit corporation under section 501(c)(3) of the United States Internal Revenue Code. EDF has offices in Austin, TX; New York, NY; Washington, D.C.; Boston, MA; San Francisco and Sacramento, CA; Raleigh, NC; Boulder, CO; and, Bentonville, AR.

4. EDF relies on science, economics, and law to protect and restore the quality of our air, water, and other natural resources, and to support policies that mitigate the impacts of climate change.

5. Through its programs aimed at protecting human health, EDF has long pursued initiatives at the state and national levels designed to reduce exposure to toxic chemicals. Among other goals, EDF seeks to significantly reduce exposure to high-risk chemicals in consumer products, water, and food, in part, by significantly expanding actionable

information on chemical risks. EDF uses information about chemical substances in its research and advocacy efforts.

6. I understand that the U.S. Environmental Protection Agency issued a final rule entitled “TSCA Inventory Notification (Active-Inactive) Requirements,” published at 82 Fed. Reg. 37,520 (Aug. 11, 2017). It is my understanding that flaws in the rule mean that EPA will not publish and disclose all of the information about chemical substances in U.S. commerce that EPA must publish and disclose under the Frank R. Lautenberg Chemical Safety for the 21st Century Act.
7. EDF has a strong organizational interest in gaining access to information about chemical substances in U.S. commerce. EDF uses this type of information in its advocacy efforts to reduce exposure to high-risk chemicals. Those advocacy efforts serve our members’ health, environmental, recreational, aesthetic, professional, educational, and economic interests.
8. When an individual becomes a member of EDF, his or her current residential address is recorded in our membership database. The database entry reflecting the member’s residential address is verified or updated as needed. The database is maintained in the regular course of business and each entry reflecting a member’s residential address and

membership status is promptly updated to reflect changes. I obtained the information about our membership discussed below from our membership database.

9. EDF has over 353,000 members in the United States, and we have members in all 50 states and the District of Columbia. These members likewise have a strong interest in protecting human health and the environment from exposure to toxic chemicals.

10. I understand that if EPA collected and disclosed information as EDF requests, then EDF would have access to more information about chemical substances in U.S. commerce, including more information about specific chemical identities. Therefore, were the court to require EPA to promulgate regulations to collect and disclose that information, then there is a likelihood that the harms that EDF suffers from the lack of that information would be lessened.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: 3/2/2018

JOHN STITH

CERTIFICATE OF SERVICE

I hereby certify that on March 6, 2018, I electronically filed the foregoing addendum with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system.

All parties to the case have counsel who are registered CM/ECF users and service will be accomplished through the appellate CM/ECF system. Those counsel served by the appellate CM/ECF system include:

- Michael David Boucher
- Samuel B. Boxerman
- James Watson Conrad Jr.
- Phillip Dupre
- Donald P. Gallo
- Peter Douglas Keisler
- Linda Ellen Kelly
- Steven Paul Lehotsky
- Warren U. Lehrenbaum
- Martha E. Marrapese
- Roger Hebert Miksad
- Richard S. Moskowitz
- Michael Benjamin Schon
- Timothy Kenly Webster

March 6, 2018

ROBERT P. STOCKMAN
/s/ ROBERT P. STOCKMAN

Environmental Defense Fund
1875 Connecticut Ave. NW,
Suite 600
Washington, DC 20009
(202) 572-3398
rstockman@edf.org
Attorney for Petitioner
Environmental Defense Fund